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117TH CONGRESS
2d Session

HOUSE OF REPRESENTATIVES

REPT. 117–364
Part 1

RESTORING HOPE FOR MENTAL HEALTH AND WELL-BEING ACT OF 2022

R E P O R T

OF THE

COMMITTEE ON ENERGY AND COMMERCE

TO ACCOMPANY H.R. 7666

JUNE 13, 2022.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

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Mr. PALLONE, from the Committee on Energy and Commerce, submitted the following

R E P O R T

[To accompany H.R. 7666]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 7666) to amend the Public Health Service Act to reauthorize certain programs relating to mental health and substance use disorders, and for other purposes, having considered the same, reports favorably thereon with an amendment and recommends that the bill as amended do pass.

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The amendment is as follows:

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the "Restoring Hope for Mental Health and Well-Being Act of 2022".

(b) TABLE OF CONTENTS.—The table of contents for this Act is as follows:

Sec. 1. Short title; table of contents.

TITLE I—MENTAL HEALTH AND CRISIS CARE NEEDS

Subtitle A—Crisis Care Services and 9–8–8 Implementation

Sec. 101. Behavioral Health Crisis Coordinating Office.
Sec. 102. Crisis response continuum of care.

Subtitle B—Into the Light for Maternal Mental Health and Substance Use Disorders

Sec. 111. Screening and treatment for maternal mental health and substance use disorders.
Sec. 112. Maternal mental health hotline.
Sec. 113. Task force on maternal mental health.

Subtitle C—Reaching Improved Mental Health Outcomes for Patients

Sec. 121. Innovation for mental health.
Sec. 122. Crisis care coordination.
Sec. 123. Treatment of serious mental illness.

Subtitle D—Anna Westin Legacy

Sec. 131. Maintaining education and training on eating disorders.

Subtitle E—Community Mental Health Services Block Grant Reauthorization

Sec. 141. Reauthorization of block grants for community mental health services.

Subtitle F—Peer-Supported Mental Health Services

Sec. 151. Peer-supported mental health services.

TITLE II—SUBSTANCE USE DISORDER PREVENTION, TREATMENT, AND RECOVERY SERVICES

Subtitle A—Native Behavioral Health Access Improvement

Sec. 201. Behavioral health and substance use disorder services for Native Americans.

Subtitle B—Summer Barrow Prevention, Treatment, and Recovery

Sec. 211. Grants for the benefit of homeless individuals.
Sec. 212. Priority substance abuse treatment needs of regional and national significance.
Sec. 213. Evidence-based prescription opioid and heroin treatment and interventions demonstration.
Sec. 214. Priority substance use disorder prevention needs of regional and national significance.
Sec. 215. Sober Truth on Preventing (STOP) Underage Drinking Reauthorization.
Sec. 216. Grants for jail diversion programs.
Sec. 217. Formula grants to States.
Sec. 218. Projects for Assistance in Transition From Homelessness.
Sec. 219. Grants for reducing overdose deaths.
Sec. 220. Opioid overdose reversal medication access and education grant programs.
Sec. 221. State demonstration grants for comprehensive opioid abuse response.
Sec. 222. Emergency department alternatives to opioids.

Subtitle C—Excellence in Recovery Housing

Sec. 231. Clarifying the role of SAMHSA in promoting the availability of high-quality recovery housing.
Sec. 232. Developing guidelines for States to promote the availability of high-quality recovery housing.
Sec. 233. Coordination of Federal activities to promote the availability of recovery housing.
Sec. 234. NAS study and report.
Sec. 235. Grants for States to promote the availability of recovery housing and services.
Sec. 236. Funding.
Sec. 237. Technical correction.

Subtitle D—Substance Use Prevention, Treatment, and Recovery Services Block Grant

Sec. 241. Eliminating stigmatizing language relating to substance use.
Sec. 242. Authorized activities.
Sec. 243. Requirements relating to certain infectious diseases and human immunodeficiency virus.
Sec. 244. State plan requirements.
Sec. 245. Updating certain language relating to Tribes.
Sec. 246. Block grants for substance use prevention, treatment, and recovery services.
Sec. 247. Requirement of reports and audits by States.
Sec. 248. Study on assessment for use in distribution of limited State resources.

Subtitle E—Timely Treatment for Opioid Use Disorder

Sec. 251. Study on exemptions for treatment of opioid use disorder through opioid treatment programs during the COVID–19 public health emergency.
Sec. 252. Changes to Federal opioid treatment standards.

Subtitle F—Additional Provisions Relating to Addiction Treatment

Sec. 261. Prohibition.
Sec. 262. Eliminating additional requirements for dispensing narcotic drugs in schedule III, IV, and V for maintenance or detoxification treatment.
Sec. 263. Requiring prescribers of controlled substances to complete training.

TITLE III—ACCESS TO MENTAL HEALTH CARE AND COVERAGE

Subtitle A—Collaborate in an Orderly and Cohesive Manner

Sec. 301. Increasing uptake of the collaborative care model.

Subtitle B—Helping Enable Access to Lifesaving Services

Sec. 311. Reauthorization and provision of certain programs to strengthen the health care workforce.

Subtitle C—Eliminating the Opt-Out for Nonfederal Governmental Health Plans

Sec. 321. Eliminating the opt-out for nonfederal governmental health plans.

Subtitle D—Mental Health and Substance Use Disorder Parity Implementation

Sec. 331. Grants to support mental health and substance use disorder parity implementation.

TITLE IV—CHILDREN AND YOUTH

Subtitle A—Supporting Children's Mental Health Care Access

Sec. 401. Pediatric mental health care access grants.
Sec. 402. Infant and early childhood mental health promotion, intervention, and treatment.

Subtitle B—Continuing Systems of Care for Children

Sec. 411. Comprehensive Community Mental Health Services for Children with Serious Emotional Disturbances.
Sec. 412. Substance Use Disorder Treatment and Early Intervention Services for Children and Adolescents.

Subtitle C—Garrett Lee Smith Memorial Reauthorization

Sec. 421. Suicide prevention technical assistance center.
Sec. 422. Youth suicide early intervention and prevention strategies.
Sec. 423. Mental health and substance use disorder services for students in higher education.
Sec. 424. Mental and behavioral health outreach and education at institutions of higher education.

TITLE I—MENTAL HEALTH AND CRISIS CARE NEEDS

Subtitle A—Crisis Care Services and 9–8–8 Implementation

SEC. 101. BEHAVIORAL HEALTH CRISIS COORDINATING OFFICE.

Part A of title V of the Public Health Service Act (42 U.S.C. 290aa et seq.) is amended by adding at the end the following:

"SEC. 506B. BEHAVIORAL HEALTH CRISIS COORDINATING OFFICE.

"(a) IN GENERAL.—The Secretary shall establish, within the Substance Abuse and Mental Health Services Administration, an office to coordinate work relating to behavioral health crisis care across the operating divisions and agencies of the Department of Health and Human Services, including the Substance Abuse and Mental Health Services Administration, the Centers for Medicare & Medicaid Services, and the Health Resources and Services Administration, and external stakeholders.

"(b) DUTY.—The office established under subsection (a) shall—

"(1) convene Federal, State, Tribal, local, and private partners;

"(2) launch and manage Federal workgroups charged with making recommendations regarding behavioral health crisis issues, including with respect to health care best practices, workforce development, mental health disparities, data collection, technology, program oversight, public awareness, and engagement; and

"(3) support technical assistance, data analysis, and evaluation functions in order to assist States, localities, Territories, Tribes, and Tribal communities to develop crisis care systems and establish nationwide best practices with the objective of expanding the capacity of, and access to, local crisis call centers, mobile crisis care, crisis stabilization, psychiatric emergency services, and rapid post-crisis follow-up care provided by—

"(A) the National Suicide Prevention and Mental Health Crisis Hotline and Response System;

"(B) community mental health centers (as defined in section 1861(ff)(3)(B) of the Social Security Act);

"(C) certified community behavioral health clinics, as described in section 223 of the Protecting Access to Medicare Act of 2014; and

"(D) other community mental health and substance use disorder providers.

"(c) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section $5,000,000 for each of fiscal years 2023 through 2027.".

SEC. 102. CRISIS RESPONSE CONTINUUM OF CARE.

Subpart 3 of part B of title V of the Public Health Service Act (42 U.S.C. 290bb–31 et seq.) is amended by adding at the end the following:

"SEC. 520N. CRISIS RESPONSE CONTINUUM OF CARE.

"(a) IN GENERAL.—The Secretary shall publish best practices for a crisis response continuum of care for use by health care providers, crisis services administrators, and crisis services providers in responding to individuals (including children and adolescents) experiencing mental health crises, substance-related crises, and crises arising from co-occurring disorders.

"(b) BEST PRACTICES.—

"(1) SCOPE OF BEST PRACTICES.—The best practices published under subsection (a) shall define—

"(A) a minimum set of core crisis response services, as determined by the Secretary, for each entity that furnishes such services, that—

"(i) do not require prior authorization from an insurance provider or group health plan nor a referral from a health care provider prior to the delivery of services;

"(ii) provide for serving all individuals regardless of age or ability to pay;

"(iii) provide for operating 24 hours a day, 7 days a week; and

"(iv) provide for care and support through resources described in paragraph (2)(A) until the individual has been stabilized or transferred to the next level of crisis care; and

"(B) psychiatric stabilization, including the point at which a case may be closed for—

"(i) individuals screened over the phone; and

"(ii) individuals stabilized on the scene by mobile teams.

"(2) IDENTIFICATION OF ESSENTIAL FUNCTIONS.—The best practices published under subsection (a) shall identify the essential functions of each service in the crisis response continuum, which shall include at least the following:

"(A) Identification of resources for referral and enrollment in continuing mental health, substance use, or other human services relevant for the individual in crisis where necessary.

"(B) Delineation of access and entry points to services within the crisis response continuum.

"(C) Development of protocols and agreements for the transfer and receipt of individuals to and from other segments of the crisis response continuum segments as needed, and from outside referrals including health care providers, first responders including law enforcement, paramedics, and firefighters, education institutions, and community-based organizations.

"(D) Description of the qualifications of crisis services staff, including roles for physicians, licensed clinicians, case managers, and peers (in accordance with State licensing requirements or requirements applicable to Tribal health professionals).

"(E) The convening of collaborative meetings of crisis response service providers, first responders including law enforcement, paramedics, and firefighters, and community partners (including National Suicide Prevention Lifeline or 9–8–8 call centers, 9–1–1 public service answering points, and local mental health and substance use disorder treatment providers) operating in a common region for the discussion of case management, best practices, and general performance improvement.

"(3) SERVICE CAPACITY AND QUALITY BEST PRACTICES.—The best practices under subsection (a) shall include recommendations on—

"(A) adequate volume of services to meet population need;

"(B) appropriate timely response; and

"(C) capacity to meet the needs of different patient populations that may experience a mental health or substance use crisis, including children, families, and all age groups, cultural and linguistic minorities, individuals with co-occurring mental health and substance use disorders, individuals with cognitive disabilities, individuals with developmental delays, and individuals with chronic medical conditions and physical disabilities.

"(4) IMPLEMENTATION TIMEFRAME.—The Secretary shall—

"(A) not later than 1 year after the date of enactment of this section, publish and maintain the best practices required by subsection (a); and

"(B) every two years thereafter, publish updates.

"(5) DATA COLLECTION AND EVALUATIONS.—The Secretary, directly or through grants, contracts, or interagency agreements, shall collect data and conduct evaluations with respect to the provision of services and programs offered on the crisis response continuum for purposes of assessing the extent to which the provision of such services and programs meet certain objectives and outcomes measures as determined by the Secretary. Such objectives shall include—

"(A) a reduction in reliance on law enforcement response, as appropriate, to individuals in crisis who would be more appropriately served by a mobile crisis team capable of responding to mental health and substance-related crises;

"(B) a reduction in boarding or extended holding of patients in emergency room facilities who require further psychiatric care, including care for substance use disorders;

"(C) evidence of adequate access to crisis care centers and crisis bed services; and

"(D) evidence of adequate linkage to appropriate post-crisis care and longitudinal treatment for mental health or substance use disorder when relevant.".

Subtitle B—Into the Light for Maternal Mental Health and Substance Use Disorders

SEC. 111. SCREENING AND TREATMENT FOR MATERNAL MENTAL HEALTH AND SUBSTANCE USE DISORDERS.

(a) IN GENERAL.—Section 317L–1 of the Public Health Service Act (42 U.S.C. 247b–13a) is amended—

(1) in the section heading, by striking "**MATERNAL DEPRESSION**" and inserting "**MATERNAL MENTAL HEALTH AND SUBSTANCE USE DISORDERS**"; and

(2) in subsection (a)—

(A) by inserting ", Indian Tribes and Tribal organizations (as such terms are defined in section 4 of the Indian Self-Determination and Education Assistance Act), and Urban Indian organizations (as such term is defined under the Federally Recognized Indian Tribe List Act of 1994)" after "States"; and

(B) by striking "for women who are pregnant, or who have given birth within the preceding 12 months, for maternal depression" and inserting "for women who are postpartum, pregnant, or have given birth within the preceding 12 months, for maternal mental health and substance use disorders".

(b) APPLICATION.—Subsection (b) of section 317L–1 of the Public Health Service Act (42 U.S.C. 247b–13a) is amended—

(1) by striking "a State shall submit" and inserting "an entity listed in subsection (a) shall submit"; and

(2) in paragraphs (1) and (2), by striking "maternal depression" each place it appears and inserting "maternal mental health and substance use disorders".

(c) PRIORITY.—Subsection (c) of section 317L–1 of the Public Health Service Act (42 U.S.C. 247b–13a) is amended—

(1) by striking "may give priority to States proposing to improve or enhance access to screening" and inserting the following: "shall give priority to entities listed in subsection (a) that—

"(1) are proposing to create, improve, or enhance screening, prevention, and treatment";

(2) by striking "maternal depression" and inserting "maternal mental health and substance use disorders";

(3) by striking the period at the end of paragraph (1), as so designated, and inserting a semicolon; and

(4) by inserting after such paragraph (1) the following:

"(2) are currently partnered with, or will partner with, a community-based organization to address maternal mental health and substance use disorders;

"(3) are located in an area with high rates of adverse maternal health outcomes or significant health, economic, racial, or ethnic disparities in maternal health and substance use disorder outcomes; and

"(4) operate in a health professional shortage area designated under section 332.".

(d) USE OF FUNDS.—Subsection (d) of section 317L–1 of the Public Health Service Act (42 U.S.C. 247b–13a) is amended—

(1) in paragraph (1)—

(A) in subparagraph (A), by striking "to health care providers; and" and inserting "on maternal mental health and substance use disorder screening, brief intervention, treatment (as applicable for health care providers), and referrals for treatment to health care providers in the primary care setting and nonclinical perinatal support workers;";

(B) in subparagraph (B), by striking "to health care providers, including information on maternal depression screening, treatment, and followup support services, and linkages to community-based resources; and" and inserting "on maternal mental health and substance use disorder screening, brief intervention, treatment (as applicable for health care providers) and referrals for treatment, follow-up support services, and linkages to community-based resources to health care providers in the primary care setting and clinical perinatal support workers; and"; and

(C) by adding at the end the following:

"(C) enabling health care providers (such as obstetrician-gynecologists, nurse practitioners, nurse midwives, pediatricians, psychiatrists, mental and other behavioral health care providers, and adult primary care clinicians) to provide or receive real-time psychiatric consultation (in-person or remotely), including through the use of technology-enabled collaborative learning and capacity building models (as defined in section 330N), to aid in the treatment of pregnant and postpartum women; and"; and

(2) in paragraph (2)—

(A) by striking subparagraph (A) and redesignating subparagraphs (B) and (C) as subparagraphs (A) and (B), respectively;

(B) in subparagraph (A), as redesignated, by striking "and" at the end;

(C) in subparagraph (B), as redesignated—

(i) by inserting ", including" before "for rural areas"; and

(ii) by striking the period at the end and inserting a semicolon; and

(D) by inserting after subparagraph (B), as redesignated, the following:

"(C) providing assistance to pregnant and postpartum women to receive maternal mental health and substance use disorder treatment, including patient consultation, care coordination, and navigation for such treatment;

"(D) coordinating with maternal and child health programs of the Federal Government and State, local, and Tribal governments, including child psychiatric access programs;

"(E) conducting public outreach and awareness regarding grants under subsection (a);

"(F) creating multistate consortia to carry out the activities required or authorized under this subsection; and

"(G) training health care providers in the primary care setting and non-clinical perinatal support workers on trauma-informed care, culturally and linguistically appropriate services, and best practices related to training to improve the provision of maternal mental health and substance use disorder care for racial and ethnic minority populations, including with respect to perceptions and biases that may affect the approach to, and provision of, care.".

(e) ADDITIONAL PROVISIONS.—Section 317L–1 of the Public Health Service Act (42 U.S.C. 247b–13a) is amended—

(1) by redesignating subsection (e) as subsection (h); and

(2) by inserting after subsection (d) the following:

"(e) TECHNICAL ASSISTANCE.—The Secretary shall provide technical assistance to grantees and entities listed in subsection (a) for carrying out activities pursuant to this section.

"(f) DISSEMINATION OF BEST PRACTICES.—The Secretary, based on evaluation of the activities funded pursuant to this section, shall identify and disseminate evidence-based or evidence-informed best practices for screening, assessment, and treatment services for maternal mental health and substance use disorders, including culturally and linguistically appropriate services, for women during pregnancy and 12 months following pregnancy.

"(g) MATCHING REQUIREMENT.—The Federal share of the cost of the activities for which a grant is made to an entity under subsection (a) shall not exceed 90 percent of the total cost of such activities.".

(f) AUTHORIZATION OF APPROPRIATIONS.—Subsection (h) of section 317L–1 (42 U.S.C. 247b–13a) of the Public Health Service Act, as redesignated, is further amended—

(1) by striking "$5,000,000" and inserting "$24,000,000"; and

(2) by striking "2018 through 2022" and inserting "2023 through 2027".

SEC. 112. MATERNAL MENTAL HEALTH HOTLINE.

Part P of title III of the Public Health Service Act (42 U.S.C. 280g et seq.) is amended by adding at the end the following:

"SEC. 399V–7. MATERNAL MENTAL HEALTH HOTLINE.

"(a) IN GENERAL.—The Secretary shall maintain, directly or by grant or contract, a national hotline to provide emotional support, information, brief intervention, and

mental health and substance use disorder resources to pregnant and postpartum women at risk of, or affected by, maternal mental health and substance use disorders, and to their families or household members.

"(b) REQUIREMENTS FOR HOTLINE.—The hotline under subsection (a) shall—

"(1) be a 24/7 real-time hotline;

"(2) provide voice and text support;

"(3) be staffed by certified peer specialists, licensed health care professionals, or licensed mental health professionals who are trained on—

"(A) maternal mental health and substance use disorder prevention, identification, and intervention; and

"(B) providing culturally and linguistically appropriate support; and

"(4) provide maternal mental health and substance use disorder assistance and referral services to meet the needs of underserved populations, individuals with disabilities, and family and household members of pregnant or postpartum women at risk of experiencing maternal mental health and substance use disorders.

"(c) ADDITIONAL REQUIREMENTS.—In maintaining the hotline under subsection (a), the Secretary shall—

"(1) consult with the Domestic Violence Hotline, National Suicide Prevention Lifeline, and Veterans Crisis Line to ensure that pregnant and postpartum women are connected in real-time to the appropriate specialized hotline service, when applicable;

"(2) conduct a public awareness campaign for the hotline; and

"(3) consult with Federal departments and agencies, including the Centers of Excellence of the Substance Abuse and Mental Health Services Administration and the Department of Veterans Affairs, to increase awareness regarding the hotline.

"(d) ANNUAL REPORT.—The Secretary shall submit an annual report to the Congress on the hotline under subsection (a) and implementation of this section, including—

"(1) an evaluation of the effectiveness of activities conducted or supported under subsection (a);

"(2) a directory of entities or organizations to which staff maintaining the hotline funded under this section may make referrals; and

"(3) such additional information as the Secretary determines appropriate.

"(e) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated $10,000,000 for each of fiscal years 2023 through 2027.".

SEC. 113. TASK FORCE ON MATERNAL MENTAL HEALTH.

Part B of title III of the Public Health Service Act (42 U.S.C. 243 et seq.) is amended by inserting after section 317L–1 (42 U.S.C. 247b–13a) the following:

"SEC. 317L–2. TASK FORCE ON MATERNAL MENTAL HEALTH.

"(a) ESTABLISHMENT.—Not later than 180 days after the date of enactment of the Restoring Hope for the Mental Health and Well-Being Act of 2022, the Secretary, for purposes of identifying, evaluating, and making recommendations to coordinate and improve Federal responses to maternal mental health conditions, shall—

"(1) establish a task force to be known as the Task Force on Maternal Mental Health (in this section referred to as the 'Task Force'); or

"(2) incorporate the duties, public meetings, and reports specified in subsections (c) through (f) into existing Federal policy forums, including the Maternal Health Interagency Policy Committee and the Maternal Health Working Group, as appropriate.

"(b) MEMBERSHIP.—

"(1) COMPOSITION.—The Task Force shall be composed of—

"(A) the Federal members under paragraph (2); and

"(B) the non-Federal members under paragraph (3).

"(2) FEDERAL MEMBERS.—The Federal members of the Task Force shall consist of the following heads of Federal departments and agencies (or their designees):

"(A) The Assistant Secretary for Health of the Department of Health and Human Services, who shall serve as Chair.

"(B) The Assistant Secretary for Planning and Evaluation of the Department of Health and Human Services.

"(C) The Assistant Secretary of the Administration for Children and Families.

"(D) The Director of the Centers for Disease Control and Prevention.

"(E) The Administrator of the Centers for Medicare & Medicaid Services.

"(F) The Administrator of the Health Resources and Services Administration.

"(G) The Director of the Indian Health Service.

"(H) The Assistant Secretary for Mental Health and Substance Use.

"(I) Such other Federal departments and agencies as the Secretary determines appropriate that serve individuals with maternal mental health conditions.

"(3) NON-FEDERAL MEMBERS.—The non-Federal members of the Task Force shall—

"(A) compose not more than one-half, and not less than one-third, of the total membership of the Task Force;

"(B) be appointed by the Secretary; and

"(C) include—

"(i) representatives of medical societies with expertise in maternal or mental health;

"(ii) representatives of nonprofit organizations with expertise in maternal or mental health;

"(iii) relevant industry representatives; and

"(iv) other representatives, as appropriate.

"(4) DEADLINE FOR DESIGNATING DESIGNEES.—If the Assistant Secretary for Health, or the head of a Federal department or agency serving as a member of the Task Force under paragraph (2), chooses to be represented on the Task Force by a designee, the Assistant Secretary or department or agency head shall designate such designee not later than 90 days after the date of the enactment of this section.

"(c) DUTIES.—The Task Force shall—

"(1) prepare and regularly update a report that analyzes and evaluates the state of national maternal mental health policy and programs at the Federal, State, and local levels, and identifies best practices with respect to maternal mental health policy, including—

"(A) a set of evidence-based, evidence-informed, and promising practices with respect to—

"(i) prevention strategies for individuals at risk of experiencing a maternal mental health condition, including strategies and recommendations to address health inequities;

"(ii) the identification, screening, diagnosis, intervention, and treatment of individuals and families affected by a maternal mental health condition;

"(iii) the expeditious referral to, and implementation of, practices and supports that prevent and mitigate the effects of a maternal mental health condition, including strategies and recommendations to eliminate the racial and ethnic disparities that exist in maternal mental health; and

"(iv) community-based or multigenerational practices that support individuals and families affected by a maternal mental health condition; and

"(B) Federal and State programs and activities to prevent, screen, diagnose, intervene, and treat maternal mental health conditions;

"(2) develop and regularly update a national strategy for maternal mental health, taking into consideration the findings of the report under paragraph (1), on how the Task Force and Federal departments and agencies represented on the Task Force may prioritize options for, and may implement a coordinated approach to, addressing maternal mental health conditions, including by—

"(A) increasing prevention, screening, diagnosis, intervention, treatment, and access to care, including clinical and nonclinical care such as peer-support and community health workers, through the public and private sectors;

"(B) providing support for pregnant or postpartum individuals who are at risk for or experiencing a maternal mental health condition, and their families, as appropriate;

"(C) reducing racial, ethnic, geographic, and other health disparities for prevention, diagnosis, intervention, treatment, and access to care;

"(D) identifying options for modifying, strengthening, and coordinating Federal programs and activities, such as the Medicaid program under title XIX of the Social Security Act and the State Children's Health Insurance Program under title XXI of such Act, including existing infant and maternity programs, in order to increase research, prevention, identification, intervention, and treatment with respect to maternal mental health; and

"(E) planning, data sharing, and communication within and across Federal departments, agencies, offices, and programs;

"(3) solicit public comments from stakeholders for the report under paragraph (1) and the national strategy under paragraph (2), including comments from

frontline service providers, mental health professionals, researchers, experts in maternal mental health, institutions of higher education, public health agencies (including maternal and child health programs), and industry representatives, in order to inform the activities and reports of the Task Force; and

"(4) disaggregate any data collected under this section by race, ethnicity, geographical location, age, marital status, socioeconomic level, and other factors, as the Secretary determines appropriate.

"(d) MEETINGS.—The Task Force shall—

"(1) meet not less than two times each year; and

"(2) convene public meetings, as appropriate, to fulfill its duties under this section.

"(e) REPORTS TO PUBLIC AND FEDERAL LEADERS.—The Task Force shall make publicly available and submit to the heads of relevant Federal departments and agencies, the Committee on Energy and Commerce of the House of Representatives, the Committee on Health, Education, Labor, and Pensions of the Senate, and other relevant congressional committees, the following:

"(1) Not later than 1 year after the first meeting of the Task Force, an initial report under subsection (c)(1).

"(2) Not later than 2 years after the first meeting of the Task Force, an initial national strategy under subsection (c)(2).

"(3) Each year thereafter—

"(A) an updated report under subsection (c)(1);

"(B) an updated national strategy under subsection (c)(2); or

"(C) if no update is made under subsection (c)(1) or (c)(2), a report summarizing the activities of the Task Force.

"(f) REPORTS TO GOVERNORS.—Upon finalizing the initial national strategy under subsection (c)(2), and upon making relevant updates to such strategy, the Task Force shall submit a report to the Governors of all States describing opportunities for local- and State-level partnerships identified under subsection (c)(2)(D).

"(g) SUNSET.—The Task Force shall terminate on September 30, 2027.

"(h) NONDUPLICATION OF FEDERAL EFFORTS.—The Secretary may relieve the Task Force, in carrying out subsections (c) through (f), from responsibility for carrying out such activities as may be specified by the Secretary as duplicative with other activities carried out by the Department of Health and Human Services.".

Subtitle C—Reaching Improved Mental Health Outcomes for Patients

SEC. 121. INNOVATION FOR MENTAL HEALTH.

(a) NATIONAL MENTAL HEALTH AND SUBSTANCE USE POLICY LABORATORY.—Section 501A of the Public Health Service Act (42 U.S.C. 290aa–0) is amended—

(1) in subsection (e)(1), by striking "Indian tribes or tribal organizations" and inserting "Indian Tribes or Tribal organizations";

(2) by striking subsection (e)(3); and

(3) by adding at the end the following:

"(f) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there is authorized to be appropriated $10,000,000 for each of fiscal years 2023 through 2027.".

(b) INTERDEPARTMENTAL SERIOUS MENTAL ILLNESS COORDINATING COMMITTEE.—

(1) IN GENERAL.—Part A of title V of the Public Health Service Act (42 U.S.C. 290aa et seq.) is amended by inserting after section 501A (42 U.S.C. 290aa–0) the following:

"SEC. 501B. INTERDEPARTMENTAL SERIOUS MENTAL ILLNESS COORDINATING COMMITTEE.

"(a) ESTABLISHMENT.—

"(1) IN GENERAL.—The Secretary of Health and Human Services, or the designee of the Secretary, shall establish a committee to be known as the Interdepartmental Serious Mental Illness Coordinating Committee (in this section referred to as the 'Committee').

"(2) FEDERAL ADVISORY COMMITTEE ACT.—Except as provided in this section, the provisions of the Federal Advisory Committee Act (5 U.S.C. App.) shall apply to the Committee.

"(b) MEETINGS.—The Committee shall meet not fewer than 2 times each year.

"(c) RESPONSIBILITIES.—The Committee shall submit, on a biannual basis, to Congress and any other relevant Federal department or agency a report including—

"(1) a summary of advances in serious mental illness and serious emotional disturbance research related to the prevention of, diagnosis of, intervention in, and treatment and recovery of serious mental illnesses, serious emotional dis-

turbances, and advances in access to services and support for adults with a serious mental illness or children with a serious emotional disturbance;

"(2) an evaluation of the effect Federal programs related to serious mental illness have on public health, including public health outcomes such as—

"(A) rates of suicide, suicide attempts, incidence and prevalence of serious mental illnesses, serious emotional disturbances, and substance use disorders, overdose, overdose deaths, emergency hospitalizations, emergency room boarding, preventable emergency room visits, interaction with the criminal justice system, homelessness, and unemployment;

"(B) increased rates of employment and enrollment in educational and vocational programs;

"(C) quality of mental and substance use disorders treatment services; or

"(D) any other criteria as may be determined by the Secretary; and

"(3) specific recommendations for actions that agencies can take to better coordinate the administration of mental health services for adults with a serious mental illness or children with a serious emotional disturbance.

"(d) MEMBERSHIP.—

"(1) FEDERAL MEMBERS.—The Committee shall be composed of the following Federal representatives, or the designees of such representatives—

"(A) the Secretary of Health and Human Services, who shall serve as the Chair of the Committee;

"(B) the Assistant Secretary for Mental Health and Substance Use;

"(C) the Attorney General;

"(D) the Secretary of Veterans Affairs;

"(E) the Secretary of Defense;

"(F) the Secretary of Housing and Urban Development;

"(G) the Secretary of Education;

"(H) the Secretary of Labor;

"(I) the Administrator of the Centers for Medicare & Medicaid Services; and

"(J) the Commissioner of Social Security.

"(2) NON-FEDERAL MEMBERS.—The Committee shall also include not less than 14 non-Federal public members appointed by the Secretary of Health and Human Services, of which—

"(A) at least 2 members shall be an individual who has received treatment for a diagnosis of a serious mental illness;

"(B) at least 1 member shall be a parent or legal guardian of an adult with a history of a serious mental illness or a child with a history of a serious emotional disturbance;

"(C) at least 1 member shall be a representative of a leading research, advocacy, or service organization for adults with a serious mental illness;

"(D) at least 2 members shall be—

"(i) a licensed psychiatrist with experience in treating serious mental illnesses;

"(ii) a licensed psychologist with experience in treating serious mental illnesses or serious emotional disturbances;

"(iii) a licensed clinical social worker with experience treating serious mental illnesses or serious emotional disturbances; or

"(iv) a licensed psychiatric nurse, nurse practitioner, or physician assistant with experience in treating serious mental illnesses or serious emotional disturbances;

"(E) at least 1 member shall be a licensed mental health professional with a specialty in treating children and adolescents with a serious emotional disturbance;

"(F) at least 1 member shall be a mental health professional who has research or clinical mental health experience in working with minorities;

"(G) at least 1 member shall be a mental health professional who has research or clinical mental health experience in working with medically underserved populations;

"(H) at least 1 member shall be a State certified mental health peer support specialist;

"(I) at least 1 member shall be a judge with experience in adjudicating cases related to criminal justice or serious mental illness;

"(J) at least 1 member shall be a law enforcement officer or corrections officer with extensive experience in interfacing with adults with a serious mental illness, children with a serious emotional disturbance, or individuals in a mental health crisis; and

"(K) at least 1 member shall have experience providing services for homeless individuals and working with adults with a serious mental illness, chil-

dren with a serious emotional disturbance, or individuals in a mental health crisis.

"(3) TERMS.—A member of the Committee appointed under paragraph (2) shall serve for a term of 3 years, and may be reappointed for 1 or more additional 3-year terms. Any member appointed to fill a vacancy for an unexpired term shall be appointed for the remainder of such term. A member may serve after the expiration of the member's term until a successor has been appointed.

"(e) WORKING GROUPS.—In carrying out its functions, the Committee may establish working groups. Such working groups shall be composed of Committee members, or their designees, and may hold such meetings as are necessary.

"(f) SUNSET.—The Committee shall terminate on September 30, 2027.".

(2) CONFORMING AMENDMENTS.—

(A) Section 501(l)(2) of the Public Health Service Act (42 U.S.C. 290aa(l)(2)) is amended by striking "section 6031 of such Act" and inserting "section 501B of this Act".

(B) Section 6031 of the Helping Families in Mental Health Crisis Reform Act of 2016 (Division B of Public Law 114–255) is repealed (and by conforming the item relating to such section in the table of contents in section 1(b)).

(c) PRIORITY MENTAL HEALTH NEEDS OF REGIONAL AND NATIONAL SIGNIFICANCE.—Section 520A of the Public Health Service Act (42 U.S.C. 290bb–32) is amended—

(1) in subsection (a), by striking "Indian tribes or tribal organizations" and inserting "Indian Tribes or Tribal organizations"; and

(2) in subsection (f), by striking "$394,550,000 for each of fiscal years 2018 through 2022" and inserting "$599,036,000 for each of fiscal years 2023 through 2027".

SEC. 122. CRISIS CARE COORDINATION.

(a) STRENGTHENING COMMUNITY CRISIS RESPONSE SYSTEMS.—Section 520F of the Public Health Service Act (42 U.S.C. 290bb–37) is amended to read as follows:

"SEC. 520F. MENTAL HEALTH CRISIS RESPONSE PARTNERSHIP PILOT PROGRAM.

"(a) IN GENERAL.—The Secretary shall establish a pilot program under which the Secretary will award competitive grants to States, localities, territories, Indian Tribes, and Tribal organizations to establish new, or enhance existing, mobile crisis response teams that divert the response for mental health and substance use crises from law enforcement to mobile crisis teams, as described in subsection (b).

"(b) MOBILE CRISIS TEAMS DESCRIBED.—A mobile crisis team described in this subsection is a team of individuals—

"(1) that is available to respond to individuals in crisis and provide immediate stabilization, referrals to community-based mental health and substance use disorder services and supports, and triage to a higher level of care if medically necessary;

"(2) which may include licensed counselors, clinical social workers, physicians, paramedics, crisis workers, peer support specialists, or other qualified individuals; and

"(3) which may provide support to divert behavioral health crisis calls from the 9–1–1 system to the 9–8–8 system.

"(c) PRIORITY.—In awarding grants under this section, the Secretary shall prioritize applications which account for the specific needs of the communities to be served, including children and families, veterans, rural and underserved populations, and other groups at increased risk of death from suicide or overdose.

"(d) REPORT.—

"(1) INITIAL REPORT.—Not later than September 30, 2024, the Secretary shall submit to Congress a report on steps taken by the entities specified in subsection (a) as of such date of enactment to strengthen the partnerships among mental health providers, substance use disorder treatment providers, primary care physicians, mental health and substance use crisis teams, paramedics, law enforcement officers, and other first responders.

"(2) PROGRESS REPORTS.—Not later than one year after the date on which the first grant is awarded to carry out this section, and for each year thereafter, the Secretary shall submit to Congress a report on the grants made during the year covered by the report, which shall include—

"(A) impact data on the teams and people served by such programs, including demographic information of individuals served, volume, and types of service utilization;

"(B) outcomes of the number of linkages to community-based resources, short-term crisis receiving and stabilization facilities, and diversion from law enforcement or hospital emergency department settings;

"(C) data consistent with the State block grant requirements for continuous evaluation and quality improvement, and other relevant data as determined by the Secretary; and

"(D) the Secretary's recommendations and best practices for—

"(i) States and localities providing mobile crisis response and stabilization services for youth and adults; and

"(ii) improvements to the program established under this section.

"(e) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section, $10,000,000 for each of fiscal years 2023 through 2027.".

(b) MENTAL HEALTH AWARENESS TRAINING GRANTS.—

(1) IN GENERAL.—Section 520J(b) of the Public Health Service Act (42 U.S.C. 290bb–41(b)) is amended—

(A) in paragraph (1), by striking "Indian tribes, tribal organizations" and inserting "Indian Tribes, Tribal organizations";

(B) in paragraph (4), by striking "Indian tribe, tribal organization" and inserting "Indian Tribe, Tribal organization";

(C) in paragraph (5)—

(i) by striking "Indian tribe, tribal organization" and inserting "Indian Tribe, Tribal organization";

(ii) in subparagraph (A), by striking "and" at the end;

(iii) in subparagraph (B)(ii), by striking the period at the end and inserting "; and"; and

(iv) by adding at the end the following:

"(C) suicide intervention and prevention, including recognizing warning signs and how to refer someone for help.";

(D) in paragraph (6), by striking "Indian tribe, tribal organization" and inserting "Indian Tribe, Tribal organization"; and

(E) in paragraph (7), by striking "$14,693,000 for each of fiscal years 2018 through 2022" and inserting "$24,963,000 for each of fiscal years 2023 through 2027".

(2) TECHNICAL CORRECTIONS.—Section 520J(b) of the Public Health Service Act (42 U.S.C. 290bb–41(b)) is amended—

(A) in the heading of paragraph (2), by striking "EMERGENCY SERVICES PERSONNEL" and inserting "EMERGENCY SERVICES PERSONNEL"; and

(B) in the heading of paragraph (3), by striking "DISTRIBUTION OF AWARDS" and inserting "DISTRIBUTION OF AWARDS".

(c) ADULT SUICIDE PREVENTION.—Section 520L of the Public Health Service Act (42 U.S.C. 290bb–43) is amended—

(1) in subsection (a)—

(A) in paragraph (2)—

(i) by striking "Indian tribe" each place it appears and inserting "Indian Tribe"; and

(ii) by striking "tribal organization" each place it appears and inserting "Tribal organization"; and

(B) by amending paragraph (3)(C) to read as follows:

"(C) Raising awareness of suicide prevention resources, promoting help seeking among those at risk for suicide."; and

(2) in subsection (d), by striking "$30,000,000 for the period of fiscal years 2018 through 2022" and inserting "$30,000,000 for each of fiscal years 2023 through 2027".

SEC. 123. TREATMENT OF SERIOUS MENTAL ILLNESS.

(a) ASSERTIVE COMMUNITY TREATMENT GRANT PROGRAM.—

(1) TECHNICAL AMENDMENT.—Section 520M(b) of the Public Health Service Act (42 U.S.C. 290bb–44(b)) is amended by striking "Indian tribe or tribal organization" and inserting "Indian Tribe or Tribal organization".

(2) REPORT TO CONGRESS.—Section 520M(d)(1) of the Public Health Service Act (42 U.S.C. 290bb–44(d)(1)) is amended by striking "not later than the end of fiscal year 2021" and inserting "not later than the end of fiscal year 2026".

(3) AUTHORIZATION OF APPROPRIATIONS.—Section 520M(e)(1) of the Public Health Service Act (42 U.S.C. 290bb–44(d)(1)) is amended by striking "$5,000,000 for the period of fiscal years 2018 through 2022" and inserting "$9,000,000 for each of fiscal years 2023 through 2027".

(b) ASSISTED OUTPATIENT TREATMENT.—Section 224 of the Protecting Access to Medicare Act of 2014 (42 U.S.C. 290aa note) is amended to read as follows:

"SEC. 224. ASSISTED OUTPATIENT TREATMENT GRANT PROGRAM FOR INDIVIDUALS WITH SERIOUS MENTAL ILLNESS.

"(a) IN GENERAL.—The Secretary shall carry out a program to award grants to eligible entities for assisted outpatient treatment programs for individuals with serious mental illness.

"(b) CONSULTATION.—The Secretary shall carry out this section in consultation with the Director of the National Institute of Mental Health, the Attorney General of the United States, the Administrator of the Administration for Community Living, and the Assistant Secretary for Mental Health and Substance Use.

"(c) SELECTING AMONG APPLICANTS.—In awarding grants under this section, the Secretary—

"(1) may give preference to applicants that have not previously implemented an assisted outpatient treatment program; and

"(2) shall evaluate applicants based on their potential to reduce hospitalization, homelessness, incarceration, and interaction with the criminal justice system while improving the health and social outcomes of the patient.

"(d) PROGRAM REQUIREMENTS.—An assisted outpatient treatment program funded with a grant awarded under this section shall include—

"(1) evaluating the medical and social needs of the patients who are participating in the program;

"(2) preparing and executing treatment plans for such patients that—

"(A) include criteria for completion of court-ordered treatment if applicable; and

"(B) provide for monitoring of the patient's compliance with the treatment plan, including compliance with medication and other treatment regimens;

"(3) providing for case management services that support the treatment plan;

"(4) ensuring appropriate referrals to medical and social services providers;

"(5) evaluating the process for implementing the program to ensure consistency with the patient's needs and State law; and

"(6) measuring treatment outcomes, including health and social outcomes such as rates of incarceration, health care utilization, and homelessness.

"(e) REPORT.—Not later than the end of fiscal year 2027, the Secretary shall submit a report to the appropriate congressional committees on the grant program under this section. Such report shall include an evaluation of the following:

"(1) Cost savings and public health outcomes such as mortality, suicide, substance abuse, hospitalization, and use of services.

"(2) Rates of incarceration of patients.

"(3) Rates of homelessness of patients.

"(4) Patient and family satisfaction with program participation.

"(5) Demographic information regarding participation of those served by the grant compared to demographic information in the population of the grant recipient.

"(f) DEFINITIONS.—In this section:

"(1) The term 'assisted outpatient treatment' means medically prescribed mental health treatment that a patient receives while living in a community under the terms of a law authorizing a State or local civil court to order such treatment.

"(2) The term 'eligible entity' means a county, city, mental health system, mental health court, or any other entity with authority under the law of the State in which the entity is located to implement, monitor, and oversee an assisted outpatient treatment program.

"(g) FUNDING.—

"(1) AMOUNT OF GRANTS.—

"(A) MAXIMUM AMOUNT.—The amount of a grant under this section shall not exceed $1,000,000 for any fiscal year.

"(B) DETERMINATION.—Subject to subparagraph (A), the Secretary shall determine the amount of each grant under this section based on the population of the area to be served through the grant and an estimate of the number of patients to be served.

"(2) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section $22,000,000 for each of fiscal years 2023 through 2027.".

Subtitle D—Anna Westin Legacy

SEC. 131. MAINTAINING EDUCATION AND TRAINING ON EATING DISORDERS.

Subpart 3 of part B of title V of the Public Health Service Act (42 U.S.C. 290bb–31 et seq.), as amended by section 102, is further amended by adding at the end the following:

"SEC. 520O. CENTER OF EXCELLENCE FOR EATING DISORDERS FOR EDUCATION AND TRAINING ON EATING DISORDERS.

"(a) IN GENERAL.—The Secretary, acting through the Assistant Secretary, shall maintain, by competitive grant or contract, a Center of Excellence for Eating Disorders (referred to in this section as the 'Center') to improve the identification of, interventions for, and treatment of eating disorders in a manner that is developmentally, culturally, and linguistically appropriate.

"(b) SUBGRANTS AND SUBCONTRACTS.—The Center shall coordinate and implement the activities under subsection (c), in whole or in part, by awarding competitive subgrants or subcontracts—

"(1) across geographical regions; and

"(2) in a manner that is not duplicative.

"(c) ACTIVITIES.—The Center—

"(1) shall—

"(A) provide training and technical assistance for—

"(i) primary care and behavioral health care providers to carry out screening, brief intervention, and referral to treatment for individuals experiencing, or at risk for, eating disorders; and

"(ii) nonclinical community support workers to identify and support individuals with, or at disproportionate risk for, eating disorders;

"(B) develop and provide training materials to health care providers, including primary care and behavioral health care providers, in the effective treatment and ongoing support of individuals with eating disorders, including children and marginalized populations at disproportionate risk for eating disorders;

"(C) provide collaboration and coordination to other centers of excellence, technical assistance centers, and psychiatric consultation lines of the Substance Abuse and Mental Health Services Administration and the Health Resources and Services Administration on the identification, effective treatment, and ongoing support of individuals with eating disorders; and

"(D) coordinate with the Director of the Centers for Disease Control and Prevention and the Administrator of the Health Resources and Services Administration to disseminate training to primary care and behavioral health care providers; and

"(2) may—

"(A) coordinate with electronic health record systems for the integration of protocols pertaining to screening, brief intervention, and referral to treatment for individuals experiencing, or at risk for, eating disorders;

"(B) develop and provide training materials to health care providers, including primary care and behavioral health care providers, in the effective treatment and ongoing support for members of the Armed Forces and veterans experiencing, or at risk for, eating disorders; and

"(C) consult with the Secretary of Defense and the Secretary of Veterans Affairs on prevention, identification, intervention for, and treatment of eating disorders.

"(d) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there is authorized to be appropriated $1,000,000 for each of fiscal years 2023 through 2027.".

Subtitle E—Community Mental Health Services Block Grant Reauthorization

SEC. 141. REAUTHORIZATION OF BLOCK GRANTS FOR COMMUNITY MENTAL HEALTH SERVICES.

(a) FUNDING.—Section 1920(a) of the Public Health Service Act (42 U.S.C. 300x–9(a)) is amended by striking "$532,571,000 for each of fiscal years 2018 through 2022" and inserting "$857,571,000 for each of fiscal years 2023 through 2027".

(b) SET-ASIDE FOR EVIDENCE-BASED CRISIS CARE SERVICES.—Section 1920 of the Public Health Service Act (42 U.S.C. 300x–9) is amended by adding at the end the following:

"(d) CRISIS CARE.—

"(1) IN GENERAL.—Except as provided in paragraph (3), a State shall expend at least 5 percent of the amount the State receives pursuant to section 1911 for each fiscal year to support evidenced-based programs that address the crisis care needs of—

"(A) individuals, including children and adolescents, experiencing mental health crises, substance-related crises, or crises arising from co-occurring disorders; and

"(B) persons with intellectual and developmental disabilities.

"(2) CORE ELEMENTS.—At the discretion of the single State agency responsible for the administration of the program of the State under a grant under section 1911, funds expended pursuant to paragraph (1) may be used to fund some or all of the core crisis care service components, delivered according to evidence-based principles, including the following:

"(A) Crisis call centers.

"(B) 24/7 mobile crisis services.

"(C) Crisis stabilization programs offering acute care or subacute care in a hospital or appropriately licensed facility, as determined by the Substance Abuse and Mental Health Services Administration, with referrals to inpatient or outpatient care.

"(3) STATE FLEXIBILITY.—In lieu of expending 5 percent of the amount the State receives pursuant to section 1911 for a fiscal year to support evidence-based programs as required by paragraph (1), a State may elect to expend not less than 10 percent of such amount to support such programs by the end of two consecutive fiscal years.

"(4) RULE OF CONSTRUCTION.—With respect to funds expended pursuant to the set-aside in paragraph (1), section 1912(b)(1)(A)(vi) shall not apply.".

(c) EARLY INTERVENTION.—

(1) STATE PLAN OPTION.—Section 1912(b)(1)(A)(vii) of the Public Health Service Act (42 U.S.C. 300x–1(b)(1)(A)(vii)) is amended—

(A) in subclause (III), by striking "and" at the end;

(B) in subclause (IV), by striking the period at the end and inserting "; and"; and

(C) by adding at the end the following:

"(V) a description of any evidence-based early intervention strategies and programs the State provides to prevent, delay, or reduce the severity and onset of mental illness and behavioral problems, including for children and adolescents, irrespective of experiencing a serious mental illness or serious emotional disturbance, as defined under subsection (c)(1).".

(2) ALLOCATION ALLOWANCE; REPORTS.—Section 1920 of the Public Health Service Act (42 U.S.C. 300x–9), as amended by subsection (c), is further amended by adding at the end the following:

"(e) EARLY INTERVENTION SERVICES.—In the case of a State with a State plan that provides for strategies and programs specified in section 1912(b)(1)(A)(vii)(VI), such State may expend not more than 5 percent of the amount of the allotment of the State pursuant to a funding agreement under section 1911 for each fiscal year to support such strategies and programs.

"(f) REPORTS TO CONGRESS.—Not later than September 30, 2025, and biennially thereafter, the Secretary shall provide a report to the Congress on the crisis care and early intervention strategies and programs pursued by States pursuant to subsections (d) and (e). Each such report shall include—

"(1) a description of the each State's crisis care and early intervention activities;

"(2) the population served, including information on demographics, including age;

"(3) the outcomes of such activities, including—

"(A) how such activities reduced hospitalizations and hospital stays;

"(B) how such activities reduced incidents of suicidal ideation and behaviors; and

"(C) how such activities reduced the severity of onset of serious mental illness and serious emotional disturbance; and

"(4) any other relevant information the Secretary deems necessary.".

Subtitle F—Peer-Supported Mental Health Services

SEC. 151. PEER-SUPPORTED MENTAL HEALTH SERVICES.

Subpart 3 of part B of title V of the Public Health Service Act (42 U.S.C. 290bb—31 et seq.) is amended by inserting after section 520G (42 U.S.C. 290bb—38) the following:

"SEC. 520H. PEER-SUPPORTED MENTAL HEALTH SERVICES.

"(a) GRANTS AUTHORIZED.—The Secretary, acting through the Director of the Center for Mental Health Services, shall award grants to eligible entities to enable such entities to develop, expand, and enhance access to mental health peer-delivered services.

"(b) USE OF FUNDS.—Grants awarded under subsection (a) shall be used to develop, expand, and enhance national, statewide, or community-focused programs, including virtual peer-support services and infrastructure, including by—

"(1) carrying out workforce development, recruitment, and retention activities, to train, recruit, and retain peer-support providers;

"(2) building connections between mental health treatment programs, including between community organizations and peer-support networks, including virtual peer-support networks, and with other mental health support services;

"(3) reducing stigma associated with mental health disorders;

"(4) expanding and improving virtual peer mental health support services, including adoption of technologies to expand access to virtual peer mental health support services, including by acquiring—

"(A) appropriate physical hardware for such virtual services;

"(B) software and programs to efficiently run peer-support services virtually; and

"(C) other technology for establishing virtual waiting rooms and virtual video platforms for meetings; and

"(5) conducting research on issues relating to mental illness and the impact peer-support has on resiliency, including identifying—

"(A) the signs of mental illness;

"(B) the resources available to individuals with mental illness and to their families; and

"(C) the resources available to help support individuals living with mental illness.

"(c) SPECIAL CONSIDERATION.—In carrying out this section, the Secretary shall give special consideration to the unique needs of rural areas.

"(d) DEFINITION.—In this section, the term 'eligible entity' means—

"(1) a nonprofit consumer-run organization that—

"(A) is principally governed by people living with a mental health condition; and

"(B) mobilizes resources within and outside of the mental health community, which may include through peer-support networks, to increase the prevalence and quality of long-term wellness of individuals living with a mental health condition, including those with a co-occurring substance use disorder; or

"(2) a Federally recognized Tribe, Tribal organization, Urban Indian organization, or consortium of Tribes or Tribal organizations.

"(e) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section $13,000,000 for each of fiscal years 2023 through 2027.".

TITLE II—SUBSTANCE USE DISORDER PREVENTION, TREATMENT, AND RECOVERY SERVICES

Subtitle A—Native Behavioral Health Access Improvement

SEC. 201. BEHAVIORAL HEALTH AND SUBSTANCE USE DISORDER SERVICES FOR NATIVE AMERICANS.

Section 506A of the Public Health Service Act (42 U.S.C. 290aa–5a) is amended to read as follows:

"SEC. 506A. BEHAVIORAL HEALTH AND SUBSTANCE USE DISORDER SERVICES FOR NATIVE AMERICANS.

"(a) DEFINITIONS.—In this section:

"(1) The term 'eligible entity' means an Indian Tribe, a Tribal organization, an Urban Indian organization, and a Native Hawaiian health organization.

"(2) The terms 'Indian Tribe', 'Tribal organization', and 'Urban Indian organization' have the meanings given to the terms 'Indian tribe', 'tribal organization', and 'Urban Indian organization' in section 4 of the Indian Health Care Improvement Act.

"(3) The term 'Native Hawaiian health organization' means 'Papa Ola Lokahi' as defined in section 12 of the Native Hawaiian Health Care Improvement Act.

"(b) FORMULA FUNDS.—

"(1) IN GENERAL.—The Secretary, in consultation with the Director of the Indian Health Service, as appropriate, shall award funds to eligible entities, in amounts determined pursuant to the formula described in paragraph (2), to be used by the eligible entity to provide culturally appropriate mental health and substance use disorder prevention, treatment, and recovery services to American Indians, Alaska Natives, and Native Hawaiians.

"(2) FORMULA.—The Secretary, using the process described in subsection (d), shall develop a formula to determine the amount of an award under paragraph (1). Such formula shall take into account the populations of eligible entities whose rates of overdose deaths or suicide are substantially higher relative to the populations of other Indian Tribes, Tribal organizations, Urban Indian organizations, or Native Hawaiian health organizations, as applicable.

"(c) TECHNICAL ASSISTANCE AND PROGRAM EVALUATION.—

"(1) IN GENERAL.—The Secretary shall—

"(A) provide technical assistance to applicants and awardees under this section; and

"(B) collect and evaluate information on the program carried out under this section.

"(2) CONSULTATION ON EVALUATION MEASURES, AND DATA SUBMISSION AND REPORTING REQUIREMENTS.—The Secretary shall, using the process described in subsection (d), develop evaluation measures and data submission and reporting requirements for purposes of the collection and evaluation of information.

"(3) DATA SUBMISSION AND REPORTING.—As a condition on receipt of funds under this section, an applicant shall agree to submit data and reports in a timely manner consistent with the evaluation measures and data submission and reporting requirements developed under subsection (d).

"(d) REGULATIONS.—

"(1) PROMULGATION.—Not later than 180 days after the date of enactment of the Restoring Hope for Mental Health and Well-Being Act of 2022, the Secretary shall initiate procedures under subchapter III of chapter 5 of title 5, United States Code, to negotiate and promulgate such regulations as are necessary to carry out this section, including development of the funding formula described in subsection (b) and the program evaluation and reporting requirements under subsection (c).

"(2) PUBLICATION.—Not later than 18 months after the date of enactment of the Restoring Hope for Mental Health and Well-Being Act of 2022, the Secretary shall publish in the Federal Register proposed regulations to implement this section.

"(3) COMMITTEE.—A negotiated rulemaking committee established pursuant to section 565 of title 5, United States Code, to carry out this subsection shall have as its members only representatives of the Federal Government, Tribal Governments, and Urban Indian organizations. For purposes of such rulemaking, the Indian Health Service shall be the lead agency for the Department.

"(4) ADAPTATION OF PROCEDURES.—In carrying out this subsection, the Secretary shall adapt any negotiated rulemaking procedures to the unique context of the government-to-government relationship between the United States and Indian Tribes.

"(5) EFFECT.—The lack of promulgated regulations under this subsection shall not limit the effect or implementation of this section.

"(e) APPLICATION.—An entity desiring an award under subsection (b) shall submit an application to the Secretary at such time, in such manner, and accompanied by such information as the Secretary may reasonably require.

"(f) REPORT.—Not later than 3 years after the date of the enactment of the Restoring Hope for Mental Health and Well-Being Act of 2022, and annually thereafter, the Secretary shall prepare and submit, to the Committee on Health, Education, Labor, and Pensions of the Senate, and the Committee on Energy and Commerce

of the House of Representatives, a report describing the services provided pursuant to this section.

"(g) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section, $40,000,000 for each of fiscal years 2023 through 2027.".

Subtitle B—Summer Barrow Prevention, Treatment, and Recovery

SEC. 211. GRANTS FOR THE BENEFIT OF HOMELESS INDIVIDUALS.

Section 506(e) of the Public Health Service Act (42 U.S.C. 290aa–5(e)) is amended by striking "2018 through 2022" and inserting "2023 through 2027".

SEC. 212. PRIORITY SUBSTANCE ABUSE TREATMENT NEEDS OF REGIONAL AND NATIONAL SIGNIFICANCE.

Section 509 of the Public Health Service Act (42 U.S.C. 290bb–2) is amended—

(1) in the section heading, by striking "**ABUSE**" and inserting "**USE DISORDER**";

(2) in subsection (a)—

(A) by striking "tribes and tribal organizations (as the terms 'Indian tribes' and 'tribal organizations' are defined" and inserting "Tribes and Tribal organizations (as such terms are defined"; and

(B) in paragraph (3), by striking "in substance abuse";

(3) in subsection (b), in the subsection heading, by striking "ABUSE" and inserting "USE DISORDER"; and

(4) in subsection (f), by striking "$333,806,000 for each of fiscal years 2018 through 2022" and inserting "$521,517,000 for each of fiscal years 2023 through 2027".

SEC. 213. EVIDENCE-BASED PRESCRIPTION OPIOID AND HEROIN TREATMENT AND INTERVENTIONS DEMONSTRATION.

Section 514B of the Public Health Service Act (42 U.S.C. 290bb–10) is amended—

(1) in subsection (a)(1)—

(A) by striking "substance abuse" and inserting "substance use disorder";

(B) by striking "tribes and tribal organizations" and inserting "Tribes and Tribal organizations"; and

(C) by striking "addiction" and inserting "substance use disorders";

(2) in subsection (e)(3), by striking "tribes and tribal organizations" and inserting "Tribes and Tribal organizations"; and

(3) in subsection (f), by striking "2017 through 2021" and inserting "2023 through 2027".

SEC. 214. PRIORITY SUBSTANCE USE DISORDER PREVENTION NEEDS OF REGIONAL AND NATIONAL SIGNIFICANCE.

Section 516 of the Public Health Service Act (42 U.S.C. 290bb–22) is amended—

(1) in subsection (a)—

(A) in paragraph (3), by striking "abuse" and inserting "use"; and

(B) in the matter following paragraph (3), by striking "tribes or tribal organizations" and inserting "Tribes or Tribal organizations";

(2) in subsection (b), in the subsection heading, by striking "ABUSE" and inserting "USE DISORDER"; and

(3) in subsection (f), by striking "$211,148,000 for each of fiscal years 2018 through 2022" and inserting "$218,219,000 for each of fiscal years 2023 through 2027".

SEC. 215. SOBER TRUTH ON PREVENTING (STOP) UNDERAGE DRINKING REAUTHORIZATION.

Section 519B of the Public Health Service Act (42 U.S.C. 290bb–25b) is amended—

(1) by amending subsection (a) to read as follows:

"(a) DEFINITIONS.—For purposes of this section:

"(1) The term 'alcohol beverage industry' means the brewers, vintners, distillers, importers, distributors, and retail or online outlets that sell or serve beer, wine, and distilled spirits.

"(2) The term 'school-based prevention' means programs, which are institutionalized, and run by staff members or school-designated persons or organizations in any grade of school, kindergarten through 12th grade.

"(3) The term 'youth' means persons under the age of 21."; and

(2) by striking subsections (c) through (g) and inserting the following:

"(c) INTERAGENCY COORDINATING COMMITTEE; ANNUAL REPORT ON STATE UNDERAGE DRINKING PREVENTION AND ENFORCEMENT ACTIVITIES.—

"(1) INTERAGENCY COORDINATING COMMITTEE ON THE PREVENTION OF UNDERAGE DRINKING.—

"(A) IN GENERAL.—The Secretary, in collaboration with the Federal officials specified in subparagraph (B), shall continue to support and enhance the efforts of the interagency coordinating committee, that began operating in 2004, focusing on underage drinking (referred to in this subsection as the 'Committee').

"(B) OTHER AGENCIES.—The officials referred to in subparagraph (A) are the Secretary of Education, the Attorney General, the Secretary of Transportation, the Secretary of the Treasury, the Secretary of Defense, the Surgeon General, the Director of the Centers for Disease Control and Prevention, the Director of the National Institute on Alcohol Abuse and Alcoholism, the Assistant Secretary for Mental Health and Substance Use, the Director of the National Institute on Drug Abuse, the Assistant Secretary for Children and Families, the Director of the Office of National Drug Control Policy, the Administrator of the National Highway Traffic Safety Administration, the Administrator of the Office of Juvenile Justice and Delinquency Prevention, the Chairman of the Federal Trade Commission, and such other Federal officials as the Secretary of Health and Human Services determines to be appropriate.

"(C) CHAIR.—The Secretary of Health and Human Services shall serve as the chair of the Committee.

"(D) DUTIES.—The Committee shall guide policy and program development across the Federal Government with respect to underage drinking, provided, however, that nothing in this section shall be construed as transferring regulatory or program authority from an Agency to the Coordinating Committee.

"(E) CONSULTATIONS.—The Committee shall actively seek the input of and shall consult with all appropriate and interested parties, including States, public health research and interest groups, foundations, and alcohol beverage industry trade associations and companies.

"(F) ANNUAL REPORT.—

"(i) IN GENERAL.—The Secretary, on behalf of the Committee, shall annually submit to the Congress a report that summarizes—

"(I) all programs and policies of Federal agencies designed to prevent and reduce underage drinking, focusing particularly on programs and policies that support the adoption and enforcement of State policies designed to prevent and reduce underage drinking as specified in paragraph (2);

"(II) the extent of progress in preventing and reducing underage drinking at State and national levels;

"(III) data that the Secretary shall collect with respect to the information specified in clause (ii); and

"(IV) such other information regarding underage drinking as the Secretary determines to be appropriate.

"(ii) CERTAIN INFORMATION.—The report under clause (i) shall include information on the following:

"(I) Patterns and consequences of underage drinking as reported in research and surveys such as, but not limited to, Monitoring the Future, Youth Risk Behavior Surveillance System, the National Survey on Drug Use and Health, and the Fatality Analysis Reporting System.

"(II) Measures of the availability of alcohol from commercial and non-commercial sources to underage populations.

"(III) Measures of the exposure of underage populations to messages regarding alcohol in advertising, social media, and the entertainment media.

"(IV) Surveillance data, including information on the onset and prevalence of underage drinking, consumption patterns, beverage preferences, prevalence of drinking among students at institutions of higher education, correlations between adult and youth drinking, and the means of underage access, including trends over time for these surveillance data. The Secretary shall develop a plan to improve the collection, measurement, and consistency of reporting Federal underage alcohol data.

"(V) Any additional findings resulting from research conducted or supported under subsection (f).

"(VI) Evidence-based best practices to prevent and reduce underage drinking including a review of the research literature related

to State laws, regulations, and policies designed to prevent and reduce underage drinking, as described in paragraph (2)(B)(i).

"(2) ANNUAL REPORT ON STATE UNDERAGE DRINKING PREVENTION AND ENFORCEMENT ACTIVITIES.—

"(A) IN GENERAL.—The Secretary shall, with input and collaboration from other appropriate Federal agencies, States, Indian Tribes, territories, and public health, consumer, and alcohol beverage industry groups, annually issue a report on each State's performance in enacting, enforcing, and creating laws, regulations, and policies to prevent or reduce underage drinking based on an assessment of best practices developed pursuant to paragraph (1)(F)(ii)(VI) and subparagraph (B)(i). For purposes of this paragraph, each such report, with respect to a year, shall be referred to as the 'State Report'. Each State Report shall be designed as a resource tool for Federal agencies assisting States in the their underage drinking prevention efforts, State public health and law enforcement agencies, State and local policymakers, and underage drinking prevention coalitions including those receiving grants pursuant to subsection (e).

"(B) STATE PERFORMANCE MEASURES.—

"(i) IN GENERAL.—The Secretary shall develop, in consultation with the Committee, a set of measures to be used in preparing the State Report on best practices as they relate to State laws, regulations, policies, and enforcement practices.

"(ii) STATE REPORT CONTENT.—The State Report shall include updates on State laws, regulations, and policies included in previous reports to Congress, including with respect to the following:

"(I) Whether or not the State has comprehensive anti-underage drinking laws such as for the illegal sale, purchase, attempt to purchase, consumption, or possession of alcohol; illegal use of fraudulent ID; illegal furnishing or obtaining of alcohol for an individual under 21 years; the degree of strictness of the penalties for such offenses; and the prevalence of the enforcement of each of these infractions.

"(II) Whether or not the State has comprehensive liability statutes pertaining to underage access to alcohol such as dram shop, social host, and house party laws, and the prevalence of enforcement of each of these laws.

"(III) Whether or not the State encourages and conducts comprehensive enforcement efforts to prevent underage access to alcohol at retail outlets, such as random compliance checks and shoulder tap programs, and the number of compliance checks within alcohol retail outlets measured against the number of total alcohol retail outlets in each State, and the result of such checks.

"(IV) Whether or not the State encourages training on the proper selling and serving of alcohol for all sellers and servers of alcohol as a condition of employment.

"(V) Whether or not the State has policies and regulations with regard to direct sales to consumers and home delivery of alcoholic beverages.

"(VI) Whether or not the State has programs or laws to deter adults from purchasing alcohol for minors; and the number of adults targeted by these programs.

"(VII) Whether or not the State has enacted graduated drivers licenses and the extent of those provisions.

"(iii) ADDITIONAL CATEGORIES.—In addition to the updates on State laws, regulations, and policies listed in clause (ii), the Secretary shall consider the following:

"(I) Whether or not States have adopted laws, regulations, and policies that deter underage alcohol use, as described in 'The Surgeon General's Call to Action to Prevent and Reduce Underage Drinking' issued in 2007 and 'Facing Addiction in America: The Surgeon General's Report on Alcohol, Drugs and Health' issued in 2016, including restrictions on low-price, high-volume drink specials, and wholesaler pricing provisions.

"(II) Whether or not States have adopted laws, regulations, and policies designed to reduce alcohol advertising messages attractive to youth and youth exposure to alcohol advertising and marketing in measured and unmeasured media and digital and social media.

"(III) Whether or not States have laws and policies that promote underage drinking prevention policy development by local jurisdictions.

"(IV) Whether or not States have adopted laws, regulations, and policies to restrict youth access to alcoholic beverages that may pose special risks to youth, including but not limited to alcoholic mists, gelatins, freezer pops, premixed caffeinated alcoholic beverages, and flavored malt beverages.

"(V) Whether or not States have adopted uniform best practices protocols for conducting compliance checks and shoulder tap programs.

"(VI) Whether or not States have adopted uniform best practices penalty protocols for violations of laws prohibiting retail licensees from selling or furnishing of alcohol to minors.

"(iv) UNIFORM DATA SYSTEM.—For performance measures related to enforcement of underage drinking laws as specified in clauses (ii) and (iii), the Secretary shall develop and test a uniform data system for reporting State enforcement data, including the development of a pilot program for this purpose. The pilot program shall include procedures for collecting enforcement data from both State and local law enforcement jurisdictions.

"(3) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this subsection $1,000,000 for each of fiscal years 2023 through 2027.

"(d) NATIONAL MEDIA CAMPAIGN TO PREVENT UNDERAGE DRINKING.—

"(1) IN GENERAL.—The Secretary, in consultation with the National Highway Traffic Safety Administration, shall develop an intensive, multifaceted, adult-oriented national media campaign to reduce underage drinking by influencing attitudes regarding underage drinking, increasing the willingness of adults to take actions to reduce underage drinking, and encouraging public policy changes known to decrease underage drinking rates.

"(2) PURPOSE.—The purpose of the national media campaign described in this section shall be to achieve the following objectives:

"(A) Instill a broad societal commitment to reduce underage drinking.

"(B) Increase specific actions by adults that are meant to discourage or inhibit underage drinking.

"(C) Decrease adult conduct that tends to facilitate or condone underage drinking.

"(3) COMPONENTS.—When implementing the national media campaign described in this section, the Secretary shall—

"(A) educate the public about the public health and safety benefits of evidence-based policies to reduce underage drinking, including minimum legal drinking age laws, and build public and parental support for and cooperation with enforcement of such policies;

"(B) educate the public about the negative consequences of underage drinking;

"(C) promote specific actions by adults that are meant to discourage or inhibit underage drinking, including positive behavior modeling, general parental monitoring, and consistent and appropriate discipline;

"(D) discourage adult conduct that tends to facilitate underage drinking, including the hosting of underage parties with alcohol and the purchasing of alcoholic beverages on behalf of underage youth;

"(E) establish collaborative relationships with local and national organizations and institutions to further the goals of the campaign and assure that the messages of the campaign are disseminated from a variety of sources;

"(F) conduct the campaign through multi-media sources; and

"(G) conduct the campaign with regard to changing demographics and cultural and linguistic factors.

"(4) CONSULTATION REQUIREMENT.—In developing and implementing the national media campaign described in this section, the Secretary shall consult recommendations for reducing underage drinking published by the National Academy of Sciences and the Surgeon General. The Secretary shall also consult with interested parties including medical, public health, and consumer and parent groups, law enforcement, institutions of higher education, community organizations and coalitions, and other stakeholders supportive of the goals of the campaign.

"(5) ANNUAL REPORT.—The Secretary shall produce an annual report on the progress of the development or implementation of the media campaign described in this subsection, including expenses and projected costs, and, as such

information is available, report on the effectiveness of such campaign in affecting adult attitudes toward underage drinking and adult willingness to take actions to decrease underage drinking.

"(6) RESEARCH ON YOUTH-ORIENTED CAMPAIGN.—The Secretary may, based on the availability of funds, conduct research on the potential success of a youth-oriented national media campaign to reduce underage drinking. The Secretary shall report any such results to Congress with policy recommendations on establishing such a campaign.

"(7) ADMINISTRATION.—The Secretary may enter into a subcontract with another Federal agency to delegate the authority for execution and administration of the adult-oriented national media campaign.

"(8) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section $2,500,000 for each of fiscal years 2023 through 2027.

"(e) COMMUNITY-BASED COALITION ENHANCEMENT GRANTS TO PREVENT UNDERAGE DRINKING.—

"(1) AUTHORIZATION OF PROGRAM.—The Assistant Secretary for Mental Health and Substance Use, in consultation with the Director of the Office of National Drug Control Policy, shall award enhancement grants to eligible entities to design, implement, evaluate, and disseminate comprehensive strategies to maximize the effectiveness of community-wide approaches to preventing and reducing underage drinking. This subsection is subject to the availability of appropriations.

"(2) PURPOSES.—The purposes of this subsection are to—

"(A) prevent and reduce alcohol use among youth in communities throughout the United States;

"(B) strengthen collaboration among communities, the Federal Government, Tribal Governments, and State and local governments;

"(C) enhance intergovernmental cooperation and coordination on the issue of alcohol use among youth;

"(D) serve as a catalyst for increased citizen participation and greater collaboration among all sectors and organizations of a community that first demonstrates a long-term commitment to reducing alcohol use among youth;

"(E) implement state-of-the-art science-based strategies to prevent and reduce underage drinking by changing local conditions in communities; and

"(F) enhance, not supplant, effective local community initiatives for preventing and reducing alcohol use among youth.

"(3) APPLICATION.—An eligible entity desiring an enhancement grant under this subsection shall submit an application to the Assistant Secretary at such time, and in such manner, and accompanied by such information and assurances, as the Assistant Secretary may require. Each application shall include—

"(A) a complete description of the entity's current underage alcohol use prevention initiatives and how the grant will appropriately enhance the focus on underage drinking issues; or

"(B) a complete description of the entity's current initiatives, and how it will use this grant to enhance those initiatives by adding a focus on underage drinking prevention.

"(4) USES OF FUNDS.—Each eligible entity that receives a grant under this subsection shall use the grant funds to carry out the activities described in such entity's application submitted pursuant to paragraph (3) and obtain specialized training and technical assistance by the entity funded under section 4 of Public Law 107–82, as amended (21 U.S.C. 1521 note). Grants under this subsection shall not exceed $60,000 per year and may not exceed four years.

"(5) SUPPLEMENT NOT SUPPLANT.—Grant funds provided under this subsection shall be used to supplement, not supplant, Federal and non-Federal funds available for carrying out the activities described in this subsection.

"(6) EVALUATION.—Grants under this subsection shall be subject to the same evaluation requirements and procedures as the evaluation requirements and procedures imposed on recipients of drug-free community grants.

"(7) DEFINITIONS.—For purposes of this subsection, the term 'eligible entity' means an organization that is currently receiving or has received grant funds under the Drug-Free Communities Act of 1997.

"(8) ADMINISTRATIVE EXPENSES.—Not more than 6 percent of a grant under this subsection may be expended for administrative expenses.

"(9) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this subsection $11,500,000 for each of fiscal years 2023 through 2027.

"(f) GRANTS TO PROFESSIONAL PEDIATRIC PROVIDER ORGANIZATIONS TO REDUCE UNDERAGE DRINKING THROUGH SCREENING AND BRIEF INTERVENTIONS.—

"(1) IN GENERAL.—The Secretary, acting through the Assistant Secretary for Mental Health and Substance Use, shall make one or more grants to professional pediatric provider organizations to increase among the members of such organizations effective practices to reduce the prevalence of alcohol use among individuals under the age of 21, including college students.

"(2) PURPOSES.—Grants under this subsection shall be made to promote the practices of—

"(A) screening adolescents for alcohol use;

"(B) offering brief interventions to adolescents to discourage such use;

"(C) educating parents about the dangers of and methods of discouraging such use;

"(D) diagnosing and treating alcohol use disorders; and

"(E) referring patients, when necessary, to other appropriate care.

"(3) USE OF FUNDS.—A professional pediatric provider organization receiving a grant under this section may use the grant funding to promote the practices specified in paragraph (2) among its members by—

"(A) providing training to health care providers;

"(B) disseminating best practices, including culturally and linguistically appropriate best practices, and developing, printing, and distributing materials; and

"(C) supporting other activities approved by the Assistant Secretary.

"(4) APPLICATION.—To be eligible to receive a grant under this subsection, a professional pediatric provider organization shall submit an application to the Assistant Secretary at such time, and in such manner, and accompanied by such information and assurances as the Secretary may require. Each application shall include—

"(A) a description of the pediatric provider organization;

"(B) a description of the activities to be completed that will promote the practices specified in paragraph (2);

"(C) a description of the organization's qualifications for performing such practices; and

"(D) a timeline for the completion of such activities.

"(5) DEFINITIONS.—For the purpose of this subsection:

"(A) BRIEF INTERVENTION.—The term 'brief intervention' means, after screening a patient, providing the patient with brief advice and other brief motivational enhancement techniques designed to increase the insight of the patient regarding the patient's alcohol use, and any realized or potential consequences of such use to effect the desired related behavioral change.

"(B) ADOLESCENTS.—The term 'adolescents' means individuals under 21 years of age.

"(C) PROFESSIONAL PEDIATRIC PROVIDER ORGANIZATION.—The term 'professional pediatric provider organization' means an organization or association that—

"(i) consists of or represents pediatric health care providers; and

"(ii) is qualified to promote the practices specified in paragraph (2).

"(D) SCREENING.—The term 'screening' means using validated patient interview techniques to identify and assess the existence and extent of alcohol use in a patient.

"(6) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this subsection $3,000,000 for each of fiscal years 2023 through 2027.

"(g) DATA COLLECTION AND RESEARCH.—

"(1) ADDITIONAL RESEARCH ON UNDERAGE DRINKING.—

"(A) IN GENERAL.—The Secretary shall, subject to the availability of appropriations, collect data, and conduct or support research that is not duplicative of research currently being conducted or supported by the Department of Health and Human Services, on underage drinking, with respect to the following:

"(i) Improve data collection in support of evaluation of the effectiveness of comprehensive community-based programs or strategies and statewide systems to prevent and reduce underage drinking, across the underage years from early childhood to age 21, such as programs funded and implemented by governmental entities, public health interest groups and foundations, and alcohol beverage companies and trade associations, through the development of models of State-level epidemiological surveillance of underage drinking by funding in States or large

metropolitan areas new epidemiologists focused on excessive drinking including underage alcohol use.

"(ii) Obtain and report more precise information than is currently collected on the scope of the underage drinking problem and patterns of underage alcohol consumption, including improved knowledge about the problem and progress in preventing, reducing, and treating underage drinking, as well as information on the rate of exposure of youth to advertising and other media messages encouraging and discouraging alcohol consumption.

"(iii) Synthesize, expand on, and widely disseminate existing research on effective strategies for reducing underage drinking, including translational research, and make this research easily accessible to the general public.

"(iv) Improve and conduct public health surveillance on alcohol use and alcohol-related conditions in States by increasing the use of surveys, such as the Behavioral Risk Factor Surveillance System, to monitor binge and excessive drinking and related harms among individuals who are at least 18 years of age, but not more than 20 years of age, including harm caused to self or others as a result of alcohol use that is not duplicative of research currently being conducted or supported by the Department of Health and Human Services.

"(B) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this paragraph $5,000,000 for each of fiscal years 2023 through 2027.

"(2) NATIONAL ACADEMY OF SCIENCES STUDY.—

"(A) IN GENERAL.—Not later than 12 months after the enactment of the Restoring Hope for Mental Health and Well-Being Act of 2022, the Secretary shall—

"(i) contract with the National Academy of Sciences to study developments in research on underage drinking and the public policy implications of these developments; and

"(ii) report to the Congress on the results of such review.

"(B) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this paragraph $500,000 for fiscal year 2023.".

SEC. 216. GRANTS FOR JAIL DIVERSION PROGRAMS.

Section 520G of the Public Health Service Act (42 U.S.C. 290bb–38) is amended—

(1) in subsection (a)—

(A) by striking "up to 125"; and

(B) by striking "tribes and tribal organizations" and inserting "Tribes and Tribal organizations";

(2) in subsection (b)(2), by striking "tribes, and tribal organizations" and inserting "Tribes, and Tribal organizations";

(3) in subsection (c)—

(A) in paragraph (1), by striking "tribe or tribal organization" and inserting "Tribe or Tribal organization, health facility or program described in subsection (a), or public or nonprofit entity referred to in subsection (a)"; and

(B) in paragraph (2)(A)(iii), by striking "tribe, or tribal organization" and inserting "Tribe, or Tribal organization";

(4) in subsection (e)—

(A) in the matter preceding paragraph (1), by striking "tribe, or tribal organization" and inserting "Tribe, or Tribal organization"; and

(B) in paragraph (5), by striking "or arrest" and inserting ", arrest, or release";

(5) in subsection (f), by striking "tribe, or tribal organization" each place it appears and inserting "Tribe, or Tribal organization";

(6) in subsection (h), by striking "tribe, or tribal organization" and inserting "Tribe, or Tribal organization"; and

(7) in subsection (j), by striking "$4,269,000 for each of fiscal years 2018 through 2022" and inserting "$14,000,000 for each of fiscal years 2023 through 2027".

SEC. 217. FORMULA GRANTS TO STATES.

Section 521 of the Public Health Service Act (42 U.S.C. 290cc–21) is amended by striking "2018 through 2022" and inserting "2023 through 2027".

SEC. 218. PROJECTS FOR ASSISTANCE IN TRANSITION FROM HOMELESSNESS.

Section 535(a) of the Public Health Service Act (42 U.S.C. 290cc–35(a)) is amended by striking "2018 through 2022" and inserting "2023 through 2027".

SEC. 219. GRANTS FOR REDUCING OVERDOSE DEATHS.

(a) GRANTS.—

(1) REPEAL OF MAXIMUM GRANT AMOUNT.—Paragraph (2) of section 544(a) of the Public Health Service Act (42 U.S.C. 290dd–3(a)) is hereby repealed.

(2) ELIGIBLE ENTITY; SUBGRANTS.—Section 544(a) of the Public Health Service Act (42 U.S.C. 290dd–3(a)) is amended by striking paragraph (3) and inserting the following:

"(2) ELIGIBLE ENTITY.—For purposes of this section, the term 'eligible entity' means a State, Territory, locality, Indian Tribe (as defined in the Federally Recognized Indian Tribe List Act of 1994), Tribal organization, or Urban Indian organization (as those terms are defined in section 4 of the Indian Health Care Improvement Act).

"(3) SUBGRANTS.—For the purposes for which a grant is awarded under this section, the eligible entity receiving the grant may award subgrants to a Federally qualified health center (as defined in section 1861(aa) of the Social Security Act), an opioid treatment program (as defined in section 8.2 of title 42, Code of Federal Regulations (or any successor regulations)), any practitioner dispensing narcotic drugs pursuant to section 303(g) of the Controlled Substances Act, or any nonprofit organization that the Secretary deems appropriate.".

(3) PRESCRIBING.—Section 544(a)(4) of the Public Health Service Act (42 U.S.C. 290dd–3(a)(4)) is amended—

(A) in subparagraph (A), by inserting ", including patients prescribed with both an opioid and a benzodiazepine" before the semicolon at the end; and

(B) in subparagraph (D), by striking "drug overdose" and inserting "substance overdose".

(4) USE OF FUNDS.—Paragraph (5) of section 544(c) of the Public Health Service Act (42 U.S.C. 290dd–3(c)) is amended to read as follows:

"(5) To establish protocols to connect patients who have experienced an overdose with appropriate treatment, including overdose reversal medications, medication assisted treatment, and appropriate counseling and behavioral therapies.".

(5) IMPROVING ACCESS TO OVERDOSE TREATMENT.—Section 544 of the Public Health Service Act (42 U.S.C. 290dd–3) is amended—

(A) by redesignating subsections (d) through (f) as subsections (e) through (g), respectively;

(B) in subsection (f), as so redesignated, by striking "subsection (d)" and inserting "subsection (e)"; and

(C) by inserting after subsection (c) the following:

"(d) IMPROVING ACCESS TO OVERDOSE TREATMENT.—

"(1) INFORMATION ON BEST PRACTICES.—

"(A) HEALTH AND HUMAN SERVICES.—The Secretary of Health and Human Services may provide information to States, localities, Indian Tribes, Tribal organizations, and Urban Indian organizations on best practices for prescribing or co-prescribing a drug or device approved, cleared, or otherwise authorized under the Federal Food, Drug, and Cosmetic Act for emergency treatment of known or suspected opioid overdose, including for patients receiving chronic opioid therapy and patients being treated for opioid use disorders.

"(B) DEFENSE.—The Secretary of Defense may provide information to prescribers within Department of Defense medical facilities on best practices for prescribing or co-prescribing a drug or device approved, cleared, or otherwise authorized under the Federal Food, Drug, and Cosmetic Act for emergency treatment of known or suspected opioid overdose, including for patients receiving chronic opioid therapy and patients being treated for opioid use disorders.

"(C) VETERANS AFFAIRS.—The Secretary of Veterans Affairs may provide information to prescribers within Department of Veterans Affairs medical facilities on best practices for prescribing or co-prescribing a drug or device approved, cleared, or otherwise authorized under the Federal Food, Drug, and Cosmetic Act for emergency treatment of known or suspected opioid overdose, including for patients receiving chronic opioid therapy and patients being treated for opioid use disorders.

"(2) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed as establishing or contributing to a medical standard of care.".

(6) AUTHORIZATION OF APPROPRIATIONS.—Section 544(g) of the Public Health Service Act (42 U.S.C. 290dd–3), as redesignated, is amended by striking "fiscal years 2017 through 2021" and inserting "fiscal years 2023 through 2027".

(7) TECHNICAL AMENDMENTS.—

(A) Section 544 of the Public Health Service Act (42 U.S.C. 290dd–3), as amended, is further amended by striking "approved or cleared" each place it appears and inserting "approved, cleared, or otherwise authorized".

(B) Section 107 of the Comprehensive Addiction and Recovery Act of 2016 (Public Law 114–198) is amended by striking subsection (b).

SEC. 220. OPIOID OVERDOSE REVERSAL MEDICATION ACCESS AND EDUCATION GRANT PROGRAMS.

(a) GRANTS.—Section 545 of the Public Health Service Act (42 U.S.C. 290ee) is amended—

(1) in the section heading, by striking "**ACCESS AND EDUCATION GRANT PROGRAMS**" and inserting "**ACCESS, EDUCATION, AND CO-PRESCRIBING GRANT PROGRAMS**";

(2) in the heading of subsection (a), by striking "GRANTS TO STATES" and inserting "GRANTS";

(3) in subsection (a), by striking "shall make grants to States" and inserting "shall make grants to States, localities, Indian Tribes (as defined by the Federally Recognized Indian Tribe List Act of 1994), Tribal organizations, and Urban Indian organizations (as those terms are defined in section 4 of the Indian Health Care Improvement Act)";

(4) in subsection (a)(1), by striking "implement strategies for pharmacists to dispense a drug or device" and inserting "implement strategies that increase access to drugs or devices";

(5) by redesignating paragraphs (3) and (4) as paragraphs (4) and (5), respectively; and

(6) by inserting after paragraph (2) the following:

"(3) encourage health care providers to co-prescribe, as appropriate, drugs or devices approved, cleared, or otherwise authorized under the Federal Food, Drug, and Cosmetic Act for emergency treatment of known or suspected opioid overdose;".

(b) GRANT PERIOD.—Section 545(d)(2) of the Public Health Service Act (42 U.S.C. 290ee(d)(2)) is amended by striking "3 years" and inserting "5 years".

(c) LIMITATION.—Paragraph (3) of section 545(d) of the Public Health Service Act (42 U.S.C. 290ee(d)) is amended to read as follows:

"(3) LIMITATIONS.—A State may—

"(A) use not more than 10 percent of a grant under this section for educating the public pursuant to subsection (a)(5); and

"(B) use not less than 20 percent of a grant under this section to offset cost-sharing for distribution and dispensing of drugs or devices approved, cleared, or otherwise authorized under the Federal Food, Drug, and Cosmetic Act for emergency treatment of known or suspected opioid overdose.".

(d) AUTHORIZATION OF APPROPRIATIONS.—Section 545(h)(1) of the Public Health Service Act, is amended by striking "fiscal years 2017 through 2019" and inserting "fiscal years 2023 through 2027".

(e) TECHNICAL AMENDMENT.—Section 545 of the Public Health Service Act (42 U.S.C. 290ee), as amended, is further amended by striking "approved or cleared" each place it appears and inserting "approved, cleared, or otherwise authorized".

SEC. 221. STATE DEMONSTRATION GRANTS FOR COMPREHENSIVE OPIOID ABUSE RESPONSE.

Section 548 of the Public Health Service Act (42 U.S.C. 290ee–3) is amended—

(1) in the section heading, by striking "**ABUSE**" and inserting "**USE DISORDER**";

(2) in subsection (b)—

(A) in the subsection heading, by striking "ABUSE" and inserting "USE DISORDER";

(B) in paragraph (1), by striking "abuse" and inserting "use disorder";

(C) in paragraph (2)—

(i) in the matter preceding subparagraph (A), by striking "abuse" and inserting "use disorder";

(ii) in subparagraph (A), by striking "opioid use, treatment, and addiction recovery" and inserting "opioid use disorders, and treatment for, and recovery from opioid use disorders";

(iii) in subparagraph (C), by striking "addiction" each place it appears and inserting "use disorder";

(iv) by amending subparagraph (D) to read as follows:

"(D) developing, implementing, and expanding efforts to prevent overdose death from opioid or other prescription medication use disorders; and"; and

(v) in subparagraph (E), by striking "abuse" and inserting "use disorders"; and

(D) in paragraph (4), by striking "abuse" each place it appears and inserting "use disorders"; and

(3) by striking "2017 through 2021" and inserting "2023 through 2027".

SEC. 222. EMERGENCY DEPARTMENT ALTERNATIVES TO OPIOIDS.

Section 7091 of the SUPPORT for Patients and Communities Act (Public Law 115–271) is amended—

(1) in the section heading, by striking "**DEMONSTRATION**" (and by conforming the item relating to such section in the table of contents in section 1(b));

(2) in subsection (a)—

(A) by amending the subsection heading to read as follows: "GRANT PROGRAM"; and

(B) in paragraph (1), by striking "demonstration";

(3) in subsection (b), in the subsection heading, by striking "DEMONSTRATION";

(4) in subsection (d)(4), by striking "tribal" and inserting "Tribal";

(5) in subsection (f), by striking "Not later than 1 year after completion of the demonstration program under this section, the Secretary shall submit a report to the Congress on the results of the demonstration program" and inserting "Not later than the end of each of fiscal years 2024 and 2027, the Secretary shall submit to the Congress a report on the results of the program"; and

(6) in subsection (g), by striking "2019 through 2021" and inserting "2023 through 2027".

Subtitle C—Excellence in Recovery Housing

SEC. 231. CLARIFYING THE ROLE OF SAMHSA IN PROMOTING THE AVAILABILITY OF HIGH-QUALITY RECOVERY HOUSING.

Section 501(d) of the Public Health Service Act (42 U.S.C. 290aa) is amended—

(1) in paragraph (24)(E), by striking "and" at the end;

(2) in paragraph (25), by striking the period at the end and inserting "; and"; and

(3) by adding at the end the following:

"(26) collaborate with national accrediting entities, reputable providers, organizations or individuals with established expertise in delivery of recovery housing services, States, Federal agencies (including the Department of Health and Human Services, the Department of Housing and Urban Development, and the agencies listed in section 550(e)(2)(B)), and other relevant stakeholders, to promote the availability of high-quality recovery housing and services for individuals with a substance use disorder.".

SEC. 232. DEVELOPING GUIDELINES FOR STATES TO PROMOTE THE AVAILABILITY OF HIGH-QUALITY RECOVERY HOUSING.

Section 550(a) of the Public Health Service Act (42 U.S.C. 290ee–5(a)) (relating to national recovery housing best practices) is amended—

(1) by amending paragraph (1) to read as follows:

"(1) IN GENERAL.—The Secretary, in consultation with the individuals and entities specified in paragraph (2), shall build on existing best practices and previously developed guidelines to develop and periodically update consensus-based best practices, which may include model laws for implementing suggested minimum standards for operating, and promoting the availability of, high-quality recovery housing.";

(2) in paragraph (2)—

(A) by striking subparagraphs (A) and (B) and inserting the following:

"(A) Officials representing the agencies described in subsection (e)(2).";

and

(B) by redesignating subparagraphs (C) through (G) as subparagraphs (B) through (F), respectively; and

(3) by adding at the end the following:

"(3) AVAILABILITY.—The best practices referred to in paragraph (1) shall be—

"(A) made publicly available; and

"(B) published on the public website of the Substance Abuse and Mental Health Services Administration.

"(4) EXCLUSION OF GUIDELINE ON TREATMENT SERVICES.—In developing the guidelines under paragraph (1), the Secretary may not include any guidelines with respect to substance use disorder treatment services.".

SEC. 233. COORDINATION OF FEDERAL ACTIVITIES TO PROMOTE THE AVAILABILITY OF RECOVERY HOUSING.

Section 550 of the Public Health Service Act (42 U.S.C. 290ee–5) (relating to national recovery housing best practices) is amended—

(1) by redesignating subsections (e), (f), and (g) as subsections (g), (h), and (i), respectively; and

(2) by inserting after subsection (d) the following:

"(e) COORDINATION OF FEDERAL ACTIVITIES TO PROMOTE THE AVAILABILITY OF HOUSING FOR INDIVIDUALS EXPERIENCING HOMELESSNESS, INDIVIDUALS WITH A MENTAL ILLNESS, AND INDIVIDUALS WITH A SUBSTANCE USE DISORDER.—

"(1) IN GENERAL.—The Secretary, acting through the Assistant Secretary, and the Secretary of Housing and Urban Development shall convene an interagency working group for the following purposes:

"(A) To increase collaboration, cooperation, and consultation among the Department of Health and Human Services, the Department of Housing and Urban Development, and the Federal agencies listed in paragraph (2)(B), with respect to promoting the availability of housing, including recovery housing, for individuals experiencing homelessness, individuals with mental illnesses, and individuals with substance use disorder.

"(B) To align the efforts of such agencies and avoid duplication of such efforts by such agencies.

"(C) To develop objectives, priorities, and a long-term plan for supporting State, Tribal, and local efforts with respect to the operation of recovery housing that is consistent with the best practices developed under this section.

"(D) To coordinate enforcement of fair housing practices, as appropriate, among Federal and State agencies.

"(E) To coordinate data collection on the quality of recovery housing.

"(2) COMPOSITION.—The interagency working group under paragraph (1) shall be composed of—

"(A) the Secretary, acting through the Assistant Secretary, and the Secretary of Housing and Urban Development, who shall serve as the co-chairs; and

"(B) representatives of each of the following Federal agencies:

"(i) The Centers for Medicare & Medicaid Services.

"(ii) The Substance Abuse and Mental Health Services Administration.

"(iii) The Health Resources and Services Administration.

"(iv) The Office of Inspector General.

"(v) The Indian Health Service.

"(vi) The Department of Agriculture.

"(vii) The Department of Justice.

"(viii) The Office of National Drug Control Policy.

"(ix) The Bureau of Indian Affairs.

"(x) The Department of Labor.

"(xi) The Department of Veterans Affairs.

"(xii) Any other Federal agency as the co-chairs determine appropriate.

"(3) MEETINGS.—The working group shall meet on a quarterly basis.

"(4) REPORTS TO CONGRESS.—Not later than 4 years after the date of the enactment of this section, the working group shall submit to the Committee on Energy and Commerce, the Committee on Ways and Means, the Committee on Agriculture, and the Committee on Financial Services of the House of Representatives and the Committee on Health, Education, Labor, and Pensions, the Committee on Agriculture, Nutrition, and Forestry, and the Committee on Finance of the Senate a report describing the work of the working group and any recommendations of the working group to improve Federal, State, and local coordination with respect to recovery housing and other housing resources and operations for individuals experiencing homelessness, individuals with a mental illness, and individuals with a substance use disorder.".

SEC. 234. NAS STUDY AND REPORT.

(a) IN GENERAL.—Not later than 60 days after the date of enactment of this Act, the Secretary of Health and Human Services, acting through the Assistant Secretary for Mental Health and Substance Use shall—

(1) contract with the National Academies of Sciences, Engineering, and Medicine—

(A) to study the quality and effectiveness of recovery housing in the United States and whether the availability of such housing meets demand; and

(B) to identify recommendations to promote the availability of high-quality recovery housing; and

(2) report to the Congress on the results of such review.

(b) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section there is authorized to be appropriated $1,500,000 for fiscal year 2023.

SEC. 235. GRANTS FOR STATES TO PROMOTE THE AVAILABILITY OF RECOVERY HOUSING AND SERVICES.

Section 550 of the Public Health Service Act (42 U.S.C. 290ee–5) (relating to national recovery housing best practices), as amended by sections 232 and 233, is further amended by inserting after subsection (e) (as inserted by section 233) the following:

"(f) GRANTS FOR IMPLEMENTING NATIONAL RECOVERY HOUSING BEST PRACTICES.—

"(1) IN GENERAL.—The Secretary shall award grants to States (and political subdivisions thereof), Tribes, and territories—

"(A) for the provision of technical assistance to implement the guidelines and recommendations developed under subsection (a); and

"(B) to promote—

"(i) the availability of recovery housing for individuals with a substance use disorder; and

"(ii) the maintenance of recovery housing in accordance with best practices developed under this section.

"(2) STATE PROMOTION PLANS.—Not later than 90 days after receipt of a grant under paragraph (1), and every 2 years thereafter, each State (or political subdivisions thereof,) Tribe, or territory receiving a grant under paragraph (1) shall submit to the Secretary, and publish on a publicly accessible internet website of the State (or political subdivisions thereof), Tribe, or territory—

"(A) the plan of the State (or political subdivisions thereof), Tribe, or territory, with respect to the promotion of recovery housing for individuals with a substance use disorder located within the jurisdiction of such State (or political subdivisions thereof), Tribe, or territory; and

"(B) a description of how such plan is consistent with the best practices developed under this section.".

SEC. 236. FUNDING.

Subsection (i) of section 550 of the Public Health Service Act (42 U.S.C. 290ee–5) (relating to national recovery housing best practices), as redesignated by section 233, is amended by striking "$3,000,000 for the period of fiscal years 2019 through 2021" and inserting "$5,000,000 for the period of fiscal years 2023 through 2027".

SEC. 237. TECHNICAL CORRECTION.

Title V of the Public Health Service Act (42 U.S.C. 290aa et seq.) is amended—

(1) by redesignating section 550 (relating to Sobriety Treatment and Recovery Teams) (42 U.S.C. 290ee–10), as added by section 8214 of Public Law 115–271, as section 550A; and

(2) by moving such section so it appears after section 550 (relating to national recovery housing best practices).

Subtitle D—Substance Use Prevention, Treatment, and Recovery Services Block Grant

SEC. 241. ELIMINATING STIGMATIZING LANGUAGE RELATING TO SUBSTANCE USE.

(a) BLOCK GRANTS FOR PREVENTION AND TREATMENT OF SUBSTANCE USE.—Part B of title XIX of the Public Health Service Act (42 U.S.C. 300x et seq.) is amended—

(1) in the part heading, by striking "**SUBSTANCE ABUSE**" and inserting "**SUBSTANCE USE**";

(2) in subpart II, by amending the subpart heading to read as follows: "**Block Grants for Substance Use Prevention, Treatment, and Recovery Services**";

(3) in section 1922(a) (42 U.S.C. 300x–22(a))—

(A) in paragraph (1), in the matter preceding subparagraph (A), by striking "substance abuse" and inserting "substance use disorders"; and

(B) by striking "such abuse" each place it appears in paragraphs (1) and (2) and inserting "such disorders";

(4) in section 1923 (42 U.S.C. 300x–23)—

(A) in the section heading, by striking "**SUBSTANCE ABUSE**" and inserting "**SUBSTANCE USE**"; and

(B) in subsection (a), by striking "drug abuse" and inserting "substance use disorders";

(5) in section 1925(a)(1) (42 U.S.C. 300x–25(a)(1)), by striking "alcohol or drug abuse" and inserting "alcohol or other substance use disorders";

(6) in section 1926(b)(2)(B) (42 U.S.C. 300x–26(b)(2)(B)), by striking "substance abuse";

(7) in section 1931(b)(2) (42 U.S.C. 300x–31(b)(2)), by striking "substance abuse" and inserting "substance use disorders";

(8) in section 1933(d)(1) (42 U.S.C. 300x–33(d)), in the matter following subparagraph (B), by striking "abuse of alcohol and other drugs" and inserting "use of substances";

(9) by amending paragraph (4) of section 1934 (42 U.S.C. 300x–34) to read as follows:

"(4) The term 'substance use disorder' means the recurrent use of alcohol or other drugs that causes clinically significant impairment.";

(10) in section 1935 (42 U.S.C. 300x–35)—

(A) in subsection (a), by striking "substance abuse" and inserting "substance use disorders"; and

(B) in subsection (b)(1), by striking "substance abuse" each place it appears and inserting "substance use disorders";

(11) in section 1949 (42 U.S.C. 300x–59), by striking "substance abuse" each place it appears in subsections (a) and (d) and inserting "substance use disorders";

(12) in section 1954(b)(4) (42 U.S.C. 300x–64(b)(4))—

(A) by striking "substance abuse" and inserting "substance use disorders"; and

(B) by striking "such abuse" and inserting "such disorders";

(13) in section 1955 (42 U.S.C. 300x–65), by striking "substance abuse" each place it appears and inserting "substance use disorder"; and

(14) in section 1956 (42 U.S.C. 300x–66), by striking "substance abuse" and inserting "substance use disorders".

(b) CERTAIN PROGRAMS REGARDING MENTAL HEALTH AND SUBSTANCE ABUSE.—Part C of title XIX of the Public Health Service Act (42 U.S.C. 300y et seq.) is amended—

(1) in the part heading, by striking "**SUBSTANCE ABUSE**" and inserting "**SUBSTANCE USE**";

(2) in section 1971 (42 U.S.C. 300y), by striking "substance abuse" each place it appears in subsections (a), (b), and (f) and inserting "substance use"; and

(3) in section 1976 (42 U.S.C. 300y–11), by striking "intravenous abuse" each place it appears and inserting "intravenous use".

SEC. 242. AUTHORIZED ACTIVITIES.

Section 1921(b) of the Public Health Service Act (42 U.S.C. 300x–21(b)) is amended by striking "prevent and treat substance use disorders" and inserting "prevent, treat, and provide recovery support services for substance use disorders".

SEC. 243. REQUIREMENTS RELATING TO CERTAIN INFECTIOUS DISEASES AND HUMAN IMMUNODEFICIENCY VIRUS.

Section 1924 of the Public Health Service Act (42 U.S.C. 300x–24) is amended—

(1) in the section heading, by striking "**TUBERCULOSIS AND HUMAN IMMUNODEFICIENCY VIRUS**" and inserting "**TUBERCULOSIS, VIRAL HEPATITIS, AND HUMAN IMMUNODEFICIENCY VIRUS**";

(2) by amending subsection (a)(2) to read as follows:

"(2) DESIGNATED STATES.—

"(A) FISCAL YEARS THROUGH FISCAL YEAR 2024.—For purposes of this subsection, through September 30, 2024, a State described in this paragraph is any State whose rate of cases of acquired immune deficiency syndrome is 10 or more such cases per 100,000 individuals (as indicated by the number of such cases reported to and confirmed by the Director of the Centers for Disease Control and Prevention for the most recent calendar year for which such data are available).

"(B) FISCAL YEAR 2025 AND SUCCEEDING FISCAL YEARS.—

"(i) IN GENERAL.—Beginning with fiscal year 2025, for purposes of this subsection, a State described in this paragraph is any State whose rate of cases of human immunodeficiency virus is 10 or more such cases per 100,000 individuals (as indicated by the number of such cases newly reported to and confirmed by the Director of the Centers for Disease Control and Prevention for the most recent calendar year for which such data are available).

"(ii) CONTINUATION OF DESIGNATED STATE STATUS.—In the case of a State whose rate of cases of human immunodeficiency virus falls below the threshold specified in clause (i) for a calendar year, such State shall, notwithstanding clause (i), continue to be described in this para-

graph unless the rate of cases falls below such threshold for three consecutive calendar years.".

(3) by redesignating subsections (c) and (d) as subsections (d) and (e), respectively; and

(4) by inserting after subsection (b) the following:

"(c) VIRAL HEPATITIS.—

"(1) IN GENERAL.—A funding agreement for a grant under section 1921 is that the State involved will require that any entity receiving amounts from the grant for operating a program of treatment for substance use disorders—

"(A) will, directly or through arrangements with other public or nonprofit private entities, routinely make available viral hepatitis services to each individual receiving treatment for such disorders; and

"(B) in the case of an individual in need of such treatment who is denied admission to the program on the basis of the lack of the capacity of the program to admit the individual, will refer the individual to another provider of viral hepatitis services.

"(2) VIRAL HEPATITIS SERVICES.—For purposes of paragraph (1), the term 'viral hepatitis services', with respect to an individual, means—

"(A) screening the individual for viral hepatitis; and

"(B) referring the individual to a provider whose practice includes viral hepatitis vaccination and treatment.".

SEC. 244. STATE PLAN REQUIREMENTS.

Section 1932(b)(1)(A) of the Public Health Service Act (42 U.S.C. 300x–32(b)(1)(A)) is amended—

(1) by redesignating clauses (vi) through (ix) as clauses (vii) through (x), respectively; and

(2) by inserting after clause (v) the following:

"(vi) provides a description of—

"(I) the State's comprehensive statewide recovery support services activities, including the number of individuals being served, target populations, and priority needs; and

"(II) the amount of funds received under this subpart expended on recovery support services, disaggregated by the amount expended for type of service activity;".

SEC. 245. UPDATING CERTAIN LANGUAGE RELATING TO TRIBES.

Section 1933(d) of the Public Health Service Act (42 U.S.C. 300x–33(d)) is amended—

(1) in paragraph (1)—

(A) in subparagraph (A)—

(i) by striking "of an Indian tribe or tribal organization" and inserting "of an Indian Tribe or Tribal organization"; and

(ii) by striking "such tribe" and inserting "such Tribe";

(B) in subparagraph (B)—

(i) by striking "tribe or tribal organization" and inserting "Tribe or Tribal organization"; and

(ii) by striking "Secretary under this" and inserting "Secretary under this subpart"; and

(C) in the matter following subparagraph (B), by striking "tribe or tribal organization" and inserting "Tribe or Tribal organization";

(2) by amending paragraph (2) to read as follows:

"(2) INDIAN TRIBE OR TRIBAL ORGANIZATION AS GRANTEE.—The amount reserved by the Secretary on the basis of a determination under this subsection shall be granted to the Indian Tribe or Tribal organization serving the individuals for whom such a determination has been made.";

(3) in paragraph (3), by striking "tribe or tribal organization" and inserting "Tribe or Tribal organization"; and

(4) in paragraph (4)—

(A) in the paragraph heading, by striking "DEFINITION" and inserting "DEFINITIONS"; and

(B) by striking "The terms" and all that follows through "given such terms" and inserting the following: "The terms 'Indian Tribe' and 'Tribal organization' have the meanings given the terms 'Indian tribe' and 'tribal organization'".

SEC. 246. BLOCK GRANTS FOR SUBSTANCE USE PREVENTION, TREATMENT, AND RECOVERY SERVICES.

(a) IN GENERAL.—Section 1935(a) of the Public Health Service Act (42 U.S.C. 300x–35(a)), as amended by section 241, is further amended by striking "appro-

priated" and all that follows through "2022.." and inserting the following: "appropriated $1,908,079,000 for each of fiscal years 2023 through 2027.".

(b) TECHNICAL CORRECTIONS.—Section 1935(b)(1)(B) of the Public Health Service Act (42 U.S.C. 300x–35(b)(1)(B)) is amended by striking "the collection of data in this paragraph is".

SEC. 247. REQUIREMENT OF REPORTS AND AUDITS BY STATES.

Section 1942(a) of the Public Health Service Act (42 U.S.C. 300x–52(a)) is amended—

(1) in paragraph (1), by striking "and" at the end;

(2) in paragraph (2), by striking the period at the end and inserting "; and"; and

(3) by adding at the end the following:

"(3) the amount provided to each recipient in the previous fiscal year.".

SEC. 248. STUDY ON ASSESSMENT FOR USE IN DISTRIBUTION OF LIMITED STATE RESOURCES.

(a) IN GENERAL.—The Secretary of Health and Human Services, acting through the Assistant Secretary for Mental Health and Substance Use (in this section referred to as the "Secretary"), shall, in consultation with States and other local entities providing prevention, treatment, or recovery support services related to substance use, conduct a study to develop a model needs assessment process for States to consider to help determine how best to allocate block grant funding received under subpart II of part B of title XIX of the Public Health Service Act (42 U.S.C. 300x–21) to provide services to substance use disorder prevention, treatment, and recovery support. The study shall include cost estimates with each model needs assessment process.

(b) REPORT.—Not later than 2 years after the date of the enactment of this Act, the Secretary shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report on the results of the study conducted under paragraph (1).

Subtitle E—Timely Treatment for Opioid Use Disorder

SEC. 251. STUDY ON EXEMPTIONS FOR TREATMENT OF OPIOID USE DISORDER THROUGH OPIOID TREATMENT PROGRAMS DURING THE COVID–19 PUBLIC HEALTH EMERGENCY.

(a) STUDY.—The Assistant Secretary for Mental Health and Substance Use shall conduct a study, in consultation with patients and other stakeholders, on activities carried out pursuant to exemptions granted—

(1) to a State (including the District of Columbia or any territory of the United States) or an opioid treatment program;

(2) pursuant to section 8.11(h) of title 42, Code of Federal Regulations; and

(3) during the period—

(A) beginning on the declaration of the public health emergency for the COVID–19 pandemic under section 319 of the Public Health Service Act (42 U.S.C. 247d); and

(B) ending on the earlier of—

(i) the termination of such public health emergency, including extensions thereof pursuant to such section 319; and

(ii) the end of calendar year 2022.

(b) PRIVACY.—The section does not authorize the disclosure by the Department of Health and Human Services of individually identifiable information about patients.

(c) FEEDBACK.—In conducting the study under subsection (a), the Assistant Secretary for Mental Health and Substance Use shall gather feedback from the States and opioid treatment programs on their experiences in implementing exemptions described in subsection (a).

(d) REPORT.—Not later than 180 days after the end of the period described in subsection (a)(3)(B), and subject to subsection (c), the Assistant Secretary for Mental Health and Substance Use shall publish a report on the results of the study under this section.

SEC. 252. CHANGES TO FEDERAL OPIOID TREATMENT STANDARDS.

(a) MOBILE MEDICATION UNITS.—Section 302(e) of the Controlled Substances Act (21 U.S.C. 822(e)) is amended by adding at the end the following:

"(3) Notwithstanding paragraph (1), a registrant that is dispensing pursuant to section 303(g) narcotic drugs to individuals for maintenance treatment or detoxification treatment shall not be required to have a separate registration to incorporate

one or more mobile medication units into the registrant's practice to dispense such narcotics at locations other than the registrant's principal place of business or professional practice described in paragraph (1), so long as the registrant meets such standards for operation of a mobile medication unit as the Attorney General may establish.".

(b) REVISE OPIOID TREATMENT PROGRAM ADMISSION CRITERIA TO ELIMINATE REQUIREMENT THAT PATIENTS HAVE AN OPIOID USE DISORDER FOR AT LEAST 1 YEAR.—Not later than 18 months after the date of enactment of this Act, the Secretary of Health and Human Services shall revise section 8.12(e)(1) of title 42, Code of Federal Regulations (or successor regulations), to eliminate the requirement that an opioid treatment program only admit an individual for treatment under the program if the individual has been addicted to opioids for at least 1 year before being so admitted for treatment.

(c) FINAL REGULATION ON PERIODS FOR TAKE-HOME SUPPLY REQUIREMENTS.—

(1) IN GENERAL.—Not later than 18 months after the date of enactment of this Act, the Secretary of Health and Human Services shall promulgate a final regulation amending paragraphs (i)(3)(i) through (i)(3)(vi) of section 8.12 of title 42, Code of Federal Regulations, as appropriate based on the findings of the study under section 251 of this Act.

(2) CRITERIA.—The regulation under paragraph (1) shall establish relevant criteria for the medical director or an appropriately licensed practitioner of an opioid treatment program, to determine whether a patient is stable and may qualify for unsupervised use, which criteria may allow for consideration of each of the following:

(A) Whether the benefits of providing unsupervised doses to a patient outweigh the risks.

(B) The patient's demonstrated adherence to their treatment plan.

(C) The patient's history of negative toxicology tests.

(D) Whether there is an absence of serious behavioral problems.

(E) The patient's stability in living arrangements and social relationships.

(F) Whether there is an absence of substance misuse-related behaviors.

(G) Whether there is an absence of recent diversion activity.

(H) Whether there is an assurance that the medication can be safely stored by the patient.

(I) Any other criterion the Secretary of Health and Human Services determines appropriate.

(3) PROHIBITED SOLE CONSIDERATION.—The regulation under paragraph (1) shall prohibit the medical director of an opioid treatment program from considering, as the sole consideration in determining whether a patient is sufficiently responsible in handling opioid drugs for unsupervised use, whether the patient has an absence of recent misuse of drugs (whether narcotic or nonnarcotic), including alcohol.

Subtitle F—Additional Provisions Relating to Addiction Treatment

SEC. 261. PROHIBITION.

Notwithstanding any provision of this Act and the amendments made by this Act, no funds made available to carry out this Act or any amendment made by this Act shall be used to purchase, procure, or distribute pipes or cylindrical objects intended to be used to smoke or inhale illegal scheduled substances.

SEC. 262. ELIMINATING ADDITIONAL REQUIREMENTS FOR DISPENSING NARCOTIC DRUGS IN SCHEDULE III, IV, AND V FOR MAINTENANCE OR DETOXIFICATION TREATMENT.

(a) IN GENERAL.—Section 303(g) of the Controlled Substances Act (21 U.S.C. 823(g)) is amended—

(1) by striking paragraph (2);

(2) by striking "(g)(1) Except as provided in paragraph (2), practitioners who dispense narcotic drugs to individuals for maintenance treatment or detoxification treatment" and inserting "(g) Practitioners who dispense narcotic drugs (other than narcotic drugs in schedule III, IV, or V) to individuals for maintenance treatment or detoxification treatment";

(3) by redesignating subparagraphs (A), (B), and (C) as paragraphs (1), (2), and (3), respectively; and

(4) in paragraph (2), as so redesignated—

(A) by striking "(i) security of stocks" and inserting "(A) security of stocks"; and

(B) by striking "(ii) the maintenance of records" and inserting "(B) the maintenance of records".

(b) CONFORMING CHANGES.—

(1) Subsections (a) and (d)(1) of section 304 of the Controlled Substances Act (21 U.S.C. 824) are each amended by striking "303(g)(1)" each place it appears and inserting "303(g)".

(2) Section 309A(a)(2) of the Controlled Substances Act (21 U.S.C. 829a) is amended—

(A) in the matter preceding subparagraph (A), by striking "the controlled substance is to be administered for the purpose of maintenance or detoxification treatment under section 303(g)(2)" and inserting "the controlled substance is a narcotic drug in schedule III, IV, or V to be administered for the purpose of maintenance or detoxification treatment"; and

(B) by striking "and—" and all that follows through "is to be administered by injection or implantation;" and inserting "and is to be administered by injection or implantation;".

(3) Section 520E–4(c) of the Public Health Service Act (42 U.S.C. 290bb–36d(c)) is amended by striking "information on any qualified practitioner that is certified to prescribe medication for opioid dependency under section 303(g)(2)(B) of the Controlled Substances Act" and inserting "information on any practitioner who prescribes narcotic drugs in schedule III, IV, or V of section 202 of the Controlled Substances Act for the purpose of maintenance or detoxification treatment".

(4) Section 544(a)(3) of the Public Health Service Act (42 U.S.C. 290dd–3), as added by section 219(a)(2), is amended by striking "any practitioner dispensing narcotic drugs pursuant to section 303(g) of the Controlled Substances Act" and inserting "any practitioner dispensing narcotic drugs for the purpose of maintenance or detoxification treatment".

(5) Section 1833(bb)(3)(B) of the Social Security Act (42 U.S.C. 1395l(bb)(3)(B)) is amended by striking "first receives a waiver under section 303(g) of the Controlled Substances Act on or after January 1, 2019" and inserting "first begins prescribing narcotic drugs in schedule III, IV, or V of section 202 of the Controlled Substances Act for the purpose of maintenance or detoxification treatment on or after January 1, 2021".

(6) Section 1834(o)(3)(C)(ii) of the Social Security Act (42 U.S.C. 1395m(o)(3)(C)(ii)) is amended by striking "first receives a waiver under section 303(g) of the Controlled Substances Act on or after January 1, 2019" and inserting "first begins prescribing narcotic drugs in schedule III, IV, or V of section 202 of the Controlled Substances Act for the purpose of maintenance or detoxification treatment on or after January 1, 2021".

(7) Section 1866F(c)(3) of the Social Security Act (42 U.S.C. 1395cc–6(c)(3)) is amended—

(A) in subparagraph (A), by adding "and" at the end;

(B) in subparagraph (B), by striking "; and" and inserting a period; and

(C) by striking subparagraph (C).

(8) Section 1903(aa)(2)(C) of the Social Security Act (42 U.S.C. 1396b(aa)(2)(C)) is amended—

(A) in clause (i), by adding "and" at the end;

(B) by striking clause (ii); and

(C) by redesignating clause (iii) as clause (ii).

SEC. 263. REQUIRING PRESCRIBERS OF CONTROLLED SUBSTANCES TO COMPLETE TRAINING.

Section 303 of the Controlled Substances Act (21 U.S.C. 823) is amended by adding at the end the following:

"(l) REQUIRED TRAINING FOR PRESCRIBERS.—

"(1) TRAINING REQUIRED.—As a condition on registration under this section to dispense controlled substances in schedule II, III, IV, or V, the Attorney General shall require any qualified practitioner, beginning with the first applicable registration for the practitioner, to meet the following:

"(A) If the practitioner is a physician, the practitioner meets one or more of the following conditions:

"(i) The physician holds a board certification in addiction psychiatry or addiction medicine from the American Board of Medical Specialties.

"(ii) The physician holds a board certification from the American Board of Addiction Medicine.

"(iii) The physician holds a board certification in addiction medicine from the American Osteopathic Association.

"(iv) The physician has, with respect to the treatment and management of patients with opioid or other substance use disorders, com-

pleted not less than 8 hours of training (through classroom situations, seminars at professional society meetings, electronic communications, or otherwise) that is provided by—

"(I) the American Society of Addiction Medicine, the American Academy of Addiction Psychiatry, the American Medical Association, the American Osteopathic Association, the American Psychiatric Association, or any other organization accredited by the Accreditation Council for Continuing Medical Education (commonly known as the 'ACCME');

"(II) any organization accredited by a State medical society accreditor that is recognized by the ACCME;

"(III) any organization accredited by the American Osteopathic Association to provide continuing medical education; or

"(IV) any organization approved by the Assistant Secretary for Mental Health and Substance Abuse or the ACCME.

"(v) The physician graduated in good standing from an accredited school of allopathic medicine or osteopathic medicine in the United States during the 5-year period immediately preceding the date on which the physician first registers or renews under this section and has successfully completed a comprehensive allopathic or osteopathic medicine curriculum or accredited medical residency that included not less than 8 hours of training on treating and managing patients with opioid and other substance use disorders, including the appropriate clinical use of all drugs approved by the Food and Drug Administration for the treatment of a substance use disorder.

"(B) If the practitioner is not a physician, the practitioner meets one or more of the following conditions:

"(i) The practitioner has completed not fewer than 8 hours of training with respect to the treatment and management of patients with opioid or other substance use disorders (through classroom situations, seminars at professional society meetings, electronic communications, or otherwise) provided by the American Society of Addiction Medicine, the American Academy of Addiction Psychiatry, the American Medical Association, the American Osteopathic Association, the American Nurses Credentialing Center, the American Psychiatric Association, the American Association of Nurse Practitioners, the American Academy of Physician Associates, or any other organization approved or accredited by the Assistant Secretary for Mental Health and Substance Abuse or the or the Accreditation Council for Continuing Medical Education.

"(ii) The practitioner has graduated in good standing from an accredited physician assistant school or accredited school of advanced practice nursing in the United States during the 5-year period immediately preceding the date on which the practitioner first registers or renews under this section and has successfully completed a comprehensive physician assistant or advanced practice nursing curriculum that included not fewer than 8 hours of training on treating and managing patients with opioid and other substance use disorders, including the appropriate clinical use of all drugs approved by the Food and Drug Administration for the treatment of a substance use disorder.

"(2) ONE-TIME TRAINING.—The Attorney General shall not require any qualified practitioner to complete the training described in clause (iv) or (v) of paragraph (1)(A) or clause (i) or (ii) of paragraph (1)(B) more than once.

"(3) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed to preclude the use, by a qualified practitioner, of training received pursuant to this subsection to satisfy registration requirements of a State or for some other lawful purpose.

"(4) DEFINITIONS.—In this section:

"(A) FIRST APPLICABLE REGISTRATION.—The term 'first applicable registration' means the first registration or renewal of registration by a qualified practitioner under this section that occurs on or after the date that is 180 days after the date of enactment of the Restoring Hope for Mental Health and Well-Being Act of 2022.

"(B) QUALIFIED PRACTITIONER.—In this subsection, the term 'qualified practitioner' means a practitioner who—

"(i) is licensed under State law to prescribe controlled substances; and

"(ii) is not solely a veterinarian.".

TITLE III—ACCESS TO MENTAL HEALTH CARE AND COVERAGE

Subtitle A—Collaborate in an Orderly and Cohesive Manner

SEC. 301. INCREASING UPTAKE OF THE COLLABORATIVE CARE MODEL.

Section 520K of the Public Health Service Act (42 U.S.C. 290bb–42) is amended to read as follows:

"SEC. 520K. INTEGRATION INCENTIVE GRANTS AND COOPERATIVE AGREEMENTS.

"(a) DEFINITIONS.—In this section:

"(1) COLLABORATIVE CARE MODEL.—The term 'collaborative care model' means the evidence-based, integrated behavioral health service delivery method that includes—

"(A) care directed by the primary care team;

"(B) structured care management;

"(C) regular assessments of clinical status using developmentally appropriate, validated tools; and

"(D) modification of treatment as appropriate.

"(2) ELIGIBLE ENTITY.—The term 'eligible entity' means a State, or an appropriate State agency, in collaboration with—

"(A) 1 or more qualified community programs as described in section 1913(b)(1);

"(B) 1 or more health centers (as defined in section 330(a)), a rural health clinic (as defined in section 1961(aa) of the Social Security Act), or a Federally qualified health center (as defined in such section); or

"(C) 1 or more primary health care practices.

"(3) INTEGRATED CARE; BIDIRECTIONAL INTEGRATED CARE.—

"(A) The term 'integrated care' means models or practices for coordinating and jointly delivering behavioral and physical health services, which may include practices that share the same space in the same facility.

"(B) The term 'bidirectional integrated care' means the integration of behavioral health care and specialty physical health care, as well as the integration of primary and physical health care with specialty behavioral health settings, including within primary health care settings.

"(4) PRIMARY HEALTH CARE PROVIDER.—The term 'primary health care provider' means a provider who—

"(A) provides health services related to family medicine, internal medicine, pediatrics, obstetrics, gynecology, or geriatrics; or

"(B) is a doctor of medicine or osteopathy, physician assistant, or nurse practitioner, who is licensed to practice medicine by the State in which such physician, assistant, or practitioner primarily practices, including within primary health care settings.

"(5) PRIMARY HEALTH CARE PRACTICE.—The term 'primary health care practice' means a medical practice of primary health care providers, including a practice within a larger health care system.

"(6) SPECIAL POPULATION.—The term 'special population', for an eligible entity that is collaborating with an entity described in subparagraph (A) or (B) of paragraph (3), means—

"(A) adults with a serious mental illness who have a co-occurring physical health condition or chronic disease;

"(B) children and adolescents with a mental illness who have a co-occurring physical health condition or chronic disease;

"(C) individuals with a substance use disorder; or

"(D) individuals with a mental illness who have a co-occurring substance use disorder.

"(b) GRANTS AND COOPERATIVE AGREEMENTS.—

"(1) IN GENERAL.—The Secretary may award grants and cooperative agreements to eligible entities to support the improvement of integrated care for physical and behavioral health care in accordance with paragraph (2).

"(2) USE OF FUNDS.—A grant or cooperative agreement awarded under this section shall be used—

"(A) in the case of an eligible entity that is collaborating with an entity described in subparagraph (A) or (B) of subsection (a)(2)—

"(i) to promote full integration and collaboration in clinical practices between physical and behavioral health care for special populations including each population listed in subsection (a)(7);

"(ii) to support the improvement of integrated care models for physical and behavioral health care to improve the overall wellness and physical health status of—

"(I) adults with a serious mental illness or children with a serious emotional disturbance; and

"(II) individuals with a substance use disorder; and

"(iii) to promote bidirectional integrated care services including screening, diagnosis, prevention, treatment, and recovery of mental and substance use disorders, and co-occurring physical health conditions and chronic diseases; and

"(B) in the case of an eligible entity that is collaborating with a primary health care practice, to support the uptake of the collaborative care model, including by—

"(i) hiring staff;

"(ii) identifying and formalizing contractual relationships with other health care providers, including providers who will function as psychiatric consultants and behavioral health care managers in providing behavioral health integration services through the collaborative care model;

"(iii) purchasing or upgrading software and other resources needed to appropriately provide behavioral health integration services through the collaborative care model, including resources needed to establish a patient registry and implement measurement-based care; and

"(iv) for such other purposes as the Secretary determines to be necessary.

"(c) APPLICATIONS.—

"(1) IN GENERAL.—An eligible entity that is collaborating with an entity described in subparagraph (A) or (B) of subsection (a)(2) seeking a grant or cooperative agreement under subsection (b)(2)(A) shall submit an application to the Secretary at such time, in such manner, and accompanied by such information as the Secretary may require, including the contents described in paragraph (2).

"(2) CONTENTS.—Any such application of an eligible entity described in subparagraph (A) or (B) of subsection (a)(2) shall include—

"(A) a description of a plan to achieve fully collaborative agreements to provide bidirectional integrated care to special populations;

"(B) a document that summarizes the policies, if any, that are barriers to the provision of integrated care, and the specific steps, if applicable, that will be taken to address such barriers;

"(C) a description of partnerships or other arrangements with local health care providers to provide services to special populations;

"(D) an agreement and plan to report to the Secretary performance measures necessary to evaluate patient outcomes and facilitate evaluations across participating projects;

"(E) a description of how validated rating scales will be implemented to support the improvement of patient outcomes using measurement-based care, including those related to depression screening, patient follow-up, and symptom remission; and

"(F) a plan for sustainability beyond the grant or cooperative agreement period under subsection (e).

"(3) COLLABORATIVE CARE MODEL GRANTS.—An eligible entity that is collaborating with a primary health care practice seeking a grant pursuant to subsection (b)(2)(B) shall submit an application to the Secretary at such time, in such manner, and accompanied by such information as the Secretary may require.

"(d) GRANT AND COOPERATIVE AGREEMENT AMOUNTS.—

"(1) TARGET AMOUNT.—The target amount that an eligible entity may receive for a year through a grant or cooperative agreement under this section shall be—

"(A) $2,000,000 for an eligible entity described in subparagraph (A) or (B) of subsection (a)(2); or

"(B) $100,000 or less for an eligible entity described in subparagraph (C) of subsection (a)(2).

"(2) ADJUSTMENT PERMITTED.—The Secretary, taking into consideration the quality of an eligible entity's application and the number of eligible entities that received grants under this section prior to the date of enactment of the Restoring Hope for Mental Health and Well-Being Act of 2022, may adjust the target

amount that an eligible entity may receive for a year through a grant or cooperative agreement under this section.

"(3) LIMITATION.—An eligible entity that is collaborating with an entity described in subparagraph (A) or (B) of subsection (a)(2) receiving funding under this section—

"(A) may not allocate more than 20 percent of the funds awarded to such eligible entity under this section to administrative functions; and

"(B) shall allocate the remainder of such funding to health facilities that provide integrated care.

"(e) DURATION.—A grant or cooperative agreement under this section shall be for a period not to exceed 5 years.

"(f) REPORT ON PROGRAM OUTCOMES.—An eligible entity receiving a grant or cooperative agreement under this section—

"(1) that is collaborating with an entity described in subparagraph (A) or (B) of subsection (a)(2) shall submit an annual report to the Secretary that includes—

"(A) the progress made to reduce barriers to integrated care as described in the entity's application under subsection (c); and

"(B) a description of outcomes with respect to each special population listed in subsection (a)(7), including outcomes related to education, employment, and housing; or

"(2) that is collaborating with a primary health care practice shall submit an annual report to the Secretary that includes—

"(A) the progress made to improve access;

"(B) the progress made to improve patient outcomes; and

"(C) the progress made to reduce referrals to specialty care.

"(g) TECHNICAL ASSISTANCE FOR PRIMARY-BEHAVIORAL HEALTH CARE INTEGRATION.—

"(1) CERTAIN RECIPIENTS.—The Secretary may provide appropriate information, training, and technical assistance to eligible entities that are collaborating with an entity described in subparagraph (A) or (B) of subsection (a)(2) that receive a grant or cooperative agreement under this section, in order to help such entities meet the requirements of this section, including assistance with—

"(A) development and selection of integrated care models;

"(B) dissemination of evidence-based interventions in integrated care;

"(C) establishment of organizational practices to support operational and administrative success; and

"(D) other activities, as the Secretary determines appropriate.

"(2) COLLABORATIVE CARE MODEL RECIPIENTS.—The Secretary shall provide appropriate information, training, and technical assistance to eligible entities that are collaborating with primary health care practices that receive funds under this section to help such entities implement the collaborative care model, including—

"(A) developing financial models and budgets for implementing and maintaining a collaborative care model, based on practice size;

"(B) developing staffing models for essential staff roles;

"(C) providing strategic advice to assist practices seeking to utilize other clinicians for additional psychotherapeutic interventions;

"(D) providing information technology expertise to assist with building the collaborative care model into electronic health records, including assistance with care manager tools, patient registry, ongoing patient monitoring, and patient records;

"(E) training support for all key staff and operational consultation to develop practice workflows;

"(F) establishing methods to ensure the sharing of best practices and operational knowledge among primary health care physicians and primary health care practices that provide behavioral health integration services through the collaborative care model; and

"(G) providing guidance and instruction to primary health care physicians and primary health care practices on developing and maintaining relationships with community-based mental health and substance use disorder facilities for referral and treatment of patients whose clinical presentation or diagnosis is best suited for treatment at such facilities.

"(3) ADDITIONAL DISSEMINATION OF TECHNICAL INFORMATION.—In addition to providing the assistance described in paragraphs (1) and (2) to recipients of a grant or cooperative agreement under this section, the Secretary may also provide such assistance to other States and political subdivisions of States, Indian Tribes and Tribal organizations (as defined under the Federally Recognized Indian Tribe List Act of 1994), outpatient mental health and addiction treatment

centers, community mental health centers that meet the criteria under section 1913(c), certified community behavioral health clinics described in section 223 of the Protecting Access to Medicare Act of 2014, primary care organizations such as Federally qualified health centers or rural health clinics as defined in section 1861(aa) of the Social Security Act, primary health care practices, other community-based organizations, and other entities engaging in integrated care activities, as the Secretary determines appropriate.

"(h) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there is authorized to be appropriated $60,000,000 for each of fiscal years 2023 through 2027.".

Subtitle B—Helping Enable Access to Lifesaving Services

SEC. 311. REAUTHORIZATION AND PROVISION OF CERTAIN PROGRAMS TO STRENGTHEN THE HEALTH CARE WORKFORCE.

(a) LIABILITY PROTECTIONS FOR HEALTH PROFESSIONAL VOLUNTEERS.—Section 224(q)(6) of the Public Health Service Act (42 U.S.C. 233(q)(6)) is amended by striking "October 1, 2022" and inserting "October 1, 2027".

(b) MINORITY FELLOWSHIPS IN CRISIS CARE MANAGEMENT.—Section 597(b) of the Public Health Service Act (42 U.S.C. 290ll(b)) is amended by striking "in the fields of psychiatry," and inserting "in the fields of crisis care management, psychiatry,".

(c) MENTAL AND BEHAVIORAL HEALTH EDUCATION AND TRAINING GRANTS.—Section 756 of the Public Health Service Act (42 U.S.C. 294e–1) is amended—

(1) in subsection (a)(1), by inserting "(which may include master's and doctoral level programs)" after "occupational therapy"; and

(2) in subsection (f), by striking "For each of fiscal years 2019 through 2023" and inserting "For each of fiscal years 2023 through 2027".

(d) TRAINING DEMONSTRATION PROGRAM.—Section 760(g) of the Public Health Service Act (42 U.S.C. 294k(g)) is amended by inserting "and $31,700,000 for each of fiscal years 2023 through 2027" before the period at the end.

Subtitle C—Eliminating the Opt-Out for Nonfederal Governmental Health Plans

SEC. 321. ELIMINATING THE OPT-OUT FOR NONFEDERAL GOVERNMENTAL HEALTH PLANS.

Section 2722(a)(2) of the Public Health Service Act (42 U.S.C. 300gg–21(a)(2)) is amended by adding at the end the following new subparagraph:

"(F) SUNSET OF ELECTION OPTION.—

"(i) IN GENERAL.—Notwithstanding the preceding provisions of this paragraph—

"(I) no election described in subparagraph (A) with respect to section 2726 may be made on or after the date of the enactment of this subparagraph; and

"(II) except as provided in clause (ii), no such election with respect to section 2726 expiring on or after the date that is 180 days after the date of such enactment may be renewed.

"(ii) EXCEPTION FOR CERTAIN COLLECTIVELY BARGAINED PLANS.—Notwithstanding clause (i)(II), a plan described in subparagraph (B)(ii) that is subject to multiple agreements described in such subparagraph of varying lengths and that has an election described in subparagraph (A) with respect to section 2726 in effect as of the date of the enactment of this subparagraph that expires on or after the date that is 180 days after the date of such enactment may extend such election until the date on which the term of the last such agreement expires.".

Subtitle D—Mental Health and Substance Use Disorder Parity Implementation

SEC. 331. GRANTS TO SUPPORT MENTAL HEALTH AND SUBSTANCE USE DISORDER PARITY IMPLEMENTATION.

(a) IN GENERAL.—Section 2794(c) of the Public Health Service Act (42 U.S.C. 300gg–94(c)) (as added by section 1003 of the Patient Protection and Affordable Care Act (Public Law 111–148)) is amended by adding at the end the following:

"(3) PARITY IMPLEMENTATION.—

"(A) IN GENERAL.—Beginning during the first fiscal year that begins after the date of enactment of this paragraph, the Secretary shall, out of funds made available pursuant to subparagraph (C), award grants to eligible States to enforce and ensure compliance with the mental health and substance use disorder parity provisions of section 2726.

"(B) ELIGIBLE STATE.—A State shall be eligible for a grant awarded under this paragraph only if such State—

"(i) submits to the Secretary an application for such grant at such time, in such manner, and containing such information as specified by the Secretary; and

"(ii) agrees to request and review from health insurance issuers offering group or individual health insurance coverage the comparative analyses and other information required of such health insurance issuers under subsection (a)(8)(A) of section 2726 relating to the design and application of nonquantitative treatment limitations imposed on mental health or substance use disorder benefits.

"(C) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated $10,000,000 for each of the first five fiscal years beginning after the date of the enactment of this paragraph, to remain available until expended, for purposes of awarding grants under subparagraph (A).".

(b) TECHNICAL AMENDMENT.—Section 2794 of the Public Health Service Act (42 U.S.C. 300gg–95), as added by section 6603 of the Patient Protection and Affordable Care Act (Public Law 111–148) is redesignated as section 2795.

TITLE IV—CHILDREN AND YOUTH

Subtitle A—Supporting Children's Mental Health Care Access

SEC. 401. PEDIATRIC MENTAL HEALTH CARE ACCESS GRANTS.

Section 330M of the Public Health Service Act (42 U.S.C. 254c–19) is amended—

(1) in the section enumerator, by striking "**330M**" and inserting "**330M.**";

(2) in subsection (a)—

(A) by striking "Indian tribes and tribal organizations" and inserting "Indian Tribes and Tribal organizations"; and

(B) by inserting "or, in the case of a State that does not submit an application, a nonprofit entity that has the support of the State" after "450b))";

(3) in subsection (b)—

(A) in paragraph (1)—

(i) in subparagraph (G), by inserting "developmental-behavioral pediatricians," after "adolescent psychiatrists,";

(ii) in subparagraph (H), by striking "; and" at the end and inserting a semicolon;

(iii) by redesignating subparagraph (I) as subparagraph (J); and

(iv) by inserting after subparagraph (H) the following:

"(I) maintain an up-to-date list of community-based supports for children with mental health problems; and";

(B) by redesignating paragraph (2) as paragraph (4);

(C) by inserting after paragraph (1) the following:

"(2) SUPPORT TO SCHOOLS AND EMERGENCY DEPARTMENTS.—In addition to the activities required by paragraph (1), a pediatric mental health care telehealth access program referred to in subsection (a), with respect to which a grant under such subsection may be used, may provide support to schools and emergency departments.

"(3) PRIORITY.—In awarding grants under this section, the Secretary shall give priority to applicants proposing to—

"(A) continue existing programs that meet the requirements of paragraph (1);

"(B) establish a pediatric mental health care telehealth access program in the jurisdiction of a State, Territory, Indian Tribe, or Tribal organization that does not yet have such a program; or

"(C) expand a pediatric mental health care telehealth access program to include one or more new sites of care, such as a school or emergency department."; and

(D) in paragraph (4), as redesignated by subparagraph (B), by inserting "Such a team may include a developmental-behavioral pediatrician." after "mental health counselor.";

(4) in subsections (c), (d), and (f), by striking "Indian tribe, or tribal organization" each place it appears and inserting "Indian Tribe, Tribal organization, or nonprofit entity"; and

(5) by striking subsection (g) and inserting the following:

"(g) TECHNICAL ASSISTANCE.—The Secretary shall award grants or contracts to one or more eligible entities (as defined by the Secretary) for the purposes of providing technical assistance and evaluation support to grantees under subsection (a).

"(h) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated—

"(1) $14,000,000 for each of fiscal years 2023 through 2025; and

"(2) $30,000,000 for each of fiscal years 2026 through 2027.".

SEC. 402. INFANT AND EARLY CHILDHOOD MENTAL HEALTH PROMOTION, INTERVENTION, AND TREATMENT.

Section 399Z–2(f) of the Public Health Service Act (42 U.S.C. 280h–6(f)) is amended by striking "$20,000,000 for the period of fiscal years 2018 through 2022" and inserting "$50,000,000 for the period of fiscal years 2023 through 2027".

Subtitle B—Continuing Systems of Care for Children

SEC. 411. COMPREHENSIVE COMMUNITY MENTAL HEALTH SERVICES FOR CHILDREN WITH SERIOUS EMOTIONAL DISTURBANCES.

(a) DEFINITION OF FAMILY.—Section 565(d)(2)(B) of the Public Health Service Act (42 U.S.C. 290ff–4(d)(2)(B)) is amended by striking "as appropriate regarding mental health services for the child, the parents of the child (biological or adoptive, as the case may be) and any foster parents of the child" and inserting "as appropriate regarding mental health services for the child and the parents or kinship caregivers of the child".

(b) AUTHORIZATION OF APPROPRIATIONS.—Paragraph (1) of section 565(f) of the Public Health Service Act (42 U.S.C. 290ff–4(f)) is amended—

(1) by moving the margin of such paragraph 2 ems to the right; and

(2) by striking "$119,026,000 for each of fiscal years 2018 through 2022" and inserting "$125,000,000 for each of fiscal years 2023 through 2027".

SEC. 412. SUBSTANCE USE DISORDER TREATMENT AND EARLY INTERVENTION SERVICES FOR CHILDREN AND ADOLESCENTS.

Section 514 of the Public Health Service Act (42 U.S.C. 290bb–7) is amended—

(1) in subsection (a), by striking "Indian tribes or tribal organizations" and inserting "Indian Tribes or Tribal organizations"; and

(2) in subsection (f), by striking "2018 through 2022" and inserting "2023 through 2027".

Subtitle C—Garrett Lee Smith Memorial Reauthorization

SEC. 421. SUICIDE PREVENTION TECHNICAL ASSISTANCE CENTER.

(a) TECHNICAL AMENDMENT.—Section 520C of the Public Health Service Act (42 U.S.C. 290bb–34) is amended—

(1) by striking "tribes" and inserting "Tribes"; and

(2) by striking "tribal" each place it appears and inserting "Tribal".

(b) AUTHORIZATION OF APPROPRIATIONS.—Section 520C(c) of the Public Health Service Act (42 U.S.C. 290bb–34(c)) is amended by striking "$5,988,000 for each of fiscal years 2018 through 2022" and inserting "$9,000,000 for each of fiscal years 2023 through 2027".

(c) ANNUAL REPORT.—Section 520C(d) of the Public Health Service Act (42 U.S.C. 290bb–34(d)) is amended by striking "Not later than 2 years after the date of enactment of this subsection" and inserting "Not later than 2 years after the date of enactment of the Restoring Hope for Mental Health and Well-Being Act of 2022".

SEC. 422. YOUTH SUICIDE EARLY INTERVENTION AND PREVENTION STRATEGIES.

Section 520E of the Public Health Service Act (42 U.S.C. 290bb–36) is amended—

(1) by striking "tribe" and inserting "Tribe";

(2) by striking "tribal" each place it appears and inserting "Tribal";

(3) in subsection (a)(1), by inserting "pediatric health programs," after "foster care systems,";

(4) by amending subsection (b)(1)(B) to read as follows:

"(B) a public organization or private nonprofit organization designated by a State or Indian Tribe (as defined under the Federally Recognized Indian Tribe List Act of 1994) to develop or direct the State-sponsored statewide or Tribal youth suicide early intervention and prevention strategy; or";

(5) in subsection (c)—

(A) in paragraph (1), by inserting "pediatric health programs," after "foster care systems,";

(B) in paragraph (7), by inserting "pediatric health programs," after "foster care systems,";

(C) in paragraph (9), by inserting "pediatric health programs," after "educational institutions,";

(D) in paragraph (13), by striking "and" at the end;

(E) in paragraph (14), by striking the period at the end and inserting "; and"; and

(F) by adding at the end the following:

"(15) provide to parents, legal guardians, and family members of youth, supplies to securely store means commonly used in suicide, if applicable, within the household.";

(6) in subsection (d)—

(A) in the heading, by striking "DIRECT SERVICES" and inserting "SUICIDE PREVENTION ACTIVITIES"; and

(B) by striking "direct services, of which not less than 5 percent shall be used for activities authorized under subsection (a)(3)" and inserting "suicide prevention activities";

(7) in subsection (e)(3)(A), by inserting "and Department of Education" after "Department of Health and Human Services";

(8) in subsection (g)—

(A) in paragraph (1), by striking "18" and inserting "24"; and

(B) in paragraph (2), by striking "2 years after the date of enactment of Helping Families in Mental Health Crisis Reform Act of 2016" and inserting "3 years after December 31, 2022";

(9) in subsection (l)(4), by striking "between 10 and 24 years of age" and inserting "up to 24 years of age"; and

(10) in subsection (m), by striking "$30,000,000 for each of fiscal years 2018 through 2022" and inserting "$40,000,000 for each of fiscal years 2023 through 2027".

SEC. 423. MENTAL HEALTH AND SUBSTANCE USE DISORDER SERVICES FOR STUDENTS IN HIGHER EDUCATION.

Section 520E–2 of the Public Health Service Act (42 U.S.C. 290bb–36b) is amended—

(1) in the heading, by striking "**ON CAMPUS**" and inserting "**FOR STUDENTS IN HIGHER EDUCATION**"; and

(2) in subsection (i), by striking "2018 through 2022" and inserting "2023 through 2027".

SEC. 424. MENTAL AND BEHAVIORAL HEALTH OUTREACH AND EDUCATION AT INSTITUTIONS OF HIGHER EDUCATION.

Section 549 of the Public Health Service Act (42 U.S.C. 290ee–4) is amended—

(1) in the heading, by striking "**ON COLLEGE CAMPUSES**" and inserting "**AT INSTITUTIONS OF HIGHER EDUCATION**";

(2) in subsection (c)(2), by inserting ", including minority-serving institutions as described in section 371(a) of the Higher Education Act of 1965 (20 U.S.C. 1067q) and community colleges" after "higher education"; and

(3) in subsection (f), by striking "2018 through 2022" and inserting "2023 through 2027".

I. PURPOSE AND SUMMARY

H.R. 7666, the "Restoring Hope for Mental Health and Well-Being Act of 2022," amends the Public Health Service Act to reauthorize and establish certain mental health and substance use disorder programs at the Substance Abuse and Mental Health Services Administration (SAMHSA) and the Health Resources and Services Administration (HRSA) through fiscal year 2027, for the

purposes of improving Americans' mental health and addressing substance use disorders. H.R. 7666 includes provisions to support crisis care and other mental health services for a range of populations, as well as substance use disorder prevention, treatment, and recovery support services. The legislation provides increased support for youth suicide prevention, maternal mental health, and jail diversion programs. Further, the bill includes provisions to assist in addiction and overdose prevention and treatment, including expanded access to medication-assisted treatment and provider training. H.R. 7666 also facilitates further integration of mental health and primary care services, bolsters the mental health care workforce, applies mental health parity requirements to self-funded, non-governmental plans, and supports enforcement of mental health parity requirements.

II. Background and Need for Legislation

Americans have been in the midst of a mental health and substance use disorder crisis predating the emergence of the coronavirus disease of 2019 (COVID–19). Increased social isolation and stress caused by the pandemic further exacerbated these challenges,[1] with American adults reporting elevated levels of mental illness (AMI) including anxiety, depression, and suicidal ideation.[2] Children and teens have also experienced major increases in adverse mental health symptoms.[3] Among youth ages 10 and older, the national suicide rate increased by more than 25 percent since 1999, nearly doubling in some states.[4] In addition, one out of five women will experience maternal mental health conditions, such as depression, anxiety, or substance use disorder, during pregnancy or the first year following childbirth.[5] Suicide and substance use disorder are some of the leading causes of death in the first year postpartum.[6]

The state of substance use disorders in the United States has followed a similar upward trajectory in recent years. Nearly 108,000 people died due to drug overdose in 2021, a record-breaking number that followed a 30 percent increase in the rate of overdose deaths from 2019 to 2020.[7] Additionally, substance use disorders frequently co-occur with mental health disorders, such as anxiety

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[1] Kaiser Family Foundation, *The implications of COVID–19 for mental health and substance use* (Feb. 10, 2021).

[2] Centers for Disease Control and Prevention, *Morbidity and Mortality Weekly Report, Mental Health, Substance Use, and Suicidal Ideation During the COVID–19 Pandemic—United States, June 24–30, 2020* (Aug. 14, 2020).

[3] Surgeon General, *Protecting Youth Mental Health: The U.S. Surgeon General's Advisory* (Dec. 7, 2021).

[4] Centers for Disease Control and Prevention, *Supplementary Table. Trends in Suicide Rates among Persons ≥ 10 Years of Age, by State and Sex, National Vital Statistics System, 1999–2016* (June 8, 2018) (https://stacks.cdc.gov/view/cdc/53785).

[5] Obstetrics & Gynecology, *ACOG Committee Opinion No. 757, Screening for Perinatal Depression* (journals.lww.com/greenjournal/Fulltext/2018/11000/ACOG_Committee_Opinion_No_757_Screening_for.42.aspx); Fawcett, et. al, *The Prevalence of Anxiety Disorders During Pregnancy and the Postpartum Period*, J. Clin Psychiatry (July 23, 2019) (pubmed.ncbi.nlm.nih.gov/31347796/).

[6] *See* Pregnancy-Related Deaths; Data from 14 U.S. Maternal Mortality Review Committees, 2008–2017 (www.cdc.gov/reproductivehealth/maternal-mortality/erase-mm/MMR-Data-Brief_2019-h.pdf).

[7] Centers for Disease Control and Prevention, Vital Statistics Rapid Release (www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm) (accessed June 6, 2022); *Overdose Deaths Continue Rising, With Fentanyl and Meth Key Culprits*, New York Times (May 11, 2022).

and depression.[8] Nearly 50 percent of individuals who develop a mental health disorder will also experience a substance use disorder, and vice versa.[9]

Despite high rates of mental health conditions and substance use disorders, access to treatment and services remains limited. In 2020, for instance, only 1.4 percent of individuals who were classified as in need of substance use treatment, and just 46.2 percent of adults with any mental illness, received treatment.[10] Major barriers to treatment include the shortage of mental health professionals which affects one-third of Americans.[11] The treatment burden of mental illnesses is particularly acute among those who experience disability due to serious mental illness (SMI). SMI is defined as a mental, behavioral, or emotional disorder resulting in serious functional impairment, which substantially interferes with or limits one or more major life activities.[12] Those living with SMI—including bipolar disorder, schizophrenia, and severe depression—are jailed more than 2 million times each year, often for misdemeanor crimes.[13] The U.S. criminal justice system has witnessed dramatic increases in its mentally ill population during the past years, with decreasing numbers of psychiatric beds being identified as one of the major causes.[14] One-third of the total homeless population consists of individuals with untreated SMI, with the rates being even higher in homeless women and individuals who are chronically homeless.[15]

H.R. 7666 reauthorizes 35 SAMHSA and HRSA grant programs that provide critical support for mental health and substance use disorder activities at a time when increased services for these conditions are needed more than ever. These programs were established or most recently reauthorized through the 21st Century Cures Act,[16] the Comprehensive Addiction and Recovery Act,[17] or the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act,[18] in efforts to curb rising rates of mental health conditions and substance use disorders.

Collectively, through funding to states, territories, Tribes, Tribal organizations, community-based and consumer-led organizations, and a range of providers, these programs—including the respective

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[8] National Institute on Drug Abuse, *Common Comorbidities with Substance Use Disorders Research Report* (April 2020).

[9] *Id.*

[10] Substance Abuse and Mental Health Services Administration. *Key substance use and mental health indicators in the United States: Results from the 2020 National Survey on Drug Use and Health*, Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration (June 1, 2022).

[11] USA FACTS, *Over one-third of Americans live in areas lacking mental health professionals* (June 9, 2021) (https://usafacts.org/articles/over-one-third-of-americans-live-in-areas-lacking-mental-health-professionals/); U.S. Department of Labor, *U.S. Departments of Labor, Health and Human Services, Treasury Issue 2022 Mental Health Parity and Addiction Equity Act Report to Congress* (June 1, 2022).

[12] National Institute of Mental Health, *Mental Illness* (www.nimh.nih.gov/health/statistics/mental-illness) (accessed June 8, 2022).

[13] The Pew Charitable Trusts, *Project: Mental Health and Justice Partnerships* (www.pewtrusts.org/en/projects/mental-health-and-justice-partnerships) (accessed June 8, 2022).

[14] Y. Nina Gao, *Relationship Between Psychiatric Inpatient Beds and Jail Populations in the United States*, Journal of Psychiatric Practice (Jan. 21, 2021).

[15] Treatment Advocacy Center Office of Research & Public Affairs, Serious Mental Illness and Homelessness (Sept. 2016) (https://www.treatmentadvocacycenter.org/storage/documents/backgrounders/smi-and-homelessness.pdf).

[16] Pub. L. 114–255.

[17] Pub. L. 114–198.

[18] Pub. L. 115–271.

Community Mental Health Services Block Grants and the Substance Use Disorder Treatment and Recovery Services Block Grants—target communities and populations at increased need for mental health support or services and substance use disorder prevention, treatment, or recovery support services—such as for children and adolescents, college students, pregnant or postpartum women, people of color, Veterans, those experiencing homelessness, those facing or at risk of incarceration, and rural communities.

In addition, to respond to the urgent mental health crisis care needs of Americans, and in preparation of the 9–8–8 National Suicide Prevention Lifeline dialing code launch in July 2022, H.R. 7666 establishes the SAMHSA Behavioral Health Crisis Coordinating Office to convene partners and provide technical assistance to enhance access to crisis care. Further, the bill requires the Secretary of Health and Human Services (HHS) to publish best practices for a crisis response continuum of care, and replaces the reauthorization of the Community Crisis Response Systems Grants with a Mental Health Crisis Response Partnership Pilot Program.

To address the rising maternal mental health and substance use disorder needs across the country, H.R. 7666 establishes a national hotline to provide information, interventions, and resources to pregnant and postpartum women at risk of, or affected by, maternal mental health and substance use disorders, and establishes a task force to make recommendations to coordinate and inform a national strategy to improve Federal and State responses to maternal mental health conditions.

Further, as nearly 29 million Americans have had or will have an eating disorder at some point in their lives,[19] the bill meets an ongoing specific mental health disorder need and establishes an authorization for the SAMHSA National Center of Excellence for Eating Disorders. It also authorizes grants to consumer-led nonprofits and Tribal entities to provide peer-supported mental health services, including virtual peer support.

H.R. 7666 also rises to meet the needs of young Americans disproportionately impacted by mental health challenges and substance use disorders. Prior to the COVID–19 pandemic, mental health crises experienced by adolescents were already on the rise, with 13.2 percent of American children between the ages of three and 17 experiencing a current, diagnosed mental or behavioral health condition from 2018 to 2019.[20] In addition, suicide rates for Americans ages 10 to 24 has jumped nearly 60 percent between 2007 and 2018.[21] These trends were exacerbated by the pandemic, so much so that on December 7, 2021, the Surgeon General issued an advisory on the impact that COVID–19 has had on the ongoing children's mental health crisis.[22] The bill takes numerous steps aimed to address youth mental health, including: reauthorizing

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[19] Deloitte Access Economic. *The Social and Economic Cost of Eating Disorders in the United States of America: A Report for the Strategic Training Initiative for the Prevention of Eating Disorders and the Academy for Eating Disorders* (June 2020).

[20] Health Resources and Services Administration, *Mental and Behavioral Health, NSCH Data Brief* (Oct. 2020) (mchb.hrsa.gov/sites/default/files/mchb/data-research/nsch-data-brief-2019-mental-bh.pdf)

[21] Centers for Disease Control and Prevention, National Vital Statistics Reports, Volume 69, Number 11: State Suicide Rates Among Adolescents and Young Adults Aged 10–24: United States, 2000–2018 (Sept. 11, 2020) (www.cdc.gov/nchs/data/nvsr/nvsr69/nvsr-69-11-508.pdf).

[22] Department of Health and Human Services, *U.S. Surgeon General Issues Advisory on Youth Mental Health Crisis Further Exposed by COVID–19 Pandemic* (Dec. 7, 2021) (press release).

HRSA's Pediatric Mental Health Care Access grant program, which promotes behavioral health integration into pediatric primary care by supporting pediatric mental health care telehealth access programs in states, and SAMHSA's Infant and Early Childhood Mental Health Grant Program, which helps to improve outcomes for children from birth to age 12 by developing, maintaining, or enhancing mental health promotion, intervention, and treatment services. The bill further supports continuing mental health and substance use disorder systems of care for children through the five-year reauthorization of the Comprehensive Community Mental Health Services for Children with Serious Emotional Disturbances Grants and the Enhancement and Expansion of Treatment and Recovery Services for Adolescents, Transitional Aged Youth, and their Families—known as the Youth and Family TREE Grants.

Many of the millions of older adolescents and young adults living with a mental or substance use disorder may not realize they have one or know how to seek help.[23] H.R. 7666 further supports youth and young adults across the country through the reauthorization of the Garrett Lee Smith Memorial Act programs including the Suicide Prevention Resource Center, the State and Tribal Youth Suicide Prevention and Early Intervention Grants Program, the Mental Health Youth Suicide Prevention Campus Grants, and the Mental and Behavioral Health Public Outreach and Education at Institutions of Higher Education program.

In addition, H.R. 7666 reauthorizes the Sober Truth on Prevention Underage Drinking Programs, supporting a national media campaign, community-based coalition enhancement grants, and grants for pediatric provider screening and brief interventions as well as data collection and research to prevent and address underage drinking at a time when alcohol remains the most widely used substance among America's young people.[24] The bill reauthorizes a range of other substance- or intervention-specific programs, such as the grants for reducing overdose deaths and the emergency department alternatives to opioids grant program. Further, the bill requires that the Secretary of HHS, acting through the SAMHSA Assistant Secretary, collaborate with federal agencies and stakeholders to update, disseminate and promote through grants high-quality recovery housing best practices.

The climbing rate of Americans experiencing mental health conditions is projected to put a strain on the mental and behavioral health workforce—according to HRSA's Bureau of Health Workforce, a majority of states will experience shortages of licensed mental health counselors by 2030.[25] In addition, as of March 2021, about 122 million Americans were living in areas experiencing mental health professional shortages.[26] H.R. 7666 includes a number of programs to bolster mental and behavioral health workforce capacity, including Liability Protections for Health Professional

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[23] Substance Abuse and Mental Health Services Administration, *Mental Illness and Substance Use in Young Adults* (www.samhsa.gov.young-adults) (accessed June 7, 2022).

[24] National Institutes of Health, Underage Drinking (www.niaaa.nih.gov/publications/brochures-and-fact-sheets/underage-drinking) (accessed June 7, 2022).

[25] Health Resources and Services Administration, *Behavioral Health Workforce Projections, 2017–2030* (bhw.hrsa.gov/sites/default/files/bureau-health-workforce/data-research/bh-workforce-projections-fact-sheet.pdf) (accessed June 7, 2022).

[26] U.S. News and World Report, *Many States Face Shortage of Mental Health Providers* (June 10, 2021) (www.usnews.com/news/best-states/articles/2021-06-10/northeastern-states-have-fewest-mental-health-provider-shortages).

Volunteers, Mental and Behavioral Health Education and Training Grants (including updates to the education reference for occupational therapist), the Training Demonstration Program, and expansion of the Integration Incentive Grants and Cooperative Agreements to increase uptake of the collaborate care model.

Even with access to mental health and substance use disorder prevention, treatment, and care, consumers with health care coverage face numerous challenges accessing mental health and substance disorder benefits provided by their health insurance plans.[27] The Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA) requires parity between mental health and substance use disorder benefits and medical/surgical benefits of health plans.[28] The MHPAEA prohibits coverage requirements for mental health and substance disorder benefits from being more restrictive than those for medical/surgical benefits, and prevents health insurance plans that provide mental health or substance use disorder benefits from imposing less favorable financial requirements and treatment limitations on those benefits than on medical/surgical benefits. However, some health insurance plans fail to comply with parity requirements of the MHPAEA, and as a result, consumers face more coverage limitations for behavioral health services than for medical/surgical benefits.[29] A recent report by the Departments of HHS, Treasury, and Labor found that some health plans and health insurance issuers are failing to deliver parity for mental health and substance use disorder benefits to those they cover.[30] H.R. 7666 authorizes funding to assist States to enforce and ensure compliance with mental health parity, and requires self-funded, non-federal governmental plans to comply with mental health parity requirements.

It is estimated that more than 2 million people in the United States have an opioid use disorder (OUD), a chronic brain disease caused by prolonged use of opioids, such as fentanyl, oxycodone, and heroin.[31] There are three FDA-approved medications used to treat OUD, methadone, buprenorphine, and extended-release naltrexone; these medications reduce cravings and reduce the risk future use, which greatly reduces the risk of fatal overdose.[32] However, access to these medications is not widely available to those who may benefit the most, and there are disparities in access across different populations.[33] The bill includes provisions that reduce regulatory barriers, enhance provider education, and increase access to medication-assisted treatment for OUD.

Scientific literature shows that regulatory and administrative burdens create barriers to accessing treatment for OUD. For example, methadone is only accessible through specialty treatment facilities known as opioid treatment programs (OTPs). OTPs are strictly regulated by the Drug Enforcement Administration (DEA)

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[27] Government Accountability Office, *Mental Health Care: Consumers with Coverage Face Access Challenges* (Mar. 30, 2022).

[28] Pub. L. 110–343.

[29] *Id*; Department of Treasury, Realizing Parity, Reducing Stigma, and Raising Awareness: Increasing Access to Mental Health and Substance Use Disorder Coverage (2022) www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/laws/mental-health-parity/report-to-congress-2022-realizing-parity-reducing-stigma-and-raising-awareness.pdf (Report to Congress).

[30] *Id.*

[31] National Academy of Sciences, Engineering, and Science (NASEM), *Consensus Study Report: Medications for Opioid Use Disorder Save Lives* (2019) (https://bit.ly/2NJnNXQ).

[32]

[33] *Id.*

and SAMHSA.[34] Limits to how, where, and when patients can access OUD treatment limits uptake of life-saving medications.[35] During the public health emergency declared to respond to the COVID–19 pandemic, regulatory flexibilities were provided to OTPs and practitioners seeking to dispense medications to treat OUD. In 2020, SAMHSA implemented regulatory flexibilities for take-home-methadone doses; preliminary studies show that methadone uptake among patients with OUD nearly doubled and was not associated with negative health outcomes, such as increased fatal drug overdoses.[36,37] Provisions in this bill allow OTPs to operate mobile medication units to dispense methadone without a separate DEA registration; eliminate the requirement that patients have OUD for one year before becoming eligible for admission into an OTP; direct SAMHSA to study the regulatory flexibilities exercised during the COVID–19 pandemic and submit a report to Congress with their findings; and requires SAMHSA to develop criteria and update regulations for OTPs to dispense take-home methadone doses.

Buprenorphine can be prescribed in office-based settings by providers who apply for a special DEA waiver, known as the "X Waiver."[38] It is estimated that one in ten medical providers hold these waivers and many do not prescribe at the allotted cap due to perceptions of regulatory complexity.[39] Further, studies show that lack of provider education about medication-assisted treatment for OUD compounds stigma and leads to reduced patient access.[40] Integrating OUD treatment education into mainstream health systems and reducing regulatory barriers is likely to increase provider knowledge and patient access.[41] During the COVID–19 pandemic, SAMHSA has also allowed practitioners to treat up to 30 patients with buprenorphine for OUD without a separate DEA registration, citing it as an important first step in decreasing barriers to treatment.[42]

The legislation eliminates the requirement for health practitioners to apply for the "X-waiver" in order to prescribe buprenorphine. It further requires health practitioners to meet a one-time, eight-hour training requirement on treating and identifying patients with substance use disorders as a condition of receiving or renewing a DEA registration to dispense controlled substances.

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[34] 42 CFR 8.12.

[35] *Id.*

[36] Substance Abuse and Mental Health Services Administration, *SAMHSA Extends the Methadone Take-Home Flexibility for One Year While Working Toward a Permanent Solution* (2021) (www.samhsa.gov/newsroom/press-announcements/202111181000).

[37] American Journal of Drug and Alcohol Abuse, *The impact of relaxation of methadone take-home protocols on treatment outcomes in the COVID–19 era* (Nov. 2021) (pubmed.ncbi.nlm.nih.gov/34670453/).

[38] End Substance Use Disorder, *Federal barriers to prescribing buprenorphine (the X-Waiver)* (www.endsud.org/mat-act-federal-barriers/#mat-act).

[39] *Id.*

[40] National Academy of Sciences, Engineering, and Science, *Consensus Study Report: Medications for Opioid Use Disorder Save Lives* (2019) (https://nap.nationalacademies.org/catalog/25310/medications-for-opioid-use-disorder-save-lives).

[41] *Id.*

[42] Substance Abuse and Mental Health Services Administration, *FAQs About the New Buprenorphine Practice Guidelines* (2021) (www.samhsa.gov/medication-assisted-treatment/become-buprenorphine-waivered-practitioner/new-practice-guidelines-faqs).

III. Committee Hearings

For the purposes of section 3(c) of rule XIII of the Rules of the House of Representatives, the following hearing was used to develop or consider H.R. 7666:

The Subcommittee on Health held a legislative hearing on April 5, 2022, entitled "Communities in Need: Legislation to Support Mental Health and Well-Being." The Subcommittee received testimony from the following witnesses:

Panel I:

- Miriam E. Delphin-Rittmon, Ph.D., Assistant Secretary for Mental Health and Substance Use, Substance Abuse and Mental Health Services Administration; and
- Carole Johnson, M.A., Administrator, Health Resources and Services Administration.

Panel II:

- Rebecca W. Brendel, M.D., J.D., President-Elect, American Psychiatric Association;
- Sandy L. Chung, M.D., F.A.A.P., F.A.C.H.E., President-Elect, American Academy of Pediatrics;
- Steven Adelsheim, M.D., Clinical Professor of Psychiatry and Director, Stanford Center for Youth Mental Health and Wellbeing, Stanford University School of Medicine, Stanford Children's Health;
- Debra Pinals, M.D., Medical Director, Behavioral Health and Forensic Programs, Michigan Department of Health and Human Services, On behalf of the National Association of State Mental Health Program Directors;
- Cassandra Price, M.B.A., Director, Office of Addictive Diseases, Georgia Department of Behavioral Health and Developmental Disabilities, On behalf of the National Association of State Alcohol and Drug Abuse Directors; and
- LeVail W. Smith, C.P.S.S., Peer Support Specialist Instructor and Mentor.

IV. Committee Consideration

H.R. 7666, the "Restoring Hope for Mental Health and Well-Being Act of 2022," was introduced on May 6, 2022, by Representatives Pallone (D–NJ) and Rodgers (R–WA) and referred to the Committee on Energy and Commerce. Subsequently, on May 9, 2022, the bill was referred to the Subcommittee on Health.

On May 11, 2022, the Subcommittee on Health met in open markup session, pursuant to notice, to consider H.R. 7666 and five other bills. During consideration of the bill, no amendments were offered. Upon conclusion of consideration of the bill, the Subcommittee on Health agreed to report the bill favorably to the full Committee, without amendment, by a roll call vote of 32 yeas to zero nays.

On May 18, 2022, the full Committee met in open markup session, pursuant to notice, to consider H.R. 7666 and five other bills. An amendment in the nature of a substitute (AINS), offered by Representative Pallone, was agreed to by a voice vote. An amendment to the AINS, offered by Representative Tonko (D–NY), was agreed to by a roll call vote of 45 yeas to 10 nays. An amendment to the Tonko amendment to the AINS, offered by Representative

Burgess (R–TX), was withdrawn. An amendment to the AINS, offered by Representative Trahan (D–MA), was agreed to by a roll call vote of 46 yeas to 8 nays. An amendment to the AINS, offered by Representative Upton (R–MI), was agreed to by a roll call vote of 55 yeas to one nay. An amendment to the AINS, offered by Representative Cárdenas (D–CA), was agreed to by a roll call vote of 31 yeas to 24 nays. An amendment to the bill, offered by Representative Curtis (R–UT), was withdrawn. Upon conclusion of consideration of the bill, the full Committee agreed to a motion on final passage offered by Representative Pallone, Chairman of the Committee, to order H.R. 7666 reported favorably to the House, amended, by a voice vote.

V. Committee Votes

Clause 3(b) of rule XIII of the Rules of the House of Representatives requires the Committee to list each record vote on the motion to report legislation and amendments thereto. The Committee advises that there were five record votes taken on H.R. 7666. The motion on final passage of the bill ordering H.R. 7666 favorably reported to the House, amended, was approved by a voice vote. The following are the record votes taken during Committee consideration, including the names of those members voting for and against:

Committee on Energy and Commerce
117th Congress

Subcommittee on Health
(ratio: 19-15)
ROLL CALL VOTE #2

Bill: **H.R. 7666**, the "Restoring Hope for Mental Health and Well-Being Act of 2022"

Motion: A motion by Ms. Eshoo of California to order **H.R. 7666** transmitted favorably to the full Committee, amended (Final Passage).

Disposition: **AGREED TO** by a roll call vote of 32 yeas to 0 nays

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Ms. Eshoo	X			Mr. Guthrie	X		
Mr. Butterfield				Mr. Upton	X		
Ms. Matsui	X			Mr. Burgess	X		
Ms. Castor	X			Mr. Griffith	X		
Mr. Sarbanes	X			Mr. Bilirakis	X		
Mr. Welch	X			Mr. Long	X		
Mr. Schrader	X			Mr. Bucshon	X		
Mr. Cárdenas	X			Mr. Mullin	X		
Mr. Ruiz	X			Mr. Hudson	X		
Mrs. Dingell	X			Mr. Carter	X		
Ms. Kuster	X			Mr. Dunn	X		
Ms. Kelly				Mr. Curtis	X		
Ms. Barragán	X			Mr. Crenshaw	X		
Ms. Blunt Rochester	X			Mr. Joyce	X		
Ms. Craig	X			Mrs. Rodgers	X		
Ms. Schrier	X						
Ms. Trahan	X						
Ms. Fletcher	X						
Mr. Pallone	X						

05/11/22

Committee on Energy and Commerce
117th Congress

Full Committee
(ratio: 32-26)
ROLL CALL VOTE #120

Bill: **H.R. 7666**, the "Restoring Hope for Mental Health and Well-Being Act of 2022"

Amendment: An amendment (H7666-SCD-AMD_01) to the AINS by Mr. Tonko of New York, No. 1a

Disposition: **AGREED TO** by a roll call vote of 45 yeas to 10 nays

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Pallone	X			Mrs. Rodgers	X		
Mr. Rush				Mr. Upton	X		
Ms. Eshoo	X			Mr. Burgess		X	
Ms. DeGette	X			Mr. Scalise			
Mr. Doyle	X			Mr. Latta	X		
Ms. Schakowsky	X			Mr. Guthrie		X	
Mr. Butterfield	X			Mr. McKinley		X	
Ms. Matsui	X			Mr. Kinzinger			
Ms. Castor	X			Mr. Griffith		X	
Mr. Sarbanes	X			Mr. Bilirakis	X		
Mr. McNerney	X			Mr. Johnson	X		
Mr. Welch	X			Mr. Long		X	
Mr. Tonko	X			Mr. Bucshon		X	
Ms. Clarke	X			Mr. Mullin		X	
Mr. Schrader		X		Mr. Hudson	X		
Mr. Cárdenas	X			Mr. Walberg	X		
Mr. Ruiz	X			Mr. Carter	X		
Mr. Peters	X			Mr. Duncan	X		
Mrs. Dingell	X			Mr. Palmer		X	
Mr. Veasey	X			Mr. Dunn		X	
Ms. Kuster	X			Mr. Curtis	X		
Ms. Kelly	X			Ms. Lesko	X		
Ms. Barragán	X			Mr. Pence	X		
Mr. McEachin	X			Mr. Crenshaw	X		
Ms. Blunt Rochester	X			Mr. Joyce	X		
Mr. Soto	X			Mr. Armstrong	X		
Mr. O'Halleran	X						
Ms. Rice	X						
Ms. Craig	X						
Ms. Schrier	X						
Ms. Trahan	X						
Ms. Fletcher	X						

Committee on Energy and Commerce
117th Congress

Full Committee
(ratio: 32-26)
ROLL CALL VOTE #121

Bill: **H.R. 7666**, the "Restoring Hope for Mental Health and Well-Being Act of 2022"

Amendment: An amendment (H7666-SCD-AMD_02) to the AINS by Ms. Trahan of Massachusetts, No. 1b

Disposition: **AGREED TO** by a roll call vote of 46 yeas to 8 nays

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Pallone	X			Mrs. Rodgers	X		
Mr. Rush				Mr. Upton	X		
Ms. Eshoo	X			Mr. Burgess		X	
Ms. DeGette	X			Mr. Scalise			
Mr. Doyle	X			Mr. Latta	X		
Ms. Schakowsky	X			Mr. Guthrie	X		
Mr. Butterfield				Mr. McKinley	X		
Ms. Matsui	X			Mr. Kinzinger			
Ms. Castor	X			Mr. Griffith		X	
Mr. Sarbanes	X			Mr. Bilirakis	X		
Mr. McNerney	X			Mr. Johnson	X		
Mr. Welch	X			Mr. Long		X	
Mr. Tonko	X			Mr. Bucshon		X	
Ms. Clarke	X			Mr. Mullin		X	
Mr. Schrader	X			Mr. Hudson	X		
Mr. Cárdenas	X			Mr. Walberg	X		
Mr. Ruiz	X			Mr. Carter	X		
Mr. Peters	X			Mr. Duncan	X		
Mrs. Dingell	X			Mr. Palmer	X		
Mr. Veasey	X			Mr. Dunn		X	
Ms. Kuster	X			Mr. Curtis	X		
Ms. Kelly	X			Ms. Lesko		X	
Ms. Barragán	X			Mr. Pence	X		
Mr. McEachin	X			Mr. Crenshaw	X		
Ms. Blunt Rochester	X			Mr. Joyce		X	
Mr. Soto	X			Mr. Armstrong	X		
Mr. O'Halleran	X						
Ms. Rice	X						
Ms. Craig	X						
Ms. Schrier	X						
Ms. Trahan	X						
Ms. Fletcher	X						

Committee on Energy and Commerce
117th Congress

Full Committee
(ratio: 32-26)
ROLL CALL VOTE #122

Bill: **H.R. 7666**, the "Restoring Hope for Mental Health and Well-Being Act of 2022"

Amendment: An amendment (H7666-FCD-AMD_01) to the AINS by Mr. Upton of Michigan, No. 1c

Disposition: **AGREED TO** by a roll call vote of 55 yeas to 1 nay

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Pallone	X			Mrs. Rodgers	X		
Mr. Rush	X			Mr. Upton	X		
Ms. Eshoo	X			Mr. Burgess	X		
Ms. DeGette	X			Mr. Scalise			
Mr. Doyle	X			Mr. Latta	X		
Ms. Schakowsky	X			Mr. Guthrie	X		
Mr. Butterfield	X			Mr. McKinley	X		
Ms. Matsui	X			Mr. Kinzinger			
Ms. Castor	X			Mr. Griffith	X		
Mr. Sarbanes	X			Mr. Bilirakis	X		
Mr. McNerney	X			Mr. Johnson	X		
Mr. Welch	X			Mr. Long	X		
Mr. Tonko	X			Mr. Bucshon	X		
Ms. Clarke	X			Mr. Mullin	X		
Mr. Schrader	X			Mr. Hudson	X		
Mr. Cárdenas	X			Mr. Walberg	X		
Mr. Ruiz	X			Mr. Carter	X		
Mr. Peters	X			Mr. Duncan	X		
Mrs. Dingell	X			Mr. Palmer	X		
Mr. Veasey	X			Mr. Dunn	X		
Ms. Kuster	X			Mr. Curtis	X		
Ms. Kelly	X			Ms. Lesko		X	
Ms. Barragán	X			Mr. Pence	X		
Mr. McEachin	X			Mr. Crenshaw	X		
Ms. Blunt Rochester	X			Mr. Joyce	X		
Mr. Soto	X			Mr. Armstrong	X		
Mr. O'Halleran	X						
Ms. Rice	X						
Ms. Craig	X						
Ms. Schrier	X						
Ms. Trahan	X						
Ms. Fletcher	X						

Committee on Energy and Commerce
117th Congress

Full Committee
(ratio: 32-26)
ROLL CALL VOTE #123

Bill: **H.R. 7666**, the "Restoring Hope for Mental Health and Well-Being Act of 2022"

Amendment: An amendment (H7666-FC-AMD_01) to the AINS by Mr. Cárdenas of California, No. 1d

Disposition: **AGREED TO** by a roll call vote of 31 yeas to 24 nays

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Pallone	X			Mrs. Rodgers		X	
Mr. Rush	X			Mr. Upton		X	
Ms. Eshoo	X			Mr. Burgess		X	
Ms. DeGette	X			Mr. Scalise			
Mr. Doyle	X			Mr. Latta		X	
Ms. Schakowsky	X			Mr. Guthrie		X	
Mr. Butterfield	X			Mr. McKinley		X	
Ms. Matsui	X			Mr. Kinzinger			
Ms. Castor	X			Mr. Griffith		X	
Mr. Sarbanes	X			Mr. Bilirakis		X	
Mr. McNerney	X			Mr. Johnson		X	
Mr. Welch	X			Mr. Long		X	
Mr. Tonko	X			Mr. Bucshon		X	
Ms. Clarke	X			Mr. Mullin		X	
Mr. Schrader	X			Mr. Hudson		X	
Mr. Cárdenas	X			Mr. Walberg		X	
Mr. Ruiz	X			Mr. Carter		X	
Mr. Peters	X			Mr. Duncan		X	
Mrs. Dingell	X			Mr. Palmer		X	
Mr. Veasey	X			Mr. Dunn		X	
Ms. Kuster	X			Mr. Curtis		X	
Ms. Kelly	X			Ms. Lesko		X	
Ms. Barragán				Mr. Pence		X	
Mr. McEachin	X			Mr. Crenshaw		X	
Ms. Blunt Rochester	X			Mr. Joyce		X	
Mr. Soto	X			Mr. Armstrong		X	
Mr. O'Halleran	X						
Ms. Rice	X						
Ms. Craig	X						
Ms. Schrier	X						
Ms. Trahan	X						
Ms. Fletcher	X						

VI. Oversight Findings

Pursuant to clause 3(c)(1) of rule XIII and clause 2(b)(1) of rule X of the Rules of the House of Representatives, the oversight findings and recommendations of the Committee are reflected in the descriptive portion of the report.

VII. New Budget Authority, Entitlement Authority, and Tax Expenditures

Pursuant to 3(c)(2) of rule XIII of the Rules of the House of Representatives, the Committee adopts as its own the estimate of new budget authority, entitlement authority, or tax expenditures or revenues contained in the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974.

The Committee has requested but not received from the Director of the Congressional Budget Office a statement as to whether this bill contains any new budget authority, spending authority, credit authority, or an increase or decrease in revenues or tax expenditures.

VIII. Federal Mandates Statement

The Committee adopts as its own the estimate of Federal mandates prepared by the Director of the Congressional Budget Office pursuant to section 423 of the Unfunded Mandates Reform Act.

IX. Statement of General Performance Goals and Objectives

Pursuant to clause 3(c)(4) of rule XIII, the general performance goal or objective of this legislation is to amend the Public Health Service Act to reauthorize certain programs relating to mental health and substance use disorders to support the mental health of Americans.

X. Duplication of Federal Programs

Pursuant to clause 3(c)(5) of rule XIII, no provision of H.R. 7666 is known to be duplicative of another Federal program, including any program that was included in a report to Congress pursuant to section 21 of Public Law 111–139 or the most recent Catalog of Federal Domestic Assistance.

XI. Committee Cost Estimate

Pursuant to clause 3(d)(1) of rule XIII, the Committee adopts as its own the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974.

XII. Earmarks, Limited Tax Benefits, and Limited Tariff Benefits

Pursuant to clause 9(e), 9(f), and 9(g) of rule XXI, the Committee finds that H.R. 7666 contains no earmarks, limited tax benefits, or limited tariff benefits.

XIII. Advisory Committee Statement

No advisory committee within the meaning of section 5(b) of the Federal Advisory Committee Act was created by this legislation.

XIV. Applicability to Legislative Branch

The Committee finds that the legislation does not relate to the terms and conditions of employment or access to public services or accommodations within the meaning of section 102(b)(3) of the Congressional Accountability Act.

XV. Section-by-Section Analysis of the Legislation

Section. 1. Short title; Table of contents

Section 1 designates that the short title may be cited as the "Restoring Hope for Mental Health and Well-Being Act of 2022."

TITLE I: MENTAL HEALTH AND CRISIS CARE NEEDS

SUBTITLE A—CRISIS CARE SERVICES AND 9–8–8 IMPLEMENTATION

Sec. 101. Behavioral Health Crisis Coordinating Office

Section 101 establishes the Behavioral Health Crisis Coordinating Office within the Substance Abuse and Mental Health Services Administration (SAMHSA) to convene partners and provide technical assistance to enhance access to crisis care, authorized at $5 million annually for fiscal years 2023 through 2027.

Sec. 102. Crisis response continuum of care

Section 102 requires the Secretary of HHS to publish best practices for a crisis response continuum of care not later than one year after the date of enactment for use by health care providers, crisis services administrators, and crisis services providers.

SUBTITLE B—INTO THE LIGHT FOR MATERNAL MENTAL HEALTH AND SUBSTANCE USE DISORDERS

Sec. 111. Screening and treatment for maternal mental health and substance use disorders

Section 111 reauthorizes section 317L–1 of the Public Health Service Act (PHSA) to award Screening and Treatment for Maternal Mental Health and Substance Use Disorders grants to states to establish, improve, or maintain programs for screening, assessment, and treatment services for women who are postpartum, pregnant, or have given birth within the preceding 12 months, for maternal mental health and substance use disorders. The grants are authorized at $24 million annually for fiscal years 2023 through 2027.

Sec. 112. Maternal mental health hotline

Section 112 establishes a national hotline to provide information, brief intervention, and mental health and substance use disorder resources to pregnant and postpartum women at risk of, or affected by, maternal mental health and substance use disorders, and authorizes $10 million annually for fiscal years 2023 through 2027.

Sec. 113. Task force on maternal mental health

Section 113 establishes a task force to make recommendations to coordinate and inform a national strategy to improve federal and state responses to maternal mental health conditions and requires a report to Congress and to governors and state leaders two years after the first meeting of the task force.

SUBTITLE C—REACHING IMPROVED MENTAL HEALTH OUTCOMES FOR PATIENTS

Sec. 121. Innovation for mental health

Section 121 replaces the unfunded Community Crisis Response Systems Grants authorization with an authorization of $10 million annually for fiscal years 2023 through 2027 for the establishment of a Mental Health Crisis Response Partnership Pilot Program.

Sec. 122. Crisis care coordination

Section 122 reauthorizes five additional SAMHSA programs to address mental health needs, provide crisis response care, and prevent suicide among adults for fiscal years 2023 through 2027, including: National Mental Health and Substance Abuse Policy Laboratory, authorized at $10 million for each fiscal year; Interdepartmental Serious Mental Illness Coordinating Committee; Mental Health Needs Priority Regions of National Significance (PRNS), authorized at $599.036 million for each fiscal year; Mental Health Awareness Training (MHAT) Grants, authorized at $24.963 million for each fiscal year; and Adult Suicide Prevention, authorized at $30 million for each fiscal year.

Sec. 123. Treatment of serious mental illness

Section 123 reauthorizes two programs for the treatment of serious mental illness, the Assertive Community Treatment Grants, authorized at $9 million for each fiscal year for fiscal years 2023 through 2027 and the Assisted Outpatient Treatment Grant Program for Individuals with Serious Mental Illness, authorized at $22 million for each fiscal year for the same period.

SUBTITLE D—ANNA WESTIN LEGACY

Sec. 131. Maintaining education and training on eating disorders

Section 131 establishes an authorization for the SAMHSA National Center of Excellence for Eating Disorders at $1 million annually for fiscal years 2023 through 2027 to award competitive subgrants or subcontracts for the development and provision of training and technical assistance to primary and behavioral health providers and non-clinical community support workers as well as collaboration and coordination with SAMHSA, the Centers for Disease Control and Prevention, and the Health Resources and Services Administration (HRSA) on the identification, effective treatment, and ongoing support of individuals with eating disorders.

SUBTITLE E—COMMUNITY MENTAL HEALTH SERVICES BLOCK GRANT REAUTHORIZATION

Sec. 141. Reauthorization of block grants for community mental health services

Section 141 reauthorizes the Community Mental Health Services Block Grants for states, territories, Tribes, and Tribal organizations to support community mental health services for adults with serious mental illness and children with serious emotional disturbance and to support the collection of performance and outcome data. This section also requires that five percent of the funds granted be used for crisis-care services and allows for up to five percent of funds for early intervention activities. This section authorizes $857.571 million annually for fiscal years 2023 through 2027.

SUBTITLE F—PEER-SUPPORTED MENTAL HEALTH SERVICES

Sec. 151. Peer-supported mental health services

Section 151 authorizes $13 million annually for fiscal years 2023 through 2027 for grants to consumer-led nonprofits, Tribes and Tribal organizations, Urban Indian organizations, or Tribal consortium to provide peer-supported mental health services, including virtual peer support.

TITLE II: SUBSTANCE USE DISORDER PREVENTION, TREATMENT, AND RECOVERY SERVICES

SUBTITLE A—NATIVE BEHAVIORAL HEALTH ACCESS IMPROVEMENT

Sec. 201. Behavioral health and substance use disorder services for Native Americans

Section 201 reauthorizes the Alcohol and Drug Prevention or Treatment Services for Indians and Native Alaskans Grant Program to provide culturally appropriate mental health and substance use disorder prevention, treatment, and recovery services to American Indians, Alaska Natives, and Native Hawaiians. This section requires the convening of a negotiated rulemaking committee composed of representatives of the federal government, Tribal Governments, and Urban Indian Organizations to establish a funding formula and program evaluation standards. This section authorizes $40 million annually for fiscal years 2023 through 2027.

SUBTITLE B—SUMMER BARROW PREVENTION, TREATMENT, AND RECOVERY

Sec. 211. Grants for the benefit of homeless individuals

Section 211 reauthorizes formula grants for the benefit of homeless individuals, administered through SAMHSA, authorized at $41.304 million for each fiscal year for fiscal years 2023 through 2027.

Sec. 212. Priority substance abuse treatment needs of regional and national significance

Section 212 reauthorizes the SAMHSA Substance Use Disorder Treatment Programs of Regional and National Significance

(PRNS), authorized at $521.517 million for each fiscal year for fiscal years 2023 through 2027.

Sec. 213. Evidence-based prescription opioid and heroin treatment and interventions demonstration

Section 213 reauthorizes the Prescription Opioid and Heroin Treatment and Interventions Demonstration Grants, administered by SAMHSA, authorized at $25 million for each fiscal year for fiscal years 2023 through 2027.

Sec. 214. Priority substance use disorder prevention needs of regional and national significance

Section 214 reauthorizes the SAMHSA Substance Use Disorder Prevention PRNS, authorized at $218.219 million for each fiscal year for fiscal years 2023 through 2027.

Sec. 215. Sober Truth on Preventing (STOP) Underage Drinking Reauthorization

Section 215 reauthorizes programs to reduce underage drinking, including requiring an annual report, a national media campaign, extending Community-based Coalition Enhancement Grants to Prevent Underage Drinking, Pediatric Provider Screening and Brief Intervention Grants, and data collection and research, collectively authorized at $23 million for each fiscal year for fiscal years 2023 through 2027. This section also requires a National Academy of Sciences review and report to Congress authorized at $500,000 for fiscal year 2023.

Sec. 216. Grants for jail diversion programs

Section 216 reauthorizes the SAMHSA Jail Diversion Program and Grants, authorized at $14 million each fiscal year for fiscal years 2023 through 2027.

Sec. 217. Formula grants to States

Section 217 authorizes formula grants to states from fiscal years 2023 through 2027.

Sec. 218. Projects for Assistance in Transition From Homelessness

Section 218 reauthorizes SAMHSA's Projects for Assistance in Transition from Homelessness Program, authorized at $64.635 million each fiscal year for fiscal years 2023 through 2027.

Sec. 219. Grants for reducing overdose deaths

Section 219 reauthorizes SAMHSA grants for reducing overdose deaths, including supporting the development of strategic opioid crisis response plans, authorized at $5 million each fiscal year for fiscal years 2023 through 2027.

Sec. 220. Opioid overdose reversal medication access and education grant programs

Section 220 reauthorizes Opioid Overdose Reversal Medication Access, Education, and Co-prescribing Grants, requiring health care practitioners to prescribe an opioid reversal drug when prescribing an opioid for certain patients, authorized at $5 million each fiscal year for fiscal years 2023 through 2027.

Sec. 221. State demonstration grants for comprehensive opioid abuse response

Section 221 reauthorizes SAMHSA grants for State and Local Integrated Comprehensive Opioid Use Disorder Response, authorized at $5 million each fiscal year for fiscal years 2023 through 2027.

Sec. 222. Emergency department alternatives to opioids

Section 222 reauthorizes Emergency Department Alternatives to Opioids Demonstration Grants, authorized at $10 million each fiscal year for fiscal years 2023 through 2027.

SUBTITLE C—EXCELLENCE IN RECOVERY HOUSING

Sec. 231. Clarifying the role of SAMHSA in promoting the availability of high-quality recovery housing

Section 231 requires the Secretary, acting through the SAMHSA Assistant Secretary, to collaborate with federal agencies and relevant stakeholders to promote the availability of high-quality recovery housing and services for individuals with substance use disorder.

Sec. 232. Developing guidelines for States to promote the availability of high-quality recovery housing

Section 232 requires the Secretary to develop and periodically update consensus based best practices for operating, and promoting the availability of, high-quality recovery housing.

Sec. 233. Coordination of Federal activities to promote the availability of recovery housing

Section 233 requires the Secretary, acting through the SAMHSA Assistant Secretary, and the Secretary of Housing and Urban Development, to convene an interagency working group and report to Congress on its activities to increase federal collaboration and coordination, develop a long-term plan to support state, Tribal, and local efforts to operate recovery housing consistent with best practices, and coordinate fair housing practices and data collection on the quality of recovery housing.

Sec. 234. NAS study and report

Section 234 requires the Secretary, acting through the Assistant Secretary for Mental Health and Substance Use, to contract with the National Academy of Sciences, Engineering, and Medicine to study the quality and effectiveness of recovery housing in the United States and identify recommendations, and to report to Congress the results of the review. This section authorizes $1.5 million for fiscal year 2023.

Sec. 235. Grants for States to promote the availability of recovery housing and services

Section 235 permits SAMHSA to provide grants to states, Tribes, and territories for technical assistance to promote and maintain recovery housing according to best practices and to develop related state promotion plans.

Sec. 236. Funding

Section 236 reauthorizes $5 million for the period of fiscal years 2023 through 2027 for the activities described in sections 231 through 235.

Sec. 237. Technical correction

Section 237 makes technical conforming corrections to the Public Health Services Act (PHSA).

SUBTITLE D—SUBSTANCE USE PREVENTION, TREATMENT, AND RECOVERY SERVICES BLOCK GRANT

Sec. 241. Eliminating stigmatizing language relating to substance use

Section 241 renames SAMHSA's Substance Abuse Prevention and Treatment Block Grant as the "Substance Use Prevention, Treatment, and Recovery Services Block Grant," and replaces "substance abuse" with "substance use" throughout the program.

Sec. 242. Authorized activities

Section 242 is expanded to specify that providing recovery support services is an authorized activity under the block grant use of funds.

Sec. 243. Requirements relating to certain infectious diseases and human immunodeficiency virus

Section 243 updates the basis by which states are designated as required to provide HIV related services based on HIV case rate rather than AIDS case rate effective fiscal year 2025. This section also requires states receiving block grant funds to provide viral hepatitis screening and referrals to providers whose practice includes viral hepatitis vaccination and treatment.

Sec. 244. State plan requirements

Section 233 requires that states' plans describe the recovery support service activities supported by block grant funds, including the number of individuals served, target populations, priority needs, and the amount of funds allocated to recovery support service disaggregated by type of activity.

Sec. 245. Updating certain language relating to Tribes

Section 245 updates statutory language to recognize Tribes and Tribal organizations as proper nouns.

Sec. 246. Block grants for substance use prevention, treatment, and recovery services

Section 246 authorizes the Substance Use Prevention, Treatment, and Recovery Services Block Grants at $1.908 billion annually for fiscal years 2023 through 2027. The section also makes a technical correction to the PHSA.

Sec. 247. Requirement of reports and audits by States

Section 247 requires states' report to include the amount of funds provided to each grant recipient the previous fiscal year.

Sec. 248. Study on assessment for use in distribution of limited State resources

Section 248 requires the Secretary to conduct a study to develop a model needs assessment process for states.

SUBTITLE E—TIMELY TREATMENT FOR OPIOID USE DISORDER

Sec. 251. Study on exemptions for treatment of opioid use disorder through opioid treatment programs during the COVID–19 public health emergency

Section 251 requires the Assistant Secretary for Mental Health and Substance Use to conduct a study and report within 180 days on the impact of treatment flexibilities allowed during the pandemic on an OTP's effectiveness and safety.

Sec. 252. Changes to Federal opioid treatment standards

Section 252 changes the federal opioid treatment standards to allow an OTP to operate one or more mobile units to dispense medications at locations other than the registrant's principal place of business or professional practice under the same registration. Previously, each mobile unit had to be separately registered. This section eliminates the requirement that an individual be addicted to opioids for at least one year before being admitted for treatment by an OTP. This section also requires the Secretary to establish criteria for OTP to allow certain patients to receive take home medications.

SUBTITLE F—ADDITIONAL PROVISIONS RELATING TO ADDICTION TREATMENT

Sec. 261. Prohibition

Section 261 prohibits funds authorized or amended by this Act from being used to purchase, procure, or distribute pipes or cylindrical objects intended to be used to smoke or inhale illegal schedule substances.

Sec. 262. Eliminating additional requirements for dispensing narcotic drugs in schedule III, IV, and V for maintenance or detoxification treatment

Section 262 eliminates the requirement for registered health care practitioners to apply for a separate waiver through the Drug Enforcement Administration to dispense certain narcotic drugs (e.g., buprenorphine) for maintenance or detoxification treatment.

Sec. 263. Requiring prescribers of controlled substances to complete training

Section 263 requires health care providers, as a condition of receiving or renewing a registration to prescribe controlled substances, to meet a one-time eight-hour training requirement on treating patients with substance use disorders.

TITLE III: ACCESS TO MENTAL HEALTH CARE AND COVERAGE

SUBTITLE A—COLLABORATE IN AN ORDERLY AND COHESIVE MANNER

Sec. 301. Increasing uptake of the collaborative care model

Section 301 reauthorizes a program that allows HHS to award grants to states that partner with a community program, a health center, a Federally Qualified Health Center or rural health clinic, or a primary health care physician practice to implement and evaluate specified models of care that integrate behavioral health and primary care services. Recipients who provide care to medically underserved populations and in areas where the prevalence of behavioral health conditions exceeds the national average are given priority for these grants. This section establishes incentive payments for recipients that use appropriate billing codes and quality measures for behavioral health services as well as grants for national and regional organizations that provide technical assistance to improve integration. This section authorizes $60 million annually for fiscal years 2023 through 2027.

SUBTITLE B—HELPING ENABLE ACCESS TO LIFESAVING SERVICES

Sec. 311. Reauthorization and provision of certain programs to strengthen the health care workforce

Section 311 reauthorizes multiple programs to support and strengthen the health care workforce, including Liability Protections for Health Professional Volunteers, reauthorized through October 1, 2027; Mental and Behavioral Health Education and Training Grants including updates to the education reference for occupational therapist, reauthorized at $50 million for fiscal years 2023 through 2027; and the Training Demonstration Program, reauthorized at $37.1 million annually for fiscal years 2023 through 2027. This section updates the Minority Fellowship Program to include those "in the fields of crisis care management."

SUBTITLE C—ELIMINATING THE OPT-OUT FOR NONFEDERAL GOVERNMENTAL HEALTH PLANS

Sec. 321. Eliminating the opt-out for nonfederal governmental health plans

Section 321 requires self-funded, non-federal governmental plans to comply with mental health parity requirements starting six months after the date of enactment or longer contingent on the terms of the plan agreement.

SUBTITLE D—MENTAL HEALTH AND SUBSTANCE USE DISORDER PARITY IMPLEMENTATION

Sec. 331. Grants to support mental health and substance use disorder parity implementation

Section 331 authorizes $10 million annually for fiscal years 2023 through 2027 for grants to states to enforce and ensure compliance with mental health parity.

TITLE IV: CHILDREN AND YOUTH

SUBTITLE A—SUPPORTING CHILDREN'S MENTAL HEALTH CARE ACCESS

Sec. 401. Pediatric mental health care access grants

Section 401 reauthorizes HRSA's Pediatric Mental Health Care Access grant program that promotes behavioral health integration into pediatric primary care by supporting pediatric mental health care telehealth access programs in states at $14 million annually for fiscal years 2023 through 2025 and $30 million annually for fiscal years 2026 through 2027.

Sec. 402. Infant and early childhood mental health promotion, intervention, and treatment

Section 402 reauthorizes SAMHSA's Infant and Early Childhood Mental Health Grant Program, which is intended to improve outcomes for children from birth to age 12 by developing, maintaining, or enhancing mental health promotion, intervention, and treatment services at $50 million for the period of fiscal years 2023 through 2027.

SUBTITLE B—CONTINUING SYSTEMS OF CARE FOR CHILDREN

Sec. 411. Comprehensive Community Mental Health Services for Children with Serious Emotional Disturbances

Section 411 reauthorizes the Comprehensive Community Mental Health Services for Children with Serious Emotional Disturbances Grants, maintaining the existing program structure with the exception of redefining "parents or kinship caregivers," authorized at $125 million annually for fiscal years 2023 through 2027.

Sec. 412. Substance Use Disorder Treatment and Early Intervention Services for Children and Adolescents

Section 412 reauthorizes the Enhancement and Expansion of Treatment and Recovery Services for Adolescents, Transitional Aged Youth, and their Families (Youth and Family TREE) Grants at $29.605 million annually for fiscal years 2023 through 2027.

SUBTITLE C—GARRETT LEE SMITH MEMORIAL REAUTHORIZATION

Sec. 421. Suicide prevention technical assistance center

Section 421 reauthorizes the Suicide Prevention Resource Center at $9 million annually for fiscal years 2023 through 2027.

Sec. 422. Youth suicide early intervention and prevention strategies

Section 422 reauthorizes the State and Tribal Youth Suicide Prevention and Early Intervention Grants Program at $40 million annually for fiscal years 2023 through 2027 and provides the allowable use of funds for supplies to securely store commonly used means of suicide within a household.

Sec. 423. Mental health and substance use disorder services for students in higher education

Section 423 reauthorizes the Mental Health Youth Suicide Prevention Campus Grants at $7 million for each fiscal year for fiscal years 2023 through 2027.

Sec. 424. Mental and behavioral health outreach and education at institutions of higher education

Section 424 reauthorizes and renames the Mental and Behavioral Health Public Outreach and Education at Institutions of Higher Education program at $1 million for fiscal years 2023 through 2027 and specifies that representatives from minority-serving institutions and community colleges be included on the program's working group.

XVI. Changes in Existing Law Made by the Bill, as Reported

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italics, and existing law in which no change is proposed is shown in roman):

PUBLIC HEALTH SERVICE ACT

* * * * * * *

TITLE II—ADMINISTRATION AND MISCELLANEOUS PROVISIONS

Part A—Administration

* * * * * * *

DEFENSE OF CERTAIN MALPRACTICE AND NEGLIGENCE SUITS

Sec. 224. (a) The remedy against the United States provided by sections 1346(b) and 2672 of title 28, or by alternative benefits provided by the United States where the availability of such benefits precludes a remedy under section 1346(b) of title 28, for damage for personal injury, including death, resulting from the performance of medical, surgical, dental, or related functions, including the conduct of clinical studies or investigation, by any commissioned officer or employee of the Public Health Service while acting within the scope of his office or employment, shall be exclusive of any other civil action or proceeding by reason of the same subject-matter against the officer or employee (or his estate) whose act or omission gave rise to the claim.

(b) The Attorney General shall defend any civil action or proceeding brought in any court against any person referred to in subsection (a) of this section (or his estate) for any such damage or injury. Any such person against whom such civil action or proceeding is brought shall deliver within such time after date of service or knowledge of service as determined by the Attorney General, all process served upon him or an attested true copy thereof to his immediate superior or to whomever was designated by the Secretary to receive such papers and such persons shall promptly furnish copies of the pleading and process therein to the United States attorney for the district embracing the place wherein the proceeding is brought, to the Attorney General, and to the Secretary.

(c) Upon a certification by the Attorney General that the defendant was acting in the scope of his employment at the time of the

incident out of which the suit arose, any such civil action or proceeding commenced in a State court shall be removed without bond at any time before trial by the Attorney General to the district court of the United States of the district and division embracing the place wherein it is pending and the proceeding deemed a tort action brought against the United States under the provisions of title 28 and all references thereto. Should a United States district court determine on a hearing on a motion to remand held before a trial on the merit that the case so removed is one in which a remedy by suit within the meaning of subsection (a) of this section is not available against the United States, the case shall be remanded to the State Court: *Provided*, That where such a remedy is precluded because of the availability of a remedy through proceedings for compensation or other benefits from the United States as provided by any other law, the case shall be dismissed, but in the event the running of any limitation of time for commencing, or filing an application or claim in, such proceedings for compensation or other benefits shall be deemed to have been suspended during the pendency of the civil action or proceeding under this section.

(d) The Attorney General may compromise or settle any claim asserted in such civil action or proceeding in the manner provided in section 2677 of title 28 and with the same effect.

(e) For purposes of this section, the provisions of section 2680(h) of title 28 shall not apply to assault or battery arising out of negligence in the performance of medical, surgical, dental, or related functions, including the conduct of clinical studies or investigations.

(f) The Secretary or his designee may, to the extent that he deems appropriate, hold harmless or provide liability insurance for any officer or employee of the Public Health Service for damage for personal injury, including death, negligently caused by such officer or employee while acting within the scope of his office or employment and as a result of the performance of medical, surgical, dental, or related functions, including the conduct of clinical studies or investigations, if such employee is assigned to a foreign country or detailed to a State or political subdivision thereof or to a non-profit institution, and if the circumstances are such as are likely to preclude the remedies of third persons against the United States described in section 2679(b) of title 28, for such damage or injury.

(g)(1)(A) For purposes of this section and subject to the approval by the Secretary of an application under subparagraph (D), an entity described in paragraph (4), and any officer, governing board member, or employee of such an entity, and any contractor of such an entity who is a physician or other licensed or certified health care practitioner (subject to paragraph (5)), shall be deemed to be an employee of the Public Health Service for a calendar year that begins during a fiscal year for which a transfer was made under subsection (k)(3) (subject to paragraph (3)). The remedy against the United States for an entity described in paragraph (4) and any officer, governing board member, employee, or contractor (subject to paragraph (5)) of such an entity who is deemed to be an employee of the Public Health Service pursuant to this paragraph shall be exclusive of any other civil action or proceeding to the same extent as the remedy against the United States is exclusive pursuant to subsection (a).

(B) The deeming of any entity or officer, governing board member, employee, or contractor of the entity to be an employee of the Public Health Service for purposes of this section shall apply with respect to services provided—

(i) to all patients of the entity, and

(ii) subject to subparagraph (C), to individuals who are not patients of the entity.

(C) Subparagraph (B)(ii) applies to services provided to individuals who are not patients of an entity if the Secretary determines, after reviewing an application submitted under subparagraph (D), that the provision of the services to such individuals—

(i) benefits patients of the entity and general populations that could be served by the entity through community-wide intervention efforts within the communities served by such entity;

(ii) facilitates the provision of services to patients of the entity; or

(iii) are otherwise required under an employment contract (or similar arrangement) between the entity and an officer, governing board member, employee, or contractor of the entity.

(D) The Secretary may not under subparagraph (A) deem an entity or an officer, governing board member, employee, or contractor of the entity to be an employee of the Public Health Service for purposes of this section, and may not apply such deeming to services described in subparagraph (B)(ii), unless the entity has submitted an application for such deeming to the Secretary in such form and such manner as the Secretary shall prescribe. The application shall contain detailed information, along with supporting documentation, to verify that the entity, and the officer, governing board member, employee, or contractor of the entity, as the case may be, meets the requirements of subparagraphs (B) and (C) of this paragraph and that the entity meets the requirements of paragraphs (1) through (4) of subsection (h).

(E) The Secretary shall make a determination of whether an entity or an officer, governing board member, employee, or contractor of the entity is deemed to be an employee of the Public Health Service for purposes of this section within 30 days after the receipt of an application under subparagraph (D). The determination of the Secretary that an entity or an officer, governing board member, employee, or contractor of the entity is deemed to be an employee of the Public Health Service for purposes of this section shall apply for the period specified by the Secretary under subparagraph (A).

(F) Once the Secretary makes a determination that an entity or an officer, governing board member, employee, or contractor of an entity is deemed to be an employee of the Public Health Service for purposes of this section, the determination shall be final and binding upon the Secretary and the Attorney General and other parties to any civil action or proceeding. Except as provided in subsection (i), the Secretary and the Attorney General may not determine that the provision of services which are the subject of such a determination are not covered under this section.

(G) In the case of an entity described in paragraph (4) that has not submitted an application under subparagraph (D):

(i) The Secretary may not consider the entity in making estimates under subsection (k)(1).

(ii) This section does not affect any authority of the entity to purchase medical malpractice liability insurance coverage with Federal funds provided to the entity under section 329, 330, or 340A.

(H) In the case of an entity described in paragraph (4) for which an application under subparagraph (D) is in effect, the entity may, through notifying the Secretary in writing, elect to terminate the applicability of this subsection to the entity. With respect to such election by the entity:

(i) The election is effective upon the expiration of the 30-day period beginning on the date on which the entity submits such notification.

(ii) Upon taking effect, the election terminates the applicability of this subsection to the entity and each officer, governing board member, employee, and contractor of the entity.

(iii) Upon the effective date for the election, clauses (i) and (ii) of subparagraph (G) apply to the entity to the same extent and in the same manner as such clauses apply to an entity that has not submitted an application under subparagraph (D).

(iv) If after making the election the entity submits an application under subparagraph (D), the election does not preclude the Secretary from approving the application (and thereby restoring the applicability of this subsection to the entity and each officer, governing board member, employee, and contractor of the entity, subject to the provisions of this subsection and the subsequent provisions of this section.

(2) If, with respect to an entity or person deemed to be an employee for purposes of paragraph (1), a cause of action is instituted against the United States pursuant to this section, any claim of the entity or person for benefits under an insurance policy with respect to medical malpractice relating to such cause of action shall be subrogated to the United States.

(3) This subsection shall apply with respect to a cause of action arising from an act or omission which occurs on or after January 1, 1993.

(4) An entity described in this paragraph is a public or non-profit private entity receiving Federal funds under section 330.

(5) For purposes of paragraph (1), an individual may be considered a contractor of an entity described in paragraph (4) only if—

(A) the individual normally performs on average at least 32½ hours of service per week for the entity for the period of the contract; or

(B) in the case of an individual who normally performs an average of less than 32½ hours of services per week for the entity for the period of the contract, the individual is a licensed or certified provider of services in the fields of family practice, general internal medicine, general pediatrics, or obstetrics and gynecology.

(h) The Secretary may not approve an application under subsection (g)(1)(D) unless the Secretary determines that the entity—

(1) has implemented appropriate policies and procedures to reduce the risk of malpractice and the risk of lawsuits arising out of any health or health-related functions performed by the entity;

(2) has reviewed and verified the professional credentials, references, claims history, fitness, professional review organization findings, and license status of its physicians and other licensed or certified health care practitioners, and, where necessary, has obtained the permission from these individuals to gain access to this information;

(3) has no history of claims having been filed against the United States as a result of the application of this section to the entity or its officers, employees, or contractors as provided for under this section, or, if such a history exists, has fully cooperated with the Attorney General in defending against any such claims and either has taken, or will take, any necessary corrective steps to assure against such claims in the future; and

(4) will fully cooperate with the Attorney General in providing information relating to an estimate described under subsection (k).

(i)(1) Notwithstanding subsection (g)(1), the Attorney General, in consultation with the Secretary, may on the record determine, after notice and opportunity for a full and fair hearing, that an individual physician or other licensed or certified health care practitioner who is an officer, employee, or contractor of an entity described in subsection (g)(4) shall not be deemed to be an employee of the Public Health Service for purposes of this section, if treating such individual as such an employee would expose the Government to an unreasonably high degree of risk of loss because such individual—

(A) does not comply with the policies and procedures that the entity has implemented pursuant to subsection (h)(1);

(B) has a history of claims filed against him or her as provided for under this section that is outside the norm for licensed or certified health care practitioners within the same specialty;

(C) refused to reasonably cooperate with the Attorney General in defending against any such claim;

(D) provided false information relevant to the individual's performance of his or her duties to the Secretary, the Attorney General, or an applicant for or recipient of funds under this Act; or

(E) was the subject of disciplinary action taken by a State medical licensing authority or a State or national professional society.

(2) A final determination by the Attorney General under this subsection that an individual physician or other licensed or certified health care professional shall not be deemed to be an employee of the Public Health Service shall be effective upon receipt by the entity employing such individual of notice of such determination, and shall apply only to acts or omissions occurring after the date such notice is received.

(j) In the case of a health care provider who is an officer, employee, or contractor of an entity described in subsection (g)(4), section 335(e) shall apply with respect to the provider to the same extent and in the same manner as such section applies to any member of the National Health Service Corps.

(k)(1)(A) For each fiscal year, the Attorney General, in consultation with the Secretary, shall estimate by the beginning of the year the amount of all claims which are expected to arise under this section (together with related fees and expenses of witnesses) for which payment is expected to be made in accordance with section 1346 and chapter 171 of title 28, United States Code, from the acts or omissions, during the calendar year that begins during that fiscal year, of entities described in subsection (g)(4) and of officers, employees, or contractors (subject to subsection (g)(5)) of such entities.

(B) The estimate under subparagraph (A) shall take into account—

(i) the value and frequency of all claims for damage for personal injury, including death, resulting from the performance of medical, surgical, dental, or related functions by entities described in subsection (g)(4) or by officers, employees, or contractors (subject to subsection (g)(5)) of such entities who are deemed to be employees of the Public Health Service under subsection (g)(1) that, during the preceding 5-year period, are filed under this section or, with respect to years occurring before this subsection takes effect, are filed against persons other than the United States,

(ii) the amounts paid during that 5-year period on all claims described in clause (i), regardless of when such claims were filed, adjusted to reflect payments which would not be permitted under section 1346 and chapter 171 of title 28, United States Code, and

(iii) amounts in the fund established under paragraph (2) but unspent from prior fiscal years.

(2) Subject to appropriations, for each fiscal year, the Secretary shall establish a fund of an amount equal to the amount estimated under paragraph (1) that is attributable to entities receiving funds under each of the grant programs described in paragraph (4) of subsection (g), but not to exceed a total of $10,000,000 for each such fiscal year. Appropriations for purposes of this paragraph shall be made separate from appropriations made for purposes of sections 329, 330 and 340A.

(3) In order for payments to be made for judgments against the United States (together with related fees and expenses of witnesses) pursuant to this section arising from the acts or omissions of entities described in subsection (g)(4) and of officers, employees, or contractors (subject to subsection (g)(5)) of such entities, the total amount contained within the fund established by the Secretary under paragraph (2) for a fiscal year shall be transferred not later than the December 31 that occurs during the fiscal year to the appropriate accounts in the Treasury.

(l)(1) If a civil action or proceeding is filed in a State court against any entity described in subsection (g)(4) or any officer, governing board member, employee, or any contractor of such an entity for damages described in subsection (a), the Attorney General, within 15 days after being notified of such filing, shall make an appearance in such court and advise such court as to whether the Secretary has determined under subsections (g) and (h), that such entity, officer, governing board member, employee, or contractor of the entity is deemed to be an employee of the Public Health Service

for purposes of this section with respect to the actions or omissions that are the subject of such civil action or proceeding. Such advice shall be deemed to satisfy the provisions of subsection (c) that the Attorney General certify that an entity, officer, governing board member, employee, or contractor of the entity was acting within the scope of their employment or responsibility.

(2) If the Attorney General fails to appear in State court within the time period prescribed under paragraph (1), upon petition of any entity or officer, governing board member, employee, or contractor of the entity named, the civil action or proceeding shall be removed to the appropriate United States district court. The civil action or proceeding shall be stayed in such court until such court conducts a hearing, and makes a determination, as to the appropriate forum or procedure for the assertion of the claim for damages described in subsection (a) and issues an order consistent with such determination.

(m)(1) An entity or officer, governing board member, employee, or contractor of an entity described in subsection (g)(1) shall, for purposes of this section, be deemed to be an employee of the Public Health Service with respect to services provided to individuals who are enrollees of a managed care plan if the entity contracts with such managed care plan for the provision of services.

(2) Each managed care plan which enters into a contract with an entity described in subsection (g)(4) shall deem the entity and any officer, governing board member, employee, or contractor of the entity as meeting whatever malpractice coverage requirements such plan may require of contracting providers for a calendar year if such entity or officer, governing board member, employee, or contractor of the entity has been deemed to be an employee of the Public Health Service for purposes of this section for such calendar year. Any plan which is found by the Secretary on the record, after notice and an opportunity for a full and fair hearing, to have violated this subsection shall upon such finding cease, for a period to be determined by the Secretary, to receive and to be eligible to receive any Federal funds under titles XVIII or XIX of the Social Security Act.

(3) For purposes of this subsection, the term "managed care plan" shall mean health maintenance organizations and similar entities that contract at-risk with payors for the provision of health services or plan enrollees and which contract with providers (such as entities described in subsection (g)(4)) for the delivery of such services to plan enrollees.

(n)(1) Not later than one year after the date of the enactment of the Federally Supported Health Centers Assistance Act of 1995, the Comptroller General of the United States shall submit to the Congress a report on the following:

(A) The medical malpractice liability claims experience of entities that have been deemed to be employees for purposes of this section.

(B) The risk exposure of such entities.

(C) The value of private sector risk-management services, and the value of risk-management services and procedures required as a condition of receiving a grant under section 329, 330, or 340A.

(D) A comparison of the costs and the benefits to taxpayers of maintaining medical malpractice liability coverage for such entities pursuant to this section, taking into account—

(i) a comparison of the costs of premiums paid by such entities for private medical malpractice liability insurance with the cost of coverage pursuant to this section; and

(ii) an analysis of whether the cost of premiums for private medical malpractice liability insurance coverage is consistent with the liability claims experience of such entities.

(2) The report under paragraph (1) shall include the following:

(A) A comparison of—

(i) an estimate of the aggregate amounts that such entities (together with the officers, governing board members, employees, and contractors of such entities who have been deemed to be employees for purposes of this section) would have directly or indirectly paid in premiums to obtain medical malpractice liability insurance coverage if this section were not in effect; with

(ii) the aggregate amounts by which the grants received by such entities under this Act were reduced pursuant to subsection (k)(2).

(B) A comparison of—

(i) an estimate of the amount of privately offered such insurance that such entities (together with the officers, governing board members, employees, and contractors of such entities who have been deemed to be employees for purposes of this section) purchased during the three-year period beginning on January 1, 1993; with

(ii) an estimate of the amount of such insurance that such entities (together with the officers, governing board members, employees, and contractors of such entities who have been deemed to be employees for purposes of this section) will purchase after the date of the enactment of the Federally Supported Health Centers Assistance Act of 1995.

(C) An estimate of the medical malpractice liability loss history of such entities for the 10-year period preceding October 1, 1996, including but not limited to the following:

(i) Claims that have been paid and that are estimated to be paid, and legal expenses to handle such claims that have been paid and that are estimated to be paid, by the Federal Government pursuant to deeming entities as employees for purposes of this section.

(ii) Claims that have been paid and that are estimated to be paid, and legal expenses to handle such claims that have been paid and that are estimated to be paid, by private medical malpractice liability insurance.

(D) An analysis of whether the cost of premiums for private medical malpractice liability insurance coverage is consistent with the liability claims experience of entities that have been deemed as employees for purposes of this section.

(3) In preparing the report under paragraph (1), the Comptroller General of the United States shall consult with public and private

entities with expertise on the matters with which the report is concerned.

(o)(1) For purposes of this section, a free clinic health professional shall in providing a qualifying health service to an individual, or an officer, governing board member, employee, or contractor of a free clinic shall in providing services for the free clinic, be deemed to be an employee of the Public Health Service for a calendar year that begins during a fiscal year for which a transfer was made under paragraph (6)(D). The preceding sentence is subject to the provisions of this subsection.

(2) In providing a health service to an individual, a health care practitioner shall for purposes of this subsection be considered to be a free clinic health professional if the following conditions are met:

(A) The service is provided to the individual at a free clinic, or through offsite programs or events carried out by the free clinic.

(B) The free clinic is sponsoring the health care practitioner pursuant to paragraph (5)(C).

(C) The service is a qualifying health service (as defined in paragraph (4)).

(D) Neither the health care practitioner nor the free clinic receives any compensation for the service from the individual or from any third-party payor (including reimbursement under any insurance policy or health plan, or under any Federal or State health benefits program). With respect to compliance with such condition:

(i) The health care practitioner may receive repayment from the free clinic for reasonable expenses incurred by the health care practitioner in the provision of the service to the individual.

(ii) The free clinic may accept voluntary donations for the provision of the service by the health care practitioner to the individual.

(E) Before the service is provided, the health care practitioner or the free clinic provides written notice to the individual of the extent to which the legal liability of the health care practitioner is limited pursuant to this subsection (or in the case of an emergency, the written notice is provided to the individual as soon after the emergency as is practicable). If the individual is a minor or is otherwise legally incompetent, the condition under this subparagraph is that the written notice be provided to a legal guardian or other person with legal responsibility for the care of the individual.

(F) At the time the service is provided, the health care practitioner is licensed or certified in accordance with applicable law regarding the provision of the service.

(3)(A) For purposes of this subsection, the term "free clinic" means a health care facility operated by a nonprofit private entity meeting the following requirements:

(i) The entity does not, in providing health services through the facility, accept reimbursement from any third-party payor (including reimbursement under any insurance policy or health plan, or under any Federal or State health benefits program).

(ii) The entity, in providing health services through the facility, either does not impose charges on the individuals to whom the services are provided, or imposes a charge according to the ability of the individual involved to pay the charge.

(iii) The entity is licensed or certified in accordance with applicable law regarding the provision of health services.

(B) With respect to compliance with the conditions under subparagraph (A), the entity involved may accept voluntary donations for the provision of services.

(4) For purposes of this subsection, the term "qualifying health service" means any medical assistance required or authorized to be provided in the program under title XIX of the Social Security Act, without regard to whether the medical assistance is included in the plan submitted under such program by the State in which the health care practitioner involved provides the medical assistance. References in the preceding sentence to such program shall as applicable be considered to be references to any successor to such program.

(5) Subsection (g) (other than paragraphs (3) through (5)) and subsections (h), (i), and (l) apply to a health care practitioner for purposes of this subsection to the same extent and in the same manner as such subsections apply to an officer, governing board member, employee, or contractor of an entity described in subsection (g)(4), subject to paragraph (6) and subject to the following:

(A) The first sentence of paragraph (1) applies in lieu of the first sentence of subsection (g)(1)(A).

(B) This subsection may not be construed as deeming any free clinic to be an employee of the Public Health Service for purposes of this section.

(C) With respect to a free clinic, a health care practitioner is not a free clinic health professional unless the free clinic sponsors the health care practitioner. For purposes of this subsection, the free clinic shall be considered to be sponsoring the health care practitioner if—

(i) with respect to the health care practitioner, the free clinic submits to the Secretary an application meeting the requirements of subsection (g)(1)(D); and

(ii) the Secretary, pursuant to subsection (g)(1)(E), determines that the health care practitioner is deemed to be an employee of the Public Health Service.

(D) In the case of a health care practitioner who is determined by the Secretary pursuant to subsection (g)(1)(E) to be a free clinic health professional, this subsection applies to the health care practitioner (with respect to the free clinic sponsoring the health care practitioner pursuant to subparagraph (C)) for any cause of action arising from an act or omission of the health care practitioner occurring on or after the date on which the Secretary makes such determination.

(E) Subsection (g)(1)(F) applies to a health care practitioner for purposes of this subsection only to the extent that, in providing health services to an individual, each of the conditions specified in paragraph (2) is met.

(6)(A) For purposes of making payments for judgments against the United States (together with related fees and expenses of witnesses) pursuant to this section arising from the acts or omissions

of free clinic health professionals, there is authorized to be appropriated $10,000,000 for each fiscal year.

(B) The Secretary shall establish a fund for purposes of this subsection. Each fiscal year amounts appropriated under subparagraph (A) shall be deposited in such fund.

(C) Not later than May 1 of each fiscal year, the Attorney General, in consultation with the Secretary, shall submit to the Congress a report providing an estimate of the amount of claims (together with related fees and expenses of witnesses) that, by reason of the acts or omissions of free clinic health professionals, will be paid pursuant to this section during the calendar year that begins in the following fiscal year. Subsection (k)(1)(B) applies to the estimate under the preceding sentence regarding free clinic health professionals to the same extent and in the same manner as such subsection applies to the estimate under such subsection regarding officers, governing board members, employees, and contractors of entities described in subsection (g)(4).

(D) Not later than December 31 of each fiscal year, the Secretary shall transfer from the fund under subparagraph (B) to the appropriate accounts in the Treasury an amount equal to the estimate made under subparagraph (C) for the calendar year beginning in such fiscal year, subject to the extent of amounts in the fund.

(7)(A) This subsection takes effect on the date of the enactment of the first appropriations Act that makes an appropriation under paragraph (6)(A), except as provided in subparagraph (B)(i).

(B)(i) Effective on the date of the enactment of the Health Insurance Portability and Accountability Act of 1996—

(I) the Secretary may issue regulations for carrying out this subsection, and the Secretary may accept and consider applications submitted pursuant to paragraph (5)(C); and

(II) reports under paragraph (6)(C) may be submitted to the Congress.

(ii) For the first fiscal year for which an appropriation is made under subparagraph (A) of paragraph (6), if an estimate under subparagraph (C) of such paragraph has not been made for the calendar year beginning in such fiscal year, the transfer under subparagraph (D) of such paragraph shall be made notwithstanding the lack of the estimate, and the transfer shall be made in an amount equal to the amount of such appropriation.

(p) ADMINISTRATION OF SMALLPOX COUNTERMEASURES BY HEALTH PROFESSIONALS.—

(1) IN GENERAL.—For purposes of this section, and subject to other provisions of this subsection, a covered person shall be deemed to be an employee of the Public Health Service with respect to liability arising out of administration of a covered countermeasure against smallpox to an individual during the effective period of a declaration by the Secretary under paragraph (2)(A).

(2) DECLARATION BY SECRETARY CONCERNING COUNTERMEASURE AGAINST SMALLPOX.—

(A) AUTHORITY TO ISSUE DECLARATION.—

(i) IN GENERAL.—The Secretary may issue a declaration, pursuant to this paragraph, concluding that an actual or potential bioterrorist incident or other actual or potential public health emergency makes advisable

the administration of a covered countermeasure to a category or categories of individuals.

(ii) COVERED COUNTERMEASURE.—The Secretary shall specify in such declaration the substance or substances that shall be considered covered countermeasures (as defined in paragraph (7)(A)) for purposes of administration to individuals during the effective period of the declaration.

(iii) EFFECTIVE PERIOD.—The Secretary shall specify in such declaration the beginning and ending dates of the effective period of the declaration, and may subsequently amend such declaration to shorten or extend such effective period, provided that the new closing date is after the date when the declaration is amended.

(iv) PUBLICATION.—The Secretary shall promptly publish each such declaration and amendment in the Federal Register.

(B) LIABILITY OF UNITED STATES ONLY FOR ADMINISTRATIONS WITHIN SCOPE OF DECLARATION.—Except as provided in paragraph (5)(B)(ii), the United States shall be liable under this subsection with respect to a claim arising out of the administration of a covered countermeasure to an individual only if—

(i) the countermeasure was administered by a qualified person, for a purpose stated in paragraph (7)(A)(i), and during the effective period of a declaration by the Secretary under subparagraph (A) with respect to such countermeasure; and

(ii)(I) the individual was within a category of individuals covered by the declaration; or

(II) the qualified person administering the countermeasure had reasonable grounds to believe that such individual was within such category.

(C) PRESUMPTION OF ADMINISTRATION WITHIN SCOPE OF DECLARATION IN CASE OF ACCIDENTAL VACCINIA INOCULATION.—

(i) IN GENERAL.—If vaccinia vaccine is a covered countermeasure specified in a declaration under subparagraph (A), and an individual to whom the vaccinia vaccine is not administered contracts vaccinia, then, under the circumstances specified in clause (ii), the individual—

(I) shall be rebuttably presumed to have contracted vaccinia from an individual to whom such vaccine was administered as provided by clauses (i) and (ii) of subparagraph (B); and

(II) shall (unless such presumption is rebutted) be deemed for purposes of this subsection to be an individual to whom a covered countermeasure was administered by a qualified person in accordance with the terms of such declaration and as described by subparagraph (B).

(ii) CIRCUMSTANCES IN WHICH PRESUMPTION APPLIES.—The presumption and deeming stated in clause (i) shall apply if—

(I) the individual contracts vaccinia during the effective period of a declaration under subparagraph (A) or by the date 30 days after the close of such period; or

(II) the individual has resided with, or has had contact with, an individual to whom such vaccine was administered as provided by clauses (i) and (ii) of subparagraph (B) and contracts vaccinia after such date.

(D) ACTS AND OMISSIONS DEEMED TO BE WITHIN SCOPE OF EMPLOYMENT.—

(i) IN GENERAL.—In the case of a claim arising out of alleged transmission of vaccinia from an individual described in clause (ii), acts or omissions by such individual shall be deemed to have been taken within the scope of such individual's office or employment for purposes of—

(I) subsection (a); and

(II) section 1346(b) and chapter 171 of title 28, United States Code.

(ii) INDIVIDUALS TO WHOM DEEMING APPLIES.—An individual is described by this clause if—

(I) vaccinia vaccine was administered to such individual as provided by subparagraph (B); and

(II) such individual was within a category of individuals covered by a declaration under subparagraph (A)(i).

(3) EXHAUSTION; EXCLUSIVITY; OFFSET.—

(A) EXHAUSTION.—

(i) IN GENERAL.—A person may not bring a claim under this subsection unless such person has exhausted such remedies as are available under part C of this title, except that if the Secretary fails to make a final determination on a request for benefits or compensation filed in accordance with the requirements of such part within 240 days after such request was filed, the individual may seek any remedy that may be available under this section.

(ii) TOLLING OF STATUTE OF LIMITATIONS.—The time limit for filing a claim under this subsection, or for filing an action based on such claim, shall be tolled during the pendency of a request for benefits or compensation under part C of this title.

(iii) CONSTRUCTION.—This subsection shall not be construed as superseding or otherwise affecting the application of a requirement, under chapter 171 of title 28, United States Code, to exhaust administrative remedies.

(B) EXCLUSIVITY.—The remedy provided by subsection (a) shall be exclusive of any other civil action or proceeding for any claim or suit this subsection encompasses, except for a proceeding under part C of this title.

(C) OFFSET.—The value of all compensation and benefits provided under part C of this title for an incident or series of incidents shall be offset against the amount of an award, compromise, or settlement of money damages in a claim or suit under this subsection based on the same incident or series of incidents.

(4) CERTIFICATION OF ACTION BY ATTORNEY GENERAL.—Subsection (c) applies to actions under this subsection, subject to the following provisions:

(A) NATURE OF CERTIFICATION.—The certification by the Attorney General that is the basis for deeming an action or proceeding to be against the United States, and for removing an action or proceeding from a State court, is a certification that the action or proceeding is against a covered person and is based upon a claim alleging personal injury or death arising out of the administration of a covered countermeasure.

(B) CERTIFICATION OF ATTORNEY GENERAL CONCLUSIVE.—The certification of the Attorney General of the facts specified in subparagraph (A) shall conclusively establish such facts for purposes of jurisdiction pursuant to this subsection.

(5) COVERED PERSON TO COOPERATE WITH UNITED STATES.—

(A) IN GENERAL.—A covered person shall cooperate with the United States in the processing and defense of a claim or action under this subsection based upon alleged acts or omissions of such person.

(B) CONSEQUENCES OF FAILURE TO COOPERATE.—Upon the motion of the United States or any other party and upon finding that such person has failed to so cooperate—

(i) the court shall substitute such person as the party defendant in place of the United States and, upon motion, shall remand any such suit to the court in which it was instituted if it appears that the court lacks subject matter jurisdiction;

(ii) the United States shall not be liable based on the acts or omissions of such person; and

(iii) the Attorney General shall not be obligated to defend such action.

(6) RECOURSE AGAINST COVERED PERSON IN CASE OF GROSS MISCONDUCT OR CONTRACT VIOLATION.—

(A) IN GENERAL.—Should payment be made by the United States to any claimant bringing a claim under this subsection, either by way of administrative determination, settlement, or court judgment, the United States shall have, notwithstanding any provision of State law, the right to recover for that portion of the damages so awarded or paid, as well as interest and any costs of litigation, resulting from the failure of any covered person to carry out any obligation or responsibility assumed by such person under a contract with the United States or from any grossly negligent, reckless, or illegal conduct or willful misconduct on the part of such person.

(B) VENUE.—The United States may maintain an action under this paragraph against such person in the district

court of the United States in which such person resides or has its principal place of business.

(7) DEFINITIONS.—As used in this subsection, terms have the following meanings:

(A) COVERED COUNTERMEASURE.—The term "covered countermeasure" or "covered countermeasure against smallpox", means a substance that is—

(i)(I) used to prevent or treat smallpox (including the vaccinia or another vaccine); or

(II) used to control or treat the adverse effects of vaccinia inoculation or of administration of another covered countermeasure; and

(ii) specified in a declaration under paragraph (2).

(B) COVERED PERSON.—The term "covered person", when used with respect to the administration of a covered countermeasure, means a person who is—

(i) a manufacturer or distributor of such countermeasure;

(ii) a health care entity under whose auspices—

(I) such countermeasure was administered;

(II) a determination was made as to whether, or under what circumstances, an individual should receive a covered countermeasure;

(III) the immediate site of administration on the body of a covered countermeasure was monitored, managed, or cared for; or

(IV) an evaluation was made of whether the administration of a countermeasure was effective;

(iii) a qualified person who administered such countermeasure;

(iv) a State, a political subdivision of a State, or an agency or official of a State or of such a political subdivision, if such State, subdivision, agency, or official has established requirements, provided policy guidance, supplied technical or scientific advice or assistance, or otherwise supervised or administered a program with respect to administration of such countermeasures;

(v) in the case of a claim arising out of alleged transmission of vaccinia from an individual—

(I) the individual who allegedly transmitted the vaccinia, if vaccinia vaccine was administered to such individual as provided by paragraph (2)(B) and such individual was within a category of individuals covered by a declaration under paragraph (2)(A)(i); or

(II) an entity that employs an individual described by clause (I) or where such individual has privileges or is otherwise authorized to provide health care;

(vi) an official, agent, or employee of a person described in clause (i), (ii), (iii), or (iv);

(vii) a contractor of, or a volunteer working for, a person described in clause (i), (ii), or (iv), if the contractor or volunteer performs a function for which a

person described in clause (i), (ii), or (iv) is a covered person; or

(viii) an individual who has privileges or is otherwise authorized to provide health care under the auspices of an entity described in clause (ii) or (v)(II).

(C) QUALIFIED PERSON.—The term "qualified person", when used with respect to the administration of a covered countermeasure, means a licensed health professional or other individual who—

(i) is authorized to administer such countermeasure under the law of the State in which the countermeasure was administered; or

(ii) is otherwise authorized by the Secretary to administer such countermeasure.

(D) ARISING OUT OF ADMINISTRATION OF A COVERED COUNTERMEASURE.—The term "arising out of administration of a covered countermeasure", when used with respect to a claim or liability, includes a claim or liability arising out of—

(i) determining whether, or under what conditions, an individual should receive a covered countermeasure;

(ii) obtaining informed consent of an individual to the administration of a covered countermeasure;

(iii) monitoring, management, or care of an immediate site of administration on the body of a covered countermeasure, or evaluation of whether the administration of the countermeasure has been effective; or

(iv) transmission of vaccinia virus by an individual to whom vaccinia vaccine was administered as provided by paragraph (2)(B).

(q)(1) For purposes of this section, a health professional volunteer at a deemed entity described in subsection (g)(4) shall, in providing a health professional service eligible for funding under section 330 to an individual, be deemed to be an employee of the Public Health Service for a calendar year that begins during a fiscal year for which a transfer was made under paragraph (4)(C). The preceding sentence is subject to the provisions of this subsection.

(2) In providing a health service to an individual, a health care practitioner shall for purposes of this subsection be considered to be a health professional volunteer at an entity described in subsection (g)(4) if the following conditions are met:

(A) The service is provided to the individual at the facilities of an entity described in subsection (g)(4), or through offsite programs or events carried out by the entity.

(B) The entity is sponsoring the health care practitioner pursuant to paragraph (3)(B).

(C) The health care practitioner does not receive any compensation for the service from the individual, the entity described in subsection (g)(4), or any third-party payer (including reimbursement under any insurance policy or health plan, or under any Federal or State health benefits program), except that the health care practitioner may receive repayment from the entity described in subsection (g)(4) for reasonable expenses incurred by the health care practitioner in the provision

of the service to the individual, which may include travel expenses to or from the site of services.

(D) Before the service is provided, the health care practitioner or the entity described in subsection (g)(4) posts a clear and conspicuous notice at the site where the service is provided of the extent to which the legal liability of the health care practitioner is limited pursuant to this subsection.

(E) At the time the service is provided, the health care practitioner is licensed or certified in accordance with applicable Federal and State laws regarding the provision of the service.

(F) At the time the service is provided, the entity described in subsection (g)(4) maintains relevant documentation certifying that the health care practitioner meets the requirements of this subsection.

(3) Subsection (g) (other than paragraphs (3) and (5)) and subsections (h), (i), and (l) apply to a health care practitioner for purposes of this subsection to the same extent and in the same manner as such subsections apply to an officer, governing board member, employee, or contractor of an entity described in subsection (g)(4), subject to paragraph (4), and subject to the following:

(A) The first sentence of paragraph (1) applies in lieu of the first sentence of subsection (g)(1)(A).

(B) With respect to an entity described in subsection (g)(4), a health care practitioner is not a health professional volunteer at such entity unless the entity sponsors the health care practitioner. For purposes of this subsection, the entity shall be considered to be sponsoring the health care practitioner if—

(i) with respect to the health care practitioner, the entity submits to the Secretary an application meeting the requirements of subsection (g)(1)(D); and

(ii) the Secretary, pursuant to subsection (g)(1)(E), determines that the health care practitioner is deemed to be an employee of the Public Health Service.

(C) In the case of a health care practitioner who is determined by the Secretary pursuant to subsection (g)(1)(E) to be a health professional volunteer at such entity, this subsection applies to the health care practitioner (with respect to services performed on behalf of the entity sponsoring the health care practitioner pursuant to subparagraph (B)) for any cause of action arising from an act or omission of the health care practitioner occurring on or after the date on which the Secretary makes such determination.

(D) Subsection (g)(1)(F) applies to a health care practitioner for purposes of this subsection only to the extent that, in providing health services to an individual, each of the conditions specified in paragraph (2) is met.

(4)(A) Amounts in the fund established under subsection (k)(2) shall be available for transfer under subparagraph (C) for purposes of carrying out this subsection.

(B)(i) Not later than May 1 of each fiscal year, the Attorney General, in consultation with the Secretary, shall submit to the Congress a report providing an estimate of the amount of claims (together with related fees and expenses of witnesses) that, by reason of the acts or omissions of health professional volunteers, will be

paid pursuant to this section during the calendar year that begins in the following fiscal year.

(ii) Subsection (k)(1)(B) applies to the estimate under clause (i) regarding health professional volunteers to the same extent and in the same manner as such subsection applies to the estimate under such subsection regarding officers, governing board members, employees, and contractors of entities described in subsection (g)(4).

(iii) The report shall include a summary of the data relied upon for the estimate in clause (i), including the number of claims filed and paid from the previous calendar year.

(C) Not later than December 31 of each fiscal year, the Secretary shall transfer from the fund under subsection (k)(2) to the appropriate accounts in the Treasury an amount equal to the estimate made under subparagraph (B) for the calendar year beginning in such fiscal year, subject to the extent of amounts in the fund.

(5)(A) This subsection shall take effect on October 1, 2017, except as provided in subparagraph (B) and paragraph (6).

(B) Effective on the date of the enactment of this subsection—

(i) the Secretary may issue regulations for carrying out this subsection, and the Secretary may accept and consider applications submitted pursuant to paragraph (3)(B); and

(ii) reports under paragraph (4)(B) may be submitted to Congress.

(6) Beginning on [October 1, 2022] *October 1, 2027*, this subsection shall cease to have any force or effect.

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TITLE III—GENERAL POWERS AND DUTIES OF PUBLIC HEALTH SERVICE

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PART B—FEDERAL-STATE COOPERATION

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SEC. 317L–1. SCREENING AND TREATMENT FOR [MATERNAL DEPRESSION] *MATERNAL MENTAL HEALTH AND SUBSTANCE USE DISORDERS.*

(a) GRANTS.—The Secretary shall make grants to States*, Indian Tribes and Tribal organizations (as such terms are defined in section 4 of the Indian Self-Determination and Education Assistance Act), and Urban Indian organizations (as such term is defined under the Federally Recognized Indian Tribe List Act of 1994)* to establish, improve, or maintain programs for screening, assessment, and treatment services, including culturally and linguistically appropriate services, as appropriate, [for women who are pregnant, or who have given birth within the preceding 12 months, for maternal depression] *for women who are postpartum, pregnant, or have given birth within the preceding 12 months, for maternal mental health and substance use disorders*.

(b) APPLICATION.—To seek a grant under this section, [a State shall submit] *an entity listed in subsection (a) shall submit* an application to the Secretary at such time, in such manner, and containing such information as the Secretary may require. At a minimum, any such application shall include explanations of—

(1) how a program, or programs, will increase the percentage of women screened and treated, as appropriate, for [maternal depression] *maternal mental health and substance use disorders* in 1 or more communities; and

(2) how a program, or programs, if expanded, would increase access to screening and treatment services for [maternal depression] *maternal mental health and substance use disorders*.

(c) PRIORITY.—In awarding grants under this section, the Secretary [may give priority to States proposing to improve or enhance access to screening] *shall give priority to entities listed in subsection (a) that—*

(1) are proposing to create, improve, or enhance screening, prevention, and treatment services for [maternal depression] *maternal mental health and substance use disorders* in primary care settings[.]*;*

(2) are currently partnered with, or will partner with, a community-based organization to address maternal mental health and substance use disorders;

(3) are located in an area with high rates of adverse maternal health outcomes or significant health, economic, racial, or ethnic disparities in maternal health and substance use disorder outcomes; and

(4) operate in a health professional shortage area designated under section 332.

(d) USE OF FUNDS.—The activities eligible for funding through a grant under subsection (a)—

(1) shall include—

(A) providing appropriate training [to health care providers; and] *on maternal mental health and substance use disorder screening, brief intervention, treatment (as applicable for health care providers), and referrals for treatment to health care providers in the primary care setting and nonclinical perinatal support workers;*

(B) providing information [to health care providers, including information on maternal depression screening, treatment, and followup support services, and linkages to community-based resources; and] *on maternal mental health and substance use disorder screening, brief intervention, treatment (as applicable for health care providers) and referrals for treatment, follow-up support services, and linkages to community-based resources to health care providers in the primary care setting and clinical perinatal support workers; and*

(C) enabling health care providers (such as obstetrician-gynecologists, nurse practitioners, nurse midwives, pediatricians, psychiatrists, mental and other behavioral health care providers, and adult primary care clinicians) to provide or receive real-time psychiatric consultation (in-person or remotely), including through the use of technology-enabled collaborative learning and capacity building models (as defined in section 330N), to aid in the treatment of pregnant and postpartum women; and

(2) may include—

[(A) enabling health care providers (including obstetrician-gynecologists, pediatricians, psychiatrists, mental

health care providers, and adult primary care clinicians) to provide or receive real-time psychiatric consultation (in-person or remotely) to aid in the treatment of pregnant and parenting women;]

[(B)] *(A)* establishing linkages with and among community-based resources, including mental health resources, primary care resources, and support groups; [and]

[(C)] *(B)* utilizing telehealth services*, including* for rural areas and medically underserved areas (as defined in section 330I(a))[.]*;*

(C) providing assistance to pregnant and postpartum women to receive maternal mental health and substance use disorder treatment, including patient consultation, care coordination, and navigation for such treatment;

(D) coordinating with maternal and child health programs of the Federal Government and State, local, and Tribal governments, including child psychiatric access programs;

(E) conducting public outreach and awareness regarding grants under subsection (a);

(F) creating multistate consortia to carry out the activities required or authorized under this subsection; and

(G) training health care providers in the primary care setting and nonclinical perinatal support workers on trauma-informed care, culturally and linguistically appropriate services, and best practices related to training to improve the provision of maternal mental health and substance use disorder care for racial and ethnic minority populations, including with respect to perceptions and biases that may affect the approach to, and provision of, care.

(e) TECHNICAL ASSISTANCE.—The Secretary shall provide technical assistance to grantees and entities listed in subsection (a) for carrying out activities pursuant to this section.

(f) DISSEMINATION OF BEST PRACTICES.—The Secretary, based on evaluation of the activities funded pursuant to this section, shall identify and disseminate evidence-based or evidence-informed best practices for screening, assessment, and treatment services for maternal mental health and substance use disorders, including culturally and linguistically appropriate services, for women during pregnancy and 12 months following pregnancy.

(g) MATCHING REQUIREMENT.—The Federal share of the cost of the activities for which a grant is made to an entity under subsection (a) shall not exceed 90 percent of the total cost of such activities.

[(e)] *(h)* AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated [$5,000,000] *$24,000,000* for each of fiscal years [2018 through 2022] *2023 through 2027*.

SEC. 317L–2. TASK FORCE ON MATERNAL MENTAL HEALTH.

(a) ESTABLISHMENT.—Not later than 180 days after the date of enactment of the Restoring Hope for the Mental Health and Well-Being Act of 2022, the Secretary, for purposes of identifying, evaluating, and making recommendations to coordinate and improve Federal responses to maternal mental health conditions, shall—

(1) establish a task force to be known as the Task Force on Maternal Mental Health (in this section referred to as the "Task Force"); or

(2) incorporate the duties, public meetings, and reports specified in subsections (c) through (f) into existing Federal policy forums, including the Maternal Health Interagency Policy Committee and the Maternal Health Working Group, as appropriate.

(b) MEMBERSHIP.—

(1) COMPOSITION.—The Task Force shall be composed of—

(A) the Federal members under paragraph (2); and

(B) the non-Federal members under paragraph (3).

(2) FEDERAL MEMBERS.—The Federal members of the Task Force shall consist of the following heads of Federal departments and agencies (or their designees):

(A) The Assistant Secretary for Health of the Department of Health and Human Services, who shall serve as Chair.

(B) The Assistant Secretary for Planning and Evaluation of the Department of Health and Human Services.

(C) The Assistant Secretary of the Administration for Children and Families.

(D) The Director of the Centers for Disease Control and Prevention.

(E) The Administrator of the Centers for Medicare & Medicaid Services.

(F) The Administrator of the Health Resources and Services Administration.

(G) The Director of the Indian Health Service.

(H) The Assistant Secretary for Mental Health and Substance Use.

(I) Such other Federal departments and agencies as the Secretary determines appropriate that serve individuals with maternal mental health conditions.

(3) NON-FEDERAL MEMBERS.—The non-Federal members of the Task Force shall—

(A) compose not more than one-half, and not less than one-third, of the total membership of the Task Force;

(B) be appointed by the Secretary; and

(C) include—

(i) representatives of medical societies with expertise in maternal or mental health;

(ii) representatives of nonprofit organizations with expertise in maternal or mental health;

(iii) relevant industry representatives; and

(iv) other representatives, as appropriate.

(4) DEADLINE FOR DESIGNATING DESIGNEES.—If the Assistant Secretary for Health, or the head of a Federal department or agency serving as a member of the Task Force under paragraph (2), chooses to be represented on the Task Force by a designee, the Assistant Secretary or department or agency head shall designate such designee not later than 90 days after the date of the enactment of this section.

(c) DUTIES.—The Task Force shall—

(1) prepare and regularly update a report that analyzes and evaluates the state of national maternal mental health policy

and programs at the Federal, State, and local levels, and identifies best practices with respect to maternal mental health policy, including—

(A) a set of evidence-based, evidence-informed, and promising practices with respect to—

(i) prevention strategies for individuals at risk of experiencing a maternal mental health condition, including strategies and recommendations to address health inequities;

(ii) the identification, screening, diagnosis, intervention, and treatment of individuals and families affected by a maternal mental health condition;

(iii) the expeditious referral to, and implementation of, practices and supports that prevent and mitigate the effects of a maternal mental health condition, including strategies and recommendations to eliminate the racial and ethnic disparities that exist in maternal mental health; and

(iv) community-based or multigenerational practices that support individuals and families affected by a maternal mental health condition; and

(B) Federal and State programs and activities to prevent, screen, diagnose, intervene, and treat maternal mental health conditions;

(2) develop and regularly update a national strategy for maternal mental health, taking into consideration the findings of the report under paragraph (1), on how the Task Force and Federal departments and agencies represented on the Task Force may prioritize options for, and may implement a coordinated approach to, addressing maternal mental health conditions, including by—

(A) increasing prevention, screening, diagnosis, intervention, treatment, and access to care, including clinical and nonclinical care such as peer-support and community health workers, through the public and private sectors;

(B) providing support for pregnant or postpartum individuals who are at risk for or experiencing a maternal mental health condition, and their families, as appropriate;

(C) reducing racial, ethnic, geographic, and other health disparities for prevention, diagnosis, intervention, treatment, and access to care;

(D) identifying options for modifying, strengthening, and coordinating Federal programs and activities, such as the Medicaid program under title XIX of the Social Security Act and the State Children's Health Insurance Program under title XXI of such Act, including existing infant and maternity programs, in order to increase research, prevention, identification, intervention, and treatment with respect to maternal mental health; and

(E) planning, data sharing, and communication within and across Federal departments, agencies, offices, and programs;

(3) solicit public comments from stakeholders for the report under paragraph (1) and the national strategy under paragraph (2), including comments from frontline service providers,

mental health professionals, researchers, experts in maternal mental health, institutions of higher education, public health agencies (including maternal and child health programs), and industry representatives, in order to inform the activities and reports of the Task Force; and

(4) disaggregate any data collected under this section by race, ethnicity, geographical location, age, marital status, socioeconomic level, and other factors, as the Secretary determines appropriate.

(d) MEETINGS.—The Task Force shall—

(1) meet not less than two times each year; and

(2) convene public meetings, as appropriate, to fulfill its duties under this section.

(e) REPORTS TO PUBLIC AND FEDERAL LEADERS.—The Task Force shall make publicly available and submit to the heads of relevant Federal departments and agencies, the Committee on Energy and Commerce of the House of Representatives, the Committee on Health, Education, Labor, and Pensions of the Senate, and other relevant congressional committees, the following:

(1) Not later than 1 year after the first meeting of the Task Force, an initial report under subsection (c)(1).

(2) Not later than 2 years after the first meeting of the Task Force, an initial national strategy under subsection (c)(2).

(3) Each year thereafter—

(A) an updated report under subsection (c)(1);

(B) an updated national strategy under subsection (c)(2); or

(C) if no update is made under subsection (c)(1) or (c)(2), a report summarizing the activities of the Task Force.

(f) REPORTS TO GOVERNORS.—Upon finalizing the initial national strategy under subsection (c)(2), and upon making relevant updates to such strategy, the Task Force shall submit a report to the Governors of all States describing opportunities for local- and State-level partnerships identified under subsection (c)(2)(D).

(g) SUNSET.—The Task Force shall terminate on September 30, 2027.

(h) NONDUPLICATION OF FEDERAL EFFORTS.—The Secretary may relieve the Task Force, in carrying out subsections (c) through (f), from responsibility for carrying out such activities as may be specified by the Secretary as duplicative with other activities carried out by the Department of Health and Human Services.

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PART D—PRIMARY HEALTH CARE

Subpart I—Health Centers

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SEC. 330M. PEDIATRIC MENTAL HEALTH CARE ACCESS GRANTS.

(a) IN GENERAL.—The Secretary, acting through the Administrator of the Health Resources and Services Administration and in coordination with other relevant Federal agencies, shall award grants to States, political subdivisions of States, and [Indian tribes and tribal organizations] *Indian Tribes and Tribal organizations* (for purposes of this section, as such terms are defined in section

4 of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 450b)) *or, in the case of a State that does not submit an application, a nonprofit entity that has the support of the State* to promote behavioral health integration in pediatric primary care by—

(1) supporting the development of statewide or regional pediatric mental health care telehealth access programs; and

(2) supporting the improvement of existing statewide or regional pediatric mental health care telehealth access programs.

(b) PROGRAM REQUIREMENTS.—

(1) IN GENERAL.—A pediatric mental health care telehealth access program referred to in subsection (a), with respect to which a grant under such subsection may be used, shall—

(A) be a statewide or regional network of pediatric mental health teams that provide support to pediatric primary care sites as an integrated team;

(B) support and further develop organized State or regional networks of pediatric mental health teams to provide consultative support to pediatric primary care sites;

(C) conduct an assessment of critical behavioral consultation needs among pediatric providers and such providers' preferred mechanisms for receiving consultation, training, and technical assistance;

(D) develop an online database and communication mechanisms, including telehealth, to facilitate consultation support to pediatric practices;

(E) provide rapid statewide or regional clinical telephone or telehealth consultations when requested between the pediatric mental health teams and pediatric primary care providers;

(F) conduct training and provide technical assistance to pediatric primary care providers to support the early identification, diagnosis, treatment, and referral of children with behavioral health conditions;

(G) provide information to pediatric providers about, and assist pediatric providers in accessing, pediatric mental health care providers, including child and adolescent psychiatrists, *developmental-behavioral pediatricians,* and licensed mental health professionals, such as psychologists, social workers, or mental health counselors and in scheduling and conducting technical assistance;

(H) assist with referrals to specialty care and community or behavioral health resources[; and]*;*

(I) maintain an up-to-date list of community-based supports for children with mental health problems; and

[(I)] *(J)* establish mechanisms for measuring and monitoring increased access to pediatric mental health care services by pediatric primary care providers and expanded capacity of pediatric primary care providers to identify, treat, and refer children with mental health problems.

(2) SUPPORT TO SCHOOLS AND EMERGENCY DEPARTMENTS.—In addition to the activities required by paragraph (1), a pediatric mental health care telehealth access program referred to in subsection (a), with respect to which a grant under such subsection

may be used, may provide support to schools and emergency departments.

(3) PRIORITY.—In awarding grants under this section, the Secretary shall give priority to applicants proposing to—

(A) continue existing programs that meet the requirements of paragraph (1);

(B) establish a pediatric mental health care telehealth access program in the jurisdiction of a State, Territory, Indian Tribe, or Tribal organization that does not yet have such a program; or

(C) expand a pediatric mental health care telehealth access program to include one or more new sites of care, such as a school or emergency department.

[(2)] *(4)* PEDIATRIC MENTAL HEALTH TEAMS.—In this subsection, the term "pediatric mental health team" means a team consisting of at least one case coordinator, at least one child and adolescent psychiatrist, and at least one licensed clinical mental health professional, such as a psychologist, social worker, or mental health counselor. *Such a team may include a developmental-behavioral pediatrician.* Such a team may be regionally based.

(c) APPLICATION.—A State, political subdivision of a State, [Indian tribe, or tribal organization] *Indian Tribe, Tribal organization, or nonprofit entity* seeking a grant under this section shall submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may require, including a plan for the comprehensive evaluation of activities that are carried out with funds received under such grant.

(d) EVALUATION.—A State, political subdivision of a State, [Indian tribe, or tribal organization] *Indian Tribe, Tribal organization, or nonprofit entity* that receives a grant under this section shall prepare and submit an evaluation of activities that are carried out with funds received under such grant to the Secretary at such time, in such manner, and containing such information as the Secretary may reasonably require, including a process and outcome evaluation.

(e) ACCESS TO BROADBAND.—In administering grants under this section, the Secretary may coordinate with other agencies to ensure that funding opportunities are available to support access to reliable, high-speed Internet for providers.

(f) MATCHING REQUIREMENT.—The Secretary may not award a grant under this section unless the State, political subdivision of a State, [Indian tribe, or tribal organization] *Indian Tribe, Tribal organization, or nonprofit entity* involved agrees, with respect to the costs to be incurred by the State, political subdivision of a State, [Indian tribe, or tribal organization] *Indian Tribe, Tribal organization, or nonprofit entity* in carrying out the purpose described in this section, to make available non-Federal contributions (in cash or in kind) toward such costs in an amount that is not less than 20 percent of Federal funds provided in the grant.

[(g) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated, $9,000,000 for the period of fiscal years 2018 through 2022.]

(g) TECHNICAL ASSISTANCE.—The Secretary shall award grants or contracts to one or more eligible entities (as defined by the Sec-

retary) for the purposes of providing technical assistance and evaluation support to grantees under subsection (a).

(h) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated—

(1) $14,000,000 for each of fiscal years 2023 through 2025; and

(2) $30,000,000 for each of fiscal years 2026 through 2027.

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PART P—ADDITIONAL PROGRAMS

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SEC. 399V–7. MATERNAL MENTAL HEALTH HOTLINE.

(a) IN GENERAL.—The Secretary shall maintain, directly or by grant or contract, a national hotline to provide emotional support, information, brief intervention, and mental health and substance use disorder resources to pregnant and postpartum women at risk of, or affected by, maternal mental health and substance use disorders, and to their families or household members.

(b) REQUIREMENTS FOR HOTLINE.—The hotline under subsection (a) shall—

(1) be a 24/7 real-time hotline;

(2) provide voice and text support;

(3) be staffed by certified peer specialists, licensed health care professionals, or licensed mental health professionals who are trained on—

(A) maternal mental health and substance use disorder prevention, identification, and intervention; and

(B) providing culturally and linguistically appropriate support; and

(4) provide maternal mental health and substance use disorder assistance and referral services to meet the needs of underserved populations, individuals with disabilities, and family and household members of pregnant or postpartum women at risk of experiencing maternal mental health and substance use disorders.

(c) ADDITIONAL REQUIREMENTS.—In maintaining the hotline under subsection (a), the Secretary shall—

(1) consult with the Domestic Violence Hotline, National Suicide Prevention Lifeline, and Veterans Crisis Line to ensure that pregnant and postpartum women are connected in real-time to the appropriate specialized hotline service, when applicable;

(2) conduct a public awareness campaign for the hotline; and

(3) consult with Federal departments and agencies, including the Centers of Excellence of the Substance Abuse and Mental Health Services Administration and the Department of Veterans Affairs, to increase awareness regarding the hotline.

(d) ANNUAL REPORT.—The Secretary shall submit an annual report to the Congress on the hotline under subsection (a) and implementation of this section, including—

(1) an evaluation of the effectiveness of activities conducted or supported under subsection (a);

(2) a directory of entities or organizations to which staff maintaining the hotline funded under this section may make referrals; and

(3) such additional information as the Secretary determines appropriate.

(e) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated $10,000,000 for each of fiscal years 2023 through 2027.

PART Q—PROGRAMS TO IMPROVE THE HEALTH OF CHILDREN

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SEC. 399Z–2. INFANT AND EARLY CHILDHOOD MENTAL HEALTH PROMOTION, INTERVENTION, AND TREATMENT.

(a) GRANTS.—The Secretary shall—

(1) award grants to eligible entities to develop, maintain, or enhance infant and early childhood mental health promotion, intervention, and treatment programs, including—

(A) programs for infants and children at significant risk of developing, showing early signs of, or having been diagnosed with mental illness, including a serious emotional disturbance; and

(B) multigenerational therapy and other services that support the caregiving relationship; and

(2) ensure that programs funded through grants under this section are evidence-informed or evidence-based models, practices, and methods that are, as appropriate, culturally and linguistically appropriate, and can be replicated in other appropriate settings.

(b) ELIGIBLE CHILDREN AND ENTITIES.—In this section:

(1) ELIGIBLE CHILD.—The term "eligible child" means a child from birth to not more than 12 years of age who—

(A) is at risk for, shows early signs of, or has been diagnosed with a mental illness, including a serious emotional disturbance; and

(B) may benefit from infant and early childhood intervention or treatment programs or specialized preschool or elementary school programs that are evidence-based or that have been scientifically demonstrated to show promise but would benefit from further applied development.

(2) ELIGIBLE ENTITY.—The term "eligible entity" means a human services agency or nonprofit institution that—

(A) employs licensed mental health professionals who have specialized training and experience in infant and early childhood mental health assessment, diagnosis, and treatment, or is accredited or approved by the appropriate State agency, as applicable, to provide for children from infancy to 12 years of age mental health promotion, intervention, or treatment services; and

(B) provides services or programs described in subsection (a) that are evidence-based or that have been scientifically demonstrated to show promise but would benefit from further applied development.

(c) APPLICATION.—An eligible entity seeking a grant under subsection (a) shall submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require.

(d) USE OF FUNDS FOR EARLY INTERVENTION AND TREATMENT PROGRAMS.—An eligible entity may use amounts awarded under a grant under subsection (a)(1) to carry out the following:

(1) Provide age-appropriate mental health promotion and early intervention services or mental illness treatment services, which may include specialized programs, for eligible children at significant risk of developing, showing early signs of, or having been diagnosed with a mental illness, including a serious emotional disturbance. Such services may include social and behavioral services as well as multigenerational therapy and other services that support the caregiving relationship.

(2) Provide training for health care professionals with expertise in infant and early childhood mental health care with respect to appropriate and relevant integration with other disciplines such as primary care clinicians, early intervention specialists, child welfare staff, home visitors, early care and education providers, and others who work with young children and families.

(3) Provide mental health consultation to personnel of early care and education programs (including licensed or regulated center-based and home-based child care, home visiting, preschool special education, and early intervention programs) who work with children and families.

(4) Provide training for mental health clinicians in infant and early childhood in promising and evidence-based practices and models for infant and early childhood mental health treatment and early intervention, including with regard to practices for identifying and treating mental illness and behavioral disorders of infants and children resulting from exposure or repeated exposure to adverse childhood experiences or childhood trauma.

(5) Provide age-appropriate assessment, diagnostic, and intervention services for eligible children, including early mental health promotion, intervention, and treatment services.

(e) MATCHING FUNDS.—The Secretary may not award a grant under this section to an eligible entity unless the eligible entity agrees, with respect to the costs to be incurred by the eligible entity in carrying out the activities described in subsection (d), to make available non-Federal contributions (in cash or in kind) toward such costs in an amount that is not less than 10 percent of the total amount of Federal funds provided in the grant.

(f) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated **[**$20,000,000 for the period of fiscal years 2018 through 2022**]** *$50,000,000 for the period of fiscal years 2023 through 2027*.

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TITLE V—SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION

PART A—ORGANIZATION AND GENERAL AUTHORITIES

SEC. 501. SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION.

(a) ESTABLISHMENT.—The Substance Abuse and Mental Health Services Administration (hereafter referred to in this title as the "Administration") is an agency of the Service.

(b) CENTERS.—The following Centers are agencies of the Administration:

(1) The Center for Substance Abuse Treatment.

(2) The Center for Substance Abuse Prevention.

(3) The Center for Mental Health Services.

(c) ASSISTANT SECRETARY AND DEPUTY ASSISTANT SECRETARY.—

(1) ASSISTANT SECRETARY.—The Administration shall be headed by an official to be known as the Assistant Secretary for Mental Health and Substance Use (hereinafter in this title referred to as the "Assistant Secretary") who shall be appointed by the President, by and with the advice and consent of the Senate.

(2) DEPUTY ASSISTANT SECRETARY.—The Assistant Secretary, with the approval of the Secretary, may appoint a Deputy Assistant Secretary and may employ and prescribe the functions of such officers and employees, including attorneys, as are necessary to administer the activities to be carried out through the Administration.

(d) AUTHORITIES.—The Secretary, acting through the Assistant Secretary, shall—

(1) supervise the functions of the Centers of the Administration in order to assure that the programs carried out through each such Center receive appropriate and equitable support and that there is cooperation among the Centers in the implementation of such programs;

(2) establish and implement, through the respective Centers, a comprehensive program to improve the provision of treatment and related services to individuals with respect to substance use disorders and mental illness and to improve prevention services, promote mental health and protect the legal rights of individuals with mental illnesses and individuals with substance use disorders;

(3) carry out the administrative and financial management, policy development and planning, evaluation, knowledge dissemination, and public information functions that are required for the implementation of this title;

(4) assure that the Administration conduct and coordinate demonstration projects, evaluations, and service system assessments and other activities necessary to improve the availability and quality of treatment, prevention and related services;

(5) support activities that will improve the provision of treatment, prevention and related services, including the development of national mental health and substance use disorder goals and model programs;

(6) in cooperation with the National Institutes of Health, the Centers for Disease Control and Prevention, and the Health Resources and Services Administration, develop educational materials and intervention strategies to reduce the risks of HIV, hepatitis, tuberculosis, and other communicable diseases among individuals with mental or substance use disorders, and to develop appropriate mental health services for individuals with such diseases or disorders;

(7) coordinate Federal policy with respect to the provision of treatment services for substance use disorders, including services that utilize drugs or devices approved or cleared by the Food and Drug Administration for the treatment of substance use disorders;

(8) conduct programs, and assure the coordination of such programs with activities of the National Institutes of Health and the Agency for Healthcare Research and Quality, as appropriate, to evaluate the process, outcomes and community impact of prevention and treatment services and systems of care in order to identify the manner in which such services can most effectively be provided;

(9) collaborate with the Director of the National Institutes of Health in the development and maintenance of a system by which the relevant research findings of the National Institute on Drug Abuse, the National Institute on Alcohol Abuse and Alcoholism, the National Institute of Mental Health, and, as appropriate, the Agency for Healthcare Research and Quality are disseminated to service providers in a manner designed to improve the delivery and effectiveness of prevention, treatment, and recovery support services and are appropriately incorporated into programs carried out by the Administration;

(10) encourage public and private entities that provide health insurance to provide benefits for substance use disorder and mental health services;

(11) work with relevant agencies of the Department of Health and Human Services on integrating mental health promotion and substance use disorder prevention with general health promotion and disease prevention and integrating mental and substance use disorders treatment services with physical health treatment services;

(12) monitor compliance by hospitals and other facilities with the requirements of sections 542 and 543;

(13) with respect to grant programs authorized under this title or part B of title XIX, or grant programs otherwise funded by the Administration—

(A) require that all grants that are awarded for the provision of services are subject to performance and outcome evaluations;

(B) ensure that the director of each Center of the Administration consistently documents the application of criteria when awarding grants and the ongoing oversight of grantees after such grants are awarded;

(C) require that all grants that are awarded to entities other than States are awarded only after the State in which the entity intends to provide services—

(i) is notified of the pendency of the grant application; and

(ii) is afforded an opportunity to comment on the merits of the application; and

(D) inform a State when any funds are awarded through such a grant to any entity within such State;

(14) assure that services provided with amounts appropriated under this title are provided bilingually, if appropriate;

(15) improve coordination among prevention programs, treatment facilities and nonhealth care systems such as employers, labor unions, and schools, and encourage the adoption of employee assistance programs and student assistance programs;

(16) maintain a clearinghouse for substance use disorder information, including evidence-based and promising best practices for prevention, treatment, and recovery support services for individuals with mental and substance use disorders, to assure the widespread dissemination of such information to States, political subdivisions, educational agencies and institutions, treatment providers, and the general public;

(17) in collaboration with the National Institute on Aging, and in consultation with the National Institute on Drug Abuse, the National Institute on Alcohol Abuse and Alcoholism and the National Institute of Mental Health, as appropriate, promote and evaluate substance use disorder services for older Americans in need of such services, and mental health services for older Americans who are seriously mentally ill;

(18) promote the coordination of service programs conducted by other departments, agencies, organizations and individuals that are or may be related to the problems of individuals suffering from mental illness or substance abuse, including liaisons with the Social Security Administration, Centers for Medicare & Medicaid Services, and other programs of the Department, as well as liaisons with the Department of Education, Department of Justice, and other Federal Departments and offices, as appropriate;

(19) consult with State, local, and tribal governments, nongovernmental entities, and individuals with mental illness, particularly adults with a serious mental illness, children with a serious emotional disturbance, and the family members of such adults and children, with respect to improving community-based and other mental health services;

(20) collaborate with the Secretary of Defense and the Secretary of Veterans Affairs to improve the provision of mental and substance use disorder services provided by the Department of Defense and the Department of Veterans Affairs to members of the Armed Forces, veterans, and the family members of such members and veterans, including through the provision of services using the telehealth capabilities of the Department of Defense and the Department of Veterans Affairs;

(21) collaborate with the heads of relevant Federal agencies and departments, States, communities, and nongovernmental experts to improve mental and substance use disorders services for chronically homeless individuals, including by designing strategies to provide such services in supportive housing;

(22) work with States and other stakeholders to develop and support activities to recruit and retain a workforce addressing mental and substance use disorders;

(23) collaborate with the Attorney General and representatives of the criminal justice system to improve mental and substance use disorders services for individuals who have been arrested or incarcerated;

(24) after providing an opportunity for public input, set standards for grant programs under this title for mental and substance use disorders services and prevention programs, which standards may address—

(A) the capacity of the grantee to implement the award;

(B) requirements for the description of the program implementation approach;

(C) the extent to which the grant plan submitted by the grantee as part of its application must explain how the grantee will reach the population of focus and provide a statement of need, which may include information on how the grantee will increase access to services and a description of measurable objectives for improving outcomes;

(D) the extent to which the grantee must collect and report on required performance measures; and

(E) the extent to which the grantee is proposing to use evidence-based practices; **[**and**]**

(25) advance, through existing programs, the use of performance metrics, including those based on the recommendations on performance metrics from the Assistant Secretary for Planning and Evaluation under section 6021(d) of the Helping Families in Mental Health Crisis Reform Act of 2016**[**.**]***; and*

(26) collaborate with national accrediting entities, reputable providers, organizations or individuals with established expertise in delivery of recovery housing services, States, Federal agencies (including the Department of Health and Human Services, the Department of Housing and Urban Development, and the agencies listed in section 550(e)(2)(B)), and other relevant stakeholders, to promote the availability of high-quality recovery housing and services for individuals with a substance use disorder.

(e) ASSOCIATE ADMINISTRATOR FOR ALCOHOL PREVENTION AND TREATMENT POLICY.—

(1) IN GENERAL.—There may be in the Administration an Associate Administrator for Alcohol Prevention and Treatment Policy to whom the Assistant Secretary may delegate the functions of promoting, monitoring, and evaluating service programs for the prevention and treatment of alcoholism and alcohol abuse within the Center for Substance Abuse Prevention, the Center for Substance Abuse Treatment and the Center for Mental Health Services, and coordinating such programs among the Centers, and among the Centers and other public and private entities. The Associate Administrator also may ensure that alcohol prevention, education, and policy strategies are integrated into all programs of the Centers that address substance abuse prevention, education, and policy, and that the Center for Substance Abuse Prevention addresses the Healthy People 2010 goals and the National Dietary Guide-

lines of the Department of Health and Human Services and the Department of Agriculture related to alcohol consumption.

(2) PLAN.—

(A) The Assistant Secretary, acting through the Associate Administrator for Alcohol Prevention and Treatment Policy, shall develop, and periodically review and as appropriate revise, a plan for programs and policies to treat and prevent alcoholism and alcohol abuse. The plan shall be developed (and reviewed and revised) in collaboration with the Directors of the Centers of the Administration and in consultation with members of other Federal agencies and public and private entities.

(B) Not later than 1 year after the date of the enactment of the ADAMHA Reorganization Act, the Assistant Secretary shall submit to the Congress the first plan developed under subparagraph (A).

(3) REPORT.—

(A) Not less than once during each 2 years, the Assistant Secretary, acting through the Associate Administrator for Alcohol Prevention and Treatment Policy, shall prepare a report describing the alcoholism and alcohol abuse prevention and treatment programs undertaken by the Administration and its agencies, and the report shall include a detailed statement of the expenditures made for the activities reported on and the personnel used in connection with such activities.

(B) Each report under subparagraph (A) shall include a description of any revisions in the plan under paragraph (2) made during the preceding 2 years.

(C) Each report under subparagraph (A) shall be submitted to the Assistant Secretary for inclusion in the biennial report under subsection (m).

(f) ASSOCIATE ADMINISTRATOR FOR WOMEN'S SERVICES.—

(1) APPOINTMENT.—The Assistant Secretary, with the approval of the Secretary, shall appoint an Associate Administrator for Women's Services who shall report directly to the Assistant Secretary.

(2) DUTIES.—The Associate Administrator appointed under paragraph (1) shall—

(A) establish a committee to be known as the Coordinating Committee for Women's Services (hereafter in this subparagraph referred to as the "Coordinating Committee"), which shall be composed of the Directors of the agencies of the Administration (or the designees of the Directors);

(B) acting through the Coordinating Committee, with respect to women's substance abuse and mental health services—

(i) identify the need for such services, and make an estimate each fiscal year of the funds needed to adequately support the services;

(ii) identify needs regarding the coordination of services;

(iii) encourage the agencies of the Administration to support such services; and

(iv) assure that the unique needs of minority women, including Native American, Hispanic, African-American and Asian women, are recognized and addressed within the activities of the Administration; and

(C) establish an advisory committee to be known as the Advisory Committee for Women's Services, which shall be composed of not more than 10 individuals, a majority of whom shall be women, who are not officers or employees of the Federal Government, to be appointed by the Assistant Secretary from among physicians, practitioners, treatment providers, and other health professionals, whose clinical practice, specialization, or professional expertise includes a significant focus on women's substance abuse and mental health conditions, that shall—

(i) advise the Associate Administrator on appropriate activities to be undertaken by the agencies of the Administration with respect to women's substance abuse and mental health services, including services which require a multidisciplinary approach;

(ii) collect and review data, including information provided by the Secretary (including the material referred to in paragraph (3)), and report biannually to the Assistant Secretary regarding the extent to which women are represented among senior personnel, and make recommendations regarding improvement in the participation of women in the workforce of the Administration; and

(iii) prepare, for inclusion in the biennial report required pursuant to subsection (m), a description of activities of the Committee, including findings made by the Committee regarding—

(I) the extent of expenditures made for women's substance abuse and mental health services by the agencies of the Administration; and

(II) the estimated level of funding needed for substance abuse and mental health services to meet the needs of women;

(D) improve the collection of data on women's health by—

(i) reviewing the current data at the Administration to determine its uniformity and applicability;

(ii) developing standards for all programs funded by the Administration so that data are, to the extent practicable, collected and reported using common reporting formats, linkages and definitions; and

(iii) reporting to the Assistant Secretary a plan for incorporating the standards developed under clause (ii) in all Administration programs and a plan to assure that the data so collected are accessible to health professionals, providers, researchers, and members of the public; and

(E) shall establish, maintain, and operate a program to provide information on women's substance abuse and mental health services.

(3) STUDY.—

(A) The Secretary, acting through the Assistant Secretary for Personnel, shall conduct a study to evaluate the extent to which women are represented among senior personnel at the Administration.

(B) Not later than 90 days after the date of the enactment of the ADAMHA Reorganization Act, the Assistant Secretary for Personnel shall provide the Advisory Committee for Women's Services with a study plan, including the methodology of the study and any sampling frames. Not later than 180 days after such date of enactment, the Assistant Secretary shall prepare and submit directly to the Advisory Committee a report concerning the results of the study conducted under subparagraph (A).

(C) The Secretary shall prepare and provide to the Advisory Committee for Women's Services any additional data as requested.

(4) OFFICE.—Nothing in this subsection shall be construed to preclude the Secretary from establishing within the Substance Abuse and Mental Health Administration an Office of Women's Health.

(5) DEFINITION.—For purposes of this subsection, the term "women's substance abuse and mental health conditions", with respect to women of all age, ethnic, and racial groups, means all aspects of substance abuse and mental illness—

(A) unique to or more prevalent among women; or

(B) with respect to which there have been insufficient services involving women or insufficient data.

(g) CHIEF MEDICAL OFFICER.—

(1) IN GENERAL.—The Assistant Secretary, with the approval of the Secretary, shall appoint a Chief Medical Officer to serve within the Administration.

(2) ELIGIBLE CANDIDATES.—The Assistant Secretary shall select the Chief Medical Officer from among individuals who—

(A) have a doctoral degree in medicine or osteopathic medicine;

(B) have experience in the provision of mental or substance use disorder services;

(C) have experience working with mental or substance use disorder programs;

(D) have an understanding of biological, psychosocial, and pharmaceutical treatments of mental or substance use disorders; and

(E) are licensed to practice medicine in one or more States.

(3) DUTIES.—The Chief Medical Officer shall—

(A) serve as a liaison between the Administration and providers of mental and substance use disorders prevention, treatment, and recovery services;

(B) assist the Assistant Secretary in the evaluation, organization, integration, and coordination of programs operated by the Administration;

(C) promote evidence-based and promising best practices, including culturally and linguistically appropriate practices, as appropriate, for the prevention and treatment

of, and recovery from, mental and substance use disorders, including serious mental illness and serious emotional disturbances;

(D) participate in regular strategic planning with the Administration;

(E) coordinate with the Assistant Secretary for Planning and Evaluation to assess the use of performance metrics to evaluate activities within the Administration related to mental and substance use disorders; and

(F) coordinate with the Assistant Secretary to ensure mental and substance use disorders grant programs within the Administration consistently utilize appropriate performance metrics and evaluation designs.

(h) SERVICES OF EXPERTS.—

(1) IN GENERAL.—The Assistant Secretary may obtain (in accordance with section 3109 of title 5, United States Code, but without regard to the limitation in such section on the number of days or the period of service) the services of not more than 20 experts or consultants who have professional qualifications. Such experts and consultants shall be obtained for the Administration and for each of its agencies.

(2) COMPENSATION AND EXPENSES.—

(A) Experts and consultants whose services are obtained under paragraph (1) shall be paid or reimbursed for their expenses associated with traveling to and from their assignment location in accordance with sections 5724, 5724a(a), 5724a(c), and 5726(c) of title 5, United States Code.

(B) Expenses specified in subparagraph (A) may not be allowed in connection with the assignment of an expert or consultant whose services are obtained under paragraph (1), unless and until the expert or consultant agrees in writing to complete the entire period of assignment or one year, whichever is shorter, unless separated or reassigned for reasons beyond the control of the expert or consultant that are acceptable to the Secretary. If the expert or consultant violates the agreement, the money spent by the United States for the expenses specified in subparagraph (A) is recoverable from the expert or consultant as a debt of the United States. The Secretary may waive in whole or in part a right of recovery under this subparagraph.

(i) PEER REVIEW GROUPS.—The Assistant Secretary shall, without regard to the provisions of title 5, United States Code, governing appointments in the competitive service, and without regard to the provisions of chapter 51 and subchapter III of chapter 53 of such title, relating to classification and General Schedule pay rates, establish such peer review groups and program advisory committees as are needed to carry out the requirements of this title and appoint and pay members of such groups, except that officers and employees of the United States shall not receive additional compensation for services as members of such groups. The Federal Advisory Committee Act shall not apply to the duration of a peer review group appointed under this subsection.

(j) VOLUNTARY SERVICES.—The Assistant Secretary may accept voluntary and uncompensated services.

(k) ADMINISTRATION.—The Assistant Secretary shall ensure that programs and activities assigned under this title to the Administration are fully administered by the respective Centers to which such programs and activities are assigned.

(l) STRATEGIC PLAN.—

(1) IN GENERAL.—Not later than September 30, 2018, and every 4 years thereafter, the Assistant Secretary shall develop and carry out a strategic plan in accordance with this subsection for the planning and operation of activities carried out by the Administration, including evidence-based programs.

(2) COORDINATION.—In developing and carrying out the strategic plan under this subsection, the Assistant Secretary shall take into consideration the findings and recommendations of the Assistant Secretary for Planning and Evaluation under section 6021(d) of the Helping Families in Mental Health Crisis Reform Act of 2016 and the report of the Interdepartmental Serious Mental Illness Coordinating Committee under [section 6031 of such Act] *section 501B of this Act*.

(3) PUBLICATION OF PLAN.—Not later than September 30, 2018, and every 4 years thereafter, the Assistant Secretary shall—

(A) submit the strategic plan developed under paragraph (1) to the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives and the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate; and

(B) post such plan on the Internet website of the Administration.

(4) CONTENTS.—The strategic plan developed under paragraph (1) shall—

(A) identify strategic priorities, goals, and measurable objectives for mental and substance use disorders activities and programs operated and supported by the Administration, including priorities to prevent or eliminate the burden of mental and substance use disorders;

(B) identify ways to improve the quality of services for individuals with mental and substance use disorders, and to reduce homelessness, arrest, incarceration, violence, including self-directed violence, and unnecessary hospitalization of individuals with a mental or substance use disorder, including adults with a serious mental illness or children with a serious emotional disturbance;

(C) ensure that programs provide, as appropriate, access to effective and evidence-based prevention, diagnosis, intervention, treatment, and recovery services, including culturally and linguistically appropriate services, as appropriate, for individuals with a mental or substance use disorder;

(D) identify opportunities to collaborate with the Health Resources and Services Administration to develop or improve—

(i) initiatives to encourage individuals to pursue careers (especially in rural and underserved areas and with rural and underserved populations) as psychia-

trists, including child and adolescent psychiatrists, psychologists, psychiatric nurse practitioners, physician assistants, clinical social workers, certified peer support specialists, licensed professional counselors, or other licensed or certified mental health or substance use disorder professionals, including such professionals specializing in the diagnosis, evaluation, or treatment of adults with a serious mental illness or children with a serious emotional disturbance; and

(ii) a strategy to improve the recruitment, training, and retention of a workforce for the treatment of individuals with mental or substance use disorders, or co-occurring disorders;

(E) identify opportunities to improve collaboration with States, local governments, communities, and Indian tribes and tribal organizations (as such terms are defined in section 4 of the Indian Self-Determination and Education Assistance Act); and

(F) specify a strategy to disseminate evidence-based and promising best practices related to prevention, diagnosis, early intervention, treatment, and recovery services related to mental illness, particularly for adults with a serious mental illness and children with a serious emotional disturbance, and for individuals with a substance use disorder.

(m) BIENNIAL REPORT CONCERNING ACTIVITIES AND PROGRESS.—Not later than September 30, 2020, and every 2 years thereafter, the Assistant Secretary shall prepare and submit to the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives and the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate, and post on the Internet website of the Administration, a report containing at a minimum—

(1) a review of activities conducted or supported by the Administration, including progress toward strategic priorities, goals, and objectives identified in the strategic plan developed under subsection (l);

(2) an assessment of programs and activities carried out by the Assistant Secretary, including the extent to which programs and activities under this title and part B of title XIX meet identified goals and performance measures developed for the respective programs and activities;

(3) a description of the progress made in addressing gaps in mental and substance use disorders prevention, treatment, and recovery services and improving outcomes by the Administration, including with respect to serious mental illnesses, serious emotional disturbances, and co-occurring disorders;

(4) a description of the manner in which the Administration coordinates and partners with other Federal agencies and departments related to mental and substance use disorders, including activities related to—

(A) the implementation and dissemination of research findings into improved programs, including with respect to how advances in serious mental illness and serious emo-

tional disturbance research have been incorporated into programs;

(B) the recruitment, training, and retention of a mental and substance use disorders workforce;

(C) the integration of mental disorder services, substance use disorder services, and physical health services;

(D) homelessness; and

(E) veterans;

(5) a description of the manner in which the Administration promotes coordination by grantees under this title, and part B of title XIX, with State or local agencies; and

(6) a description of the activities carried out under section 501A(e), with respect to mental and substance use disorders, including—

(A) the number and a description of grants awarded;

(B) the total amount of funding for grants awarded;

(C) a description of the activities supported through such grants, including outcomes of programs supported; and

(D) information on how the National Mental Health and Substance Use Policy Laboratory is consulting with the Assistant Secretary for Planning and Evaluation and collaborating with the Center for Substance Abuse Treatment, the Center for Substance Abuse Prevention, the Center for Behavioral Health Statistics and Quality, and the Center for Mental Health Services to carry out such activities; and

(7) recommendations made by the Assistant Secretary for Planning and Evaluation under section 6021 of the Helping Families in Mental Health Crisis Reform Act of 2016 to improve programs within the Administration, and actions taken in response to such recommendations to improve programs within the Administration.

The Assistant Secretary may meet reporting requirements established under this title by providing the contents of such reports as an addendum to the biennial report established under this subsection, notwithstanding the timeline of other reporting requirements in this title. Nothing in this subsection shall be construed to alter the content requirements of such reports or authorize the Assistant Secretary to alter the timeline of any such reports to be less frequent than biennially, unless as specified in this title.

(n) APPLICATIONS FOR GRANTS AND CONTRACTS.—With respect to awards of grants, cooperative agreements, and contracts under this title, the Assistant Secretary, or the Director of the Center involved, as the case may be, may not make such an award unless—

(1) an application for the award is submitted to the official involved;

(2) with respect to carrying out the purpose for which the award is to be provided, the application provides assurances of compliance satisfactory to such official; and

(3) the application is otherwise in such form, is made in such manner, and contains such agreements, assurances, and information as the official determines to be necessary to carry out the purpose for which the award is to be provided.

(o) EMERGENCY RESPONSE.—

(1) IN GENERAL.—Notwithstanding section 504 and except as provided in paragraph (2), the Secretary may use not to exceed

2.5 percent of all amounts appropriated under this title for a fiscal year to make noncompetitive grants, contracts or cooperative agreements to public entities to enable such entities to address emergency substance abuse or mental health needs in local communities.

(2) EXCEPTIONS.—Amounts appropriated under part C shall not be subject to paragraph (1).

(3) EMERGENCIES.—The Secretary shall establish criteria for determining that a substance abuse or mental health emergency exists and publish such criteria in the Federal Register prior to providing funds under this subsection.

(4) EMERGENCY RESPONSE.—Amounts made available for carrying out this subsection shall remain available through the end of the fiscal year following the fiscal year for which such amounts are appropriated.

(p) LIMITATION ON THE USE OF CERTAIN INFORMATION.—No information, if an establishment or person supplying the information or described in it is identifiable, obtained in the course of activities undertaken or supported under section 505 may be used for any purpose other than the purpose for which it was supplied unless such establishment or person has consented (as determined under regulations of the Secretary) to its use for such other purpose. Such information may not be published or released in other form if the person who supplied the information or who is described in it is identifiable unless such person has consented (as determined under regulations of the Secretary) to its publication or release in other form.

(q) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of providing grants, cooperative agreements, and contracts under this section, there are authorized to be appropriated $25,000,000 for fiscal year 2001, and such sums as may be necessary for each of the fiscal years 2002 and 2003.

SEC. 501A. NATIONAL MENTAL HEALTH AND SUBSTANCE USE POLICY LABORATORY.

(a) IN GENERAL.—There shall be established within the Administration a National Mental Health and Substance Use Policy Laboratory (referred to in this section as the "Laboratory").

(b) RESPONSIBILITIES.—The Laboratory shall—

(1) continue to carry out the authorities and activities that were in effect for the Office of Policy, Planning, and Innovation as such Office existed prior to the date of enactment of the Helping Families in Mental Health Crisis Reform Act of 2016;

(2) identify, coordinate, and facilitate the implementation of policy changes likely to have a significant effect on mental health, mental illness, recovery supports, and the prevention and treatment of substance use disorder services;

(3) work with the Center for Behavioral Health Statistics and Quality to collect, as appropriate, information from grantees under programs operated by the Administration in order to evaluate and disseminate information on evidence-based practices, including culturally and linguistically appropriate services, as appropriate, and service delivery models;

(4) provide leadership in identifying and coordinating policies and programs, including evidence-based programs, related to mental and substance use disorders;

(5) periodically review programs and activities operated by the Administration relating to the diagnosis or prevention of, treatment for, and recovery from, mental and substance use disorders to—

(A) identify any such programs or activities that are duplicative;

(B) identify any such programs or activities that are not evidence-based, effective, or efficient; and

(C) formulate recommendations for coordinating, eliminating, or improving programs or activities identified under subparagraph (A) or (B) and merging such programs or activities into other successful programs or activities;

(6) issue and periodically update information for entities applying for grants or cooperative agreements from the Substance Abuse and Mental Health Services Administration in order to—

(A) encourage the implementation and replication of evidence-based practices; and

(B) provide technical assistance to applicants for funding, including with respect to justifications for such programs and activities; and

(7) carry out other activities as deemed necessary to continue to encourage innovation and disseminate evidence-based programs and practices.

(c) EVIDENCE-BASED PRACTICES AND SERVICE DELIVERY MODELS.—

(1) IN GENERAL.—In carrying out subsection (b)(3), the Laboratory—

(A) may give preference to models that improve—

(i) the coordination between mental health and physical health providers;

(ii) the coordination among such providers and the justice and corrections system; and

(iii) the cost effectiveness, quality, effectiveness, and efficiency of health care services furnished to adults with a serious mental illness, children with a serious emotional disturbance, or individuals in a mental health crisis; and

(B) may include clinical protocols and practices that address the needs of individuals with early serious mental illness.

(2) CONSULTATION.—In carrying out this section, the Laboratory shall consult with—

(A) the Chief Medical Officer appointed under section 501(g);

(B) representatives of the National Institute of Mental Health, the National Institute on Drug Abuse, and the National Institute on Alcohol Abuse and Alcoholism, on an ongoing basis;

(C) other appropriate Federal agencies;

(D) clinical and analytical experts with expertise in psychiatric medical care and clinical psychological care, health care management, education, corrections health care, and mental health court systems, as appropriate; and

(E) other individuals and agencies as determined appropriate by the Assistant Secretary.

(d) DEADLINE FOR BEGINNING IMPLEMENTATION.—The Laboratory shall begin implementation of this section not later than January 1, 2018.

(e) PROMOTING INNOVATION.—

(1) IN GENERAL.—The Assistant Secretary, in coordination with the Laboratory, may award grants to States, local governments, [Indian tribes or tribal organizations] *Indian Tribes or Tribal organizations* (as such terms are defined in section 4 of the Indian Self-Determination and Education Assistance Act), educational institutions, and nonprofit organizations to develop evidence-based interventions, including culturally and linguistically appropriate services, as appropriate, for—

(A) evaluating a model that has been scientifically demonstrated to show promise, but would benefit from further applied development, for—

(i) enhancing the prevention, diagnosis, intervention, and treatment of, and recovery from, mental illness, serious emotional disturbances, substance use disorders, and co-occurring illness or disorders; or

(ii) integrating or coordinating physical health services and mental and substance use disorders services; and

(B) expanding, replicating, or scaling evidence-based programs across a wider area to enhance effective screening, early diagnosis, intervention, and treatment with respect to mental illness, serious mental illness, serious emotional disturbances, and substance use disorders, primarily by—

(i) applying such evidence-based programs to the delivery of care, including by training staff in effective evidence-based treatments; or

(ii) integrating such evidence-based programs into models of care across specialties and jurisdictions.

(2) CONSULTATION.—In awarding grants under this subsection, the Assistant Secretary shall, as appropriate, consult with the Chief Medical Officer, appointed under section 501(g), the advisory councils described in section 502, the National Institute of Mental Health, the National Institute on Drug Abuse, and the National Institute on Alcohol Abuse and Alcoholism, as appropriate.

[(3) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated—

[(A) to carry out paragraph (1)(A), $7,000,000 for the period of fiscal years 2018 through 2020; and

[(B) to carry out paragraph (1)(B), $7,000,000 for the period of fiscal years 2018 through 2020.]

(f) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there is authorized to be appropriated $10,000,000 for each of fiscal years 2023 through 2027.

SEC. 501B. INTERDEPARTMENTAL SERIOUS MENTAL ILLNESS COORDINATING COMMITTEE.

(a) ESTABLISHMENT.—

(1) IN GENERAL.—The Secretary of Health and Human Services, or the designee of the Secretary, shall establish a com-

mittee to be known as the Interdepartmental Serious Mental Illness Coordinating Committee (in this section referred to as the "Committee").

(2) FEDERAL ADVISORY COMMITTEE ACT.—Except as provided in this section, the provisions of the Federal Advisory Committee Act (5 U.S.C. App.) shall apply to the Committee.

(b) MEETINGS.—The Committee shall meet not fewer than 2 times each year.

(c) RESPONSIBILITIES.—The Committee shall submit, on a biannual basis, to Congress and any other relevant Federal department or agency a report including—

(1) a summary of advances in serious mental illness and serious emotional disturbance research related to the prevention of, diagnosis of, intervention in, and treatment and recovery of serious mental illnesses, serious emotional disturbances, and advances in access to services and support for adults with a serious mental illness or children with a serious emotional disturbance;

(2) an evaluation of the effect Federal programs related to serious mental illness have on public health, including public health outcomes such as—

(A) rates of suicide, suicide attempts, incidence and prevalence of serious mental illnesses, serious emotional disturbances, and substance use disorders, overdose, overdose deaths, emergency hospitalizations, emergency room boarding, preventable emergency room visits, interaction with the criminal justice system, homelessness, and unemployment;

(B) increased rates of employment and enrollment in educational and vocational programs;

(C) quality of mental and substance use disorders treatment services; or

(D) any other criteria as may be determined by the Secretary; and

(3) specific recommendations for actions that agencies can take to better coordinate the administration of mental health services for adults with a serious mental illness or children with a serious emotional disturbance.

(d) MEMBERSHIP.—

(1) FEDERAL MEMBERS.—The Committee shall be composed of the following Federal representatives, or the designees of such representatives—

(A) the Secretary of Health and Human Services, who shall serve as the Chair of the Committee;

(B) the Assistant Secretary for Mental Health and Substance Use;

(C) the Attorney General;

(D) the Secretary of Veterans Affairs;

(E) the Secretary of Defense;

(F) the Secretary of Housing and Urban Development;

(G) the Secretary of Education;

(H) the Secretary of Labor;

(I) the Administrator of the Centers for Medicare & Medicaid Services; and

(J) the Commissioner of Social Security.

(2) NON-FEDERAL MEMBERS.—The Committee shall also include not less than 14 non-Federal public members appointed by the Secretary of Health and Human Services, of which—

(A) at least 2 members shall be an individual who has received treatment for a diagnosis of a serious mental illness;

(B) at least 1 member shall be a parent or legal guardian of an adult with a history of a serious mental illness or a child with a history of a serious emotional disturbance;

(C) at least 1 member shall be a representative of a leading research, advocacy, or service organization for adults with a serious mental illness;

(D) at least 2 members shall be—

(i) a licensed psychiatrist with experience in treating serious mental illnesses;

(ii) a licensed psychologist with experience in treating serious mental illnesses or serious emotional disturbances;

(iii) a licensed clinical social worker with experience treating serious mental illnesses or serious emotional disturbances; or

(iv) a licensed psychiatric nurse, nurse practitioner, or physician assistant with experience in treating serious mental illnesses or serious emotional disturbances;

(E) at least 1 member shall be a licensed mental health professional with a specialty in treating children and adolescents with a serious emotional disturbance;

(F) at least 1 member shall be a mental health professional who has research or clinical mental health experience in working with minorities;

(G) at least 1 member shall be a mental health professional who has research or clinical mental health experience in working with medically underserved populations;

(H) at least 1 member shall be a State certified mental health peer support specialist;

(I) at least 1 member shall be a judge with experience in adjudicating cases related to criminal justice or serious mental illness;

(J) at least 1 member shall be a law enforcement officer or corrections officer with extensive experience in interfacing with adults with a serious mental illness, children with a serious emotional disturbance, or individuals in a mental health crisis; and

(K) at least 1 member shall have experience providing services for homeless individuals and working with adults with a serious mental illness, children with a serious emotional disturbance, or individuals in a mental health crisis.

(3) TERMS.—A member of the Committee appointed under paragraph (2) shall serve for a term of 3 years, and may be reappointed for 1 or more additional 3-year terms. Any member appointed to fill a vacancy for an unexpired term shall be appointed for the remainder of such term. A member may serve after the expiration of the member's term until a successor has been appointed.

(e) WORKING GROUPS.—In carrying out its functions, the Committee may establish working groups. Such working groups shall be composed of Committee members, or their designees, and may hold such meetings as are necessary.

(f) SUNSET.—The Committee shall terminate on September 30, 2027.

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SEC. 506. GRANTS FOR THE BENEFIT OF HOMELESS INDIVIDUALS.

(a) IN GENERAL.—The Secretary shall award grants, contracts and cooperative agreements to community-based public and private nonprofit entities for the purposes of providing mental health and substance use disorder services for homeless individuals. In carrying out this section, the Secretary shall consult with the Interagency Council on the Homeless, established under section 201 of the Stewart B. McKinney Homeless Assistance Act (42 U.S.C. 11311).

(b) PREFERENCES.—In awarding grants, contracts, and cooperative agreements under subsection (a), the Secretary shall give a preference to—

(1) entities that provide integrated primary health, substance use disorder, and mental health services to homeless individuals;

(2) entities that demonstrate effectiveness in serving runaway, homeless, and street youth;

(3) entities that have experience in providing substance use disorder and mental health services to homeless individuals;

(4) entities that demonstrate experience in providing housing for individuals in treatment for or in recovery from mental illness or a substance use disorder; and

(5) entities that demonstrate effectiveness in serving homeless veterans.

(c) SERVICES FOR CERTAIN INDIVIDUALS.—In awarding grants, contracts, and cooperative agreements under subsection (a), the Secretary shall not—

(1) prohibit the provision of services under such subsection to homeless individuals who are suffering from a substance use disorder and are not suffering from a mental health disorder; and

(2) make payments under subsection (a) to any entity that has a policy of—

(A) excluding individuals from mental health services due to the existence or suspicion of a substance use disorder; or

(B) has a policy of excluding individuals from substance use disorder services due to the existence or suspicion of mental illness.

(d) TERM OF THE AWARDS.—No entity may receive a grant, contract, or cooperative agreement under subsection (a) for more than 5 years.

(e) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section$41,304,000 for each of fiscal years ❚2018 through 2022❚ *2023 through 2027.*

[SEC. 506A. ALCOHOL AND DRUG PREVENTION OR TREATMENT SERVICES FOR INDIANS AND NATIVE ALASKANS.

[(a) IN GENERAL.—The Secretary shall award grants, contracts, or cooperative agreements to public and private nonprofit entities, including Native Alaskan entities and Indian tribes and tribal organizations, for the purpose of providing alcohol and drug prevention or treatment services for Indians and Native Alaskans.

[(b) PRIORITY.—In awarding grants, contracts, or cooperative agreements under subsection (a), the Secretary shall give priority to applicants that—

[(1) propose to provide alcohol and drug prevention or treatment services on reservations;

[(2) propose to employ culturally-appropriate approaches, as determined by the Secretary, in providing such services; and

[(3) have provided prevention or treatment services to Native Alaskan entities and Indian tribes and tribal organizations for at least 1 year prior to applying for a grant under this section.

[(c) DURATION.—The Secretary shall award grants, contracts, or cooperative agreements under subsection (a) for a period not to exceed 5 years.

[(d) APPLICATION.—An entity desiring a grant, contract, or cooperative agreement under subsection (a) shall submit an application to the Secretary at such time, in such manner, and accompanied by such information as the Secretary may reasonably require.

[(e) EVALUATION.—An entity that receives a grant, contract, or cooperative agreement under subsection (a) shall submit, in the application for such grant, a plan for the evaluation of any project undertaken with funds provided under this section. Such entity shall provide the Secretary with periodic evaluations of the progress of such project and such evaluation at the completion of such project as the Secretary determines to be appropriate. The final evaluation submitted by such entity shall include a recommendation as to whether such project shall continue.

[(f) REPORT.—Not later than 3 years after the date of the enactment of this section and annually thereafter, the Secretary shall prepare and submit, to the Committee on Health, Education, Labor, and Pensions of the Senate, a report describing the services provided pursuant to this section.

[(g) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section, $15,000,000 for fiscal year 2001, and such sums as may be necessary for fiscal years 2002 and 2003.]

SEC. 506A. BEHAVIORAL HEALTH AND SUBSTANCE USE DISORDER SERVICES FOR NATIVE AMERICANS.

(a) DEFINITIONS.—In this section:

(1) The term "eligible entity" means an Indian Tribe, a Tribal organization, an Urban Indian organization, and a Native Hawaiian health organization.

(2) The terms "Indian Tribe", "Tribal organization", and "Urban Indian organization" have the meanings given to the terms "Indian tribe", "tribal organization", and "Urban Indian organization" in section 4 of the Indian Health Care Improvement Act.

(3) The term "Native Hawaiian health organization" means "Papa Ola Lokahi" as defined in section 12 of the Native Hawaiian Health Care Improvement Act.

(b) FORMULA FUNDS.—

(1) IN GENERAL.—The Secretary, in consultation with the Director of the Indian Health Service, as appropriate, shall award funds to eligible entities, in amounts determined pursuant to the formula described in paragraph (2), to be used by the eligible entity to provide culturally appropriate mental health and substance use disorder prevention, treatment, and recovery services to American Indians, Alaska Natives, and Native Hawaiians.

(2) FORMULA.—The Secretary, using the process described in subsection (d), shall develop a formula to determine the amount of an award under paragraph (1). Such formula shall take into account the populations of eligible entities whose rates of overdose deaths or suicide are substantially higher relative to the populations of other Indian Tribes, Tribal organizations, Urban Indian organizations, or Native Hawaiian health organizations, as applicable.

(c) TECHNICAL ASSISTANCE AND PROGRAM EVALUATION.—

(1) IN GENERAL.—The Secretary shall—

(A) provide technical assistance to applicants and awardees under this section; and

(B) collect and evaluate information on the program carried out under this section.

(2) CONSULTATION ON EVALUATION MEASURES, AND DATA SUBMISSION AND REPORTING REQUIREMENTS.—The Secretary shall, using the process described in subsection (d), develop evaluation measures and data submission and reporting requirements for purposes of the collection and evaluation of information.

(3) DATA SUBMISSION AND REPORTING.—As a condition on receipt of funds under this section, an applicant shall agree to submit data and reports in a timely manner consistent with the evaluation measures and data submission and reporting requirements developed under subsection (d).

(d) REGULATIONS.—

(1) PROMULGATION.—Not later than 180 days after the date of enactment of the Restoring Hope for Mental Health and Well-Being Act of 2022, the Secretary shall initiate procedures under subchapter III of chapter 5 of title 5, United States Code, to negotiate and promulgate such regulations as are necessary to carry out this section, including development of the funding formula described in subsection (b) and the program evaluation and reporting requirements under subsection (c).

(2) PUBLICATION.—Not later than 18 months after the date of enactment of the Restoring Hope for Mental Health and Well-Being Act of 2022, the Secretary shall publish in the Federal Register proposed regulations to implement this section.

(3) COMMITTEE.—A negotiated rulemaking committee established pursuant to section 565 of title 5, United States Code, to carry out this subsection shall have as its members only representatives of the Federal Government, Tribal Governments, and Urban Indian organizations. For purposes of such rule-

making, the Indian Health Service shall be the lead agency for the Department.

(4) ADAPTATION OF PROCEDURES.—In carrying out this subsection, the Secretary shall adapt any negotiated rulemaking procedures to the unique context of the government-to-government relationship between the United States and Indian Tribes.

(5) EFFECT.—The lack of promulgated regulations under this subsection shall not limit the effect or implementation of this section.

(e) APPLICATION.—An entity desiring an award under subsection (b) shall submit an application to the Secretary at such time, in such manner, and accompanied by such information as the Secretary may reasonably require.

(f) REPORT.—Not later than 3 years after the date of the enactment of the Restoring Hope for Mental Health and Well-Being Act of 2022, and annually thereafter, the Secretary shall prepare and submit, to the Committee on Health, Education, Labor, and Pensions of the Senate, and the Committee on Energy and Commerce of the House of Representatives, a report describing the services provided pursuant to this section.

(g) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section, $40,000,000 for each of fiscal years 2023 through 2027.

SEC. 506B. BEHAVIORAL HEALTH CRISIS COORDINATING OFFICE.

(a) IN GENERAL.—The Secretary shall establish, within the Substance Abuse and Mental Health Services Administration, an office to coordinate work relating to behavioral health crisis care across the operating divisions and agencies of the Department of Health and Human Services, including the Substance Abuse and Mental Health Services Administration, the Centers for Medicare & Medicaid Services, and the Health Resources and Services Administration, and external stakeholders.

(b) DUTY.—The office established under subsection (a) shall—

(1) convene Federal, State, Tribal, local, and private partners;

(2) launch and manage Federal workgroups charged with making recommendations regarding behavioral health crisis issues, including with respect to health care best practices, workforce development, mental health disparities, data collection, technology, program oversight, public awareness, and engagement; and

(3) support technical assistance, data analysis, and evaluation functions in order to assist States, localities, Territories, Tribes, and Tribal communities to develop crisis care systems and establish nationwide best practices with the objective of expanding the capacity of, and access to, local crisis call centers, mobile crisis care, crisis stabilization, psychiatric emergency services, and rapid post-crisis follow-up care provided by—

(A) the National Suicide Prevention and Mental Health Crisis Hotline and Response System;

(B) community mental health centers (as defined in section 1861(ff)(3)(B) of the Social Security Act);

(C) certified community behavioral health clinics, as described in section 223 of the Protecting Access to Medicare Act of 2014; and

(D) other community mental health and substance use disorder providers.

(c) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section $5,000,000 for each of fiscal years 2023 through 2027.

PART B—CENTERS AND PROGRAMS

Subpart 1—Center for Substance Abuse Treatment

* * * * * * *

SEC. 509. PRIORITY SUBSTANCE [ABUSE] *USE DISORDER* TREATMENT NEEDS OF REGIONAL AND NATIONAL SIGNIFICANCE.

(a) PROJECTS.—The Secretary shall address priority substance use disorder treatment needs of regional and national significance (as determined under subsection (b)) through the provision of or through assistance for—

(1) knowledge development and application projects for treatment and rehabilitation and the conduct or support of evaluations of such projects;

(2) training and technical assistance; and

(3) targeted capacity response programs that permit States, local governments, communities, and Indian [tribes and tribal organizations (as the terms "Indian tribes" and "tribal organizations" are defined] *Tribes and Tribal organizations (as such terms are defined* in section 4 of the Indian Self-Determination and Education Assistance Act) to focus on emerging trends [in substance abuse] and co-occurrence of substance use disorders with mental illness or other conditions.

The Secretary may carry out the activities described in this section directly or through grants, contracts, or cooperative agreements with States, political subdivisions of States, Indian tribes or tribal organizations (as such terms are defined in section 4 of the Indian Self-Determination and Education Assistance Act), health facilities, or programs operated by or in accordance with a contract or grant with the Indian Health Service, or other public or nonprofit private entities.

(b) PRIORITY SUBSTANCE [ABUSE] *USE DISORDER* TREATMENT NEEDS.—

(1) IN GENERAL.—Priority substance use disorder treatment needs of regional and national significance shall be determined by the Secretary after consultation with States and other interested groups. The Secretary shall meet with the States and interested groups on an annual basis to discuss program priorities.

(2) SPECIAL CONSIDERATION.—In developing program priorities under paragraph (1), the Secretary shall give special consideration to promoting the integration of substance use disorder treatment services into primary health care systems.

(c) REQUIREMENTS.—

(1) IN GENERAL.—Recipients of grants, contracts, or cooperative agreements under this section shall comply with information and application requirements determined appropriate by the Secretary.

(2) DURATION OF AWARD.—With respect to a grant, contract, or cooperative agreement awarded under this section, the pe-

riod during which payments under such award are made to the recipient may not exceed 5 years.

(3) MATCHING FUNDS.—The Secretary may, for projects carried out under subsection (a), require that entities that apply for grants, contracts, or cooperative agreements under that project provide non-Federal matching funds, as determined appropriate by the Secretary, to ensure the institutional commitment of the entity to the projects funded under the grant, contract, or cooperative agreement. Such non-Federal matching funds may be provided directly or through donations from public or private entities and may be in cash or in kind, fairly evaluated, including plant, equipment, or services.

(4) MAINTENANCE OF EFFORT.—With respect to activities for which a grant, contract, or cooperative agreement is awarded under this section, the Secretary may require that recipients for specific projects under subsection (a) agree to maintain expenditures of non-Federal amounts for such activities at a level that is not less than the level of such expenditures maintained by the entity for the fiscal year preceding the fiscal year for which the entity receives such a grant, contract, or cooperative agreement.

(d) EVALUATION.—The Secretary shall evaluate each project carried out under subsection (a)(1) and shall disseminate the findings with respect to each such evaluation to appropriate public and private entities.

(e) INFORMATION AND EDUCATION.—The Secretary shall establish comprehensive information and education programs to disseminate and apply the findings of the knowledge development and application, training and technical assistance programs, and targeted capacity response programs under this section to the general public, to health professionals and other interested groups. The Secretary shall make every effort to provide linkages between the findings of supported projects and State agencies responsible for carrying out substance use disorder prevention and treatment programs.

(f) AUTHORIZATION OF APPROPRIATION.—There are authorized to be appropriated to carry out this section, **[**$333,806,000 for each of fiscal years 2018 through 2022**]** *$521,517,000 for each of fiscal years 2023 through 2027*.

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SEC. 514. SUBSTANCE USE DISORDER TREATMENT AND EARLY INTERVENTION SERVICES FOR CHILDREN, ADOLESCENTS, AND YOUNG ADULTS.

(a) IN GENERAL.—The Secretary shall award grants, contracts, or cooperative agreements to public and private nonprofit entities, including **[**Indian tribes or tribal organizations**]** *Indian Tribes or Tribal organizations* (as such terms are defined in section 4 of the Indian Self-Determination and Education Assistance Act), or health facilities or programs operated by or in accordance with a contract or grant with the Indian Health Service, for the purpose of—

(1) providing early identification and services to meet the needs of children, adolescents, and young adults who are at risk of substance use disorders;

(2) providing substance use disorder treatment services for children, adolescents, and young adults, includingchildren, ado-

lescents, and young adults with co-occurring mental illness and substance use disorders; and

(3) providing assistance to pregnant women, and parenting women, with substance use disorders, in obtaining treatment services, linking mothers to community resources to support independent family lives, and staying in recovery so that children are in safe, stable home environments and receive appropriate health care services.

(b) PRIORITY.—In awarding grants, contracts, or cooperative agreements under subsection (a), the Secretary shall give priority to applicants who propose to—

(1) apply evidence-based and cost-effective methods;

(2) coordinate the provision of services with other social service agencies in the community, including educational, juvenile justice, child welfare, substance abuse, and mental health agencies;

(3) provide a continuum of integrated treatment services, including case management, for children, adolescents, and young adults with substance use disorders, including children, adolescents, and young adults with co-occurring mental illness and substance use disorders, and their families;

(4) provide treatment that is gender-specific and culturally appropriate;

(5) involve and work with families of children, adolescents, and young adults receiving services; and

(6) provide aftercare services for children, adolescents, and young adults and their families after completion of treatment.

(c) DURATION OF GRANTS.—The Secretary shall award grants, contracts, or cooperative agreements under subsection (a) for periods not to exceed 5 fiscal years.

(d) APPLICATION.—An entity desiring a grant, contract, or cooperative agreement under subsection (a) shall submit an application to the Secretary at such time, in such manner, and accompanied by such information as the Secretary may reasonably require.

(e) EVALUATION.—An entity that receives a grant, contract, or cooperative agreement under subsection (a) shall submit, in the application for such grant, contract, or cooperative agreement, a plan for the evaluation of any project undertaken with funds provided under this section. Such entity shall provide the Secretary with periodic evaluations of the progress of such project and such evaluation at the completion of such project as the Secretary determines to be appropriate.

(f) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section, $29,605,000 for each of fiscal years ⟦2018 through 2022⟧ *2023 through 2027*.

SEC. 514B. EVIDENCE-BASED PRESCRIPTION OPIOID AND HEROIN TREATMENT AND INTERVENTIONS DEMONSTRATION.

(a) GRANTS TO EXPAND ACCESS.—

(1) AUTHORITY TO AWARD GRANTS.—The Secretary shall award grants, contracts, or cooperative agreements to State ⟦substance abuse⟧ *substance use disorder* agencies, units of local government, nonprofit organizations, and Indian ⟦tribes and tribal organizations⟧ *Tribes and Tribal organizations* (as defined in section 4 of the Indian Self-Determination and Education Assistance Act) that have a high rate, or have had a

rapid increase, in the use of heroin or other opioids, in order to permit such entities to expand activities, including an expansion in the availability of evidence-based medication-assisted treatment and other clinically appropriate services, with respect to the treatment of [addiction] *substance use disorders* in the specific geographical areas of such entities where there is a high rate or rapid increase in the use of heroin or other opioids, such as in rural areas.

(2) NATURE OF ACTIVITIES.—Funds awarded under paragraph (1) shall be used for activities that are based on reliable scientific evidence of efficacy in the treatment of problems related to heroin or other opioids.

(b) APPLICATION.—To be eligible for a grant, contract, or cooperative agreement under subsection (a), an entity shall submit an application to the Secretary at such time, in such manner, and accompanied by such information as the Secretary may reasonably require.

(c) EVALUATION.—An entity that receives a grant, contract, or cooperative agreement under subsection (a) shall submit, in the application for such grant, contract, or agreement a plan for the evaluation of any project undertaken with funds provided under this section. Such entity shall provide the Secretary with periodic evaluations of the progress of such project and an evaluation at the completion of such project as the Secretary determines to be appropriate.

(d) GEOGRAPHIC DISTRIBUTION.—In awarding grants, contracts, and cooperative agreements under this section, the Secretary shall ensure that not less than 15 percent of funds are awarded to eligible entities that are not located in metropolitan statistical areas (as defined by the Office of Management and Budget). The Secretary shall take into account the unique needs of rural communities, including communities with an incidence of individuals with opioid use disorder that is above the national average and communities with a shortage of prevention and treatment services.

(e) ADDITIONAL ACTIVITIES.—In administering grants, contracts, and cooperative agreements under subsection (a), the Secretary shall—

(1) evaluate the activities supported under such subsection;

(2) disseminate information, as appropriate, derived from evaluations as the Secretary considers appropriate;

(3) provide States, Indian [tribes and tribal organizations] *Tribes and Tribal organizations*, and providers with technical assistance in connection with the provision of treatment of problems related to heroin and other opioids; and

(4) fund only those applications that specifically support recovery services as a critical component of the program involved.

(f) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated $25,000,000 for each of fiscal years [2017 through 2021] *2023 through 2027*.

Subpart 2—Center for Substance Abuse Prevention

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SEC. 516. PRIORITY SUBSTANCE USE DISORDER PREVENTION NEEDS OF REGIONAL AND NATIONAL SIGNIFICANCE.

(a) PROJECTS.—The Secretary shall address priority substance use disorder prevention needs of regional and national significance (as determined under subsection (b)) through the provision of or through assistance for—

(1) knowledge development and application projects for prevention and the conduct or support of evaluations of such projects;

(2) training and technical assistance; and

(3) targeted capacity response programs, including such programs that focus on emerging drug [abuse] *use* issues.

The Secretary may carry out the activities described in this section directly or through grants, contracts, or cooperative agreements with States, political subdivisions of States, Indian [tribes or tribal organizations] *Tribes or Tribal organizations* (as such terms are defined in section 4 of the Indian Self-Determination and Education Assistance Act), health facilities, or programs operated by or in accordance with a contract or grant with the Indian Health Service, or other public or nonprofit private entities.

(b) PRIORITY SUBSTANCE [ABUSE] *USE DISORDER* PREVENTION NEEDS.—

(1) IN GENERAL.—Priority substance use disorder prevention needs of regional and national significance shall be determined by the Secretary in consultation with the States and other interested groups. The Secretary shall meet with the States and interested groups on an annual basis to discuss program priorities.

(2) SPECIAL CONSIDERATION.—In developing program priorities under paragraph (1), the Secretary shall give special consideration to—

(A) applying the most promising strategies and research-based primary prevention approaches;

(B) promoting the integration of substance use disorder prevention information and activities into primary health care systems; and

(C) substance use disorder prevention among high-risk groups.

(c) REQUIREMENTS.—

(1) IN GENERAL.—Recipients of grants, contracts, and cooperative agreements under this section shall comply with information and application requirements determined appropriate by the Secretary.

(2) DURATION OF AWARD.—With respect to a grant, contract, or cooperative agreement awarded under this section, the period during which payments under such award are made to the recipient may not exceed 5 years.

(3) MATCHING FUNDS.—The Secretary may, for projects carried out under subsection (a), require that entities that apply for grants, contracts, or cooperative agreements under that project provide non-Federal matching funds, as determined appropriate by the Secretary, to ensure the institutional commitment of the entity to the projects funded under the grant, contract, or cooperative agreement. Such non-Federal matching funds may be provided directly or through donations from pub-

lic or private entities and may be in cash or in kind, fairly evaluated, including plant, equipment, or services.

(4) MAINTENANCE OF EFFORT.—With respect to activities for which a grant, contract, or cooperative agreement is awarded under this section, the Secretary may require that recipients for specific projects under subsection (a) agree to maintain expenditures of non-Federal amounts for such activities at a level that is not less than the level of such expenditures maintained by the entity for the fiscal year preceding the fiscal year for which the entity receives such a grant, contract, or cooperative agreement.

(d) EVALUATION.—The Secretary shall evaluate each project carried out under subsection (a)(1) and shall disseminate the findings with respect to each such evaluation to appropriate public and private entities.

(e) INFORMATION AND EDUCATION.—The Secretary shall establish comprehensive information and education programs to disseminate the findings of the knowledge development and application, training and technical assistance programs, and targeted capacity response programs under this section to the general public and to health professionals. The Secretary shall make every effort to provide linkages between the findings of supported projects and State agencies responsible for carrying out substance use disorder prevention and treatment programs.

(f) AUTHORIZATION OF APPROPRIATION.—There are authorized to be appropriated to carry out this section, ⟦$211,148,000 for each of fiscal years 2018 through 2022⟧ *$218,219,000 for each of fiscal years 2023 through 2027.*

SEC. 519B. PROGRAMS TO REDUCE UNDERAGE DRINKING.

⟦(a) DEFINITIONS.—For purposes of this section:

⟦(1) The term "alcohol beverage industry" means the brewers, vintners, distillers, importers, distributors, and retail or online outlets that sell or serve beer, wine, and distilled spirits.

⟦(2) The term "school-based prevention" means programs, which are institutionalized, and run by staff members or school-designated persons or organizations in any grade of school, kindergarten through 12th grade.

⟦(3) The term "youth" means persons under the age of 21.

⟦(4) The term "IOM report" means the report released in September 2003 by the National Research Council, Institute of Medicine, and entitled "Reducing Underage Drinking: A Collective Responsibility".⟧

(a) DEFINITIONS.—For purposes of this section:

(1) The term "alcohol beverage industry" means the brewers, vintners, distillers, importers, distributors, and retail or online outlets that sell or serve beer, wine, and distilled spirits.

(2) The term "school-based prevention" means programs, which are institutionalized, and run by staff members or school-designated persons or organizations in any grade of school, kindergarten through 12th grade.

(3) The term "youth" means persons under the age of 21.

(b) SENSE OF CONGRESS.—It is the sense of the Congress that:

(1) A multi-faceted effort is needed to more successfully address the problem of underage drinking in the United States. A coordinated approach to prevention, intervention, treatment,

enforcement, and research is key to making progress. This Act recognizes the need for a focused national effort, and addresses particulars of the Federal portion of that effort, as well as Federal support for State activities.

(2) The Secretary of Health and Human Services shall continue to conduct research and collect data on the short and long-range impact of alcohol use and abuse upon adolescent brain development and other organ systems.

(3) States and communities, including colleges and universities, are encouraged to adopt comprehensive prevention approaches, including—

(A) evidence-based screening, programs and curricula;

(B) brief intervention strategies;

(C) consistent policy enforcement; and

(D) environmental changes that limit underage access to alcohol.

(4) Public health groups, consumer groups, and the alcohol beverage industry should continue and expand evidence-based efforts to prevent and reduce underage drinking.

(5) The entertainment industries have a powerful impact on youth, and they should use rating systems and marketing codes to reduce the likelihood that underage audiences will be exposed to movies, recordings, or television programs with unsuitable alcohol content.

(6) The National Collegiate Athletic Association, its member colleges and universities, and athletic conferences should affirm a commitment to a policy of discouraging alcohol use among underage students and other young fans.

(7) Alcohol is a unique product and should be regulated differently than other products by the States and Federal Government. States have primary authority to regulate alcohol distribution and sale, and the Federal Government should support and supplement these State efforts. States also have a responsibility to fight youth access to alcohol and reduce underage drinking. Continued State regulation and licensing of the manufacture, importation, sale, distribution, transportation and storage of alcoholic beverages are clearly in the public interest and are critical to promoting responsible consumption, preventing illegal access to alcohol by persons under 21 years of age from commercial and non-commercial sources, maintaining industry integrity and an orderly marketplace, and furthering effective State tax collection.

[(c) INTERAGENCY COORDINATING COMMITTEE; ANNUAL REPORT ON STATE UNDERAGE DRINKING PREVENTION AND ENFORCEMENT ACTIVITIES.—

[(1) INTERAGENCY COORDINATING COMMITTEE ON THE PREVENTION OF UNDERAGE DRINKING.—

[(A) IN GENERAL.—The Secretary, in collaboration with the Federal officials specified in subparagraph (B), shall formally establish and enhance the efforts of the interagency coordinating committee, that began operating in 2004, focusing on underage drinking (referred to in this subsection as the "Committee").

[(B) OTHER AGENCIES.—The officials referred to in paragraph (1) are the Secretary of Education, the Attorney

General, the Secretary of Transportation, the Secretary of the Treasury, the Secretary of Defense, the Surgeon General, the Director of the Centers for Disease Control and Prevention, the Director of the National Institute on Alcohol Abuse and Alcoholism, the Assistant Secretary for Mental Health and Substance Use, the Director of the National Institute on Drug Abuse, the Assistant Secretary for Children and Families, the Director of the Office of National Drug Control Policy, the Administrator of the National Highway Traffic Safety Administration, the Administrator of the Office of Juvenile Justice and Delinquency Prevention, the Chairman of the Federal Trade Commission, and such other Federal officials as the Secretary of Health and Human Services determines to be appropriate.

[(C) CHAIR.—The Secretary of Health and Human Services shall serve as the chair of the Committee.

[(D) DUTIES.—The Committee shall guide policy and program development across the Federal Government with respect to underage drinking, provided, however, that nothing in this section shall be construed as transferring regulatory or program authority from an Agency to the Coordinating Committee.

[(E) CONSULTATIONS.—The Committee shall actively seek the input of and shall consult with all appropriate and interested parties, including States, public health research and interest groups, foundations, and alcohol beverage industry trade associations and companies.

[(F) ANNUAL REPORT.—

[(i) IN GENERAL.—The Secretary, on behalf of the Committee, shall annually submit to the Congress a report that summarizes—

[(I) all programs and policies of Federal agencies designed to prevent and reduce underage drinking;

[(II) the extent of progress in preventing and reducing underage drinking nationally;

[(III) data that the Secretary shall collect with respect to the information specified in clause (ii); and

[(IV) such other information regarding underage drinking as the Secretary determines to be appropriate.

[(ii) CERTAIN INFORMATION.—The report under clause (i) shall include information on the following:

[(I) Patterns and consequences of underage drinking as reported in research and surveys such as, but not limited to Monitoring the Future, Youth Risk Behavior Surveillance System, the National Survey on Drug Use and Health, and the Fatality Analysis Reporting System.

[(II) Measures of the availability of alcohol from commercial and non-commercial sources to underage populations.

[(III) Measures of the exposure of underage populations to messages regarding alcohol in ad-

vertising and the entertainment media as reported by the Federal Trade Commission.

[(IV) Surveillance data, including information on the onset and prevalence of underage drinking, consumption patterns and the means of underage access. The Secretary shall develop a plan to improve the collection, measurement and consistency of reporting Federal underage alcohol data.

[(V) Any additional findings resulting from research conducted or supported under subsection (f).

[(VI) Evidence-based best practices to prevent and reduce underage drinking and provide treatment services to those youth who need them.

[(2) ANNUAL REPORT ON STATE UNDERAGE DRINKING PREVENTION AND ENFORCEMENT ACTIVITIES.—

[(A) IN GENERAL.—The Secretary shall, with input and collaboration from other appropriate Federal agencies, States, Indian tribes, territories, and public health, consumer, and alcohol beverage industry groups, annually issue a report on each State's performance in enacting, enforcing, and creating laws, regulations, and programs to prevent or reduce underage drinking.

[(B) STATE PERFORMANCE MEASURES.—

[(i) IN GENERAL.—The Secretary shall develop, in consultation with the Committee, a set of measures to be used in preparing the report on best practices.

[(ii) CATEGORIES.—In developing these measures, the Secretary shall consider categories including, but not limited to:

[(I) Whether or not the State has comprehensive anti-underage drinking laws such as for the illegal sale, purchase, attempt to purchase, consumption, or possession of alcohol; illegal use of fraudulent ID; illegal furnishing or obtaining of alcohol for an individual under 21 years; the degree of strictness of the penalties for such offenses; and the prevalence of the enforcement of each of these infractions.

[(II) Whether or not the State has comprehensive liability statutes pertaining to underage access to alcohol such as dram shop, social host, and house party laws, and the prevalence of enforcement of each of these laws.

[(III) Whether or not the State encourages and conducts comprehensive enforcement efforts to prevent underage access to alcohol at retail outlets, such as random compliance checks and shoulder tap programs, and the number of compliance checks within alcohol retail outlets measured against the number of total alcohol retail outlets in each State, and the result of such checks.

[(IV) Whether or not the State encourages training on the proper selling and serving of alco-

hol for all sellers and servers of alcohol as a condition of employment.

[(V) Whether or not the State has policies and regulations with regard to direct sales to consumers and home delivery of alcoholic beverages.

[(VI) Whether or not the State has programs or laws to deter adults from purchasing alcohol for minors; and the number of adults targeted by these programs.

[(VII) Whether or not the State has programs targeted to youths, parents, and caregivers to deter underage drinking; and the number of individuals served by these programs.

[(VIII) Whether or not the State has enacted graduated drivers licenses and the extent of those provisions.

[(IX) The amount that the State invests, per youth capita, on the prevention of underage drinking, further broken down by the amount spent on—

[(aa) compliance check programs in retail outlets, including providing technology to prevent and detect the use of false identification by minors to make alcohol purchases;

[(bb) checkpoints and saturation patrols that include the goal of reducing and deterring underage drinking;

[(cc) community-based, school-based, and higher-education-based programs to prevent underage drinking;

[(dd) underage drinking prevention programs that target youth within the juvenile justice and child welfare systems; and

[(ee) other State efforts or programs as deemed appropriate.

[(3) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this subsection $1,000,000 for each of the fiscal years 2018 through 2022.

[(d) NATIONAL MEDIA CAMPAIGN TO PREVENT UNDERAGE DRINKING.—

[(1) SCOPE OF THE CAMPAIGN.—The Secretary shall continue to fund and oversee the production, broadcasting, and evaluation of the national adult-oriented media public service campaign if the Secretary determines that such campaign is effective in achieving the media campaign's measurable objectives.

[(2) REPORT.—The Secretary shall provide a report to the Congress annually detailing the production, broadcasting, and evaluation of the campaign referred to in paragraph (1), and to detail in the report the effectiveness of the campaign in reducing underage drinking, the need for and likely effectiveness of an expanded adult-oriented media campaign, and the feasibility and the likely effectiveness of a national youth-focused media campaign to combat underage drinking.

[(3) CONSULTATION REQUIREMENT.—In carrying out the media campaign, the Secretary shall direct the entity carrying

out the national adult-oriented media public service campaign to consult with interested parties including both the alcohol beverage industry and public health and consumer groups. The progress of this consultative process is to be covered in the report under paragraph (2).

[(4) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this subsection, $1,000,000 for each of the fiscal years 2018 through 2022.

[(e) INTERVENTIONS.—

[(1) COMMUNITY-BASED COALITION ENHANCEMENT GRANTS TO PREVENT UNDERAGE DRINKING.—

[(A) AUTHORIZATION OF PROGRAM.—The Assistant Secretary for Mental Health and Substance Use, in consultation with the Director of the Office of National Drug Control Policy, shall award, if the Assistant Secretary determines that the Department of Health and Human Services is not currently conducting activities that duplicate activities of the type described in this subsection, "enhancement grants" to eligible entities to design, test, evaluate and disseminate effective strategies to maximize the effectiveness of community-wide approaches to preventing and reducing underage drinking. This subsection is subject to the availability of appropriations.

[(B) PURPOSES.—The purposes of this paragraph are to—

[(i) prevent and reduce alcohol use among youth in communities throughout the United States;

[(ii) strengthen collaboration among communities, the Federal Government, and State, local, and tribal governments;

[(iii) enhance intergovernmental cooperation and coordination on the issue of alcohol use among youth;

[(iv) serve as a catalyst for increased citizen participation and greater collaboration among all sectors and organizations of a community that first demonstrates a long-term commitment to reducing alcohol use among youth;

[(v) disseminate to communities timely information regarding state-of-the-art practices and initiatives that have proven to be effective in preventing and reducing alcohol use among youth; and

[(vi) enhance, not supplant, effective local community initiatives for preventing and reducing alcohol use among youth.

[(C) APPLICATION.—An eligible entity desiring an enhancement grant under this paragraph shall submit an application to the Assistant Secretary at such time, and in such manner, and accompanied by such information as the Assistant Secretary may require. Each application shall include—

[(i) a complete description of the entity's current underage alcohol use prevention initiatives and how the grant will appropriately enhance the focus on underage drinking issues; or

[(ii) a complete description of the entity's current initiatives, and how it will use this grant to enhance those initiatives by adding a focus on underage drinking prevention.

[(D) USES OF FUNDS.—Each eligible entity that receives a grant under this paragraph shall use the grant funds to carry out the activities described in such entity's application submitted pursuant to subparagraph (C). Grants under this paragraph shall not exceed $50,000 per year and may not exceed four years.

[(E) SUPPLEMENT NOT SUPPLANT.—Grant funds provided under this paragraph shall be used to supplement, not supplant, Federal and non-Federal funds available for carrying out the activities described in this paragraph.

[(F) EVALUATION.—Grants under this paragraph shall be subject to the same evaluation requirements and procedures as the evaluation requirements and procedures imposed on recipients of drug free community grants.

[(G) DEFINITIONS.—For purposes of this paragraph, the term "eligible entity" means an organization that is currently receiving or has received grant funds under the Drug-Free Communities Act of 1997 (21 U.S.C. 1521 et seq.).

[(H) ADMINISTRATIVE EXPENSES.—Not more than 6 percent of a grant under this paragraph may be expended for administrative expenses.

[(I) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this paragraph $5,000,000 for each of the fiscal years 2018 through 2022.

[(2) GRANTS DIRECTED AT PREVENTING AND REDUCING ALCOHOL ABUSE AT INSTITUTIONS OF HIGHER EDUCATION.—

[(A) AUTHORIZATION OF PROGRAM.—The Secretary shall award grants to eligible entities to enable the entities to prevent and reduce the rate of underage alcohol consumption including binge drinking among students at institutions of higher education.

[(B) APPLICATIONS.—An eligible entity that desires to receive a grant under this paragraph shall submit an application to the Secretary at such time, in such manner, and accompanied by such information as the Secretary may require. Each application shall include—

[(i) a description of how the eligible entity will work to enhance an existing, or where none exists to build a, statewide coalition;

[(ii) a description of how the eligible entity will target underage students in the State;

[(iii) a description of how the eligible entity intends to ensure that the statewide coalition is actually implementing the purpose of this section and moving toward indicators described in subparagraph (D);

[(iv) a list of the members of the statewide coalition or interested parties involved in the work of the eligible entity;

[(v) a description of how the eligible entity intends to work with State agencies on substance abuse prevention and education;

[(vi) the anticipated impact of funds provided under this paragraph in preventing and reducing the rates of underage alcohol use;

[(vii) outreach strategies, including ways in which the eligible entity proposes to—

[(I) reach out to students and community stakeholders;

[(II) promote the purpose of this paragraph;

[(III) address the range of needs of the students and the surrounding communities; and

[(IV) address community norms for underage students regarding alcohol use; and

[(viii) such additional information as required by the Secretary.

[(C) USES OF FUNDS.—Each eligible entity that receives a grant under this paragraph shall use the grant funds to carry out the activities described in such entity's application submitted pursuant to subparagraph (B).

[(D) ACCOUNTABILITY.—On the date on which the Secretary first publishes a notice in the Federal Register soliciting applications for grants under this paragraph, the Secretary shall include in the notice achievement indicators for the program authorized under this paragraph. The achievement indicators shall be designed—

[(i) to measure the impact that the statewide coalitions assisted under this paragraph are having on the institutions of higher education and the surrounding communities, including changes in the number of incidents of any kind in which students have abused alcohol or consumed alcohol while under the age of 21 (including violations, physical assaults, sexual assaults, reports of intimidation, disruptions of school functions, disruptions of student studies, mental health referrals, illnesses, or deaths);

[(ii) to measure the quality and accessibility of the programs or information offered by the eligible entity; and

[(iii) to provide such other measures of program impact as the Secretary determines appropriate.

[(E) SUPPLEMENT NOT SUPPLANT.—Grant funds provided under this paragraph shall be used to supplement, and not supplant, Federal and non-Federal funds available for carrying out the activities described in this paragraph.

[(F) DEFINITIONS.—For purposes of this paragraph:

[(i) ELIGIBLE ENTITY.—The term "eligible entity" means a State, institution of higher education, or nonprofit entity.

[(ii) INSTITUTION OF HIGHER EDUCATION.—The term "institution of higher education" has the meaning given the term in section 101(a) of the Higher Education Act of 1965 (20 U.S.C. 1001(a)).

[(iii) SECRETARY.—The term "Secretary" means the Secretary of Education.

[(iv) STATE.—The term "State" means each of the 50 States, the District of Columbia, and the Commonwealth of Puerto Rico.

[(v) STATEWIDE COALITION.—The term "statewide coalition" means a coalition that—

[(I) includes, but is not limited to—

[(aa) institutions of higher education within a State; and

[(bb) a nonprofit group, a community underage drinking prevention coalition, or another substance abuse prevention group within a State; and

[(II) works toward lowering the alcohol abuse rate by targeting underage students at institutions of higher education throughout the State and in the surrounding communities.

[(vi) SURROUNDING COMMUNITY.—The term "surrounding community" means the community—

[(I) that surrounds an institution of higher education participating in a statewide coalition;

[(II) where the students from the institution of higher education take part in the community; and

[(III) where students from the institution of higher education live in off-campus housing.

[(G) ADMINISTRATIVE EXPENSES.—Not more than 5 percent of a grant under this paragraph may be expended for administrative expenses.

[(H) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this paragraph $5,000,000 for fiscal year 2007, and $5,000,000 for each of the fiscal years 2008 through 2010.

[(f) ADDITIONAL RESEARCH.—

[(1) ADDITIONAL RESEARCH ON UNDERAGE DRINKING.—

[(A) IN GENERAL.—The Secretary shall, subject to the availability of appropriations, collect data, and conduct or support research that is not duplicative of research currently being conducted or supported by the Department of Health and Human Services, on underage drinking, with respect to the following:

[(i) Comprehensive community-based programs or strategies and statewide systems to prevent and reduce underage drinking, across the underage years from early childhood to age 21, including programs funded and implemented by government entities, public health interest groups and foundations, and alcohol beverage companies and trade associations.

[(ii) Annually obtain and report more precise information than is currently collected on the scope of the underage drinking problem and patterns of underage alcohol consumption, including improved knowledge about the problem and progress in preventing, reducing and treating underage drinking; as well as information on the rate of exposure of youth to advertising

and other media messages encouraging and discouraging alcohol consumption.

[(iii) Compiling information on the involvement of alcohol in unnatural deaths of persons ages 12 to 20 in the United States, including suicides, homicides, and unintentional injuries such as falls, drownings, burns, poisonings, and motor vehicle crash deaths.

[(B) CERTAIN MATTERS.—The Secretary shall carry out activities toward the following objectives with respect to underage drinking:

[(i) Obtaining new epidemiological data within the national or targeted surveys that identify alcohol use and attitudes about alcohol use during pre- and early adolescence, including harm caused to self or others as a result of adolescent alcohol use such as violence, date rape, risky sexual behavior, and prenatal alcohol exposure.

[(ii) Developing or identifying successful clinical treatments for youth with alcohol problems.

[(C) PEER REVIEW.—Research under subparagraph (A) shall meet current Federal standards for scientific peer review.

[(2) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this subsection $3,000,000 for each of the fiscal years 2018 through 2022

[(g) REDUCING UNDERAGE DRINKING THROUGH SCREENING AND BRIEF INTERVENTION.—

[(1) GRANTS TO PEDIATRIC HEALTH CARE PROVIDERS TO REDUCE UNDERAGE DRINKING.—The Assistant Secretary may make grants to eligible entities to increase implementation of practices for reducing the prevalence of alcohol use among individuals under the age of 21, including college students.

[(2) PURPOSES.—Grants under this subsection shall be made to improve—

[(A) screening children and adolescents for alcohol use;

[(B) offering brief interventions to children and adolescents to discourage such use;

[(C) educating parents about the dangers of, and methods of discouraging, such use;

[(D) diagnosing and treating alcohol use disorders; and

[(E) referring patients, when necessary, to other appropriate care.

[(3) USE OF FUNDS.—An entity receiving a grant under this subsection may use such funding for the purposes identified in paragraph (2) by—

[(A) providing training to health care providers;

[(B) disseminating best practices, including culturally and linguistically appropriate best practices, as appropriate, and developing and distributing materials; and

[(C) supporting other activities, as determined appropriate by the Assistant Secretary.

[(4) APPLICATION.—To be eligible to receive a grant under this subsection, an entity shall submit an application to the Assistant Secretary at such time, and in such manner, and ac-

companied by such information as the Assistant Secretary may require. Each application shall include—

[(A) a description of the entity;

[(B) a description of activities to be completed;

[(C) a description of how the services specified in paragraphs (2) and (3) will be carried out and the qualifications for providing such services; and

[(D) a timeline for the completion of such activities.

[(5) DEFINITIONS.—For the purpose of this subsection:

[(A) BRIEF INTERVENTION.—The term "brief intervention" means, after screening a patient, providing the patient with brief advice and other brief motivational enhancement techniques designed to increase the insight of the patient regarding the patient's alcohol use, and any realized or potential consequences of such use, to effect the desired related behavioral change.

[(B) CHILDREN AND ADOLESCENTS.—The term "children and adolescents" means any person under 21 years of age.

[(C) ELIGIBLE ENTITY.—The term "eligible entity" means an entity consisting of pediatric health care providers and that is qualified to support or provide the activities identified in paragraph (2).

[(D) PEDIATRIC HEALTH CARE PROVIDER.—The term "pediatric health care provider" means a provider of primary health care to individuals under the age of 21 years.

[(E) SCREENING.—The term "screening" means using validated patient interview techniques to identify and assess the existence and extent of alcohol use in a patient.]

(c) INTERAGENCY COORDINATING COMMITTEE; ANNUAL REPORT ON STATE UNDERAGE DRINKING PREVENTION AND ENFORCEMENT ACTIVITIES.—

(1) INTERAGENCY COORDINATING COMMITTEE ON THE PREVENTION OF UNDERAGE DRINKING.—

(A) IN GENERAL.—The Secretary, in collaboration with the Federal officials specified in subparagraph (B), shall continue to support and enhance the efforts of the interagency coordinating committee, that began operating in 2004, focusing on underage drinking (referred to in this subsection as the "Committee").

(B) OTHER AGENCIES.—The officials referred to in subparagraph (A) are the Secretary of Education, the Attorney General, the Secretary of Transportation, the Secretary of the Treasury, the Secretary of Defense, the Surgeon General, the Director of the Centers for Disease Control and Prevention, the Director of the National Institute on Alcohol Abuse and Alcoholism, the Assistant Secretary for Mental Health and Substance Use, the Director of the National Institute on Drug Abuse, the Assistant Secretary for Children and Families, the Director of the Office of National Drug Control Policy, the Administrator of the National Highway Traffic Safety Administration, the Administrator of the Office of Juvenile Justice and Delinquency Prevention, the Chairman of the Federal Trade Commission, and such other Federal officials as the Secretary of Health and Human Services determines to be appropriate.

(C) CHAIR.—The Secretary of Health and Human Services shall serve as the chair of the Committee.

(D) DUTIES.—The Committee shall guide policy and program development across the Federal Government with respect to underage drinking, provided, however, that nothing in this section shall be construed as transferring regulatory or program authority from an Agency to the Coordinating Committee.

(E) CONSULTATIONS.—The Committee shall actively seek the input of and shall consult with all appropriate and interested parties, including States, public health research and interest groups, foundations, and alcohol beverage industry trade associations and companies.

(F) ANNUAL REPORT.—

(i) IN GENERAL.—The Secretary, on behalf of the Committee, shall annually submit to the Congress a report that summarizes—

(I) all programs and policies of Federal agencies designed to prevent and reduce underage drinking, focusing particularly on programs and policies that support the adoption and enforcement of State policies designed to prevent and reduce underage drinking as specified in paragraph (2);

(II) the extent of progress in preventing and reducing underage drinking at State and national levels;

(III) data that the Secretary shall collect with respect to the information specified in clause (ii); and

(IV) such other information regarding underage drinking as the Secretary determines to be appropriate.

(ii) CERTAIN INFORMATION.—The report under clause (i) shall include information on the following:

(I) Patterns and consequences of underage drinking as reported in research and surveys such as, but not limited to, Monitoring the Future, Youth Risk Behavior Surveillance System, the National Survey on Drug Use and Health, and the Fatality Analysis Reporting System.

(II) Measures of the availability of alcohol from commercial and non-commercial sources to underage populations.

(III) Measures of the exposure of underage populations to messages regarding alcohol in advertising, social media, and the entertainment media.

(IV) Surveillance data, including information on the onset and prevalence of underage drinking, consumption patterns, beverage preferences, prevalence of drinking among students at institutions of higher education, correlations between adult and youth drinking, and the means of underage access, including trends over time for these surveillance data. The Secretary shall develop a plan to improve the collection, measurement, and consistency of reporting Federal underage alcohol data.

(V) Any additional findings resulting from research conducted or supported under subsection (f).

(VI) Evidence-based best practices to prevent and reduce underage drinking including a review of the research literature related to State laws, regulations, and policies designed to prevent and reduce underage drinking, as described in paragraph (2)(B)(i).

(2) ANNUAL REPORT ON STATE UNDERAGE DRINKING PREVENTION AND ENFORCEMENT ACTIVITIES.—

(A) IN GENERAL.—The Secretary shall, with input and collaboration from other appropriate Federal agencies, States, Indian Tribes, territories, and public health, consumer, and alcohol beverage industry groups, annually issue a report on each State's performance in enacting, enforcing, and creating laws, regulations, and policies to prevent or reduce underage drinking based on an assessment of best practices developed pursuant to paragraph (1)(F)(ii)(VI) and subparagraph (B)(i). For purposes of this paragraph, each such report, with respect to a year, shall be referred to as the "State Report". Each State Report shall be designed as a resource tool for Federal agencies assisting States in the their underage drinking prevention efforts, State public health and law enforcement agencies, State and local policymakers, and underage drinking prevention coalitions including those receiving grants pursuant to subsection (e).

(B) STATE PERFORMANCE MEASURES.—

(i) IN GENERAL.—The Secretary shall develop, in consultation with the Committee, a set of measures to be used in preparing the State Report on best practices as they relate to State laws, regulations, policies, and enforcement practices.

(ii) STATE REPORT CONTENT.—The State Report shall include updates on State laws, regulations, and policies included in previous reports to Congress, including with respect to the following:

(I) Whether or not the State has comprehensive anti-underage drinking laws such as for the illegal sale, purchase, attempt to purchase, consumption, or possession of alcohol; illegal use of fraudulent ID; illegal furnishing or obtaining of alcohol for an individual under 21 years; the degree of strictness of the penalties for such offenses; and the prevalence of the enforcement of each of these infractions.

(II) Whether or not the State has comprehensive liability statutes pertaining to underage access to alcohol such as dram shop, social host, and house party laws, and the prevalence of enforcement of each of these laws.

(III) Whether or not the State encourages and conducts comprehensive enforcement efforts to prevent underage access to alcohol at retail outlets, such as random compliance checks and shoulder

tap programs, and the number of compliance checks within alcohol retail outlets measured against the number of total alcohol retail outlets in each State, and the result of such checks.

(IV) Whether or not the State encourages training on the proper selling and serving of alcohol for all sellers and servers of alcohol as a condition of employment.

(V) Whether or not the State has policies and regulations with regard to direct sales to consumers and home delivery of alcoholic beverages.

(VI) Whether or not the State has programs or laws to deter adults from purchasing alcohol for minors; and the number of adults targeted by these programs.

(VII) Whether or not the State has enacted graduated drivers licenses and the extent of those provisions.

(iii) ADDITIONAL CATEGORIES.—In addition to the updates on State laws, regulations, and policies listed in clause (ii), the Secretary shall consider the following:

(I) Whether or not States have adopted laws, regulations, and policies that deter underage alcohol use, as described in "The Surgeon General's Call to Action to Prevent and Reduce Underage Drinking" issued in 2007 and "Facing Addiction in America: The Surgeon General's Report on Alcohol, Drugs and Health" issued in 2016, including restrictions on low-price, high-volume drink specials, and wholesaler pricing provisions.

(II) Whether or not States have adopted laws, regulations, and policies designed to reduce alcohol advertising messages attractive to youth and youth exposure to alcohol advertising and marketing in measured and unmeasured media and digital and social media.

(III) Whether or not States have laws and policies that promote underage drinking prevention policy development by local jurisdictions.

(IV) Whether or not States have adopted laws, regulations, and policies to restrict youth access to alcoholic beverages that may pose special risks to youth, including but not limited to alcoholic mists, gelatins, freezer pops, premixed caffeinated alcoholic beverages, and flavored malt beverages.

(V) Whether or not States have adopted uniform best practices protocols for conducting compliance checks and shoulder tap programs.

(VI) Whether or not States have adopted uniform best practices penalty protocols for violations of laws prohibiting retail licensees from selling or furnishing of alcohol to minors.

(iv) UNIFORM DATA SYSTEM.—For performance measures related to enforcement of underage drinking laws as specified in clauses (ii) and (iii), the Secretary shall

develop and test a uniform data system for reporting State enforcement data, including the development of a pilot program for this purpose. The pilot program shall include procedures for collecting enforcement data from both State and local law enforcement jurisdictions.

(3) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this subsection $1,000,000 for each of fiscal years 2023 through 2027.

(d) NATIONAL MEDIA CAMPAIGN TO PREVENT UNDERAGE DRINKING.—

(1) IN GENERAL.—The Secretary, in consultation with the National Highway Traffic Safety Administration, shall develop an intensive, multifaceted, adult-oriented national media campaign to reduce underage drinking by influencing attitudes regarding underage drinking, increasing the willingness of adults to take actions to reduce underage drinking, and encouraging public policy changes known to decrease underage drinking rates.

(2) PURPOSE.—The purpose of the national media campaign described in this section shall be to achieve the following objectives:

(A) Instill a broad societal commitment to reduce underage drinking.

(B) Increase specific actions by adults that are meant to discourage or inhibit underage drinking.

(C) Decrease adult conduct that tends to facilitate or condone underage drinking.

(3) COMPONENTS.—When implementing the national media campaign described in this section, the Secretary shall—

(A) educate the public about the public health and safety benefits of evidence-based policies to reduce underage drinking, including minimum legal drinking age laws, and build public and parental support for and cooperation with enforcement of such policies;

(B) educate the public about the negative consequences of underage drinking;

(C) promote specific actions by adults that are meant to discourage or inhibit underage drinking, including positive behavior modeling, general parental monitoring, and consistent and appropriate discipline;

(D) discourage adult conduct that tends to facilitate underage drinking, including the hosting of underage parties with alcohol and the purchasing of alcoholic beverages on behalf of underage youth;

(E) establish collaborative relationships with local and national organizations and institutions to further the goals of the campaign and assure that the messages of the campaign are disseminated from a variety of sources;

(F) conduct the campaign through multi-media sources; and

(G) conduct the campaign with regard to changing demographics and cultural and linguistic factors.

(4) CONSULTATION REQUIREMENT.—In developing and implementing the national media campaign described in this section, the Secretary shall consult recommendations for reducing un-

derage drinking published by the National Academy of Sciences and the Surgeon General. The Secretary shall also consult with interested parties including medical, public health, and consumer and parent groups, law enforcement, institutions of higher education, community organizations and coalitions, and other stakeholders supportive of the goals of the campaign.

(5) ANNUAL REPORT.—The Secretary shall produce an annual report on the progress of the development or implementation of the media campaign described in this subsection, including expenses and projected costs, and, as such information is available, report on the effectiveness of such campaign in affecting adult attitudes toward underage drinking and adult willingness to take actions to decrease underage drinking.

(6) RESEARCH ON YOUTH-ORIENTED CAMPAIGN.—The Secretary may, based on the availability of funds, conduct research on the potential success of a youth-oriented national media campaign to reduce underage drinking. The Secretary shall report any such results to Congress with policy recommendations on establishing such a campaign.

(7) ADMINISTRATION.—The Secretary may enter into a subcontract with another Federal agency to delegate the authority for execution and administration of the adult-oriented national media campaign.

(8) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section $2,500,000 for each of fiscal years 2023 through 2027.

(e) COMMUNITY-BASED COALITION ENHANCEMENT GRANTS TO PREVENT UNDERAGE DRINKING.—

(1) AUTHORIZATION OF PROGRAM.—The Assistant Secretary for Mental Health and Substance Use, in consultation with the Director of the Office of National Drug Control Policy, shall award enhancement grants to eligible entities to design, implement, evaluate, and disseminate comprehensive strategies to maximize the effectiveness of community-wide approaches to preventing and reducing underage drinking. This subsection is subject to the availability of appropriations.

(2) PURPOSES.—The purposes of this subsection are to—

(A) prevent and reduce alcohol use among youth in communities throughout the United States;

(B) strengthen collaboration among communities, the Federal Government, Tribal Governments, and State and local governments;

(C) enhance intergovernmental cooperation and coordination on the issue of alcohol use among youth;

(D) serve as a catalyst for increased citizen participation and greater collaboration among all sectors and organizations of a community that first demonstrates a long-term commitment to reducing alcohol use among youth;

(E) implement state-of-the-art science-based strategies to prevent and reduce underage drinking by changing local conditions in communities; and

(F) enhance, not supplant, effective local community initiatives for preventing and reducing alcohol use among youth.

(3) APPLICATION.—An eligible entity desiring an enhancement grant under this subsection shall submit an application to the Assistant Secretary at such time, and in such manner, and accompanied by such information and assurances, as the Assistant Secretary may require. Each application shall include—

(A) a complete description of the entity's current underage alcohol use prevention initiatives and how the grant will appropriately enhance the focus on underage drinking issues; or

(B) a complete description of the entity's current initiatives, and how it will use this grant to enhance those initiatives by adding a focus on underage drinking prevention.

(4) USES OF FUNDS.—Each eligible entity that receives a grant under this subsection shall use the grant funds to carry out the activities described in such entity's application submitted pursuant to paragraph (3) and obtain specialized training and technical assistance by the entity funded under section 4 of Public Law 107–82, as amended (21 U.S.C. 1521 note). Grants under this subsection shall not exceed $60,000 per year and may not exceed four years.

(5) SUPPLEMENT NOT SUPPLANT.—Grant funds provided under this subsection shall be used to supplement, not supplant, Federal and non-Federal funds available for carrying out the activities described in this subsection.

(6) EVALUATION.—Grants under this subsection shall be subject to the same evaluation requirements and procedures as the evaluation requirements and procedures imposed on recipients of drug-free community grants.

(7) DEFINITIONS.—For purposes of this subsection, the term "eligible entity" means an organization that is currently receiving or has received grant funds under the Drug-Free Communities Act of 1997.

(8) ADMINISTRATIVE EXPENSES.—Not more than 6 percent of a grant under this subsection may be expended for administrative expenses.

(9) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this subsection $11,500,000 for each of fiscal years 2023 through 2027.

(f) GRANTS TO PROFESSIONAL PEDIATRIC PROVIDER ORGANIZATIONS TO REDUCE UNDERAGE DRINKING THROUGH SCREENING AND BRIEF INTERVENTIONS.—

(1) IN GENERAL.—The Secretary, acting through the Assistant Secretary for Mental Health and Substance Use, shall make one or more grants to professional pediatric provider organizations to increase among the members of such organizations effective practices to reduce the prevalence of alcohol use among individuals under the age of 21, including college students.

(2) PURPOSES.—Grants under this subsection shall be made to promote the practices of—

(A) screening adolescents for alcohol use;

(B) offering brief interventions to adolescents to discourage such use;

(C) educating parents about the dangers of and methods of discouraging such use;

(D) diagnosing and treating alcohol use disorders; and

(E) referring patients, when necessary, to other appropriate care.

(3) USE OF FUNDS.—A professional pediatric provider organization receiving a grant under this section may use the grant funding to promote the practices specified in paragraph (2) among its members by—

(A) providing training to health care providers;

(B) disseminating best practices, including culturally and linguistically appropriate best practices, and developing, printing, and distributing materials; and

(C) supporting other activities approved by the Assistant Secretary.

(4) APPLICATION.—To be eligible to receive a grant under this subsection, a professional pediatric provider organization shall submit an application to the Assistant Secretary at such time, and in such manner, and accompanied by such information and assurances as the Secretary may require. Each application shall include—

(A) a description of the pediatric provider organization;

(B) a description of the activities to be completed that will promote the practices specified in paragraph (2);

(C) a description of the organization's qualifications for performing such practices; and

(D) a timeline for the completion of such activities.

(5) DEFINITIONS.—For the purpose of this subsection:

(A) BRIEF INTERVENTION.—The term "brief intervention" means, after screening a patient, providing the patient with brief advice and other brief motivational enhancement techniques designed to increase the insight of the patient regarding the patient's alcohol use, and any realized or potential consequences of such use to effect the desired related behavioral change.

(B) ADOLESCENTS.—The term "adolescents" means individuals under 21 years of age.

(C) PROFESSIONAL PEDIATRIC PROVIDER ORGANIZATION.—The term "professional pediatric provider organization" means an organization or association that—

(i) consists of or represents pediatric health care providers; and

(ii) is qualified to promote the practices specified in paragraph (2).

(D) SCREENING.—The term "screening" means using validated patient interview techniques to identify and assess the existence and extent of alcohol use in a patient.

(6) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this subsection $3,000,000 for each of fiscal years 2023 through 2027.

(g) DATA COLLECTION AND RESEARCH.—

(1) ADDITIONAL RESEARCH ON UNDERAGE DRINKING.—

(A) IN GENERAL.—The Secretary shall, subject to the availability of appropriations, collect data, and conduct or support research that is not duplicative of research currently being conducted or supported by the Department of Health and Human Services, on underage drinking, with respect to the following:

(i) Improve data collection in support of evaluation of the effectiveness of comprehensive community-based programs or strategies and statewide systems to prevent and reduce underage drinking, across the underage years from early childhood to age 21, such as programs funded and implemented by governmental entities, public health interest groups and foundations, and alcohol beverage companies and trade associations, through the development of models of State-level epidemiological surveillance of underage drinking by funding in States or large metropolitan areas new epidemiologists focused on excessive drinking including underage alcohol use.

(ii) Obtain and report more precise information than is currently collected on the scope of the underage drinking problem and patterns of underage alcohol consumption, including improved knowledge about the problem and progress in preventing, reducing, and treating underage drinking, as well as information on the rate of exposure of youth to advertising and other media messages encouraging and discouraging alcohol consumption.

(iii) Synthesize, expand on, and widely disseminate existing research on effective strategies for reducing underage drinking, including translational research, and make this research easily accessible to the general public.

(iv) Improve and conduct public health surveillance on alcohol use and alcohol-related conditions in States by increasing the use of surveys, such as the Behavioral Risk Factor Surveillance System, to monitor binge and excessive drinking and related harms among individuals who are at least 18 years of age, but not more than 20 years of age, including harm caused to self or others as a result of alcohol use that is not duplicative of research currently being conducted or supported by the Department of Health and Human Services.

(B) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this paragraph $5,000,000 for each of fiscal years 2023 through 2027.

(2) NATIONAL ACADEMY OF SCIENCES STUDY.—

(A) IN GENERAL.—Not later than 12 months after the enactment of the Restoring Hope for Mental Health and Well-Being Act of 2022, the Secretary shall—

(i) contract with the National Academy of Sciences to study developments in research on underage drinking and the public policy implications of these developments; and

(ii) report to the Congress on the results of such review.

(B) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this paragraph $500,000 for fiscal year 2023.

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Subpart 3—Center for Mental Health Services

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SEC. 520A. PRIORITY MENTAL HEALTH NEEDS OF REGIONAL AND NATIONAL SIGNIFICANCE.

(a) PROJECTS.—The Secretary shall address priority mental health needs of regional and national significance (as determined under subsection (b)) through the provision of or through assistance for—

(1) knowledge development and application projects for prevention, treatment, and rehabilitation, and the conduct or support of evaluations of such projects;

(2) training and technical assistance programs;

(3) targeted capacity response programs; and

(4) systems change grants including statewide family network grants and client-oriented and consumer run self-help activities, which may include technical assistance centers.

The Secretary may carry out the activities described in this subsection directly or through grants, contracts, or cooperative agreements with States, political subdivisions of States, [Indian tribes or tribal organizations] *Indian Tribes or Tribal organizations* (as such terms are defined in section 4 of the Indian Self-Determination and Education Assistance Act), health facilities, or programs operated by or in accordance with a contract or grant with the Indian Health Service, or, other public or private nonprofit entities.

(b) PRIORITY MENTAL HEALTH NEEDS.—

(1) DETERMINATION OF NEEDS.—Priority mental health needs of regional and national significance shall be determined by the Secretary in consultation with States and other interested groups. The Secretary shall meet with the States and interested groups on an annual basis to discuss program priorities.

(2) SPECIAL CONSIDERATION.—In developing program priorities described in paragraph (1), the Secretary shall give special consideration to promoting the integration of mental health services into primary health care systems.

(c) REQUIREMENTS.—

(1) IN GENERAL.—Recipients of grants, contracts, and cooperative agreements under this section shall comply with information and application requirements determined appropriate by the Secretary.

(2) DURATION OF AWARD.—With respect to a grant, contract, or cooperative agreement awarded under this section, the period during which payments under such award are made to the recipient may not exceed 5 years.

(3) MATCHING FUNDS.—The Secretary may, for projects carried out under subsection (a), require that entities that apply for grants, contracts, or cooperative agreements under this section provide non-Federal matching funds, as determined appropriate by the Secretary, to ensure the institutional commitment of the entity to the projects funded under the grant, contract, or cooperative agreement. Such non-Federal matching funds may be provided directly or through donations from public or private entities and may be in cash or in kind, fairly evaluated, including plant, equipment, or services.

(4) MAINTENANCE OF EFFORT.—With respect to activities for which a grant, contract or cooperative agreement is awarded under this section, the Secretary may require that recipients for specific projects under subsection (a) agree to maintain expenditures of non-Federal amounts for such activities at a level that is not less than the level of such expenditures maintained by the entity for the fiscal year preceding the fiscal year for which the entity receives such a grant, contract, or cooperative agreement.

(d) EVALUATION.—The Secretary shall evaluate each project carried out under subsection (a)(1) and shall disseminate the findings with respect to each such evaluation to appropriate public and private entities.

(e) INFORMATION AND EDUCATION.—

(1) IN GENERAL.—The Secretary shall establish information and education programs to disseminate and apply the findings of the knowledge development and application, training, and technical assistance programs, and targeted capacity response programs, under this section to the general public, to health care professionals, and to interested groups. The Secretary shall make every effort to provide linkages between the findings of supported projects and State agencies responsible for carrying out mental health services.

(2) RURAL AND UNDERSERVED AREAS.—In disseminating information on evidence-based practices in the provision of children's mental health services under this subsection, the Secretary shall ensure that such information is distributed to rural and medically underserved areas.

(3) GERIATRIC MENTAL DISORDERS.—The Secretary shall, as appropriate, provide technical assistance to grantees regarding evidence-based practices for the prevention and treatment of geriatric mental disorders and co-occurring mental health and substance use disorders among geriatric populations, as well as disseminate information about such evidence-based practices to States and nongrantees throughout the United States.

(f) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section [$394,550,000 for each of fiscal years 2018 through 2022] *$599,036,000 for each of fiscal years 2023 through 2027*.

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SEC. 520C. SUICIDE PREVENTION TECHNICAL ASSISTANCE CENTER.

(a) PROGRAM AUTHORIZED.—The Secretary, acting through the Assistant Secretary, shall establish a research, training, and technical assistance resource center to provide appropriate information, training, and technical assistance to States, political subdivisions of States, federally recognized Indian [tribes] *Tribes*, [tribal] *Tribal* organizations, institutions of higher education, public organizations, or private nonprofit organizations regarding the prevention of suicide among all ages, particularly among groups that are at a high risk for suicide.

(b) RESPONSIBILITIES OF THE CENTER.—The center established under subsection (a) shall conduct activities for the purpose of—

(1) developing and continuing statewide or [tribal] *Tribal* suicide early intervention and prevention strategies for all

ages, particularly among groups that are at a high risk for suicide;

(2) ensuring the surveillance of suicide early intervention and prevention strategies for all ages, particularly among groups that are at a high risk for suicide;

(3) studying the costs and effectiveness of statewide and tribalsuicide early intervention and prevention strategies in order to provide information concerning relevant issues of importance to State, [tribal] *Tribal*, and national policymakers;

(4) further identifying and understanding causes and associated risk factors for suicide;

(5) analyzing the efficacy of new and existing suicide early intervention and prevention techniques and technology;

(6) ensuring the surveillance of suicidal behaviors and nonfatal suicidal attempts;

(7) studying the effectiveness of State-sponsored statewide and [tribal] *Tribal* suicide early intervention and prevention strategies on the overall wellness and health promotion strategies related to suicide attempts;

(8) promoting the sharing of data regarding suicide with Federal agencies involved with suicide early intervention and prevention, and State-sponsored statewide or [tribal] *Tribal* suicide early intervention and prevention strategies for the purpose of identifying previously unknown mental health causes and associated risk factors for suicide;

(9) evaluating and disseminating outcomes and best practices of mental health and substance use disorder services at institutions of higher education; and

(10) conducting other activities determined appropriate by the Secretary.

(c) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated [$5,988,000 for each of fiscal years 2018 through 2022] *$9,000,000 for each of fiscal years 2023 through 2027*.

(d) ANNUAL REPORT.—[Not later than 2 years after the date of enactment of this subsection] *Not later than 2 years after the date of enactment of the Restoring Hope for Mental Health and Well-Being Act of 2022*, the Secretary shall submit to Congress a report on the activities carried out by the center established under subsection (a) during the year involved, including the potential effects of such activities, and the States, organizations, and institutions that have worked with the center.

SEC. 520E. YOUTH SUICIDE EARLY INTERVENTION AND PREVENTION STRATEGIES.

(a) IN GENERAL.—The Secretary, acting through the Assistant Secretary for Mental Health and Substance Use, shall award grants or cooperative agreements to eligible entities to—

(1) develop and implement State-sponsored statewide or [tribal] *Tribal* youth suicide early intervention and prevention strategies in schools, educational institutions, juvenile justice systems, substance use disorder programs, mental health programs, foster care systems, *pediatric health programs,* and other child and youth support organizations;

(2) support public organizations and private nonprofit organizations actively involved in State-sponsored statewide or

[tribal] *Tribal* youth suicide early intervention and prevention strategies and in the development and continuation of State-sponsored statewide youth suicide early intervention and prevention strategies;

(3) provide grants to institutions of higher education to coordinate the implementation of State-sponsored statewide or [tribal] *Tribal* youth suicide early intervention and prevention strategies;

(4) collect and analyze data on State-sponsored statewide or [tribal] *Tribal* youth suicide early intervention and prevention services that can be used to monitor the effectiveness of such services and for research, technical assistance, and policy development; and

(5) assist eligible entities, through State-sponsored statewide or [tribal] *Tribal* youth suicide early intervention and prevention strategies, in achieving targets for youth suicide reductions under title V of the Social Security Act.

(b) ELIGIBLE ENTITY.—

(1) DEFINITION.—In this section, the term "eligible entity" means—

(A) a State;

[(B) a public organization or private nonprofit organization designated by a State to develop or direct the State-sponsored statewide youth suicide early intervention and prevention strategy; or]

(B) a public organization or private nonprofit organization designated by a State or Indian Tribe (as defined under the Federally Recognized Indian Tribe List Act of 1994) to develop or direct the State-sponsored statewide or Tribal youth suicide early intervention and prevention strategy; or

(C) a Federally recognized Indian [tribe] *Tribe* or [tribal] *Tribal* organization (as defined in the Indian Self-Determination and Education Assistance Act) or an urban Indian organization (as defined in the Indian Health Care Improvement Act) that is actively involved in the development and continuation of a [tribal] *Tribal* youth suicide early intervention and prevention strategy.

(2) LIMITATION.—In carrying out this section, the Secretary shall ensure that a State does not receive more than 1 grant or cooperative agreement under this section at any 1 time. For purposes of the preceding sentence, a State shall be considered to have received a grant or cooperative agreement if the eligible entity involved is the State or an entity designated by the State under paragraph (1)(B). Nothing in this paragraph shall be construed to apply to entities described in paragraph (1)(C).

(3) CONSIDERATION.—In awarding grants under this section, the Secretary shall take into consideration the extent of the need of the applicant, including the incidence and prevalence of suicide in the State and among the populations of focus, including rates of suicide determined by the Centers for Disease Control and Prevention for the State or population of focus.

(4) CONSULTATION.—An entity described in paragraph (1)(A) or (1)(B) that applies for a grant or cooperative agreement under this section shall agree to consult or confer with entities

described in paragraph (1)(C) and Native Hawaiian Health Care Systems, as applicable, in the applicable State with respect to the development and implementation of a statewide early intervention strategy.

(c) PREFERENCE.—In providing assistance under a grant or cooperative agreement under this section, an eligible entity shall give preference to public organizations, private nonprofit organizations, political subdivisions, institutions of higher education, and [tribal] *Tribal* organizations actively involved with the State-sponsored statewide or [tribal] *Tribal* youth suicide early intervention and prevention strategy that—

(1) provide early intervention and assessment services, including screening programs, to youth who are at risk for mental or emotional disorders that may lead to a suicide attempt, and that are integrated with school systems, educational institutions, juvenile justice systems, substance use disorder programs, mental health programs, foster care systems, *pediatric health programs,* and other child and youth support organizations;

(2) demonstrate collaboration among early intervention and prevention services or certify that entities will engage in future collaboration;

(3) employ or include in their applications a commitment to evaluate youth suicide early intervention and prevention practices and strategies adapted to the local community;

(4) provide timely referrals for appropriate community-based mental health care and treatment of youth who are at risk for suicide in child-serving settings and agencies;

(5) provide immediate support and information resources to families of youth who are at risk for suicide;

(6) offer access to services and care to youth with diverse linguistic and cultural backgrounds;

(7) offer appropriate postsuicide intervention services, care, and information to families, friends, schools, educational institutions, juvenile justice systems, substance use disorder programs, mental health programs, foster care systems, *pediatric health programs,* and other child and youth support organizations of youth who recently completed suicide;

(8) offer continuous and up-to-date information and awareness campaigns that target parents, family members, child care professionals, community care providers, and the general public and highlight the risk factors associated with youth suicide and the life-saving help and care available from early intervention and prevention services;

(9) ensure that information and awareness campaigns on youth suicide risk factors, and early intervention and prevention services, use effective communication mechanisms that are targeted to and reach youth, families, schools, educational institutions, *pediatric health programs,* and youth organizations;

(10) provide a timely response system to ensure that child-serving professionals and providers are properly trained in youth suicide early intervention and prevention strategies and that child-serving professionals and providers involved in early intervention and prevention services are properly trained in effectively identifying youth who are at risk for suicide;

(11) provide continuous training activities for child care professionals and community care providers on the latest youth suicide early intervention and prevention services practices and strategies;

(12) conduct annual self-evaluations of outcomes and activities, including consulting with interested families and advocacy organizations;

(13) provide services in areas or regions with rates of youth suicide that exceed the national average as determined by the Centers for Disease Control and Prevention; [and]

(14) obtain informed written consent from a parent or legal guardian of an at-risk child before involving the child in a youth suicide early intervention and prevention program[.]*; and*

(15) provide to parents, legal guardians, and family members of youth, supplies to securely store means commonly used in suicide, if applicable, within the household.

(d) REQUIREMENT FOR [DIRECT SERVICES] *SUICIDE PREVENTION ACTIVITIES*.—Not less than 85 percent of grant funds received under this section shall be used to provide [direct services, of which not less than 5 percent shall be used for activities authorized under subsection (a)(3)] *suicide prevention activities*.

(e) COORDINATION AND COLLABORATION.—

(1) IN GENERAL.—In carrying out this section, the Secretary shall collaborate with relevant Federal agencies and suicide working groups responsible for early intervention and prevention services relating to youth suicide.

(2) CONSULTATION.—In carrying out this section, the Secretary shall consult with—

(A) State and local agencies, including agencies responsible for early intervention and prevention services under title XIX of the Social Security Act, the State Children's Health Insurance Program under title XXI of the Social Security Act, and programs funded by grants under title V of the Social Security Act;

(B) local and national organizations that serve youth at risk for suicide and their families;

(C) relevant national medical and other health and education specialty organizations;

(D) youth who are at risk for suicide, who have survived suicide attempts, or who are currently receiving care from early intervention services;

(E) families and friends of youth who are at risk for suicide, who have survived suicide attempts, who are currently receiving care from early intervention and prevention services, or who have completed suicide;

(F) qualified professionals who possess the specialized knowledge, skills, experience, and relevant attributes needed to serve youth at risk for suicide and their families; and

(G) third-party payers, managed care organizations, and related commercial industries.

(3) POLICY DEVELOPMENT.—In carrying out this section, the Secretary shall—

(A) coordinate and collaborate on policy development at the Federal level with the relevant Department of Health and Human Services *and Department of Education* agencies and suicide working groups; and

(B) consult on policy development at the Federal level with the private sector, including consumer, medical, suicide prevention advocacy groups, and other health and education professional-based organizations, with respect to State-sponsored statewide or [tribal] *Tribal* youth suicide early intervention and prevention strategies.

(f) RULE OF CONSTRUCTION; RELIGIOUS AND MORAL ACCOMMODATION.—Nothing in this section shall be construed to require suicide assessment, early intervention, or treatment services for youth whose parents or legal guardians object based on the parents' or legal guardians' religious beliefs or moral objections.

(g) EVALUATIONS AND REPORT.—

(1) EVALUATIONS BY ELIGIBLE ENTITIES.—Not later than [18] *24* months after receiving a grant or cooperative agreement under this section, an eligible entity shall submit to the Secretary the results of an evaluation to be conducted by the entity concerning the effectiveness of the activities carried out under the grant or agreement.

(2) REPORT.—Not later than [2 years after the date of enactment of Helping Families in Mental Health Crisis Reform Act of 2016] *3 years after December 31, 2022*, the Secretary shall submit to the appropriate committees of Congress a report concerning the results of—

(A) the evaluations conducted under paragraph (1); and

(B) an evaluation conducted by the Secretary to analyze the effectiveness and efficacy of the activities conducted with grants, collaborations, and consultations under this section.

(h) RULE OF CONSTRUCTION; STUDENT MEDICATION.—Nothing in this section or section 520E–1 shall be construed to allow school personnel to require that a student obtain any medication as a condition of attending school or receiving services.

(i) PROHIBITION.—Funds appropriated to carry out this section, section 520C, section 520E–1, or section 520E–2 shall not be used to pay for or refer for abortion.

(j) PARENTAL CONSENT.—States and entities receiving funding under this section and section 520E–1 shall obtain prior written, informed consent from the child's parent or legal guardian for assessment services, school-sponsored programs, and treatment involving medication related to youth suicide conducted in elementary and secondary schools. The requirement of the preceding sentence does not apply in the following cases:

(1) In an emergency, where it is necessary to protect the immediate health and safety of the student or other students.

(2) Other instances, as defined by the State, where parental consent cannot reasonably be obtained.

(k) RELATION TO EDUCATION PROVISIONS.—Nothing in this section or section 520E–1 shall be construed to supersede section 444 of the General Education Provisions Act, including the requirement of prior parental consent for the disclosure of any education records. Nothing in this section or section 520E–1 shall be con-

strued to modify or affect parental notification requirements for programs authorized under the Elementary and Secondary Education Act of 1965 (as amended by the No Child Left Behind Act of 2001; Public Law 107–110).

(l) DEFINITIONS.—In this section:

(1) EARLY INTERVENTION.—The term "early intervention" means a strategy or approach that is intended to prevent an outcome or to alter the course of an existing condition.

(2) EDUCATIONAL INSTITUTION; INSTITUTION OF HIGHER EDUCATION; SCHOOL.—The term—

(A) "educational institution" means a school or institution of higher education;

(B) "institution of higher education" has the meaning given such term in section 101 of the Higher Education Act of 1965; and

(C) "school" means an elementary school or secondary school (as such terms are defined in section 8101 of the Elementary and Secondary Education Act of 1965).

(3) PREVENTION.—The term "prevention" means a strategy or approach that reduces the likelihood or risk of onset, or delays the onset, of adverse health problems that have been known to lead to suicide.

(4) YOUTH.—The term "youth" means individuals who are [between 10 and 24 years of age] *up to 24 years of age*.

(m) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated [$30,000,000 for each of fiscal years 2018 through 2022] *$40,000,000 for each of fiscal years 2023 through 2027*.

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SEC. 520E–2. MENTAL HEALTH AND SUBSTANCE USE DISORDER SERVICES [ON CAMPUS] *FOR STUDENTS IN HIGHER EDUCATION*.

(a) IN GENERAL.—The Secretary, acting through the Director of the Center for Mental Health Services and in consultation with the Secretary of Education, may award grants on a competitive basis to institutions of higher education to enhance services for students with mental health or substance use disorders that can lead to school failure, such as depression, substance use disorders, and suicide attempts, prevent mental and substance use disorders, reduce stigma, and improve the identification and treatment for students at risk, so that students will successfully complete their studies.

(b) USE OF FUNDS.—The Secretary may not make a grant to an institution of higher education under this section unless the institution agrees to use the grant only for one or more of the following:

(1) Educating students, families, faculty, and staff to increase awareness of mental and substance use disorders.

(2) The operation of hotlines.

(3) Preparing informational material.

(4) Providing outreach services to notify students about available mental and substance use disorder services.

(5) Administering voluntary mental and substance use disorder screenings and assessments.

(6) Supporting the training of students, faculty, and staff to respond effectively to students with mental and substance use disorders.

(7) Creating a network infrastructure to link institutions of higher education with health care providers who treat mental and substance use disorders.

(8) Providing mental and substance use disorders prevention and treatment services to students, which may include recovery support services and programming and early intervention, treatment, and management, including through the use of telehealth services.

(9) Conducting research through a counseling or health center at the institution of higher education involved regarding improving the behavioral health of students through clinical services, outreach, prevention, or academic success, in a manner that is in compliance with all applicable personal privacy laws.

(10) Supporting student groups on campus, including athletic teams, that engage in activities to educate students, including activities to reduce stigma surrounding mental and behavioral disorders, and promote mental health.

(11) Employing appropriately trained staff.

(12) Developing and supporting evidence-based and emerging best practices, including a focus on culturally and linguistically appropriate best practices.

(c) ELIGIBLE GRANT RECIPIENTS.—Any institution of higher education receiving a grant under this section may carry out activities under the grant through—

(1) college counseling centers;

(2) college and university psychological service centers;

(3) mental health centers;

(4) psychology training clinics; or

(5) institution of higher education supported, evidence-based, mental health and substance use disorder programs.

(d) APPLICATION.—To be eligible to receive a grant under this section, an institution of higher education shall prepare and submit an application to the Secretary at such time and in such manner as the Secretary may require. At a minimum, the application shall include the following:

(1) A description of the population to be targeted by the program carried out under the grant, including veterans whenever possible and appropriate, and of identified mental and substance use disorder needs of students at the institution of higher education.

(2) A description of Federal, State, local, private, and institutional resources currently available to address the needs described in paragraph (1) at the institution of higher education, which may include, as appropriate and in accordance with subsection (b)(7), a plan to seek input from relevant stakeholders in the community, including appropriate public and private entities, in order to carry out the program under the grant.

(3) A description of the outreach strategies of the institution of higher education for promoting access to services, including a proposed plan for reaching those students most in need of mental health services.

(4) A plan to evaluate program outcomes, including a description of the proposed use of funds, the program objectives, and how the objectives will be met.

(5) An assurance that the institution will submit a report to the Secretary each fiscal year on the activities carried out with the grant and the results achieved through those activities.

(6) An outline of the objectives of the program carried out under the grant.

(7) For an institution of higher education proposing to use the grant for an activity described in paragraph (8) or (9) of subsection (b), a description of the policies and procedures of the institution of higher education that are related to applicable laws regarding access to, and sharing of, treatment records of students at any campus-based mental health center or partner organization, including the policies and State laws governing when such records can be accessed and shared for non-treatment purposes and a description of the process used by the institution of higher education to notify students of these policies and procedures, including the extent to which written consent is required.

(8) An assurance that grant funds will be used to supplement and not supplant any other Federal, State, or local funds available to carry out activities of the type carried out under the grant.

(e) REQUIREMENT OF MATCHING FUNDS.—

(1) IN GENERAL.—The Secretary may make a grant under this section to an institution of higher education only if the institution agrees to make available (directly or through donations from public or private entities) non-Federal contributions in an amount that is not less than $1 for each $1 of Federal funds provided in the grant, toward the costs of activities carried out with the grant (as described in subsection (b)) and other activities by the institution to reduce student mental health and substance use disorders.

(2) DETERMINATION OF AMOUNT CONTRIBUTED.—Non-Federal contributions required under paragraph (1) may be in cash or in kind. Amounts provided by the Federal Government, or services assisted or subsidized to any significant extent by the Federal Government, may not be included in determining the amount of such non-Federal contributions.

(3) WAIVER.—The Secretary may waive the requirement established in paragraph (1) with respect to an institution of higher education if the Secretary determines that extraordinary need at the institution justifies the waiver.

(f) REPORTS.—For each fiscal year that grants are awarded under this section, the Secretary shall conduct a study on the results of the grants and submit to the Congress a report on such results that includes the following:

(1) An evaluation of the grant program outcomes, including a summary of activities carried out with the grant and the results achieved through those activities.

(2) Recommendations on how to improve access to mental health and substance use disorder services at institutions of higher education, including efforts to reduce the incidence of suicide and substance use disorders.

(g) DEFINITION.—In this section, the term "institution of higher education" has the meaning given such term in section 101 of the Higher Education Act of 1965.

(h) TECHNICAL ASSISTANCE.—The Secretary may provide technical assistance to grantees in carrying out this section.

(i) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated $7,000,000 for each of fiscal years [2018 through 2022] *2023 through 2027*.

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SEC. 520E–4. TREATMENT REFERRAL ROUTING SERVICE.

(a) IN GENERAL.—The Secretary, acting through the Assistant Secretary, shall maintain the National Treatment Referral Routing Service (referred to in this section as the "Routing Service") to assist individuals and families in locating mental and substance use disorders treatment providers.

(b) ACTIVITIES OF THE SECRETARY.—To maintain the Routing Service, the activities of the Assistant Secretary shall include administering—

(1) a nationwide, telephone number providing year-round access to information that is updated on a regular basis regarding local behavioral health providers and community-based organizations in a manner that is confidential, without requiring individuals to identify themselves, is in languages that include at least English and Spanish, and is at no cost to the individual using the Routing Service; and

(2) an Internet website to provide a searchable, online treatment services locator of behavioral health treatment providers and community-based organizations, which shall include information on the name, location, contact information, and basic services provided by such providers and organizations.

(c) REMOVING PRACTITIONER CONTACT INFORMATION.—In the event that the Internet website described in subsection (b)(2) contains [information on any qualified practitioner that is certified to prescribe medication for opioid dependency under section 303(g)(2)(B) of the Controlled Substances Act] *information on any practitioner who prescribes narcotic drugs in schedule III, IV, or V of section 202 of the Controlled Substances Act for the purpose of maintenance or detoxification treatment*, the Assistant Secretary—

(1) shall provide an opportunity to such practitioner to have the contact information of the practitioner removed from the website at the request of the practitioner; and

(2) may evaluate other methods to periodically update the information displayed on such website.

(d) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to prevent the Assistant Secretary from using any unobligated amounts otherwise made available to the Administration to maintain the Routing Service.

[SEC. 520F. STRENGTHENING COMMUNITY CRISIS RESPONSE SYSTEMS.

[(a) IN GENERAL.—The Secretary shall award competitive grants to—

[(1) State and local governments and Indian tribes and tribal organizations, to enhance community-based crisis response systems; or

[(2) States to develop, maintain, or enhance a database of beds at inpatient psychiatric facilities, crisis stabilization units,

and residential community mental health and residential substance use disorder treatment facilities, for adults with a serious mental illness, children with a serious emotional disturbance, or individuals with a substance use disorder.

[(b) APPLICATIONS.—

[(1) IN GENERAL.—To receive a grant under subsection (a), an entity shall submit to the Secretary an application, at such time, in such manner, and containing such information as the Secretary may require.

[(2) COMMUNITY-BASED CRISIS RESPONSE PLAN.—An application for a grant under subsection (a)(1) shall include a plan for—

[(A) promoting integration and coordination between local public and private entities engaged in crisis response, including first responders, emergency health care providers, primary care providers, law enforcement, court systems, health care payers, social service providers, and behavioral health providers;

[(B) developing memoranda of understanding with public and private entities to implement crisis response services;

[(C) addressing gaps in community resources for crisis intervention and prevention; and

[(D) developing models for minimizing hospital readmissions, including through appropriate discharge planning.

[(3) BEDS DATABASE PLAN.—An application for a grant under subsection (a)(2) shall include a plan for developing, maintaining, or enhancing a real-time, Internet-based bed database to collect, aggregate, and display information about beds in inpatient psychiatric facilities and crisis stabilization units, and residential community mental health and residential substance use disorder treatment facilities to facilitate the identification and designation of facilities for the temporary treatment of individuals in mental or substance use disorder crisis.

[(c) DATABASE REQUIREMENTS.—A bed database described in this section is a database that—

[(1) includes information on inpatient psychiatric facilities, crisis stabilization units, and residential community mental health and residential substance use disorder facilities in the State involved, including contact information for the facility or unit;

[(2) provides real-time information about the number of beds available at each facility or unit and, for each available bed, the type of patient that may be admitted, the level of security provided, and any other information that may be necessary to allow for the proper identification of appropriate facilities for treatment of individuals in mental or substance use disorder crisis; and

[(3) enables searches of the database to identify available beds that are appropriate for the treatment of individuals in mental or substance use disorder crisis.

[(d) EVALUATION.—An entity receiving a grant under subsection (a)(1) shall submit to the Secretary, at such time, in such manner, and containing such information as the Secretary may reasonably

require, a report, including an evaluation of the effect of such grant on—

[(1) local crisis response services and measures for individuals receiving crisis planning and early intervention supports;

[(2) individuals reporting improved functional outcomes; and

[(3) individuals receiving regular followup care following a crisis.

[(e) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section, $12,500,000 for the period of fiscal years 2018 through 2022.]

SEC. 520F. MENTAL HEALTH CRISIS RESPONSE PARTNERSHIP PILOT PROGRAM.

(a) IN GENERAL.—The Secretary shall establish a pilot program under which the Secretary will award competitive grants to States, localities, territories, Indian Tribes, and Tribal organizations to establish new, or enhance existing, mobile crisis response teams that divert the response for mental health and substance use crises from law enforcement to mobile crisis teams, as described in subsection (b).

(b) MOBILE CRISIS TEAMS DESCRIBED.—A mobile crisis team described in this subsection is a team of individuals—

(1) that is available to respond to individuals in crisis and provide immediate stabilization, referrals to community-based mental health and substance use disorder services and supports, and triage to a higher level of care if medically necessary;

(2) which may include licensed counselors, clinical social workers, physicians, paramedics, crisis workers, peer support specialists, or other qualified individuals; and

(3) which may provide support to divert behavioral health crisis calls from the 9–1–1 system to the 9–8–8 system.

(c) PRIORITY.—In awarding grants under this section, the Secretary shall prioritize applications which account for the specific needs of the communities to be served, including children and families, veterans, rural and underserved populations, and other groups at increased risk of death from suicide or overdose.

(d) REPORT.—

(1) INITIAL REPORT.—Not later than September 30, 2024, the Secretary shall submit to Congress a report on steps taken by the entities specified in subsection (a) as of such date of enactment to strengthen the partnerships among mental health providers, substance use disorder treatment providers, primary care physicians, mental health and substance use crisis teams, paramedics, law enforcement officers, and other first responders.

(2) PROGRESS REPORTS.—Not later than one year after the date on which the first grant is awarded to carry out this section, and for each year thereafter, the Secretary shall submit to Congress a report on the grants made during the year covered by the report, which shall include—

(A) impact data on the teams and people served by such programs, including demographic information of individuals served, volume, and types of service utilization;

(B) outcomes of the number of linkages to community-based resources, short-term crisis receiving and stabiliza-

tion facilities, and diversion from law enforcement or hospital emergency department settings;

(C) data consistent with the State block grant requirements for continuous evaluation and quality improvement, and other relevant data as determined by the Secretary; and

(D) the Secretary's recommendations and best practices for—

(i) States and localities providing mobile crisis response and stabilization services for youth and adults; and

(ii) improvements to the program established under this section.

(e) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section, $10,000,000 for each of fiscal years 2023 through 2027.

SEC. 520G. GRANTS FOR JAIL DIVERSION PROGRAMS.

(a) PROGRAM AUTHORIZED.—The Secretary shall make [up to 125] grants to States, political subdivisions of States, and Indian [tribes and tribal organizations] *Tribes and Tribal organizations* (as the terms "Indian tribes" and "tribal organizations" are defined in section 4 of the Indian Self-Determination and Education Assistance Act), acting directly or through agreements with other public or nonprofit entities, or a health facility or program operated by or in accordance with a contract or grant with the Indian Health Service, to develop and implement programs to divert individuals with a mental illness from the criminal justice system to community-based services.

(b) ADMINISTRATION.—

(1) CONSULTATION.—The Secretary shall consult with the Attorney General and any other appropriate officials in carrying out this section.

(2) REGULATORY AUTHORITY.—The Secretary shall issue regulations and guidelines necessary to carry out this section, including methodologies and outcome measures for evaluating programs carried out by States, political subdivisions of States, Indian [tribes, and tribal organizations] *Tribes, and Tribal organizations* receiving grants under subsection (a).

(c) APPLICATIONS.—

(1) IN GENERAL.—To receive a grant under subsection (a), the chief executive of a State, chief executive of a subdivision of a State, Indian [tribe or tribal organization] *Tribe or Tribal organization, health facility or program described in subsection (a), or public or nonprofit entity referred to in subsection (a)* shall prepare and submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary shall reasonably require.

(2) CONTENT.—Such application shall—

(A) contain an assurance that—

(i) community-based mental health services will be available for the individuals who are diverted from the criminal justice system, and that such services are based on evidence-based practices, reflect current research findings, include case management, assertive community treatment, medication management and

access, integrated mental health and co-occurring substance use disorder treatment, and psychiatric rehabilitation, and will be coordinated with social services, including life skills training, housing placement, vocational training, education job placement, and health care;

(ii) there has been relevant interagency collaboration between the appropriate criminal justice, mental health, and substance use disorder systems; and

(iii) the Federal support provided will be used to supplement, and not supplant, State, local, Indian [tribe, or tribal organization] *Tribe, or Tribal organization* sources of funding that would otherwise be available;

(B) demonstrate that the diversion program will be integrated with an existing system of care for those with mental illness;

(C) explain the applicant's inability to fund the program adequately without Federal assistance;

(D) specify plans for obtaining necessary support and continuing the proposed program following the conclusion of Federal support; and

(E) describe methodology and outcome measures that will be used in evaluating the program.

(d) SPECIAL CONSIDERATION REGARDING VETERANS.—In awarding grants under subsection (a), the Secretary shall, as appropriate, give special consideration to entities proposing to use grant funding to support jail diversion services for veterans.

(e) USE OF FUNDS.—A State, political subdivision of a State, Indian [tribe, or tribal organization] *Tribe, or Tribal organization* that receives a grant under subsection (a) may use funds received under such grant to—

(1) integrate the diversion program into the existing system of care;

(2) create or expand community-based mental health and co-occurring mental illness and substance use disorder services to accommodate the diversion program;

(3) train professionals involved in the system of care, and law enforcement officers, attorneys, and judges;

(4) provide community outreach and crisis intervention; and

(5) develop programs to divert individuals prior to booking [or arrest]*, arrest, or release*.

(f) FEDERAL SHARE.—

(1) IN GENERAL.—The Secretary shall pay to a State, political subdivision of a State, Indian [tribe, or tribal organization] *Tribe, or Tribal organization* receiving a grant under subsection (a) the Federal share of the cost of activities described in the application.

(2) FEDERAL SHARE.—The Federal share of a grant made under this section shall not exceed 75 percent of the total cost of the program carried out by the State, political subdivision of a State, Indian [tribe, or tribal organization] *Tribe, or Tribal organization*. Such share shall be used for new expenses of the program carried out by such State, political subdivision of

a State, Indian [tribe, or tribal organization] *Tribe, or Tribal organization*.

(3) NON-FEDERAL SHARE.—The non-Federal share of payments made under this section may be made in cash or in kind fairly evaluated, including planned equipment or services. The Secretary may waive the requirement of matching contributions.

(g) GEOGRAPHIC DISTRIBUTION.—The Secretary shall ensure that such grants awarded under subsection (a) are equitably distributed among the geographical regions of the United States and between urban and rural populations.

(h) TRAINING AND TECHNICAL ASSISTANCE.—Training and technical assistance may be provided by the Secretary to assist a State, political subdivision of a State, Indian [tribe, or tribal organization] *Tribe, or Tribal organization* receiving a grant under subsection (a) in establishing and operating a diversion program.

(i) EVALUATIONS.—The programs described in subsection (a) shall be evaluated not less than one time in every 12-month period using the methodology and outcome measures identified in the grant application.

(j) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section [$4,269,000 for each of fiscal years 2018 through 2022] *$14,000,000 for each of fiscal years 2023 through 2027*.

SEC. 520H. PEER-SUPPORTED MENTAL HEALTH SERVICES.

(a) GRANTS AUTHORIZED.—The Secretary, acting through the Director of the Center for Mental Health Services, shall award grants to eligible entities to enable such entities to develop, expand, and enhance access to mental health peer-delivered services.

(b) USE OF FUNDS.—Grants awarded under subsection (a) shall be used to develop, expand, and enhance national, statewide, or community-focused programs, including virtual peer-support services and infrastructure, including by—

(1) carrying out workforce development, recruitment, and retention activities, to train, recruit, and retain peer-support providers;

(2) building connections between mental health treatment programs, including between community organizations and peer-support networks, including virtual peer-support networks, and with other mental health support services;

(3) reducing stigma associated with mental health disorders;

(4) expanding and improving virtual peer mental health support services, including adoption of technologies to expand access to virtual peer mental health support services, including by acquiring—

(A) appropriate physical hardware for such virtual services;

(B) software and programs to efficiently run peer-support services virtually; and

(C) other technology for establishing virtual waiting rooms and virtual video platforms for meetings; and

(5) conducting research on issues relating to mental illness and the impact peer-support has on resiliency, including identifying—

(A) the signs of mental illness;

(B) the resources available to individuals with mental illness and to their families; and

(C) the resources available to help support individuals living with mental illness.

(c) SPECIAL CONSIDERATION.—In carrying out this section, the Secretary shall give special consideration to the unique needs of rural areas.

(d) DEFINITION.—In this section, the term "eligible entity" means—

(1) a nonprofit consumer-run organization that—

(A) is principally governed by people living with a mental health condition; and

(B) mobilizes resources within and outside of the mental health community, which may include through peer-support networks, to increase the prevalence and quality of long-term wellness of individuals living with a mental health condition, including those with a co-occurring substance use disorder; or

(2) a Federally recognized Tribe, Tribal organization, Urban Indian organization, or consortium of Tribes or Tribal organizations.

(e) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section $13,000,000 for each of fiscal years 2023 through 2027.

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SEC. 520J. MENTAL HEALTH AWARENESS TRAINING GRANTS.

(a) IN GENERAL.—The Secretary shall award grants in accordance with the provisions of this section.

(b) MENTAL HEALTH AWARENESS TRAINING GRANTS.—

(1) IN GENERAL.—The Secretary shall award grants to States, political subdivisions of States, [Indian tribes, tribal organizations] *Indian Tribes, Tribal organizations*, and nonprofit private entities to train teachers and other relevant school personnel to recognize symptoms of childhood and adolescent mental disorders, to refer family members to the appropriate mental health services if necessary, to train emergency services personnel veterans, law enforcement, and other categories of individuals, as determined by the Secretary, to identify and appropriately respond to persons with a mental illness, and to provide education to such teachers and personnel regarding resources that are available in the community for individuals with a mental illness.

(2) [EMERGENCY SERVICES PERSONNEL] *EMERGENCY SERVICES PERSONNEL*.—In this subsection, the term "emergency services personnel" includes paramedics, firefighters, and emergency medical technicians.

(3) [DISTRIBUTION OF AWARDS] *DISTRIBUTION OF AWARDS*.—The Secretary shall ensure that such grants awarded under this subsection are equitably distributed among the geographical regions of the United States and between urban and rural populations.

(4) APPLICATION.—A State, political subdivision of a State, [Indian tribe, tribal organization] *Indian Tribe, Tribal organization*, or nonprofit private entity that desires a grant under

this subsection shall submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may require, including a plan for the rigorous evaluation of activities that are carried out with funds received under a grant under this subsection.

(5) USE OF FUNDS.—A State, political subdivision of a State, [Indian tribe, tribal organization] *Indian Tribe, Tribal organization*, or nonprofit private entity receiving a grant under this subsection shall use funds from such grant for evidence-based programs that provide training and education in accordance with paragraph (1) on matters including—

(A) recognizing the signs and symptoms of mental illness; [and]

(B)(i) resources available in the community for individuals with a mental illness and other relevant resources; or

(ii) safely de-escalating crisis situations involving individuals with a mental illness[.]*; and*

(C) suicide intervention and prevention, including recognizing warning signs and how to refer someone for help.

(6) EVALUATION.—A State, political subdivision of a State, [Indian tribe, tribal organization] *Indian Tribe, Tribal organization*, or nonprofit private entity that receives a grant under this subsection shall prepare and submit an evaluation to the Secretary at such time, in such manner, and containing such information as the Secretary may reasonably require, including an evaluation of activities carried out with funds received under the grant under this subsection and a process and outcome evaluation.

(7) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this subsection [$14,693,000 for each of fiscal years 2018 through 2022] *$24,963,000 for each of fiscal years 2023 through 2027*.

[SEC. 520K. INTEGRATION INCENTIVE GRANTS AND COOPERATIVE AGREEMENTS.

[(a) DEFINITIONS.—In this section:

[(1) ELIGIBLE ENTITY.—The term "eligible entity" means a State, or other appropriate State agency, in collaboration with 1 or more qualified community programs as described in section 1913(b)(1) or 1 or more community health centers as described in section 330.

[(2) INTEGRATED CARE.—The term "integrated care" means collaborative models or practices offering mental and physical health services, which may include practices that share the same space in the same facility.

[(3) SPECIAL POPULATION.—The term "special population" means—

[(A) adults with a mental illness who have co-occurring physical health conditions or chronic diseases;

[(B) adults with a serious mental illness who have co-occurring physical health conditions or chronic diseases;

[(C) children and adolescents with a serious emotional disturbance with co-occurring physical health conditions or chronic diseases; or

[(D) individuals with a substance use disorder.

[(b) GRANTS AND COOPERATIVE AGREEMENTS.—

[(1) IN GENERAL.—The Secretary may award grants and cooperative agreements to eligible entities to support the improvement of integrated care for primary care and behavioral health care in accordance with paragraph (2).

[(2) PURPOSES.—A grant or cooperative agreement awarded under this section shall be designed to—

[(A) promote full integration and collaboration in clinical practices between primary and behavioral health care;

[(B) support the improvement of integrated care models for primary care and behavioral health care to improve the overall wellness and physical health status of adults with a serious mental illness or children with a serious emotional disturbance; and

[(C) promote integrated care services related to screening, diagnosis, prevention, and treatment of mental and substance use disorders, and co-occurring physical health conditions and chronic diseases.

[(c) APPLICATIONS.—

[(1) IN GENERAL.—An eligible entity seeking a grant or cooperative agreement under this section shall submit an application to the Secretary at such time, in such manner, and accompanied by such information as the Secretary may require, including the contents described in paragraph (2).

[(2) CONTENTS.—The contents described in this paragraph are—

[(A) a description of a plan to achieve fully collaborative agreements to provide services to special populations;

[(B) a document that summarizes the policies, if any, that serve as barriers to the provision of integrated care, and the specific steps, if applicable, that will be taken to address such barriers;

[(C) a description of partnerships or other arrangements with local health care providers to provide services to special populations;

[(D) an agreement and plan to report to the Secretary performance measures necessary to evaluate patient outcomes and facilitate evaluations across participating projects; and

[(E) a plan for sustainability beyond the grant or cooperative agreement period under subsection (e).

[(d) GRANT AND COOPERATIVE AGREEMENT AMOUNTS.—

[(1) TARGET AMOUNT.—The target amount that an eligible entity may receive for a year through a grant or cooperative agreement under this section shall be $2,000,000.

[(2) ADJUSTMENT PERMITTED.—The Secretary, taking into consideration the quality of the application and the number of eligible entities that received grants under this section prior to the date of enactment of the Helping Families in Mental Health Crisis Reform Act of 2016, may adjust the target amount that an eligible entity may receive for a year through a grant or cooperative agreement under this section.

[(3) LIMITATION.—An eligible entity receiving funding under this section may not allocate more than 10 percent of funds awarded under this section to administrative functions, and

the remaining amounts shall be allocated to health facilities that provide integrated care.

[(e) DURATION.—A grant or cooperative agreement under this section shall be for a period not to exceed 5 years.

[(f) REPORT ON PROGRAM OUTCOMES.—An eligible entity receiving a grant or cooperative agreement under this section shall submit an annual report to the Secretary that includes—

[(1) the progress made to reduce barriers to integrated care as described in the entity's application under subsection (c); and

[(2) a description of functional outcomes of special populations, including—

[(A) with respect to adults with a serious mental illness, participation in supportive housing or independent living programs, attendance in social and rehabilitative programs, participation in job training opportunities, satisfactory performance in work settings, attendance at scheduled medical and mental health appointments, and compliance with prescribed medication regimes;

[(B) with respect to individuals with co-occurring mental illness and physical health conditions and chronic diseases, attendance at scheduled medical and mental health appointments, compliance with prescribed medication regimes, and participation in learning opportunities related to improved health and lifestyle practices; and

[(C) with respect to children and adolescents with a serious emotional disturbance who have co-occurring physical health conditions and chronic diseases, attendance at scheduled medical and mental health appointments, compliance with prescribed medication regimes, and participation in learning opportunities at school and extracurricular activities.

[(g) TECHNICAL ASSISTANCE FOR PRIMARY-BEHAVIORAL HEALTH CARE INTEGRATION.—

[(1) IN GENERAL.—The Secretary may provide appropriate information, training, and technical assistance to eligible entities that receive a grant or cooperative agreement under this section, in order to help such entities meet the requirements of this section, including assistance with—

[(A) development and selection of integrated care models;

[(B) dissemination of evidence-based interventions in integrated care;

[(C) establishment of organizational practices to support operational and administrative success; and

[(D) other activities, as the Secretary determines appropriate.

[(2) ADDITIONAL DISSEMINATION OF TECHNICAL INFORMATION.—The information and resources provided by the Secretary under paragraph (1) shall, as appropriate, be made available to States, political subdivisions of States, Indian tribes or tribal organizations (as defined in section 4 of the Indian Self-Determination and Education Assistance Act), outpatient mental health and addiction treatment centers, community mental health centers that meet the criteria under sec-

tion 1913(c), certified community behavioral health clinics described in section 223 of the Protecting Access to Medicare Act of 2014, primary care organizations such as Federally qualified health centers or rural health clinics as defined in section 1861(aa) of the Social Security Act, other community-based organizations, or other entities engaging in integrated care activities, as the Secretary determines appropriate.

[(h) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated $51,878,000 for each of fiscal years 2018 through 2022.]

SEC. 520K. INTEGRATION INCENTIVE GRANTS AND COOPERATIVE AGREEMENTS.

(a) DEFINITIONS.—In this section:

(1) COLLABORATIVE CARE MODEL.—The term "collaborative care model" means the evidence-based, integrated behavioral health service delivery method that includes—

(A) care directed by the primary care team;

(B) structured care management;

(C) regular assessments of clinical status using developmentally appropriate, validated tools; and

(D) modification of treatment as appropriate.

(2) ELIGIBLE ENTITY.—The term "eligible entity" means a State, or an appropriate State agency, in collaboration with—

(A) 1 or more qualified community programs as described in section 1913(b)(1);

(B) 1 or more health centers (as defined in section 330(a)), a rural health clinic (as defined in section 1961(aa) of the Social Security Act), or a Federally qualified health center (as defined in such section); or

(C) 1 or more primary health care practices.

(3) INTEGRATED CARE; BIDIRECTIONAL INTEGRATED CARE.—

(A) The term "integrated care" means models or practices for coordinating and jointly delivering behavioral and physical health services, which may include practices that share the same space in the same facility.

(B) The term "bidirectional integrated care" means the integration of behavioral health care and specialty physical health care, as well as the integration of primary and physical health care with specialty behavioral health settings, including within primary health care settings.

(4) PRIMARY HEALTH CARE PROVIDER.—The term "primary health care provider" means a provider who—

(A) provides health services related to family medicine, internal medicine, pediatrics, obstetrics, gynecology, or geriatrics; or

(B) is a doctor of medicine or osteopathy, physician assistant, or nurse practitioner, who is licensed to practice medicine by the State in which such physician, assistant, or practitioner primarily practices, including within primary health care settings.

(5) PRIMARY HEALTH CARE PRACTICE.—The term "primary health care practice" means a medical practice of primary health care providers, including a practice within a larger health care system.

(6) SPECIAL POPULATION.—The term "special population", for an eligible entity that is collaborating with an entity described in subparagraph (A) or (B) of paragraph (3), means—

(A) adults with a serious mental illness who have a co-occurring physical health condition or chronic disease;

(B) children and adolescents with a mental illness who have a co-occurring physical health condition or chronic disease;

(C) individuals with a substance use disorder; or

(D) individuals with a mental illness who have a co-occurring substance use disorder.

(b) GRANTS AND COOPERATIVE AGREEMENTS.—

(1) IN GENERAL.—The Secretary may award grants and cooperative agreements to eligible entities to support the improvement of integrated care for physical and behavioral health care in accordance with paragraph (2).

(2) USE OF FUNDS.—A grant or cooperative agreement awarded under this section shall be used—

(A) in the case of an eligible entity that is collaborating with an entity described in subparagraph (A) or (B) of subsection (a)(2)—

(i) to promote full integration and collaboration in clinical practices between physical and behavioral health care for special populations including each population listed in subsection (a)(7);

(ii) to support the improvement of integrated care models for physical and behavioral health care to improve the overall wellness and physical health status of—

(I) adults with a serious mental illness or children with a serious emotional disturbance; and

(II) individuals with a substance use disorder; and

(iii) to promote bidirectional integrated care services including screening, diagnosis, prevention, treatment, and recovery of mental and substance use disorders, and co-occurring physical health conditions and chronic diseases; and

(B) in the case of an eligible entity that is collaborating with a primary health care practice, to support the uptake of the collaborative care model, including by—

(i) hiring staff;

(ii) identifying and formalizing contractual relationships with other health care providers, including providers who will function as psychiatric consultants and behavioral health care managers in providing behavioral health integration services through the collaborative care model;

(iii) purchasing or upgrading software and other resources needed to appropriately provide behavioral health integration services through the collaborative care model, including resources needed to establish a patient registry and implement measurement-based care; and

(iv) for such other purposes as the Secretary determines to be necessary.

(c) APPLICATIONS.—

(1) IN GENERAL.—An eligible entity that is collaborating with an entity described in subparagraph (A) or (B) of subsection (a)(2) seeking a grant or cooperative agreement under subsection (b)(2)(A) shall submit an application to the Secretary at such time, in such manner, and accompanied by such information as the Secretary may require, including the contents described in paragraph (2).

(2) CONTENTS.—Any such application of an eligible entity described in subparagraph (A) or (B) of subsection (a)(2) shall include—

(A) a description of a plan to achieve fully collaborative agreements to provide bidirectional integrated care to special populations;

(B) a document that summarizes the policies, if any, that are barriers to the provision of integrated care, and the specific steps, if applicable, that will be taken to address such barriers;

(C) a description of partnerships or other arrangements with local health care providers to provide services to special populations;

(D) an agreement and plan to report to the Secretary performance measures necessary to evaluate patient outcomes and facilitate evaluations across participating projects;

(E) a description of how validated rating scales will be implemented to support the improvement of patient outcomes using measurement-based care, including those related to depression screening, patient follow-up, and symptom remission; and

(F) a plan for sustainability beyond the grant or cooperative agreement period under subsection (e).

(3) COLLABORATIVE CARE MODEL GRANTS.—An eligible entity that is collaborating with a primary health care practice seeking a grant pursuant to subsection (b)(2)(B) shall submit an application to the Secretary at such time, in such manner, and accompanied by such information as the Secretary may require.

(d) GRANT AND COOPERATIVE AGREEMENT AMOUNTS.—

(1) TARGET AMOUNT.—The target amount that an eligible entity may receive for a year through a grant or cooperative agreement under this section shall be—

(A) $2,000,000 for an eligible entity described in subparagraph (A) or (B) of subsection (a)(2); or

(B) $100,000 or less for an eligible entity described in subparagraph (C) of subsection (a)(2).

(2) ADJUSTMENT PERMITTED.—The Secretary, taking into consideration the quality of an eligible entity's application and the number of eligible entities that received grants under this section prior to the date of enactment of the Restoring Hope for Mental Health and Well-Being Act of 2022, may adjust the target amount that an eligible entity may receive for a year through a grant or cooperative agreement under this section.

(3) LIMITATION.—An eligible entity that is collaborating with an entity described in subparagraph (A) or (B) of subsection (a)(2) receiving funding under this section—

(A) may not allocate more than 20 percent of the funds awarded to such eligible entity under this section to administrative functions; and

(B) shall allocate the remainder of such funding to health facilities that provide integrated care.

(e) DURATION.—A grant or cooperative agreement under this section shall be for a period not to exceed 5 years.

(f) REPORT ON PROGRAM OUTCOMES.—An eligible entity receiving a grant or cooperative agreement under this section—

(1) that is collaborating with an entity described in subparagraph (A) or (B) of subsection (a)(2) shall submit an annual report to the Secretary that includes—

(A) the progress made to reduce barriers to integrated care as described in the entity's application under subsection (c); and

(B) a description of outcomes with respect to each special population listed in subsection (a)(7), including outcomes related to education, employment, and housing; or

(2) that is collaborating with a primary health care practice shall submit an annual report to the Secretary that includes—

(A) the progress made to improve access;

(B) the progress made to improve patient outcomes; and

(C) the progress made to reduce referrals to specialty care.

(g) TECHNICAL ASSISTANCE FOR PRIMARY-BEHAVIORAL HEALTH CARE INTEGRATION.—

(1) CERTAIN RECIPIENTS.—The Secretary may provide appropriate information, training, and technical assistance to eligible entities that are collaborating with an entity described in subparagraph (A) or (B) of subsection (a)(2) that receive a grant or cooperative agreement under this section, in order to help such entities meet the requirements of this section, including assistance with—

(A) development and selection of integrated care models;

(B) dissemination of evidence-based interventions in integrated care;

(C) establishment of organizational practices to support operational and administrative success; and

(D) other activities, as the Secretary determines appropriate.

(2) COLLABORATIVE CARE MODEL RECIPIENTS.—The Secretary shall provide appropriate information, training, and technical assistance to eligible entities that are collaborating with primary health care practices that receive funds under this section to help such entities implement the collaborative care model, including—

(A) developing financial models and budgets for implementing and maintaining a collaborative care model, based on practice size;

(B) developing staffing models for essential staff roles;

(C) providing strategic advice to assist practices seeking to utilize other clinicians for additional psychotherapeutic interventions;

(D) providing information technology expertise to assist with building the collaborative care model into electronic health records, including assistance with care manager tools, patient registry, ongoing patient monitoring, and patient records;

(E) training support for all key staff and operational consultation to develop practice workflows;

(F) establishing methods to ensure the sharing of best practices and operational knowledge among primary health care physicians and primary health care practices that provide behavioral health integration services through the collaborative care model; and

(G) providing guidance and instruction to primary health care physicians and primary health care practices on developing and maintaining relationships with community-based mental health and substance use disorder facilities for referral and treatment of patients whose clinical presentation or diagnosis is best suited for treatment at such facilities.

(3) ADDITIONAL DISSEMINATION OF TECHNICAL INFORMATION.—In addition to providing the assistance described in paragraphs (1) and (2) to recipients of a grant or cooperative agreement under this section, the Secretary may also provide such assistance to other States and political subdivisions of States, Indian Tribes and Tribal organizations (as defined under the Federally Recognized Indian Tribe List Act of 1994), outpatient mental health and addiction treatment centers, community mental health centers that meet the criteria under section 1913(c), certified community behavioral health clinics described in section 223 of the Protecting Access to Medicare Act of 2014, primary care organizations such as Federally qualified health centers or rural health clinics as defined in section 1861(aa) of the Social Security Act, primary health care practices, other community-based organizations, and other entities engaging in integrated care activities, as the Secretary determines appropriate.

(h) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there is authorized to be appropriated $60,000,000 for each of fiscal years 2023 through 2027.

SEC. 520L. ADULT SUICIDE PREVENTION.

(a) GRANTS.—

(1) IN GENERAL.—The Assistant Secretary shall award grants to eligible entities described in paragraph (2) to implement suicide prevention and intervention programs, for individuals who are 25 years of age or older, that are designed to raise awareness of suicide, establish referral processes, and improve care and outcomes for such individuals who are at risk of suicide.

(2) ELIGIBLE ENTITIES.—To be eligible to receive a grant under this section, an entity shall be a community-based primary care or behavioral health care setting, an emergency department, a State mental health agency (or State health agency with mental or behavioral health functions), public health

agency, a territory of the United States, or an [Indian tribe] *Indian Tribe* or [tribal organization] *Tribal organization* (as the terms "[Indian tribe] *Indian Tribe*" and "[tribal organization] *Tribal organization*" are defined in section 4 of the Indian Self-Determination and Education Assistance Act).

(3) USE OF FUNDS.—The grants awarded under paragraph (1) shall be used to implement programs, in accordance with such paragraph, that include one or more of the following components:

(A) Screening for suicide risk, suicide intervention services, and services for referral for treatment for individuals at risk for suicide.

(B) Implementing evidence-based practices to provide treatment for individuals at risk for suicide, including appropriate followup services.

[(C) Raising awareness and reducing stigma of suicide.]

(C) Raising awareness of suicide prevention resources, promoting help seeking among those at risk for suicide.

(b) EVALUATIONS AND TECHNICAL ASSISTANCE.—The Assistant Secretary shall—

(1) evaluate the activities supported by grants awarded under subsection (a), and disseminate, as appropriate, the findings from the evaluation; and

(2) provide appropriate information, training, and technical assistance, as appropriate, to eligible entities that receive a grant under this section, in order to help such entities to meet the requirements of this section, including assistance with selection and implementation of evidence-based interventions and frameworks to prevent suicide.

(c) DURATION.—A grant under this section shall be for a period of not more than 5 years.

(d) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section [$30,000,000 for the period of fiscal years 2018 through 2022] *$30,000,000 for each of fiscal years 2023 through 2027*.

SEC. 520M. ASSERTIVE COMMUNITY TREATMENT GRANT PROGRAM.

(a) IN GENERAL.—The Assistant Secretary shall award grants to eligible entities—

(1) to establish assertive community treatment programs for adults with a serious mental illness; or

(2) to maintain or expand such programs.

(b) ELIGIBLE ENTITIES.—To be eligible to receive a grant under this section, an entity shall be a State, political subdivision of a State, [Indian tribe or tribal organization] *Indian Tribe or Tribal organization* (as such terms are defined in section 4 of the Indian Self-Determination and Education Assistance Act), mental health system, health care facility, or any other entity the Assistant Secretary deems appropriate.

(c) SPECIAL CONSIDERATION.—In selecting among applicants for a grant under this section, the Assistant Secretary may give special consideration to the potential of the applicant's program to reduce hospitalization, homelessness, and involvement with the criminal justice system while improving the health and social outcomes of the patient.

(d) ADDITIONAL ACTIVITIES.—The Assistant Secretary shall—

(1) [not later than the end of fiscal year 2021] *not later than the end of fiscal year 2026*, submit a report to the appropriate congressional committees on the grant program under this section, including an evaluation of—

(A) any cost savings and public health outcomes such as mortality, suicide, substance use disorders, hospitalization, and use of services;

(B) rates of involvement with the criminal justice system of patients;

(C) rates of homelessness among patients; and

(D) patient and family satisfaction with program participation; and

(2) provide appropriate information, training, and technical assistance to grant recipients under this section to help such recipients to establish, maintain, or expand their assertive community treatment programs.

(e) AUTHORIZATION OF APPROPRIATIONS.—

(1) IN GENERAL.—To carry out this section, there is authorized to be appropriated [$5,000,000 for the period of fiscal years 2018 through 2022] *$9,000,000 for each of fiscal years 2023 through 2027*.

(2) USE OF CERTAIN FUNDS.—Of the funds appropriated to carry out this section in any fiscal year, not more than 5 percent shall be available to the Assistant Secretary for carrying out subsection (d).

SEC. 520N. CRISIS RESPONSE CONTINUUM OF CARE.

(a) IN GENERAL.—The Secretary shall publish best practices for a crisis response continuum of care for use by health care providers, crisis services administrators, and crisis services providers in responding to individuals (including children and adolescents) experiencing mental health crises, substance-related crises, and crises arising from co-occurring disorders.

(b) BEST PRACTICES.—

(1) SCOPE OF BEST PRACTICES.—The best practices published under subsection (a) shall define—

(A) a minimum set of core crisis response services, as determined by the Secretary, for each entity that furnishes such services, that—

(i) do not require prior authorization from an insurance provider or group health plan nor a referral from a health care provider prior to the delivery of services;

(ii) provide for serving all individuals regardless of age or ability to pay;

(iii) provide for operating 24 hours a day, 7 days a week; and

(iv) provide for care and support through resources described in paragraph (2)(A) until the individual has been stabilized or transferred to the next level of crisis care; and

(B) psychiatric stabilization, including the point at which a case may be closed for—

(i) individuals screened over the phone; and

(ii) individuals stabilized on the scene by mobile teams.

(2) IDENTIFICATION OF ESSENTIAL FUNCTIONS.—The best practices published under subsection (a) shall identify the essential functions of each service in the crisis response continuum, which shall include at least the following:

(A) Identification of resources for referral and enrollment in continuing mental health, substance use, or other human services relevant for the individual in crisis where necessary.

(B) Delineation of access and entry points to services within the crisis response continuum.

(C) Development of protocols and agreements for the transfer and receipt of individuals to and from other segments of the crisis response continuum segments as needed, and from outside referrals including health care providers, first responders including law enforcement, paramedics, and firefighters, education institutions, and community-based organizations.

(D) Description of the qualifications of crisis services staff, including roles for physicians, licensed clinicians, case managers, and peers (in accordance with State licensing requirements or requirements applicable to Tribal health professionals).

(E) The convening of collaborative meetings of crisis response service providers, first responders including law enforcement, paramedics, and firefighters, and community partners (including National Suicide Prevention Lifeline or 9–8–8 call centers, 9–1–1 public service answering points, and local mental health and substance use disorder treatment providers) operating in a common region for the discussion of case management, best practices, and general performance improvement.

(3) SERVICE CAPACITY AND QUALITY BEST PRACTICES.—The best practices under subsection (a) shall include recommendations on—

(A) adequate volume of services to meet population need;

(B) appropriate timely response; and

(C) capacity to meet the needs of different patient populations that may experience a mental health or substance use crisis, including children, families, and all age groups, cultural and linguistic minorities, individuals with co-occurring mental health and substance use disorders, individuals with cognitive disabilities, individuals with developmental delays, and individuals with chronic medical conditions and physical disabilities.

(4) IMPLEMENTATION TIMEFRAME.—The Secretary shall—

(A) not later than 1 year after the date of enactment of this section, publish and maintain the best practices required by subsection (a); and

(B) every two years thereafter, publish updates.

(5) DATA COLLECTION AND EVALUATIONS.—The Secretary, directly or through grants, contracts, or interagency agreements, shall collect data and conduct evaluations with respect to the provision of services and programs offered on the crisis response continuum for purposes of assessing the extent to which the provision of such services and programs meet certain objectives

and outcomes measures as determined by the Secretary. Such objectives shall include—

(A) a reduction in reliance on law enforcement response, as appropriate, to individuals in crisis who would be more appropriately served by a mobile crisis team capable of responding to mental health and substance-related crises;

(B) a reduction in boarding or extended holding of patients in emergency room facilities who require further psychiatric care, including care for substance use disorders;

(C) evidence of adequate access to crisis care centers and crisis bed services; and

(D) evidence of adequate linkage to appropriate post-crisis care and longitudinal treatment for mental health or substance use disorder when relevant.

SEC. 520O. CENTER OF EXCELLENCE FOR EATING DISORDERS FOR EDUCATION AND TRAINING ON EATING DISORDERS.

(a) IN GENERAL.—The Secretary, acting through the Assistant Secretary, shall maintain, by competitive grant or contract, a Center of Excellence for Eating Disorders (referred to in this section as the "Center") to improve the identification of, interventions for, and treatment of eating disorders in a manner that is developmentally, culturally, and linguistically appropriate.

(b) SUBGRANTS AND SUBCONTRACTS.—The Center shall coordinate and implement the activities under subsection (c), in whole or in part, by awarding competitive subgrants or subcontracts—

(1) across geographical regions; and

(2) in a manner that is not duplicative.

(c) ACTIVITIES.—The Center—

(1) shall—

(A) provide training and technical assistance for—

(i) primary care and behavioral health care providers to carry out screening, brief intervention, and referral to treatment for individuals experiencing, or at risk for, eating disorders; and

(ii) nonclinical community support workers to identify and support individuals with, or at disproportionate risk for, eating disorders;

(B) develop and provide training materials to health care providers, including primary care and behavioral health care providers, in the effective treatment and ongoing support of individuals with eating disorders, including children and marginalized populations at disproportionate risk for eating disorders;

(C) provide collaboration and coordination to other centers of excellence, technical assistance centers, and psychiatric consultation lines of the Substance Abuse and Mental Health Services Administration and the Health Resources and Services Administration on the identification, effective treatment, and ongoing support of individuals with eating disorders; and

(D) coordinate with the Director of the Centers for Disease Control and Prevention and the Administrator of the Health Resources and Services Administration to disseminate training to primary care and behavioral health care providers; and

(2) may—

(A) coordinate with electronic health record systems for the integration of protocols pertaining to screening, brief intervention, and referral to treatment for individuals experiencing, or at risk for, eating disorders;

(B) develop and provide training materials to health care providers, including primary care and behavioral health care providers, in the effective treatment and ongoing support for members of the Armed Forces and veterans experiencing, or at risk for, eating disorders; and

(C) consult with the Secretary of Defense and the Secretary of Veterans Affairs on prevention, identification, intervention for, and treatment of eating disorders.

(d) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there is authorized to be appropriated $1,000,000 for each of fiscal years 2023 through 2027.

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PART C—PROJECTS FOR ASSISTANCE IN TRANSITION FROM HOMELESSNESS

SEC. 521. FORMULA GRANTS TO STATES.

For the purpose of carrying out section 522, the Secretary, acting through the Director of the Center for Mental Health Services, shall for each of the fiscal years [2018 through 2022] *2023 through 2027* make an allotment for each State in an amount determined in accordance with section 524. The Secretary shall make payments, as grants, each such fiscal year to each State from the allotment for the State if the Secretary approves for the fiscal year involved an application submitted by the State pursuant to section 529.

* * * * * * *

SEC. 535. FUNDING.

(a) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this part, there is authorized to be appropriated $64,635,000 for each of fiscal years [2018 through 2022] *2023 through 2027*.

(b) EFFECT OF INSUFFICIENT APPROPRIATIONS FOR MINIMUM ALLOTMENTS.—

(1) IN GENERAL.—If the amounts made available under subsection (a) for a fiscal year are insufficient for providing each State with an allotment under section 521 of not less than the applicable amount under section 524(a)(1), the Secretary shall, from such amounts as are made available under such subsection, make grants to the States for providing to eligible homeless individuals the services specified in section 522(b).

(2) RULE OF CONSTRUCTION.—Paragraph (1) may not be construed to require the Secretary to make a grant under such paragraph to each State.

PART D—MISCELLANEOUS PROVISIONS RELATING TO SUBSTANCE ABUSE AND MENTAL HEALTH

* * * * * * *

SEC. 544. GRANTS FOR REDUCING OVERDOSE DEATHS.

(a) ESTABLISHMENT.—

(1) IN GENERAL.—The Secretary shall award grants to eligible entities to expand access to drugs or devices [approved or cleared] *approved, cleared, or otherwise authorized* under the Federal Food, Drug, and Cosmetic Act for emergency treatment of known or suspected opioid overdose.

[(2) MAXIMUM GRANT AMOUNT.—A grant awarded under this section may not be for more than $200,000 per grant year.

[(3) ELIGIBLE ENTITY.—For purposes of this section, the term "eligible entity" means a Federally qualified health center (as defined in section 1861(aa) of the Social Security Act), an opioid treatment program under part 8 of title 42, Code of Federal Regulations, any practitioner dispensing narcotic drugs pursuant to section 303(g) of the Controlled Substances Act, or any other entity that the Secretary deems appropriate.]

(2) ELIGIBLE ENTITY.—For purposes of this section, the term "eligible entity" means a State, Territory, locality, Indian Tribe (as defined in the Federally Recognized Indian Tribe List Act of 1994), Tribal organization, or Urban Indian organization (as those terms are defined in section 4 of the Indian Health Care Improvement Act).

(3) SUBGRANTS.—For the purposes for which a grant is awarded under this section, the eligible entity receiving the grant may award subgrants to a Federally qualified health center (as defined in section 1861(aa) of the Social Security Act), an opioid treatment program (as defined in section 8.2 of title 42, Code of Federal Regulations (or any successor regulations)), any practitioner dispensing narcotic drugs for the purpose of maintenance or detoxification treatment, or any nonprofit organization that the Secretary deems appropriate.

(4) PRESCRIBING.—For purposes of this section, the term "prescribing" means, with respect to a drug or device [approved or cleared] *approved, cleared, or otherwise authorized* under the Federal Food, Drug, and Cosmetic Act for emergency treatment of known or suspected opioid overdose, the practice of prescribing such drug or device—

(A) in conjunction with an opioid prescription for patients at an elevated risk of overdose*, including patients prescribed with both an opioid and a benzodiazepine*;

(B) in conjunction with an opioid agonist approved under section 505 of the Federal Food, Drug, and Cosmetic Act for the treatment of opioid use disorder;

(C) to the caregiver or a close relative of patients at an elevated risk of overdose from opioids; or

(D) in other circumstances in which a provider identifies a patient is at an elevated risk for an intentional or unintentional [drug overdose] *substance overdose* from heroin or prescription opioid therapies.

(b) APPLICATION.—To be eligible to receive a grant under this section, an eligible entity shall submit to the Secretary, in such form and manner as specified by the Secretary, an application that describes—

(1) the extent to which the area to which the entity will furnish services through use of the grant is experiencing significant morbidity and mortality caused by opioid abuse;

(2) the criteria that will be used to identify eligible patients to participate in such program; and

(3) a plan for sustaining the program after Federal support for the program has ended.

(c) USE OF FUNDS.—An eligible entity receiving a grant under this section may use amounts under the grant for any of the following activities, but may use not more than 20 percent of the grant funds for activities described in paragraphs (3) and (4):

(1) To establish a program for prescribing a drug or device [approved or cleared] *approved, cleared, or otherwise authorized* under the Federal Food, Drug, and Cosmetic Act for emergency treatment of known or suspected opioid overdose.

(2) To train and provide resources for health care providers and pharmacists on the prescribing of drugs or devices [approved or cleared] *approved, cleared, or otherwise authorized* under the Federal Food, Drug, and Cosmetic Act for emergency treatment of known or suspected opioid overdose.

(3) To purchase drugs or devices [approved or cleared] *approved, cleared, or otherwise authorized* under the Federal Food, Drug, and Cosmetic Act for emergency treatment of known or suspected opioid overdose, for distribution under the program described in paragraph (1).

(4) To offset the co-payments and other cost sharing associated with drugs or devices [approved or cleared] *approved, cleared, or otherwise authorized* under the Federal Food, Drug, and Cosmetic Act for emergency treatment of known or suspected opioid overdose.

[(5) To establish protocols to connect patients who have experienced a drug overdose with appropriate treatment, including medication-assisted treatment and appropriate counseling and behavioral therapies.]

(5) To establish protocols to connect patients who have experienced an overdose with appropriate treatment, including overdose reversal medications, medication assisted treatment, and appropriate counseling and behavioral therapies.

(d) IMPROVING ACCESS TO OVERDOSE TREATMENT.—

(1) INFORMATION ON BEST PRACTICES.—

(A) HEALTH AND HUMAN SERVICES.—The Secretary of Health and Human Services may provide information to States, localities, Indian Tribes, Tribal organizations, and Urban Indian organizations on best practices for prescribing or co-prescribing a drug or device approved, cleared, or otherwise authorized under the Federal Food, Drug, and Cosmetic Act for emergency treatment of known or suspected opioid overdose, including for patients receiving chronic opioid therapy and patients being treated for opioid use disorders.

(B) DEFENSE.—The Secretary of Defense may provide information to prescribers within Department of Defense medical facilities on best practices for prescribing or co-prescribing a drug or device approved, cleared, or otherwise authorized under the Federal Food, Drug, and Cosmetic

Act for emergency treatment of known or suspected opioid overdose, including for patients receiving chronic opioid therapy and patients being treated for opioid use disorders.

(C) VETERANS AFFAIRS.—The Secretary of Veterans Affairs may provide information to prescribers within Department of Veterans Affairs medical facilities on best practices for prescribing or co-prescribing a drug or device approved, cleared, or otherwise authorized under the Federal Food, Drug, and Cosmetic Act for emergency treatment of known or suspected opioid overdose, including for patients receiving chronic opioid therapy and patients being treated for opioid use disorders.

(2) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed as establishing or contributing to a medical standard of care.

[(d)] *(e)* EVALUATIONS BY RECIPIENTS.—As a condition of receipt of a grant under this section, an eligible entity shall, for each year for which the grant is received, submit to the Secretary an evaluation of activities funded by the grant which contains such information as the Secretary may reasonably require.

[(e)] *(f)* REPORTS BY THE SECRETARY.—Not later than 5 years after the date on which the first grant under this section is awarded, the Secretary shall submit to the appropriate committees of the House of Representatives and of the Senate a report aggregating the information received from the grant recipients for such year under [subsection (d)] *subsection (e)* and evaluating the outcomes achieved by the programs funded by grants awarded under this section.

[(f)] *(g)* AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section, $5,000,000 for the period of [fiscal years 2017 through 2021] *fiscal years 2023 through 2027*.

SEC. 545. OPIOID OVERDOSE REVERSAL MEDICATION [ACCESS AND EDUCATION GRANT PROGRAMS] *ACCESS, EDUCATION, AND CO-PRESCRIBING GRANT PROGRAMS.*

(a) [GRANTS TO STATES] *GRANTS*.—The Secretary [shall make grants to States] *shall make grants to States, localities, Indian Tribes (as defined by the Federally Recognized Indian Tribe List Act of 1994), Tribal organizations, and Urban Indian organizations (as those terms are defined in section 4 of the Indian Health Care Improvement Act)* to—

(1) [implement strategies for pharmacists to dispense a drug or device] *implement strategies that increase access to drugs or devices* [approved or cleared] *approved, cleared, or otherwise authorized* under the Federal Food, Drug, and Cosmetic Act for emergency treatment of known or suspected opioid overdose, as appropriate, pursuant to a standing order;

(2) encourage pharmacies to dispense opioid overdose reversal medication pursuant to a standing order;

[(3)] *(4)* develop or provide training materials that persons authorized to prescribe or dispense a drug or device [approved or cleared] *approved, cleared, or otherwise authorized* under the Federal Food, Drug, and Cosmetic Act for emergency treatment of known or suspected opioid overdose may use to educate the public concerning—

(A) when and how to safely administer such drug or device; and

(B) steps to be taken after administering such drug or device; and

[(4)] *(5)* educate the public concerning the availability of drugs or devices [approved or cleared] *approved, cleared, or otherwise authorized* under the Federal Food, Drug, and Cosmetic Act for emergency treatment of known or suspected opioid overdose without a person-specific prescription.

(b) CERTAIN REQUIREMENT.—A grant may be made under this section only if the State involved has authorized standing orders to be issued for drugs or devices [approved or cleared] *approved, cleared, or otherwise authorized* under the Federal Food, Drug, and Cosmetic Act for emergency treatment of known or suspected opioid overdose.

(c) PREFERENCE IN MAKING GRANTS.—In making grants under this section, the Secretary may give preference to States that have a significantly higher rate of opioid overdoses than the national average, and that—

(1) have not implemented standing orders regarding drugs or devices [approved or cleared] *approved, cleared, or otherwise authorized* under the Federal Food, Drug, and Cosmetic Act for emergency treatment of known or suspected opioid overdose;

(2) authorize standing orders to be issued that permit community-based organizations, substance abuse programs, or other nonprofit entities to acquire, dispense, or administer drugs or devices [approved or cleared] *approved, cleared, or otherwise authorized* under the Federal Food, Drug, and Cosmetic Act for emergency treatment of known or suspected opioid overdose; or

[(3)] *(4)* authorize standing orders to be issued that permit police, fire, or emergency medical services agencies to acquire and administer drugs or devices [approved or cleared] *approved, cleared, or otherwise authorized* under the Federal Food, Drug, and Cosmetic Act for emergency treatment of known or suspected opioid overdose.

(d) GRANT TERMS.—

(1) NUMBER.—A State may not receive more than one grant under this section at a time.

(2) PERIOD.—A grant under this section shall be for a period of [3 years] *5 years*.

[[(3)] *(4)* LIMITATION.—A State may use not more than 20 percent of a grant under this section for educating the public pursuant to subsection (a)(4).]

(3) LIMITATIONS.—A State may—

(A) use not more than 10 percent of a grant under this section for educating the public pursuant to subsection (a)(5); and

(B) use not less than 20 percent of a grant under this section to offset cost-sharing for distribution and dispensing of drugs or devices approved, cleared, or otherwise authorized under the Federal Food, Drug, and Cosmetic Act for emergency treatment of known or suspected opioid overdose.

(e) APPLICATIONS.—To be eligible to receive a grant under this section, a State shall submit an application to the Secretary in

such form and manner and containing such information as the Secretary may reasonably require, including detailed proposed expenditures of grant funds.

(f) REPORTING.—A State that receives a grant under this section shall, at least annually for the duration of the grant, submit a report to the Secretary evaluating the progress of the activities supported through the grant. Such reports shall include information on the number of pharmacies in the State that dispense a drug or device [approved or cleared] *approved, cleared, or otherwise authorized* under the Federal Food, Drug, and Cosmetic Act for emergency treatment of known or suspected opioid overdose under a standing order, and other information as the Secretary determines appropriate to evaluate the use of grant funds.

(g) DEFINITIONS.—In this section the term "standing order" means a document prepared by a person authorized to prescribe medication that permits another person to acquire, dispense, or administer medication without a person-specific prescription.

(h) AUTHORIZATION OF APPROPRIATIONS.—

(1) IN GENERAL.—To carry out this section, there are authorized to be appropriated $5,000,000 for the period of [fiscal years 2017 through 2019] *fiscal years 2023 through 2027*.

(2) ADMINISTRATIVE COSTS.—Not more than 3 percent of the amounts made available to carry out this section may be used by the Secretary for administrative expenses of carrying out this section.

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SEC. 548. STATE DEMONSTRATION GRANTS FOR COMPREHENSIVE OPIOID [ABUSE] *USE DISORDER* RESPONSE.

(a) DEFINITIONS.—In this section:

(1) DISPENSER.—The term "dispenser" has the meaning given the term in section 102 of the Controlled Substances Act (21 U.S.C. 802).

(2) PRESCRIBER.—The term "prescriber" means a dispenser who prescribes a controlled substance, or the agent of such a dispenser.

(3) PRESCRIBER OF A SCHEDULE II, III, OR IV CONTROLLED SUBSTANCE.—The term "prescriber of a schedule II, III, or IV controlled substance" does not include a prescriber of a schedule II, III, or IV controlled substance that dispenses the substance—

(A) for use on the premises on which the substance is dispensed;

(B) in a hospital emergency room, when the substance is in short supply;

(C) for a certified opioid treatment program; or

(D) in other situations as the Secretary may reasonably determine.

(4) SCHEDULE II, III, OR IV CONTROLLED SUBSTANCE.—The term "schedule II, III, or IV controlled substance" means a controlled substance that is listed on schedule II, schedule III, or schedule IV of section 202(c) of the Controlled Substances Act.

(b) GRANTS FOR COMPREHENSIVE OPIOID [ABUSE] *USE DISORDER* RESPONSE.—

(1) IN GENERAL.—The Secretary shall award grants to States, and combinations of States, to implement an integrated opioid [abuse] *use disorder* response initiative.

(2) PURPOSES.—A State receiving a grant under this section shall establish a comprehensive response plan to opioid [abuse] *use disorder*, which may include—

(A) education efforts around [opioid use, treatment, and addiction recovery] *opioid use disorders, and treatment for, and recovery from opioid use disorders*, including education of residents, medical students, and physicians and other prescribers of schedule II, III, or IV controlled substances on relevant prescribing guidelines, the prescription drug monitoring program of the State described in subparagraph (B), and overdose prevention methods;

(B) establishing, maintaining, or improving a comprehensive prescription drug monitoring program to track dispensing of schedule II, III, or IV controlled substances, which may—

(i) provide for data sharing with other States; and

(ii) allow all individuals authorized by the State to write prescriptions for schedule II, III, or IV controlled substances to access the prescription drug monitoring program of the State;

(C) developing, implementing, or expanding prescription drug and opioid [addiction] *use disorder* treatment programs by—

(i) expanding the availability of treatment for prescription drug and opioid [addiction] *use disorder*, including medication-assisted treatment and behavioral health therapy, as appropriate;

(ii) developing, implementing, or expanding screening for individuals in treatment for prescription drug and opioid [addiction] *use disorder* for hepatitis C and HIV, and treating or referring those individuals if clinically appropriate; or

(iii) developing, implementing, or expanding recovery support services and programs at high schools or institutions of higher education;

[(D) developing, implementing, and expanding efforts to prevent overdose death from opioid abuse or addiction to prescription medications and opioids; and]

(D) developing, implementing, and expanding efforts to prevent overdose death from opioid or other prescription medication use disorders; and

(E) advancing the education and awareness of the public, providers, patients, consumers, and other appropriate entities regarding the dangers of opioid [abuse] *use disorders*, safe disposal of prescription medications, and detection of early warning signs of opioid use disorders.

(3) APPLICATION.—A State seeking a grant under this section shall submit to the Secretary an application in such form, and containing such information, as the Secretary may reasonably require.

(4) USE OF FUNDS.—A State that receives a grant under this section shall use the grant for the cost, including the cost for

technical assistance, training, and administration expenses, of carrying out an integrated opioid [abuse] *use disorders* response initiative as outlined by the State's comprehensive response plan to opioid [abuse] *use disorders* established under paragraph (2).

(5) PRIORITY CONSIDERATIONS.—In awarding grants under this section, the Secretary shall, as appropriate, give priority to a State that—

(A)(i) provides civil liability protection for first responders, health professionals, and family members who have received appropriate training in administering a drug or device approved or cleared under the Federal Food, Drug, and Cosmetic Act for emergency treatment of known or suspected opioid overdose; and

(ii) submits to the Secretary a certification by the attorney general of the State that the attorney general has—

(I) reviewed any applicable civil liability protection law to determine the applicability of the law with respect to first responders, health care professionals, family members, and other individuals who—

(aa) have received appropriate training in administering a drug or device approved or cleared under the Federal Food, Drug, and Cosmetic Act for emergency treatment of known or suspected opioid overdose; and

(bb) may administer a drug or device approved or cleared under the Federal Food, Drug, and Cosmetic Act for emergency treatment of known or suspected opioid overdose; and

(II) concluded that the law described in subclause (I) provides adequate civil liability protection applicable to such persons;

(B) has a process for enrollment in services and benefits necessary by criminal justice agencies to initiate or continue treatment in the community, under which an individual who is incarcerated may, while incarcerated, enroll in services and benefits that are necessary for the individual to continue treatment upon release from incarceration;

(C) ensures the capability of data sharing with other States, where applicable, such as by making data available to a prescription monitoring hub;

(D) ensures that data recorded in the prescription drug monitoring program database of the State are regularly updated, to the extent possible;

(E) ensures that the prescription drug monitoring program of the State notifies prescribers and dispensers of schedule II, III, or IV controlled substances when overuse or misuse of such controlled substances by patients is suspected; and

(F) has in effect one or more statutes or implements policies that maximize use of prescription drug monitoring programs by individuals authorized by the State to prescribe schedule II, III, or IV controlled substances.

(6) EVALUATION.—In conducting an evaluation of the program under this section pursuant to section 701 of the Comprehensive Addiction and Recovery Act of 2016, with respect to a State, the Secretary shall report on State legislation or policies related to maximizing the use of prescription drug monitoring programs and the incidence of opioid use disorders and overdose deaths in such State.

(7) STATES WITH LOCAL PRESCRIPTION DRUG MONITORING PROGRAMS.—

(A) IN GENERAL.—In the case of a State that does not have a prescription drug monitoring program, a county or other unit of local government within the State that has a prescription drug monitoring program shall be treated as a State for purposes of this section, including for purposes of eligibility for grants under paragraph (1).

(B) PLAN FOR INTEROPERABILITY.—In submitting an application to the Secretary under paragraph (3), a county or other unit of local government shall submit a plan outlining the methods such county or unit of local government shall use to ensure the capability of data sharing with other counties and units of local government within the state and with other States, as applicable.

(c) AUTHORIZATION OF FUNDING.—For the purpose of carrying out this section, there are authorized to be appropriated $5,000,000 for each of fiscal years [2017 through 2021] *2023 through 2027*.

SEC. 549. MENTAL AND BEHAVIORAL HEALTH OUTREACH AND EDUCATION [ON COLLEGE CAMPUSES] *AT INSTITUTIONS OF HIGHER EDUCATION*.

(a) PURPOSE.—It is the purpose of this section to increase access to, and reduce the stigma associated with, mental health services to ensure that students at institutions of higher education have the support necessary to successfully complete their studies.

(b) NATIONAL PUBLIC EDUCATION CAMPAIGN.—The Secretary, acting through the Assistant Secretary and in collaboration with the Director of the Centers for Disease Control and Prevention, shall convene an interagency, public-private sector working group to plan, establish, and begin coordinating and evaluating a targeted public education campaign that is designed to focus on mental and behavioral health on the campuses of institutions of higher education. Such campaign shall be designed to—

(1) improve the general understanding of mental health and mental disorders;

(2) encourage help-seeking behaviors relating to the promotion of mental health, prevention of mental disorders, and treatment of such disorders;

(3) make the connection between mental and behavioral health and academic success; and

(4) assist the general public in identifying the early warning signs and reducing the stigma of mental illness.

(c) COMPOSITION.—The working group convened under subsection (b) shall include—

(1) mental health consumers, including students and family members;

(2) representatives of institutions of higher education*, including minority-serving institutions as described in section*

371(a) of the Higher Education Act of 1965 (20 U.S.C. 1067q) and community colleges;

(3) representatives of national mental and behavioral health associations and associations of institutions of higher education;

(4) representatives of health promotion and prevention organizations at institutions of higher education;

(5) representatives of mental health providers, including community mental health centers; and

(6) representatives of private-sector and public-sector groups with experience in the development of effective public health education campaigns.

(d) PLAN.—The working group under subsection (b) shall develop a plan that—

(1) targets promotional and educational efforts to the age population of students at institutions of higher education and individuals who are employed in settings of institutions of higher education, including through the use of roundtables;

(2) develops and proposes the implementation of research-based public health messages and activities;

(3) provides support for local efforts to reduce stigma by using the National Health Information Center as a primary point of contact for information, publications, and service program referrals; and

(4) develops and proposes the implementation of a social marketing campaign that is targeted at the population of students attending institutions of higher education and individuals who are employed in settings of institutions of higher education.

(e) DEFINITION.—In this section, the term "institution of higher education" has the meaning given such term in section 101 of the Higher Education Act of 1965 (20 U.S.C. 1001).

(f) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated $1,000,000 for the period of fiscal years [2018 through 2022] *2023 through 2027*.

SEC. [550.] *550A*. NATIONAL RECOVERY HOUSING BEST PRACTICES.

(a) BEST PRACTICES FOR OPERATING RECOVERY HOUSING.—

[(1) IN GENERAL.—The Secretary, in consultation with the individuals and entities specified in paragraph (2), shall identify or facilitate the development of best practices, which may include model laws for implementing suggested minimum standards, for operating recovery housing.]

(1) IN GENERAL.—The Secretary, in consultation with the individuals and entities specified in paragraph (2), shall build on existing best practices and previously developed guidelines to develop and periodically update consensus-based best practices, which may include model laws for implementing suggested minimum standards for operating, and promoting the availability of, high-quality recovery housing.

(2) CONSULTATION.—In carrying out the activities described in paragraph (1), the Secretary shall consult with, as appropriate—

[(A) relevant divisions of the Department of Health and Human Services, including the Substance Abuse and Mental Health Services Administration, the Office of Inspector

General, the Indian Health Service, and the Centers for Medicare & Medicaid Services;

[(B) the Secretary of Housing and Urban Development;]

(A) Officials representing the agencies described in subsection (e)(2).

[(C)] *(B)* directors or commissioners, as applicable, of State health departments, tribal health departments, State Medicaid programs, and State insurance agencies;

[(D)] *(C)* representatives of health insurance issuers;

[(E)] *(D)* national accrediting entities and reputable providers of, and analysts of, recovery housing services, including Indian tribes, tribal organizations, and tribally designated housing entities that provide recovery housing services, as applicable;

[(F)] *(E)* individuals with a history of substance use disorder; and

[(G)] *(F)* other stakeholders identified by the Secretary.

(3) AVAILABILITY.—The best practices referred to in paragraph (1) shall be—

(A) made publicly available; and

(B) published on the public website of the Substance Abuse and Mental Health Services Administration.

(4) EXCLUSION OF GUIDELINE ON TREATMENT SERVICES.—In developing the guidelines under paragraph (1), the Secretary may not include any guidelines with respect to substance use disorder treatment services.

(b) IDENTIFICATION OF FRAUDULENT RECOVERY HOUSING OPERATORS.—

(1) IN GENERAL.—The Secretary, in consultation with the individuals and entities described in paragraph (2), shall identify or facilitate the development of common indicators that could be used to identify potentially fraudulent recovery housing operators.

(2) CONSULTATION.—In carrying out the activities described in paragraph (1), the Secretary shall consult with, as appropriate, the individuals and entities specified in subsection (a)(2) and the Attorney General of the United States.

(3) REQUIREMENTS.—

(A) PRACTICES FOR IDENTIFICATION AND REPORTING.—In carrying out the activities described in paragraph (1), the Secretary shall consider how law enforcement, public and private payers, and the public can best identify and report fraudulent recovery housing operators.

(B) FACTORS TO BE CONSIDERED.—In carrying out the activities described in paragraph (1), the Secretary shall identify or develop indicators, which may include indicators related to—

(i) unusual billing practices;

(ii) average lengths of stays;

(iii) excessive levels of drug testing (in terms of cost or frequency); and

(iv) unusually high levels of recidivism.

(c) DISSEMINATION.—The Secretary shall, as appropriate, disseminate the best practices identified or developed under sub-

section (a) and the common indicators identified or developed under subsection (b) to—

(1) State agencies, which may include the provision of technical assistance to State agencies seeking to adopt or implement such best practices;

(2) Indian tribes, tribal organizations, and tribally designated housing entities;

(3) the Attorney General of the United States;

(4) the Secretary of Labor;

(5) the Secretary of Housing and Urban Development;

(6) State and local law enforcement agencies;

(7) health insurance issuers;

(8) recovery housing entities; and

(9) the public.

(d) REQUIREMENTS.—In carrying out the activities described in subsections (a) and (b), the Secretary, in consultation with appropriate individuals and entities described in subsections (a)(2) and (b)(2), shall consider how recovery housing is able to support recovery and prevent relapse, recidivism, or overdose (including overdose death), including by improving access and adherence to treatment, including medication-assisted treatment.

[(e)**]** *(g)* RULE OF CONSTRUCTION.—Nothing in this section shall be construed to provide the Secretary with the authority to require States to adhere to minimum standards in the State oversight of recovery housing.

[(f)**]** *(h)* DEFINITIONS.—In this section:

(1) The term "recovery housing" means a shared living environment free from alcohol and illicit drug use and centered on peer support and connection to services that promote sustained recovery from substance use disorders.

(2) The terms "Indian tribe" and "tribal organization" have the meanings given those terms in section 4 of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 5304).

(3) The term "tribally designated housing entity" has the meaning given that term in section 4 of the Native American Housing Assistance and Self-Determination Act of 1996 (25 U.S.C. 4103).

[(g)**]** *(i)* AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there is authorized to be appropriated $3,000,000 for the period of fiscal years 2019 through 2021.

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PART E—CHILDREN WITH SERIOUS EMOTIONAL DISTURBANCES

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SEC. 565. GENERAL PROVISIONS.

(a) DURATION OF SUPPORT.—The period during which payments are made to a public entity from a grant under section 561(a) may not exceed 6 fiscal years.

(b) TECHNICAL ASSISTANCE.—

(1) IN GENERAL.—The Secretary shall, upon the request of a public entity, regardless of whether such public entity is receiving a grant under section 561(a)—

(A) provide technical assistance to the entity regarding the process of submitting to the Secretary applications for grants under section 561(a); and

(B) provide to the entity training and technical assistance with respect to the planning, development, and operation of systems of care described in section 562.

(2) AUTHORITY FOR GRANTS AND CONTRACTS.—The Secretary may provide technical assistance under subsection (a) directly or through grants to, or contracts with, public and nonprofit private entities.

(c) EVALUATIONS AND REPORTS BY SECRETARY.—

(1) IN GENERAL.—The Secretary shall, directly or through contracts with public or private entities, provide for annual evaluations of programs carried out pursuant to section 561(a). The evaluations shall assess the effectiveness of the systems of care operated pursuant to such section, including longitudinal studies of outcomes of services provided by such systems, other studies regarding such outcomes, the effect of activities under this part on the utilization of hospital and other institutional settings, the barriers to and achievements resulting from interagency collaboration in providing community-based services to children with a serious emotional disturbance, and assessments by parents of the effectiveness of the systems of care.

(2) REPORT TO CONGRESS.—The Secretary shall, not later than 1 year after the date on which amounts are first appropriated under subsection (c), and annually thereafter, submit to the Congress a report summarizing evaluations carried out pursuant to paragraph (1) during the preceding fiscal year and making such recommendations for administrative and legislative initiatives with respect to this section as the Secretary determines to be appropriate.

(d) DEFINITIONS.—For purposes of this part:

(1) The term "child" means an individual through the age of 21 years.

(2) The term "family", with respect to a child provided access to a system of care under section 562(a), means—

(A) the legal guardian of the child; and

(B) [as appropriate regarding mental health services for the child, the parents of the child (biological or adoptive, as the case may be) and any foster parents of the child] *as appropriate regarding mental health services for the child and the parents or kinship caregivers of the child.*

(3) The term "funding agreement", with respect to a grant under section 561(a) to a public entity, means that the Secretary may make such a grant only if the public entity makes the agreement involved.

(4) The term "serious emotional disturbance" includes, with respect to a child, any child who has a serious emotional disorder, a serious behavioral disorder, or a serious mental disorder.

(e) RULE OF CONSTRUCTION.—Nothing in this part shall be construed as limiting the rights of a child with a serious emotional disturbance under the Individuals with Disabilities Education Act.

(f) FUNDING.—

(1) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this part, there are authorized to be appropriated [$119,026,000 for each of fiscal years 2018 through 2022] *$125,000,000 for each of fiscal years 2023 through 2027.*

(2) LIMITATION REGARDING TECHNICAL ASSISTANCE.—Not more than 10 percent of the amounts appropriated under paragraph (1) for a fiscal year may be expended for carrying out subsection (b).

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PART K—MINORITY FELLOWSHIP PROGRAM

SEC. 597. FELLOWSHIPS.

(a) IN GENERAL.—The Secretary shall maintain a program, to be known as the Minority Fellowship Program, under which the Secretary shall award fellowships, which may include stipends, for the purposes of—

(1) increasing the knowledge of mental and substance use disorders practitioners on issues related to prevention, treatment, and recovery support for individuals who are from racial and ethnic minority populations and who have a mental or substance use disorder;

(2) improving the quality of mental and substance use disorder prevention and treatment services delivered to racial and ethnic minority populations; and

(3) increasing the number of culturally competent mental and substance use disorders professionals who teach, administer services, conduct research, and provide direct mental or substance use disorder services to racial and ethnic minority populations.

(b) TRAINING COVERED.—The fellowships awarded under subsection (a) shall be for postbaccalaureate training (including for master's and doctoral degrees) for mental and substance use disorder treatment professionals, including [in the fields of psychiatry,] *in the fields of crisis care management, psychiatry,* nursing, social work, psychology, marriage and family therapy, mental health counseling, and substance use disorder and addiction counseling.

(c) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated $12,669,000 for each of fiscal years 2018 through 2022.

SEC. [550.] *550A.* SOBRIETY TREATMENT AND RECOVERY TEAMS.

(a) IN GENERAL.—The Secretary may make grants to States, units of local government, or tribal governments to establish or expand Sobriety Treatment And Recovery Team (referred to in this section as "START") or other similar programs to determine the effectiveness of pairing social workers or mentors with families that are struggling with a substance use disorder and child abuse or neglect in order to help provide peer support, intensive treatment, and child welfare services to such families.

(b) ALLOWABLE USES.—A grant awarded under this section may be used for one or more of the following activities:

(1) Training eligible staff, including social workers, social services coordinators, child welfare specialists, substance use disorder treatment professionals, and mentors.

(2) Expanding access to substance use disorder treatment services and drug testing.

(3) Enhancing data sharing with law enforcement agencies, child welfare agencies, substance use disorder treatment providers, judges, and court personnel.

(4) Program evaluation and technical assistance.

(c) PROGRAM REQUIREMENTS.—A State, unit of local government, or tribal government receiving a grant under this section shall—

(1) serve only families for which—

(A) there is an open record with the child welfare agency; and

(B) substance use disorder was a reason for the record or finding described in paragraph (1); and

(2) coordinate any grants awarded under this section with any grant awarded under section 437(f) of the Social Security Act focused on improving outcomes for children affected by substance abuse.

(d) TECHNICAL ASSISTANCE.—The Secretary may reserve not more than 5 percent of funds provided under this section to provide technical assistance on the establishment or expansion of programs funded under this section from the National Center on Substance Abuse and Child Welfare.

(e) COORDINATION OF FEDERAL ACTIVITIES TO PROMOTE THE AVAILABILITY OF HOUSING FOR INDIVIDUALS EXPERIENCING HOMELESSNESS, INDIVIDUALS WITH A MENTAL ILLNESS, AND INDIVIDUALS WITH A SUBSTANCE USE DISORDER.—

(1) IN GENERAL.—The Secretary, acting through the Assistant Secretary, and the Secretary of Housing and Urban Development shall convene an interagency working group for the following purposes:

(A) To increase collaboration, cooperation, and consultation among the Department of Health and Human Services, the Department of Housing and Urban Development, and the Federal agencies listed in paragraph (2)(B), with respect to promoting the availability of housing, including recovery housing, for individuals experiencing homelessness, individuals with mental illnesses, and individuals with substance use disorder.

(B) To align the efforts of such agencies and avoid duplication of such efforts by such agencies.

(C) To develop objectives, priorities, and a long-term plan for supporting State, Tribal, and local efforts with respect to the operation of recovery housing that is consistent with the best practices developed under this section.

(D) To coordinate enforcement of fair housing practices, as appropriate, among Federal and State agencies.

(E) To coordinate data collection on the quality of recovery housing.

(2) COMPOSITION.—The interagency working group under paragraph (1) shall be composed of—

(A) the Secretary, acting through the Assistant Secretary, and the Secretary of Housing and Urban Development, who shall serve as the co-chairs; and

(B) representatives of each of the following Federal agencies:

(i) The Centers for Medicare & Medicaid Services.

(ii) The Substance Abuse and Mental Health Services Administration.

(iii) The Health Resources and Services Administration.

(iv) The Office of Inspector General.

(v) The Indian Health Service.

(vi) The Department of Agriculture.

(vii) The Department of Justice.

(viii) The Office of National Drug Control Policy.

(ix) The Bureau of Indian Affairs.

(x) The Department of Labor.

(xi) The Department of Veterans Affairs.

(xii) Any other Federal agency as the co-chairs determine appropriate.

(3) MEETINGS.—The working group shall meet on a quarterly basis.

(4) REPORTS TO CONGRESS.—Not later than 4 years after the date of the enactment of this section, the working group shall submit to the Committee on Energy and Commerce, the Committee on Ways and Means, the Committee on Agriculture, and the Committee on Financial Services of the House of Representatives and the Committee on Health, Education, Labor, and Pensions, the Committee on Agriculture, Nutrition, and Forestry, and the Committee on Finance of the Senate a report describing the work of the working group and any recommendations of the working group to improve Federal, State, and local coordination with respect to recovery housing and other housing resources and operations for individuals experiencing homelessness, individuals with a mental illness, and individuals with a substance use disorder.

(f) GRANTS FOR IMPLEMENTING NATIONAL RECOVERY HOUSING BEST PRACTICES.—

(1) IN GENERAL.—The Secretary shall award grants to States (and political subdivisions thereof), Tribes, and territories—

(A) for the provision of technical assistance to implement the guidelines and recommendations developed under subsection (a); and

(B) to promote—

(i) the availability of recovery housing for individuals with a substance use disorder; and

(ii) the maintenance of recovery housing in accordance with best practices developed under this section.

(2) STATE PROMOTION PLANS.—Not later than 90 days after receipt of a grant under paragraph (1), and every 2 years thereafter, each State (or political subdivisions thereof,) Tribe, or territory receiving a grant under paragraph (1) shall submit to the Secretary, and publish on a publicly accessible internet website of the State (or political subdivisions thereof), Tribe, or territory—

(A) the plan of the State (or political subdivisions thereof), Tribe, or territory, with respect to the promotion of recovery housing for individuals with a substance use disorder located within the jurisdiction of such State (or political subdivisions thereof), Tribe, or territory; and

(B) a description of how such plan is consistent with the best practices developed under this section.

TITLE VII—HEALTH PROFESSIONS EDUCATION

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PART D—INTERDISCIPLINARY, COMMUNITY-BASED LINKAGES

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SEC. 756. MENTAL AND BEHAVIORAL HEALTH EDUCATION AND TRAINING GRANTS.

(a) GRANTS AUTHORIZED.—The Secretary may award grants to eligible institutions to support the recruitment of students for, and education and clinical experience of the students in—

(1) accredited institutions of higher education or accredited professional training programs that are establishing or expanding internships or other field placement programs in mental health in psychiatry, psychology, school psychology, behavioral pediatrics, psychiatric nursing (which may include master's and doctoral level programs), social work, school social work, substance use disorder prevention and treatment, marriage and family therapy, occupational therapy *(which may include master's and doctoral level programs)*, school counseling, or professional counseling, including such programs with a focus on child and adolescent mental health, trauma, and transitional-age youth;

(2) accredited doctoral, internship, and post-doctoral residency programs of health service psychology (including clinical psychology, counseling, and school psychology) for the development and implementation of interdisciplinary training of psychology graduate students for providing behavioral health services, including trauma-informed care and substance use disorder prevention and treatment services, as well as the development of faculty in health service psychology;

(3) accredited master's and doctoral degree programs of social work for the development and implementation of interdisciplinary training of social work graduate students for providing behavioral health services, including trauma-informed care and substance use disorder prevention and treatment services, and the development of faculty in social work; and

(4) State-licensed mental health nonprofit and for-profit organizations to enable such organizations to pay for programs for preservice or in-service training in a behavioral health-related paraprofessional field with preference for preservice or in-service training of paraprofessional child and adolescent mental health workers.

(b) ELIGIBILITY REQUIREMENTS.—To be eligible for a grant under this section, an institution shall demonstrate—

(1) an ability to recruit and place the students described in subsection (a) in areas with a high need and high demand population;

(2) participation in the institutions' programs of individuals and groups from different racial, ethnic, cultural, geographic, religious, linguistic, and class backgrounds, and different genders and sexual orientations;

(3) knowledge and understanding of the concerns of the individuals and groups described in paragraph (2), especially individuals with mental disorder symptoms or diagnoses, particularly children and adolescents, and transitional-age youth;

(4) any internship or other field placement program assisted under the grant will prioritize cultural and linguistic competency; and

(5) the institution will provide to the Secretary such data, assurances, and information as the Secretary may require.

(c) INSTITUTIONAL REQUIREMENT.—For grants awarded under paragraphs (2) and (3) of subsection (a), at least 4 of the grant recipients shall be historically black colleges or universities or other minority-serving institutions.

(d) PRIORITY.—In selecting grant recipients under this section, the Secretary shall give priority to—

(1) programs that have demonstrated the ability to train psychology, psychiatry, and social work professionals to work in integrated care settings for purposes of recipients under paragraphs (1), (2), and (3) of subsection (a); and

(2) programs for paraprofessionals that emphasize the role of the family and the lived experience of the consumer and family-paraprofessional partnerships for purposes of recipients under subsection (a)(4).

(e) REPORT TO CONGRESS.—Not later than 4 years after the date of enactment of the Helping Families in Mental Health Crisis Reform Act of 2016, the Secretary shall include in the biennial report submitted to Congress under section 501(m) an assessment on the effectiveness of the grants under this section in—

(1) providing graduate students support for experiential training (internship or field placement);

(2) recruiting students interested in behavioral health practice;

(3) recruiting students in accordance with subsection (b)(1);

(4) developing and implementing interprofessional training and integration within primary care;

(5) developing and implementing accredited field placements and internships; and

(6) collecting data on the number of students trained in behavioral health care and the number of available accredited internships and field placements.

(f) AUTHORIZATION OF APPROPRIATIONS.—**[**For each of fiscal years 2019 through 2023**]** *For each of fiscal years 2023 through 2027*, there are authorized to be appropriated to carry out this section $50,000,000, to be allocated as follows:

(1) For grants described in subsection (a)(1), $15,000,000.

(2) For grants described in subsection (a)(2), $15,000,000.

(3) For grants described in subsection (a)(3), $10,000,000.

(4) For grants described in subsection (a)(4), $10,000,000.

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SEC. 760. TRAINING DEMONSTRATION PROGRAM.

(a) IN GENERAL.—The Secretary shall establish a training demonstration program to award grants to eligible entities to support—

(1) training for medical residents and fellows to practice psychiatry and addiction medicine in underserved, community-based settings that integrate primary care with mental and substance use disorders prevention and treatment services;

(2) training for nurse practitioners, physician assistants, health service psychologists, and social workers to provide mental and substance use disorders services in underserved community-based settings that integrate primary care and mental and substance use disorders services; and

(3) establishing, maintaining, or improving academic units or programs that—

(A) provide training for students or faculty, including through clinical experiences and research, to improve the ability to be able to recognize, diagnose, and treat mental and substance use disorders, with a special focus on addiction; or

(B) develop evidence-based practices or recommendations for the design of the units or programs described in subparagraph (A), including curriculum content standards.

(b) ACTIVITIES.—

(1) TRAINING FOR RESIDENTS AND FELLOWS.—A recipient of a grant under subsection (a)(1)—

(A) shall use the grant funds—

(i)(I) to plan, develop, and operate a training program for medical psychiatry residents and fellows in addiction medicine practicing in eligible entities described in subsection (c)(1); or

(II) to train new psychiatric residents and fellows in addiction medicine to provide and expand access to integrated mental and substance use disorders services; and

(ii) to provide at least 1 training track that is—

(I) a virtual training track that includes an in-person rotation at a teaching health center or in a community-based setting, followed by a virtual rotation in which the resident or fellow continues to support the care of patients at the teaching health center or in the community-based setting through the use of health information technology and, as appropriate, telehealth services;

(II) an in-person training track that includes a rotation, during which the resident or fellow practices at a teaching health center or in a community-based setting; or

(III) an in-person training track that includes a rotation during which the resident practices in a community-based setting that specializes in the treatment of infants, children, adolescents, or pregnant or postpartum women; and

(B) may use the grant funds to provide additional support for the administration of the program or to meet the costs of projects to establish, maintain, or improve faculty

development, or departments, divisions, or other units necessary to implement such training.

(2) TRAINING FOR OTHER PROVIDERS.—A recipient of a grant under subsection (a)(2)—

(A) shall use the grant funds to plan, develop, or operate a training program to provide mental and substance use disorders services in underserved, community-based settings, as appropriate, that integrate primary care and mental and substance use disorders prevention and treatment services; and

(B) may use the grant funds to provide additional support for the administration of the program or to meet the costs of projects to establish, maintain, or improve faculty development, or departments, divisions, or other units necessary to implement such program.

(3) ACADEMIC UNITS OR PROGRAMS.—A recipient of a grant under subsection (a)(3) shall enter into a partnership with organizations such as an education accrediting organization (such as the Liaison Committee on Medical Education, the Accreditation Council for Graduate Medical Education, the Commission on Osteopathic College Accreditation, the Accreditation Commission for Education in Nursing, the Commission on Collegiate Nursing Education, the Accreditation Council for Pharmacy Education, the Council on Social Work Education, American Psychological Association Commission on Accreditation, or the Accreditation Review Commission on Education for the Physician Assistant) to carry out activities under subsection (a)(3).

(c) ELIGIBLE ENTITIES.—

(1) TRAINING FOR RESIDENTS AND FELLOWS.—To be eligible to receive a grant under subsection (a)(1), an entity shall—

(A) be a consortium consisting of—

(i) at least one teaching health center; and

(ii) the sponsoring institution (or parent institution of the sponsoring institution) of—

(I) a psychiatry residency program that is accredited by the Accreditation Council of Graduate Medical Education (or the parent institution of such a program); or

(II) a fellowship in addiction medicine, as determined appropriate by the Secretary; or

(B) be an entity described in subparagraph (A)(ii) that provides opportunities for residents or fellows to train in community-based settings that integrate primary care with mental and substance use disorders prevention and treatment services.

(2) TRAINING FOR OTHER PROVIDERS.—To be eligible to receive a grant under subsection (a)(2), an entity shall be—

(A) a teaching health center (as defined in section 749A(f));

(B) a Federally qualified health center (as defined in section 1905(l)(2)(B) of the Social Security Act);

(C) a community mental health center (as defined in section 1861(ff)(3)(B) of the Social Security Act);

(D) a rural health clinic (as defined in section 1861(aa) of the Social Security Act);

(E) a health center operated by the Indian Health Service, an Indian tribe, a tribal organization, or an urban Indian organization (as defined in section 4 of the Indian Health Care Improvement Act); or

(F) an entity with a demonstrated record of success in providing training for nurse practitioners, physician assistants, health service psychologists, and social workers.

(3) ACADEMIC UNITS OR PROGRAMS.—To be eligible to receive a grant under subsection (a)(3), an entity shall be a school of medicine or osteopathic medicine, a nursing school, a physician assistant training program, a school of pharmacy, a school of social work, an accredited public or nonprofit private hospital, an accredited medical residency program, or a public or private nonprofit entity which the Secretary has determined is capable of carrying out such grant.

(d) PRIORITY.—

(1) IN GENERAL.—In awarding grants under subsection (a)(1) or (a)(2), the Secretary shall give priority to eligible entities that—

(A) demonstrate sufficient size, scope, and capacity to undertake the requisite training of an appropriate number of psychiatric residents, fellows, nurse practitioners, physician assistants, or social workers in addiction medicine per year to meet the needs of the area served;

(B) demonstrate experience in training providers to practice team-based care that integrates mental and substance use disorder prevention and treatment services with primary care in community-based settings;

(C) demonstrate experience in using health information technology and, as appropriate, telehealth to support—

(i) the delivery of mental and substance use disorders services at the eligible entities described in subsections (c)(1) and (c)(2); and

(ii) community health centers in integrating primary care and mental and substance use disorders treatment; or

(D) have the capacity to expand access to mental and substance use disorders services in areas with demonstrated need, as determined by the Secretary, such as tribal, rural, or other underserved communities.

(2) ACADEMIC UNITS OR PROGRAMS.—In awarding grants under subsection (a)(3), the Secretary shall give priority to eligible entities that—

(A) have a record of training the greatest percentage of mental and substance use disorders providers who enter and remain in these fields or who enter and remain in settings with integrated primary care and mental and substance use disorder prevention and treatment services;

(B) have a record of training individuals who are from underrepresented minority groups, including native populations, or from a rural or disadvantaged background;

(C) provide training in the care of vulnerable populations such as infants, children, adolescents, pregnant

and postpartum women, older adults, homeless individuals, victims of abuse or trauma, individuals with disabilities, and other groups as defined by the Secretary;

(D) teach trainees the skills to provide interprofessional, integrated care through collaboration among health professionals; or

(E) provide training in cultural competency and health literacy.

(e) DURATION.—Grants awarded under this section shall be for a minimum of 5 years.

(f) STUDY AND REPORT.—

(1) STUDY.—

(A) IN GENERAL.—The Secretary, acting through the Administrator of the Health Resources and Services Administration, shall conduct a study on the results of the demonstration program under this section.

(B) DATA SUBMISSION.—Not later than 90 days after the completion of the first year of the training program and each subsequent year that the program is in effect, each recipient of a grant under subsection (a) shall submit to the Secretary such data as the Secretary may require for analysis for the report described in paragraph (2).

(2) REPORT TO CONGRESS.—Not later than 1 year after receipt of the data described in paragraph (1)(B), the Secretary shall submit to Congress a report that includes—

(A) an analysis of the effect of the demonstration program under this section on the quality, quantity, and distribution of mental and substance use disorders services;

(B) an analysis of the effect of the demonstration program on the prevalence of untreated mental and substance use disorders in the surrounding communities of health centers participating in the demonstration; and

(C) recommendations on whether the demonstration program should be expanded.

(g) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section $10,000,000 for each of fiscal years 2018 through 2022 *and $31,700,000 for each of fiscal years 2023 through 2027*.

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TITLE XIX—BLOCK GRANTS

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Part B—Block Grants Regarding Mental Health and [Substance Abuse] *Substance Use*

Subpart I—Block Grants for Community Mental Health Services

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SEC. 1912. STATE PLAN FOR COMPREHENSIVE COMMUNITY MENTAL HEALTH SERVICES FOR CERTAIN INDIVIDUALS.

(a) IN GENERAL.—The Secretary may make a grant under section 1911 only if—

(1) the State involved submits to the Secretary a plan for providing comprehensive community mental health services to adults with a serious mental illness and to children with a serious emotional disturbance;

(2) the plan meets the criteria specified in subsection (b); and

(3) the plan is approved by the Secretary.

(b) CRITERIA FOR PLAN.—In accordance with subsection (a), a State shall submit to the Secretary a plan every two years that, at a minimum, includes each of the following:

(1) SYSTEM OF CARE.—A description of the State's system of care that contains the following:

(A) COMPREHENSIVE COMMUNITY-BASED HEALTH SYSTEMS.—The plan shall—

(i) identify the single State agency to be responsible for the administration of the program under the grant, including any third party who administers mental health services and is responsible for complying with the requirements of this part with respect to the grant;

(ii) provide for an organized community-based system of care for individuals with mental illness, and describe available services and resources in a comprehensive system of care, including services for individuals with co-occurring disorders;

(iii) include a description of the manner in which the State and local entities will coordinate services to maximize the efficiency, effectiveness, quality, and cost-effectiveness of services and programs to produce the best possible outcomes (including health services, rehabilitation services, employment services, housing services, educational services, substance use disorder services, legal services, law enforcement services, social services, child welfare services, medical and dental care services, and other support services to be provided with Federal, State, and local public and private resources) with other agencies to enable individuals receiving services to function outside of inpatient or residential institutions, to the maximum extent of their capabilities, including services to be provided by local school systems under the Individuals with Disabilities Education Act;

(iv) include a description of how the State promotes evidence-based practices, including those evidence-based programs that address the needs of individuals with early serious mental illness regardless of the age of the individual at onset, provide comprehensive individualized treatment, or integrate mental and physical health services;

(v) include a description of case management services;

(vi) include a description of activities that seek to engage adults with a serious mental illness or children with a serious emotional disturbance and their caregivers where appropriate in making health care decisions, including activities that enhance communication among individuals, families, caregivers, and treatment providers; and

(vii) as appropriate to, and reflective of, the uses the State proposes for the block grant funds, include—

(I) a description of the activities intended to reduce hospitalizations and hospital stays using the block grant funds;

(II) a description of the activities intended to reduce incidents of suicide using the block grant funds;

(III) a description of how the State integrates mental health and primary care using the block grant funds, which may include providing, in the case of individuals with co-occurring mental and substance use disorders, both mental and substance use disorders services in primary care settings or arrangements to provide primary and specialty care services in community-based mental and substance use disorders settings; **[**and**]**

(IV) a description of recovery and recovery support services for adults with a serious mental illness and children with a serious emotional disturbance**[**.**]***; and*

(V) a description of any evidence-based early intervention strategies and programs the State provides to prevent, delay, or reduce the severity and onset of mental illness and behavioral problems, including for children and adolescents, irrespective of experiencing a serious mental illness or serious emotional disturbance, as defined under subsection (c)(1).

(B) MENTAL HEALTH SYSTEM DATA AND EPIDEMIOLOGY.—The plan shall containan estimate of the incidence and prevalence in the State of serious mental illness among adults and serious emotional disturbance among children and present quantitative targets and outcome measures for programs and services provided under this subpart.

(C) CHILDREN'S SERVICES.—In the case of children with a serious emotional disturbance (as defined pursuant to subsection (c)), the plan shall provide for a system of integrated social services, educational services, child welfare services, juvenile justice services, law enforcement services, and substance use disorder services that, together with health and mental health services, will be provided in order for such children to receive care appropriate for their multiple needs (such system to include services provided under the Individuals with Disabilities Education Act).

(D) TARGETED SERVICES TO RURAL AND HOMELESS POPULATIONS.—Theplan shall describe the State's outreach to and services for individuals who are homeless and how

community-based services will be provided to individuals residing in rural areas.

(E) MANAGEMENT SERVICES.—The plan shall describe the financial resources available, the existing mental health workforce, and the workforce trained in treating individuals with co-occurring mental and substance use disorders, and shall provide for the training of providers of emergency health services regarding mental health. The plan shall further describe the manner in which the State intends to expend the grant under section 1911 for the fiscal year involved, and the manner in which the State intends to comply with each of the funding agreements in this subpart and subpart III.

(2) GOALS AND OBJECTIVES.—The establishment of goals and objectives for the period of the plan, including targets and milestones that are intended to be met, and the activities that will be undertaken to achieve those targets.

(c) DEFINITIONS REGARDING MENTAL ILLNESS AND EMOTIONAL DISTURBANCE; METHODS FOR ESTIMATE OF INCIDENCE AND PREVALENCE.—

(1) ESTABLISHMENT BY SECRETARY OF DEFINITIONS; DISSEMINATION.—For purposes of this subpart, the Secretary shall establish definitions for the terms "adults with a serious mental illness" and "children with a serious emotional disturbance". The Secretary shall disseminate the definitions to the States.

(2) STANDARDIZED METHODS.—The Secretary shall establish standardized methods for making the estimates required in subsection (b)(11) with respect to a State. A funding agreement for a grant under section 1911 for the State is that the State will utilize such methods in making the estimates.

(3) DATE CERTAIN FOR COMPLIANCE BY SECRETARY.—Not later than 90 days after the date of the enactment of the ADAMHA Reorganization Act, the Secretary shall establish the definitions described in paragraph (1), shall begin dissemination of the definitions to the States, and shall establish the standardized methods described in paragraph (2).

(d) REQUIREMENT OF IMPLEMENTATION OF PLAN.—

(1) COMPLETE IMPLEMENTATION.—Except as provided in paragraph (2), in making a grant under section 1911 to a State for a fiscal year, the Secretary shall make a determination of the extent to which the State has implemented the plan required in subsection (a). If the Secretary determines that a State has not completely implemented the plan, the Secretary shall reduce the amount of the allotment under section 1911 for the State for the fiscal year involved by an amount equal to 10 percent of the amount determined under section 1918 for the State for the fiscal year.

(2) SUBSTANTIAL IMPLEMENTATION AND GOOD FAITH EFFORT REGARDING FISCAL YEAR 1993.—

(A) In making a grant under section 1911 to a State for fiscal year 1993, the Secretary shall make a determination of the extent to which the State has implemented the plan required in subsection (a). If the Secretary determines that the State has not substantially implemented the plan, the Secretary shall, subject to subparagraph (B), reduce the

amount of the allotment under section 1911 for the State for such fiscal year by an amount equal to 10 percent of the amount determined under section 1918 for the State for the fiscal year.

(B) In carrying out subparagraph (A), if the Secretary determines that the State is making a good faith effort to implement the plan required in subsection (a), the Secretary may make a reduction under such subparagraph in an amount that is less than the amount specified in such subparagraph, except that the reduction may not be made in an amount that is less than 5 percent of the amount determined under section 1918 for the State for fiscal year 1993.

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SEC. 1920. FUNDING.

(a) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this subpart, and subpart III and section 505(c) with respect to mental health, there are authorized to be appropriated [$532,571,000 for each of fiscal years 2018 through 2022] *$857,571,000 for each of fiscal years 2023 through 2027*.

(b) ALLOCATIONS FOR TECHNICAL ASSISTANCE, DATA COLLECTION, AND PROGRAM EVALUATION.—

(1) IN GENERAL.—For the purpose of carrying out section 1948(a) with respect to mental health and the purposes specified in paragraphs (2) and (3), the Secretary shall obligate 5 percent of the amounts appropriated under subsection (a) for a fiscal year.

(2) DATA COLLECTION.—The purpose specified in this paragraph is carrying out sections 505(c) and 1971 with respect to mental health.

(3) PROGRAM EVALUATION.—The purpose specified in this paragraph is the conduct of evaluations of prevention and treatment programs and services with respect to mental health to determine methods for improving the availability and quality of such programs and services.

(c) EARLY SERIOUS MENTAL ILLNESS.—

(1) IN GENERAL.—Except as provided in paragraph (2), a State shall expend not less than 10 percent of the amount the State receives for carrying out this section for each fiscal year to support evidence-based programs that address the needs of individuals with early serious mental illness, including psychotic disorders, regardless of the age of the individual at onset.

(2) STATE FLEXIBILITY.—In lieu of expending 10 percent of the amount the State receives under this section for a fiscal year as required under paragraph (1), a State may elect to expend not less than 20 percent of such amount by the end of such succeeding fiscal year.

(d) CRISIS CARE.—

(1) IN GENERAL.—Except as provided in paragraph (3), a State shall expend at least 5 percent of the amount the State receives pursuant to section 1911 for each fiscal year to support evidenced-based programs that address the crisis care needs of—

(A) individuals, including children and adolescents, experiencing mental health crises, substance-related crises, or crises arising from co-occurring disorders; and

(B) persons with intellectual and developmental disabilities.

(2) CORE ELEMENTS.—At the discretion of the single State agency responsible for the administration of the program of the State under a grant under section 1911, funds expended pursuant to paragraph (1) may be used to fund some or all of the core crisis care service components, delivered according to evidence-based principles, including the following:

(A) Crisis call centers.

(B) 24/7 mobile crisis services.

(C) Crisis stabilization programs offering acute care or subacute care in a hospital or appropriately licensed facility, as determined by the Substance Abuse and Mental Health Services Administration, with referrals to inpatient or outpatient care.

(3) STATE FLEXIBILITY.—In lieu of expending 5 percent of the amount the State receives pursuant to section 1911 for a fiscal year to support evidence-based programs as required by paragraph (1), a State may elect to expend not less than 10 percent of such amount to support such programs by the end of two consecutive fiscal years.

(4) RULE OF CONSTRUCTION.—With respect to funds expended pursuant to the set-aside in paragraph (1), section 1912(b)(1)(A)(vi) shall not apply.

(e) EARLY INTERVENTION SERVICES.—In the case of a State with a State plan that provides for strategies and programs specified in section 1912(b)(1)(A)(vii)(VI), such State may expend not more than 5 percent of the amount of the allotment of the State pursuant to a funding agreement under section 1911 for each fiscal year to support such strategies and programs.

(f) REPORTS TO CONGRESS.—Not later than September 30, 2025, and biennially thereafter, the Secretary shall provide a report to the Congress on the crisis care and early intervention strategies and programs pursued by States pursuant to subsections (d) and (e). Each such report shall include—

(1) a description of the each State's crisis care and early intervention activities;

(2) the population served, including information on demographics, including age;

(3) the outcomes of such activities, including—

(A) how such activities reduced hospitalizations and hospital stays;

(B) how such activities reduced incidents of suicidal ideation and behaviors; and

(C) how such activities reduced the severity of onset of serious mental illness and serious emotional disturbance; and

(4) any other relevant information the Secretary deems necessary.

Subpart II—[Block Grants for Prevention and Treatment of Substance Abuse] *Block Grants for Substance Use Prevention, Treatment, and Recovery Services*

SEC. 1921. FORMULA GRANTS TO STATES.

(a) IN GENERAL.—For the purpose described in subsection (b), the Secretary, acting through the Center for Substance Abuse Treatment, shall make an allotment each fiscal year for each State in an amount determined in accordance with section 1933. The Secretary shall make a grant to the State of the allotment made for the State for the fiscal year if the State submits to the Secretary an application in accordance with section 1932.

(b) AUTHORIZED ACTIVITIES.—A funding agreement for a grant under subsection (a) is that, subject to section 1931, the State involved will expend the grant only for the purpose of carrying out the plan developed in accordance with section 1932(b) and for planning, carrying out, and evaluating activities to [prevent and treat substance use disorders] *prevent, treat, and provide recovery support services for substance use disorders* and for related activities authorized in section 1924.

SEC. 1922. CERTAIN ALLOCATIONS.

(a) ALLOCATION REGARDING PRIMARY PREVENTION PROGRAMS.—A funding agreement for a grant under section 1921 is that, in expending the grant, the State involved—

(1) will expend not less than 20 percent for programs for individuals who do not require treatment for [substance abuse] *substance use disorders*, which programs—

(A) educate and counsel the individuals on [such abuse] *such disorders*; and

(B) provide for activities to reduce the risk of [such abuse] *such disorders* by the individuals;

(2) will, in carrying out paragraph (1)—

(A) give priority to programs for populations that are at risk of developing a pattern of [such abuse] *such disorders*; and

(B) ensure that programs receiving priority under subparagraph (A) develop community-based strategies for the prevention of [such abuse] *such disorders*, including strategies to discourage the use of alcoholic beverages and tobacco products by individuals to whom it is unlawful to sell or distribute such beverages or products.

(b) ALLOCATIONS REGARDING WOMEN.—

(1) IN GENERAL.—Subject to paragraph (2), a funding agreement for a grant under section 1921 for a fiscal year is that—

(A) in the case of a grant for fiscal year 1993, the State involved will expend not less than 5 percent of the grant to increase (relative to fiscal year 1992) the availability of treatment services designed for pregnant women and women with dependent children (either by establishing new programs or expanding the capacity of existing programs);

(B) in the case of a grant for fiscal year 1994, the State will expend not less than 5 percent of the grant to so in-

crease (relative to fiscal year 1993) the availability of such services for such women; and

(C) in the case of a grant for any subsequent fiscal year, the State will expend for such services for such women not less than an amount equal to the amount expended by the State for fiscal year 1994.

(2) WAIVER.—

(A) Upon the request of a State, the Secretary may provide to the State a waiver of all or part of the requirement established in paragraph (1) if the Secretary determines that the State is providing an adequate level of treatments services for women described in such paragraph, as indicated by a comparison of the number of such women seeking the services with the availability in the State of the services.

(B) The Secretary shall approve or deny a request for a waiver under subparagraph (A) not later than 120 days after the date on which the request is made.

(C) Any waiver provided by the Secretary under subparagraph (A) shall be applicable only to the fiscal year involved.

(3) CHILDCARE AND PRENATAL CARE.—A funding agreement for a grant under section 1921 for a State is that each entity providing treatment services with amounts reserved under paragraph (1) by the State will, directly or through arrangements with other public or nonprofit private entities, make available prenatal care to women receiving such services and, while the women are receiving the services, childcare.

SEC. 1923. INTRAVENOUS [SUBSTANCE ABUSE] *SUBSTANCE USE*.

(a) CAPACITY OF TREATMENT PROGRAMS.—

(1) NOTIFICATION OF REACHING CAPACITY.—A funding agreement for a grant under section 1921 is that the State involved will, in the case of programs of treatment for intravenous [drug abuse] *substance use disorders*, require that any such program receiving amounts from the grant, upon reaching 90 percent of its capacity to admit individuals to the program, provide to the State a notification of such fact.

(2) PROVISION OF TREATMENT.—A funding agreement for a grant under section 1921 is that the State involved will, with respect to notifications under paragraph (1), ensure that each individual who requests and is in need of treatment for intravenous [drug abuse] *substance use disorders* is admitted to a program of such treatment not later than—

(A) 14 days after making the request for admission to such a program; or

(B) 120 days after the date of such request, if no such program has the capacity to admit the individual on the date of such request and if interim services are made available to the individual not later than 48 hours after such request.

(b) OUTREACH TO PERSONS WHO INJECT DRUGS.—A funding agreement for a grant under section 1921 is that the State involved, in providing amounts from the grant to any entity for treatment services for persons who inject drugs, will require the entity

to carry out activities to encourage individuals in need of such treatment to undergo treatment.

SEC. 1924. REQUIREMENTS REGARDING [TUBERCULOSIS AND HUMAN IMMUNODEFICIENCY VIRUS] *TUBERCULOSIS, VIRAL HEPATITIS, AND HUMAN IMMUNODEFICIENCY VIRUS.*

(a) TUBERCULOSIS.—

(1) IN GENERAL.—A funding agreement for a grant under section 1921 is that the State involved will require that any entity receiving amounts from the grant for operating a program of treatment for substance use disorders—

(A) will, directly or through arrangements with other public or nonprofit private entities, routinely make available tuberculosis services to each individual receiving treatment for such disorders; and

(B) in the case of an individual in need of such treatment who is denied admission to the program on the basis of the lack of the capacity of the program to admit the individual, will refer the individual to another provider of tuberculosis services.

[(2) TUBERCULOSIS SERVICES.—For purposes of paragraph (1), the term "tuberculosis services", with respect to an individual, means—

[(A) counseling the individual with respect to tuberculosis;

[(B) testing to determine whether the individual has contracted such disease and testing to determine the form of treatment for the disease that is appropriate for the individual; and

[(C) providing such treatment to the individual.]

(2) DESIGNATED STATES.—

(A) FISCAL YEARS THROUGH FISCAL YEAR 2024.—For purposes of this subsection, through September 30, 2024, a State described in this paragraph is any State whose rate of cases of acquired immune deficiency syndrome is 10 or more such cases per 100,000 individuals (as indicated by the number of such cases reported to and confirmed by the Director of the Centers for Disease Control and Prevention for the most recent calendar year for which such data are available).

(B) FISCAL YEAR 2025 AND SUCCEEDING FISCAL YEARS.—

(i) IN GENERAL.—Beginning with fiscal year 2025, for purposes of this subsection, a State described in this paragraph is any State whose rate of cases of human immunodeficiency virus is 10 or more such cases per 100,000 individuals (as indicated by the number of such cases newly reported to and confirmed by the Director of the Centers for Disease Control and Prevention for the most recent calendar year for which such data are available).

(ii) CONTINUATION OF DESIGNATED STATE STATUS.—In the case of a State whose rate of cases of human immunodeficiency virus falls below the threshold specified in clause (i) for a calendar year, such State shall, notwithstanding clause (i), continue to be described in this

paragraph unless the rate of cases falls below such threshold for three consecutive calendar years.

(b) HUMAN IMMUNODEFICIENCY VIRUS.—

(1) REQUIREMENT FOR CERTAIN STATES.—In the case of a State described in paragraph (2), a funding agreement for a grant under section 1921 is that—

(A) with respect to individuals undergoing treatment for substance use disorders, the State will, subject to paragraph (3), carry out 1 or more projects to make available to the individuals early intervention services for HIV disease at the sites at which the individuals are undergoing such treatment;

(B) for the purpose of providing such early intervention services through such projects, the State will make available from the grant the percentage that is applicable for the State under paragraph (4); and

(C) the State will, subject to paragraph (5), carry out such projects only in geographic areas of the State that have the greatest need for the projects.

(2) DESIGNATED STATES.—For purposes of this subsection, a State described in this paragraph is any State whose rate of cases of acquired immune deficiency syndrome is 10 or more such cases per 100,000 individuals (as indicated by the number of such cases reported to and confirmed by the Director of the Centers for Disease Control and Prevention for the most recent calendar year for which such data are available).

(3) USE OF EXISTING PROGRAMS REGARDING SUBSTANCE USE DISORDERS.—With respect to programs that provide treatment services for substance use disorders, a funding agreement for a grant under section 1921 for a designated State is that each such program participating in a project under paragraph (1) will be a program that began operation prior to the fiscal year for which the State is applying to receive the grant. A program that so began operation may participate in a project under paragraph (1) without regard to whether the program has been providing early intervention services for HIV disease.

(4) APPLICABLE PERCENTAGE REGARDING EXPENDITURES FOR SERVICES.—

(A)(i) For purposes of paragraph (1)(B), the percentage that is applicable under this paragraph for a designated State is, subject to subparagraph (B), the percentage by which the amount of the grant under section 1921 for the State for the fiscal year involved is an increase over the amount specified in clause (ii).

(ii) The amount specified in this clause is the amount that was reserved by the designated State involved from the allotment of the State under section 1912A for fiscal year 1991 in compliance with section 1916(c)(6)(A)(ii) (as such sections were in effect for such fiscal year).

(B) If the percentage determined under subparagraph (A) for a designated State for a fiscal year is less than 2 percent (including a negative percentage, in the case of a State for which there is no increase for purposes of such subparagraph), the percentage applicable under this paragraph for the State is 2 percent. If the percentage so deter-

mined is 2 percent or more, the percentage applicable under this paragraph for the State is the percentage determined under subparagraph (A), subject to not exceeding 5 percent.

(5) REQUIREMENT REGARDING RURAL AREAS.—

(A) A funding agreement for a grant under section 1921 for a designated State is that, if the State will carry out 2 or more projects under paragraph (1), the State will carry out 1 such project in a rural area of the State, subject to subparagraph (B).

(B) The Secretary shall waive the requirement established in subparagraph (A) if the State involved certifies to the Secretary that—

(i) there is insufficient demand in the State to carry out a project under paragraph (1) in any rural area of the State; or

(ii) there are no rural areas in the State.

(6) MANNER OF PROVIDING SERVICES.—With respect to the provision of early intervention services for HIV disease to an individual, a funding agreement for a grant under section 1921 for a designated State is that—

(A) such services will be undertaken voluntarily by, and with the informed consent of, the individual; and

(B) undergoing such services will not be required as a condition of receiving treatment services for substance use disorders or any other services.

(7) DEFINITIONS.—For purposes of this subsection:

(A) The term "designated State" means a State described in paragraph (2).

(B) The term "early intervention services", with respect to HIV disease, means—

(i) appropriate pretest counseling;

(ii) testing individuals with respect to such disease, including tests to confirm the presence of the disease, tests to diagnose the extent of the deficiency in the immune system, and tests to provide information on appropriate therapeutic measures for preventing and treating the deterioration of the immune system and for preventing and treating conditions arising from the disease;

(iii) appropriate post-test counseling; and

(iv) providing the therapeutic measures described in clause (ii).

(C) The term "HIV disease" means infection with the etiologic agent for acquired immune deficiency syndrome.

(c) VIRAL HEPATITIS.—

(1) IN GENERAL.—A funding agreement for a grant under section 1921 is that the State involved will require that any entity receiving amounts from the grant for operating a program of treatment for substance use disorders—

(A) will, directly or through arrangements with other public or nonprofit private entities, routinely make available viral hepatitis services to each individual receiving treatment for such disorders; and

(B) in the case of an individual in need of such treatment who is denied admission to the program on the basis of the lack of the capacity of the program to admit the individual, will refer the individual to another provider of viral hepatitis services.

(2) VIRAL HEPATITIS SERVICES.—For purposes of paragraph (1), the term "viral hepatitis services", with respect to an individual, means—

(A) screening the individual for viral hepatitis; and

(B) referring the individual to a provider whose practice includes viral hepatitis vaccination and treatment.

[(c)] *(d)* EXPENDITURE OF GRANT FOR COMPLIANCE WITH AGREEMENTS.—

(1) IN GENERAL.—A grant under section 1921 may be expended for purposes of compliance with the agreements required in this section, subject to paragraph (2).

(2) LIMITATION.—A funding agreement for a grant under section 1921 for a State is that the grant will not be expended to make payment for any service provided for purposes of compliance with this section to the extent that payment has been made, or can reasonably be expected to be made, with respect to such service—

(A) under any State compensation program, under any insurance policy, or under any Federal or State health benefits program (including the program established in title XVIII of the Social Security Act and the program established in title XIX of such Act); or

(B) by an entity that provides health services on a prepaid basis.

[(d)] *(e)* APPLICABILITY OF CERTAIN PROVISION.—Section 1931 applies to this section (and to each other provision of this subpart).

SEC. 1925. GROUP HOMES FOR PERSONS IN RECOVERY FROM SUBSTANCE USE DISORDERS.

(a) STATE REVOLVING FUNDS FOR ESTABLISHMENT OF HOMES.—A State, using funds available under section 1921, may establish and maintain the ongoing operation of a revolving fund in accordance with this section to support group homes for persons in recovery from substance use disorders as follows:

(1) The purpose of the fund is to make loans for the costs of establishing programs for the provision of housing in which individuals recovering from [alcohol or drug abuse] *alcohol or other substance use disorders* may reside in groups of not less than 6 individuals. The fund is established directly by the State or through the provision of a grant or contract to a nonprofit private entity.

(2) The programs are carried out in accordance with guidelines issued under subsection (b).

(3) Not less than $100,000 is available for the fund.

(4) Loans made from the revolving fund do not exceed $4,000 and each such loan is repaid to the revolving fund by the residents of the housing involved not later than 2 years after the date on which the loan is made.

(5) Each such loan is repaid by such residents through monthly installments, and a reasonable penalty is assessed for

each failure to pay such periodic installments by the date specified in the loan agreement involved.

(6) Such loans are made only to nonprofit private entities agreeing that, in the operation of the program established pursuant to the loan—

(A) the use of alcohol or any illegal drug in the housing provided by the program will be prohibited;

(B) any resident of the housing who violates such prohibition will be expelled from the housing;

(C) the costs of the housing, including fees for rent and utilities, will be paid by the residents of the housing; and

(D) the residents of the housing will, through a majority vote of the residents, otherwise establish policies governing residence in the housing, including the manner in which applications for residence in the housing are approved.

(b) ISSUANCE BY SECRETARY OF GUIDELINES.—The Secretary shall ensure that there are in effect guidelines under this subpart for the operation of programs described in subsection (a).

(c) APPLICABILITY TO TERRITORIES.—The requirements established in subsection (a) shall not apply to any territory of the United States other than the Commonwealth of Puerto Rico.

SEC. 1926. SALE OF TOBACCO PRODUCTS TO INDIVIDUALS UNDER AGE OF 21.

(a) IN GENERAL.—A funding agreement for a grant under section 1921 is that the State involved will—

(1) annually conduct random, unannounced inspections to ensure that retailers do not sell tobacco products to individuals under the age of 21; and

(2) annually submit to the Secretary a report describing—

(A) the activities carried out by the State to ensure that retailers do not sell tobacco products to individuals under the age of 21;

(B) the extent of success the State has achieved in ensuring that retailers do not sell tobacco products to individuals under the age of 21; and

(C) the strategies to be utilized by the State to ensure that retailers do not sell tobacco products to individuals under the age of 21 during the fiscal year for which the grant is sought.

(b) NONCOMPLIANCE OF STATE.—

(1) IN GENERAL.—Before making a grant under section 1921 to a State, the Secretary shall make a determination of whether the State has maintained compliance with subsection (a). If, after notice to the State and an opportunity for a hearing, the Secretary determines that the State is not in compliance with such subsections, the Secretary shall reduce the amount of the allotment under such section for the State for the fiscal year involved by an amount up to 10 percent of the amount determined under section 1933 for the State for the applicable fiscal year.

(2) LIMITATION.—

(A) IN GENERAL.—A State shall not have funds withheld pursuant to paragraph (1) if such State for which the Secretary has made a determination of noncompliance under such paragraph—

(i) certifies to the Secretary by May 1 of the fiscal year for which the funds are appropriated, consistent with subparagraph (B), that the State will commit additional State funds, in accordance with paragraph (1), to ensure that retailers do not sell tobacco products to individuals under 21 years of age;

(ii) agrees to comply with a negotiated agreement for a corrective action plan that is approved by the Secretary and carried out in accordance with guidelines issued by the Secretary; or

(iii) is a territory that receives less than $1,000,000 for a fiscal year under section 1921.

(B) CERTIFICATION.—

(i) IN GENERAL.—The amount of funds to be committed by a State pursuant to subparagraph (A)(i) shall be equal to 1 percent of such State's ⟦substance abuse⟧ allocation determined under section 1933 for each percentage point by which the State misses the retailer compliance rate goal established by the Secretary.

(ii) STATE EXPENDITURES.—For a fiscal year in which a State commits funds as described in clause (i), such State shall maintain State expenditures for tobacco prevention programs and for compliance activities at a level that is not less than the level of such expenditures maintained by the State for the preceding fiscal year, plus the additional funds for tobacco compliance activities required under clause (i). The State shall submit a report to the Secretary on all State obligations of funds for such fiscal year and all State expenditures for the preceding fiscal year for tobacco prevention and compliance activities by program activity by July 31 of such fiscal year.

(iii) DISCRETION.—The Secretary shall exercise discretion in enforcing the timing of the State obligation of the additional funds required by the certification described in subparagraph (A)(i) as late as July 31 of such fiscal year.

(C) FAILURE TO CERTIFY.—If a State described in subparagraph (A) fails to certify to the Secretary pursuant to subparagraph (A)(i) or enter into, or comply with, a negotiated agreement under subparagraph (A)(ii), the Secretary may take action pursuant to paragraph (1).

(c) IMPLEMENTATION OF REPORTING REQUIREMENTS.—

(1) TRANSITION PERIOD.—The Secretary shall—

(A) not withhold amounts under subsection (b) for the 3-year period immediately following the date of enactment of division N of the Further Consolidated Appropriations Act, 2020; and

(B) use discretion in exercising its authority under subsection (b) during the 2-year period immediately following the 3-year period described in subparagraph (A), to allow for a transition period for implementation of the reporting requirements under subsection (a)(2).

(2) REGULATIONS OR GUIDANCE.—Not later than 180 days after the date of enactment of division N of the Further Consolidated Appropriations Act, 2020, the Secretary shall update regulations under part 96 of title 45, Code of Federal Regulations or guidance on the retailer compliance rate goal under subsection (b), the use of funds provided under section 1921 for purposes of meeting the requirements of this section, and reporting requirements under subsection (a)(2).

(3) COORDINATION.—The Secretary shall ensure the Assistant Secretary for Mental Health and Substance Use coordinates, as appropriate, with the Commissioner of Food and Drugs to ensure that the technical assistance provided to States under subsection (e) is consistent with applicable regulations for retailers issued under part 1140 of title 21, Code of Federal Regulations.

(d) TRANSITIONAL GRANTS.—

(1) IN GENERAL.—The Secretary shall award grants under this subsection to each State that receives funding under section 1921 to ensure compliance of each such State with this section.

(2) USE OF FUNDS.—A State receiving a grant under this subsection—

(A) shall use amounts received under such grant for activities to plan for or ensure compliance in the State with subsection (a); and

(B) in the case of a State for which the Secretary has made a determination under subsection (b) that the State is prepared to meet, or has met, the requirements of subsection (a), may use such funds for tobacco cessation activities, strategies to prevent the use of tobacco products by individuals under the age of 21, or allowable uses under section 1921.

(3) SUPPLEMENT NOT SUPPLANT.—Grants under this subsection shall be used to supplement and not supplant other Federal, State, and local public funds provided for activities under paragraph (2).

(4) AUTHORIZATION OF APPROPRIATIONS.—To carry out this subsection, there are authorized to be appropriated $18,580,790 for each of fiscal years 2020 through 2024.

(5) SUNSET.—This subsection shall have no force or effect after September 30, 2024.

(e) TECHNICAL ASSISTANCE.—The Secretary shall provide technical assistance to States related to the activities required under this section.

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SEC. 1931. RESTRICTIONS ON EXPENDITURE OF GRANT.

(a) IN GENERAL.—

(1) CERTAIN RESTRICTIONS.—A funding agreement for a grant under section 1921 is that the State involved will not expend the grant—

(A) to provide inpatient hospital services, except as provided in subsection (b);

(B) to make cash payments to intended recipients of health services;

(C) to purchase or improve land, purchase, construct, or permanently improve (other than minor remodeling) any building or other facility, or purchase major medical equipment;

(D) to satisfy any requirement for the expenditure of non-Federal funds as a condition for the receipt of Federal funds;

(E) to provide financial assistance to any entity other than a public or nonprofit private entity; or

(F) to carry out any program prohibited by section 256(b) of the Health Omnibus Programs Extension of 1988 (42 U.S.C. 300ee–5).

(2) LIMITATION ON ADMINISTRATIVE EXPENSES.—A funding agreement for a grant under section 1921 is that the State involved will not expend more than 5 percent of the grant to pay the costs of administering the grant.

(3) LIMITATION REGARDING PENAL AND CORRECTIONAL INSTITUTIONS.—A funding agreement for a State for a grant under section 1921 is that, in expending the grant for the purpose of providing treatment services in penal or correctional institutions of the State, the State will not expend more than an amount equal to the amount expended for such purpose by the State from the grant made under section 1912A to the State for fiscal year 1991 (as section 1912A was in effect for such fiscal year).

(b) EXCEPTION REGARDING INPATIENT HOSPITAL SERVICES.—

(1) MEDICAL NECESSITY AS PRECONDITION.—With respect to compliance with the agreement made under subsection (a), a State may expend a grant under section 1921 to provide inpatient hospital services as treatment for substance use disorders only if it has been determined, in accordance with guidelines issued by the Secretary, that such treatment is a medical necessity for the individual involved, and that the individual cannot be effectively treated in a community-based, nonhospital, residential program of treatment.

(2) RATE OF PAYMENT.—In the case of an individual for whom a grant under section 1921 is expended to provide inpatient hospital services described in paragraph (1), a funding agreement for the grant for the State involved is that the daily rate of payment provided to the hospital for providing the services to the individual will not exceed the comparable daily rate provided for community-based, nonhospital, residential programs of treatment for [substance abuse] *substance use disorders*.

(c) WAIVER REGARDING CONSTRUCTION OF FACILITIES.—

(1) IN GENERAL.—The Secretary may provide to any State a waiver of the restriction established in subsection (a)(1)(C) for the purpose of authorizing the State to expend a grant under section 1921 for the construction of a new facility or rehabilitation of an existing facility, but not for land acquisition.

(2) STANDARD REGARDING NEED FOR WAIVER.—The Secretary may approve a waiver under paragraph (1) only if the State demonstrates to the Secretary that adequate treatment cannot be provided through the use of existing facilities and that al-

ternative facilities in existing suitable buildings are not available.

(3) AMOUNT.—In granting a waiver under paragraph (1), the Secretary shall allow the use of a specified amount of funds to construct or rehabilitate a specified number of beds for residential treatment and a specified number of slots for outpatient treatment, based on reasonable estimates by the State of the costs of construction or rehabilitation. In considering waiver applications, the Secretary shall ensure that the State has carefully designed a program that will minimize the costs of additional beds.

(4) MATCHING FUNDS.—The Secretary may grant a waiver under paragraph (1) only if the State agrees, with respect to the costs to be incurred by the State in carrying out the purpose of the waiver, to make available non-Federal contributions in cash toward such costs in an amount equal to not less than $1 for each $1 of Federal funds provided under section 1921.

(5) DATE CERTAIN FOR ACTING UPON REQUEST.—The Secretary shall act upon a request for a waiver under paragraph (1) not later than 120 days after the date on which the request is made.

SEC. 1932. APPLICATION FOR GRANT; APPROVAL OF STATE PLAN.

(a) IN GENERAL.—For purposes of section 1921, an application for a grant under such section for a fiscal year is in accordance with this section if, subject to subsection (c)—

(1) the application is received by the Secretary not later than October 1 of the fiscal year for which the State is seeking funds;

(2) the application contains each funding agreement that is described in this subpart or subpart III for such a grant (other than any such agreement that is not applicable to the State);

(3) the agreements are made through certification from the chief executive officer of the State;

(4) with respect to such agreements, the application provides assurances of compliance satisfactory to the Secretary;

(5) the application contains the report required in section 1942(a);

(6)(A) the application contains a plan in accordance with subsection (b) and the plan is approved by the Secretary; and

(B) the State provides assurances satisfactory to the Secretary that the State complied with the provisions of the plan under subparagraph (A) that was approved by the Secretary for the most recent fiscal year for which the State received a grant under section 1921; and

(7) the application (including the plan under paragraph (6)) is otherwise in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this subpart.

(b) STATE PLAN.—

(1) IN GENERAL.—In order for a State to be in compliance with subsection (a)(6), the State shall submit to the Secretary a plan that, at a minimum, includes the following:

(A) A description of the State's system of care that—

(i) identifies the single State agency responsible for the administration of the program, including any third party who administers substance use disorder services and is responsible for complying with the requirements of the grant;

(ii) provides information on the need for substance use disorder prevention and treatment services in the State, including estimates on the number of individuals who need treatment, who are pregnant women, women with dependent children, individuals with a co-occurring mental health and substance use disorder, persons who inject drugs, and persons who are experiencing homelessness;

(iii) provides aggregate information on the number of individuals in treatment within the State, including the number of such individuals who are pregnant women, women with dependent children, individuals with a co-occurring mental health and substance use disorder, persons who inject drugs, and persons who are experiencing homelessness;

(iv) provides a description of the system that is available to provide services by modality, including the provision of recovery support services;

(v) provides a description of the State's comprehensive statewide prevention efforts, including the number of individuals being served in the system, target populations, and priority needs, and provides a description of the amount of funds from the prevention set-aside expended on primary prevention;

(vi) provides a description of—

(I) the State's comprehensive statewide recovery support services activities, including the number of individuals being served, target populations, and priority needs; and

(II) the amount of funds received under this subpart expended on recovery support services, disaggregated by the amount expended for type of service activity;

[(vi)**]** *(vii)* provides a description of the financial resources available;

[(vii)**]** *(viii)* describes the existing substance use disorders workforce and workforce trained in treating co-occurring substance use and mental disorders;

[(viii)**]** *(ix)* includes a description of how the State promotes evidence-based practices; and

[(ix)**]** *(x)* describes how the State integrates substance use disorder services and primary health care, which in the case of those individuals with co-occurring mental health and substance use disorders may include providing both mental health and substance use disorder services in primary care settings or providing primary and specialty care services in community-based mental health and substance use disorder service settings.

(B) The establishment of goals and objectives for the period of the plan, including targets and milestones that are intended to be met, and the activities that will be undertaken to achieve those targets.

(C) A description of how the State will comply with each funding agreement for a grant under section 1921 that is applicable to the State, including a description of the manner in which the State intends to expend grant funds.

(2) MODIFICATIONS.—

(A) AUTHORITY OF SECRETARY.—As a condition; of making a grant under section 1921 to a State for a fiscal year, the Secretary may require that the State modify any provision of the plan submitted by the State under subsection (a)(6) (including provisions on priorities in carrying out authorized activities). If the Secretary approves the plan and makes the grant to the State for the fiscal year, the Secretary may not during such year require the State to modify the plan.

(B) STATE REQUEST FOR MODIFICATION.—If the State determines that a modification to such plan is necessary, the State may request the Secretary to approve the modification. Any such modification shall be in accordance with paragraph (1) and section 1941.

(3) AUTHORITY OF CENTER FOR SUBSTANCE ABUSE PREVENTION.—With respect to plans submitted by the States under subsection (a)(6), including any modification under paragraph (2), the Secretary, acting through the Director of the Center for Substance Abuse Prevention, shall review and approve or disapprove the provisions of the plans that relate to prevention activities.

(c) WAIVERS REGARDING CERTAIN TERRITORIES.—In the case of any territory of the United States except Puerto Rico, the Secretary may waive such provisions of this subpart and subpart III as the Secretary determines to be appropriate, other than the provisions of section 1931.

(d) ISSUANCE OF REGULATIONS; PRECONDITION TO MAKING GRANTS.—

(1) REGULATIONS.—Not later than August 25, 1992, the Secretary, acting as appropriate through the Director of the Center for Treatment Improvement or the Director of the Center for Substance Abuse Prevention, shall by regulation establish standards specifying the circumstances in which the Secretary will consider an application for a grant under section 1921 to be in accordance with this section.

(2) ISSUANCE AS PRECONDITION TO MAKING GRANTS.—The Secretary may not make payments under any grant under section 1921 for fiscal year 1993 on or after January 1, 1993, unless the Secretary has issued standards under paragraph (1).

(e) WAIVER AUTHORITY FOR CERTAIN REQUIREMENTS.—

(1) IN GENERAL.—Upon the request of a State, the Secretary may waive the requirements of all or part of the sections described in paragraph (2) using objective criteria established by the Secretary by regulation after consultation with the States and other interested parties including consumers and providers.

(2) SECTIONS.—The sections described in paragraph (1) are sections 1922(b), 1923, 1924 and 1928.

(3) DATE CERTAIN FOR ACTING UPON REQUEST.—The Secretary shall approve or deny a request for a waiver under paragraph (1) and inform the State of that decision not later than 120 days after the date on which the request and all the information needed to support the request are submitted.

(4) ANNUAL REPORTING REQUIREMENT.—The Secretary shall annually report to the general public on the States that receive a waiver under this subsection.

SEC. 1933. DETERMINATION OF AMOUNT OF ALLOTMENT.

(a) STATES.—

(1) IN GENERAL.—Subject to subsection (b), the Secretary shall determine the amount of the allotment required in section 1921 for a State for a fiscal year as follows:

(A) The formula established in paragraph (1) of section 1918(a) shall apply to this subsection to the same extent and in the same manner as the formula applies for purposes of section 1918(a), except that, in the application of such formula for purposes of this subsection, the modifications described in subparagraph (B) shall apply.

(B) For purposes of subparagraph (A), the modifications described in this subparagraph are as follows:

(i) The amount specified in paragraph (2)(A) of section 1918(a) is deemed to be the amount appropriated under section 1935(a) for allotments under section 1921 for the fiscal year involved.

(ii) The term "P" is deemed to have the meaning given in paragraph (2) of this subsection. Section 1918(a)(5)(B) applies to the data used in determining such term for the States.

(iii) The factor determined under paragraph (8) of section 1918(a) is deemed to have the purpose of reflecting the differences that exist between the State involved and other States in the costs of providing authorized services.

(2) DETERMINATION OF TERM "P".—For purposes of this subsection, the term "P" means the percentage that is the arithmetic mean of the percentage determined under subparagraph (A) and the percentage determined under subparagraph (B), as follows:

(A) The percentage constituted by the ratio of—

(i) an amount equal to the sum of the total number of individuals who reside in the State involved and are between 18 and 24 years of age (inclusive) and the number of individuals in the State who reside in urbanized areas of the State and are between such years of age; to

(ii) an amount equal to the total of the respective sums determined for the States under clause (i).

(B) The percentage constituted by the ratio of—

(i) the total number of individuals in the State who are between 25 and 64 years of age (inclusive); to

(ii) an amount equal to the sum of the respective amounts determined for the States under clause (i).

(b) MINIMUM ALLOTMENTS FOR STATES.—

(1) IN GENERAL.—With respect to fiscal year 2000, and each subsequent fiscal year, the amount of the allotment of a State under section 1921 shall not be less than the amount the State received under such section for the previous fiscal year increased by an amount equal to 30.65 percent of the percentage by which the aggregate amount allotted to all States for such fiscal year exceeds the aggregate amount allotted to all States for the previous fiscal year.

(2) LIMITATIONS.—

(A) IN GENERAL.—Except as provided in subparagraph (B), a State shall not receive an allotment under section 1921 for a fiscal year in an amount that is less than an amount equal to 0.375 percent of the amount appropriated under section 1935(a) for such fiscal year.

(B) EXCEPTION.—In applying subparagraph (A), the Secretary shall ensure that no State receives an increase in its allotment under section 1921 for a fiscal year (as compared to the amount allotted to the State in the prior fiscal year) that is in excess of an amount equal to 300 percent of the percentage by which the amount appropriated under section 1935(a) for such fiscal year exceeds the amount appropriated for the prior fiscal year.

(3) DECREASE IN OR EQUAL APPROPRIATIONS.—If the amount appropriated under section 1935(a) for a fiscal year is equal to or less than the amount appropriated under such section for the prior fiscal year, the amount of the State allotment under section 1921 shall be equal to the amount that the State received under section 1921 in the prior fiscal year decreased by the percentage by which the amount appropriated for such fiscal year is less than the amount appropriated or such section for the prior fiscal year.

(c) TERRITORIES.—

(1) DETERMINATION UNDER FORMULA.—Subject to paragraphs (2) and (4), the amount of an allotment under section 1921 for a territory of the United States for a fiscal year shall be the product of—

(A) an amount equal to the amounts reserved under paragraph (3) for the fiscal year; and

(B) a percentage equal to the quotient of—

(i) the civilian population of the territory, as indicated by the most recently available data; divided by

(ii) the aggregate civilian population of the territories of the United States, as indicated by such data.

(2) MINIMUM ALLOTMENT FOR TERRITORIES.—The amount of an allotment under section 1921 for a territory of the United States for a fiscal year shall be the greater of—

(A) the amount determined under paragraph (1) for the territory for the fiscal year;

(B) $50,000; and

(C) with respect to fiscal years 1993 and 1994, an amount equal to 79.4 percent of the amount received by the territory from allotments made pursuant to this part for fiscal year 1992.

(3) RESERVATION OF AMOUNTS.—The Secretary shall each fiscal year reserve for the territories of the United States 1.5 percent of the amounts appropriated under section 1935(a) for allotments under section 1921 for the fiscal year.

(4) AVAILABILITY OF DATA ON POPULATION.—With respect to data on the civilian population of the territories of the United States, if the Secretary determines for a fiscal year that recent such data for purposes of paragraph (1)(B) do not exist regarding a territory, the Secretary shall for such purposes estimate the civilian population of the territory by modifying the data on the territory to reflect the average extent of change occurring during the ensuing period in the population of all territories with respect to which recent such data do exist.

(5) APPLICABILITY OF CERTAIN PROVISIONS.—For purposes of subsections (a) and (b), the term "State" does not include the territories of the United States.

(d) INDIAN TRIBES AND TRIBAL ORGANIZATIONS.—

(1) IN GENERAL.—If the Secretary—

(A) receives a request from the governing body [of an Indian tribe or tribal organization] *of an Indian Tribe or Tribal organization* within any State that funds under this subpart be provided directly by the Secretary to [such tribe] *such Tribe* or organization; and

(B) makes a determination that the members of such [tribe or tribal organization] *Tribe or Tribal organization* would be better served by means of grants made directly by the [Secretary under this] *Secretary under this subpart*;

the Secretary shall reserve from the allotment under section 1921 for the State for the fiscal year involved an amount that bears the same ratio to the allotment as the amount provided under this subpart to the [tribe or tribal organization] *Tribe or Tribal organization* for fiscal year 1991 for activities relating to the prevention and treatment of the [abuse of alcohol and other drugs] *use of substances* bore to the amount of the portion of the allotment under this subpart for the State for such fiscal year that was expended for such activities.

[(2) TRIBE OR TRIBAL ORGANIZATION AS GRANTEE.—The amount reserved by the Secretary on the basis of a determination under this paragraph shall be granted to the Indian tribe or tribal organization serving the individuals for whom such a determination has been made.]

(2) INDIAN TRIBE OR TRIBAL ORGANIZATION AS GRANTEE.—The amount reserved by the Secretary on the basis of a determination under this subsection shall be granted to the Indian Tribe or Tribal organization serving the individuals for whom such a determination has been made.

(3) APPLICATION.—In order for an Indian [tribe or tribal organization] *Tribe or Tribal organization* to be eligible for a grant for a fiscal year under this paragraph, it shall submit to the Secretary a plan for such fiscal year that meets such criteria as the Secretary may prescribe.

(4) [DEFINITION] *DEFINITIONS*.—[The terms "Indian tribe" and "tribal organization" have the same meaning given such terms] *The terms "Indian Tribe" and "Tribal organization"*

have the meanings given the terms "Indian tribe" and "tribal organization" in subsections (b) and (c) of section 4 of the Indian Self-Determination and Education Assistance Act.

SEC. 1934. DEFINITIONS.

For purposes of this subpart:

(1) The term "authorized activities", subject to section 1931, means the activities described in section 1921(b).

(2) The term "funding agreement", with respect to a grant under section 1921 to a State, means that the Secretary may make such a grant only if the State makes the agreement involved.

(3) The term "prevention activities", subject to section 1931, means activities to prevent substance use disorders.

[(4) The term "substance abuse" means the abuse of alcohol or other drugs.]

(4) The term "substance use disorder" means the recurrent use of alcohol or other drugs that causes clinically significant impairment.

(5) The term "treatment activities" means treatment services and, subject to section 1931, authorized activities that are related to treatment services.

(6) The term "treatment facility" means an entity that provides treatment services.

(7) The term "treatment services", subject to section 1931, means treatment for substance use disorders.

SEC. 1935. FUNDING.

(a) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this subpart, subpart III and section 505(d) with respect to [substance abuse] *substance use disorders*, and section 515(d), there are authorized to be [appropriated $1,858,079,000 for each of fiscal years 2018 through 2022..] *appropriated $1,908,079,000 for each of fiscal years 2023 through 2027.*

(b) ALLOCATIONS FOR TECHNICAL ASSISTANCE, NATIONAL DATA BASE, DATA COLLECTION, AND PROGRAM EVALUATIONS.—

(1) IN GENERAL.—

(A) For the purpose of carrying out section 1948(a) with respect to [substance abuse] *substance use disorders*, section 515(d), and the purposes specified in subparagraphs (B) and (C), the Secretary shall obligate 5 percent of the amounts appropriated under subsection (a) each fiscal year.

(B) The purpose specified in this subparagraph is [the collection of data in this paragraph is] carrying out sections 505(d) and 1971 with respect to [substance abuse] *substance use disorders*.

(C) The purpose specified in this subparagraph is the conduct of evaluations of authorized activities to determine methods for improving the availability and quality of such activities.

(2) ACTIVITIES OF CENTER FOR SUBSTANCE ABUSE PREVENTION.—Of the amounts reserved under paragraph (1) for a fiscal year, the Secretary, acting through the Director of the Center for Substance Abuse Prevention, shall obligate 20 percent

for carrying out paragraph (1)(C), section 1948(a) with respect to prevention activities, and section 515(d).

(3) CORE DATA SET.—A State that receives a new grant, contract, or cooperative agreement from amounts available to the Secretary under paragraph (1), for the purposes of improving the data collection, analysis and reporting capabilities of the State, shall be required, as a condition of receipt of funds, to collect, analyze, and report to the Secretary for each fiscal year subsequent to receiving such funds a core data set to be determined by the Secretary in conjunction with the States.

Subpart III—General Provisions

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SEC. 1942. REQUIREMENT OF REPORTS AND AUDITS BY STATES.

(a) REPORT.—A funding agreement for a grant under section 1911 or 1921 is that the State involved will submit to the Secretary a report in such form and containing such information as the Secretary determines (after consultation with the States) to be necessary for securing a record and a description of—

(1) the purposes for which the grant received by the State for the preceding fiscal year under the program involved were expended and a description of the activities of the State under the program; [and]

(2) the recipients of amounts provided in the grant[.]*; and*

(3) the amount provided to each recipient in the previous fiscal year.

(b) AUDITS.—A funding agreement for a grant under section 1911 or 1921 is that the State will, with respect to the grant, comply with chapter 75 of title 31, United States Code.

(c) AVAILABILITY TO PUBLIC.—A funding agreement for a grant under section 1911 or 1921 is that the State involved will—

(1) make copies of the reports and audits described in this section available for public inspection within the State; and

(2) provide copies of the report under subsection (a), upon request, to any interested person (including any public agency).

* * * * * * *

SEC. 1949. PLANS FOR PERFORMANCE PARTNERSHIPS.

(a) DEVELOPMENT.—The Secretary in conjunction with States and other interested groups shall develop separate plans for the programs authorized under subparts I and II for creating more flexibility for States and accountability based on outcome and other performance measures. The plans shall each include—

(1) a description of the flexibility that would be given to the States under the plan;

(2) the common set of performance measures that would be used for accountability, including measures that would be used for the program under subpart II for pregnant addicts, HIV transmission, tuberculosis, and those with a co-occurring [substance abuse] *substance use disorders* and mental disorders, and for programs under subpart I for children with serious emotional disturbance and adults with serious mental illness and for individuals with co-occurring mental health and [substance abuse] *substance use disorders* disorders;

(3) the definitions for the data elements to be used under the plan;

(4) the obstacles to implementation of the plan and the manner in which such obstacles would be resolved;

(5) the resources needed to implement the performance partnerships under the plan; and

(6) an implementation strategy complete with recommendations for any necessary legislation.

(b) SUBMISSION.—Not later than 2 years after the date of the enactment of this Act, the plans developed under subsection (a) shall be submitted to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Commerce of the House of Representatives.

(c) INFORMATION.—As the elements of the plans described in subsection (a) are developed, States are encouraged to provide information to the Secretary on a voluntary basis.

(d) PARTICIPANTS.—The Secretary shall include among those interested groups that participate in the development of the plan consumers of mental health or [substance abuse] *substance use disorders* services, providers, representatives of political divisions of States, and representatives of racial and ethnic groups including Native Americans.

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SEC. 1954. DEFINITIONS.

(a) DEFINITIONS FOR SUBPART III.—For purposes of this subpart:

(1) The term "program involved" means the program of grants established in section 1911 or 1921, or both, as indicated by whether the State involved is receiving or is applying to receive a grant under section 1911 or 1921, or both.

(2)(A) The term "funding agreement", with respect to a grant under section 1911, has the meaning given such term in section 1919.

(B) The term "funding agreement", with respect to a grant under section 1921, has the meaning given such term in section 1934.

(b) DEFINITIONS FOR PART B.—For purposes of this part:

(1) The term "Comptroller General" means the Comptroller General of the United States.

(2) The term "State", except as provided in sections 1918(c)(5) and 1933(c)(5), means each of the several States, the District of Columbia, and each of the territories of the United States.

(3) The term "territories of the United States" means each of the Commonwealth of Puerto Rico, American Samoa, Guam, the Commonwealth of the Northern Mariana Islands, the Virgin Islands, Palau, the Marshall Islands, and Micronesia.

(4) The term "interim services", in the case of an individual in need of treatment for [substance abuse] *substance use disorders* who has been denied admission to a program of such treatment on the basis of the lack of the capacity of the program to admit the individual, means services for reducing the adverse health effects of [such abuse] *such disorders*, for promoting the health of the individual, and for reducing the risk

of transmission of disease, which services are provided until the individual is admitted to such a program.

SEC. 1955. SERVICES PROVIDED BY NONGOVERNMENTAL ORGANIZATIONS.

(a) PURPOSES.—The purposes of this section are—

(1) to prohibit discrimination against nongovernmental organizations and certain individuals on the basis of religion in the distribution of government funds to provide [substance abuse] *substance use disorder* services under this title and title V, and the receipt of services under such titles; and

(2) to allow the organizations to accept the funds to provide the services to the individuals without impairing the religious character of the organizations or the religious freedom of the individuals.

(b) RELIGIOUS ORGANIZATIONS INCLUDED AS NONGOVERNMENTAL PROVIDERS.—

(1) IN GENERAL.—A State may administer and provide [substance abuse] *substance use disorder* services under any program under this title or title V through grants, contracts, or cooperative agreements to provide assistance to beneficiaries under such titles with nongovernmental organizations.

(2) REQUIREMENT.—A State that elects to utilize nongovernmental organizations as provided for under paragraph (1) shall consider, on the same basis as other nongovernmental organizations, religious organizations to provide services under [substance abuse] *substance use disorder* programs under this title or title V, so long as the programs under such titles are implemented in a manner consistent with the Establishment Clause of the first amendment to the Constitution. Neither the Federal Government nor a State or local government receiving funds under such programs shall discriminate against an organization that provides services under, or applies to provide services under, such programs, on the basis that the organization has a religious character.

(c) RELIGIOUS CHARACTER AND INDEPENDENCE.—

(1) IN GENERAL.—A religious organization that provides services under any [substance abuse] *substance use disorder* program under this title or title V shall retain its independence from Federal, State, and local governments, including such organization's control over the definition, development, practice, and expression of its religious beliefs.

(2) ADDITIONAL SAFEGUARDS.—Neither the Federal Government nor a State or local government shall require a religious organization—

(A) to alter its form of internal governance; or

(B) to remove religious art, icons, scripture, or other symbols,

in order to be eligible to provide services under any [substance abuse] *substance use disorder* program under this title or title V.

(d) EMPLOYMENT PRACTICES.—

(1) SUBSTANCE ABUSE.—A religious organization that provides services under any [substance abuse] *substance use disorder* program under this title or title V may require that its

employees providing services under such program adhere to rules forbidding the use of drugs or alcohol.

(2) TITLE VII EXEMPTION.—The exemption of a religious organization provided under section 702 or 703(e)(2) of the Civil Rights Act of 1964 (42 U.S.C. 2000e–1, 2000e–2(e)(2)) regarding employment practices shall not be affected by the religious organization's provision of services under, or receipt of funds from, any [substance abuse] *substance use disorder* program under this title or title V.

(e) RIGHTS OF BENEFICIARIES OF ASSISTANCE.—

(1) IN GENERAL.—If an individual described in paragraph (3) has an objection to the religious character of the organization from which the individual receives, or would receive, services funded under any [substance abuse] *substance use disorder* program under this title or title V, the appropriate Federal, State, or local governmental entity shall provide to such individual (if otherwise eligible for such services) within a reasonable period of time after the date of such objection, services that—

(A) are from an alternative provider that is accessible to the individual; and

(B) have a value that is not less than the value of the services that the individual would have received from such organization.

(2) NOTICE.—The appropriate Federal, State, or local governmental entity shall ensure that notice is provided to individuals described in paragraph (3) of the rights of such individuals under this section.

(3) INDIVIDUAL DESCRIBED.—An individual described in this paragraph is an individual who receives or applies for services under any [substance abuse] *substance use disorder* program under this title or title V.

(f) NONDISCRIMINATION AGAINST BENEFICIARIES.—A religious organization providing services through a grant, contract, or cooperative agreement under any [substance abuse] *substance use disorder* program under this title or title V shall not discriminate, in carrying out such program, against an individual described in subsection (e)(3) on the basis of religion, a religious belief, a refusal to hold a religious belief, or a refusal to actively participate in a religious practice.

(g) FISCAL ACCOUNTABILITY.—

(1) IN GENERAL.—Except as provided in paragraph (2), any religious organization providing services under any [substance abuse] *substance use disorder* program under this title or title V shall be subject to the same regulations as other nongovernmental organizations to account in accord with generally accepted accounting principles for the use of such funds provided under such program.

(2) LIMITED AUDIT.—Such organization shall segregate government funds provided under such [substance abuse] *substance use disorder* program into a separate account. Only the government funds shall be subject to audit by the government.

(h) COMPLIANCE.—Any party that seeks to enforce such party's rights under this section may assert a civil action for injunctive re-

lief exclusively in an appropriate Federal or State court against the entity, agency or official that allegedly commits such violation.

(i) LIMITATIONS ON USE OF FUNDS FOR CERTAIN PURPOSES.—No funds provided through a grant or contract to a religious organization to provide services under any [substance abuse] *substance use disorder* program under this title or title V shall be expended for sectarian worship, instruction, or proselytization.

(j) EFFECT ON STATE AND LOCAL FUNDS.—If a State or local government contributes State or local funds to carry out any [substance abuse] *substance use disorder* program under this title or title V, the State or local government may segregate the State or local funds from the Federal funds provided to carry out the program or may commingle the State or local funds with the Federal funds. If the State or local government commingles the State or local funds, the provisions of this section shall apply to the commingled funds in the same manner, and to the same extent, as the provisions apply to the Federal funds.

(k) TREATMENT OF INTERMEDIATE CONTRACTORS.—If a nongovernmental organization (referred to in this subsection as an "intermediate organization"), acting under a contract or other agreement with the Federal Government or a State or local government, is given the authority under the contract or agreement to select nongovernmental organizations to provide services under any [substance abuse] *substance use disorder* program under this title or title V, the intermediate organization shall have the same duties under this section as the government but shall retain all other rights of a nongovernmental organization under this section.

SEC. 1956. SERVICES FOR INDIVIDUALS WITH CO-OCCURRING DISORDERS.

States may use funds available for treatment under sections 1911 and 1921 to treat persons with co-occurring [substance abuse] *substance use disorders* and mental disorders as long as funds available under such sections are used for the purposes for which they were authorized by law and can be tracked for accounting purposes.

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PART C—CERTAIN PROGRAMS REGARDING MENTAL HEALTH AND [SUBSTANCE ABUSE] *SUBSTANCE USE*

Subpart I—Data Infrastructure Development

SEC. 1971. DATA INFRASTRUCTURE DEVELOPMENT.

(a) IN GENERAL.—The Secretary may make grants to, and enter into contracts or cooperative agreements with States for the purpose of developing and operating mental health or [substance abuse] *substance use* data collection, analysis, and reporting systems with regard to performance measures including capacity, process, and outcomes measures.

(b) PROJECTS.—The Secretary shall establish criteria to ensure that services will be available under this section to States that have a fundamental basis for the collection, analysis, and reporting

of mental health and [substance abuse] *substance use* performance measures and States that do not have such basis. The Secretary will establish criteria for determining whether a State has a fundamental basis for the collection, analysis, and reporting of data.

(c) CONDITION OF RECEIPT OF FUNDS.—As a condition of the receipt of an award under this section a State shall agree to collect, analyze, and report to the Secretary within 2 years of the date of the award on a core set of performance measures to be determined by the Secretary in conjunction with the States.

(d) MATCHING REQUIREMENT.—

(1) IN GENERAL.—With respect to the costs of the program to be carried out under subsection (a) by a State, the Secretary may make an award under such subsection only if the applicant agrees to make available (directly or through donations from public or private entities) non-Federal contributions toward such costs in an amount that is not less than 50 percent of such costs.

(2) DETERMINATION OF AMOUNT CONTRIBUTED.—Non-Federal contributions under paragraph (1) may be in cash or in kind, fairly evaluated, including plant, equipment, or services. Amounts provided by the Federal Government, or services assisted or subsidized to any significant extent by the Federal Government, may not be included in determining the amount of such contributions.

(e) DURATION OF SUPPORT.—The period during which payments may be made for a project under subsection (a) may be not less than 3 years nor more than 5 years.

(f) AUTHORIZATION OF APPROPRIATION.—

(1) IN GENERAL.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2001, 2002 and 2003.

(2) ALLOCATION.—Of the amounts appropriated under paragraph (1) for a fiscal year, 50 percent shall be expended to support data infrastructure development for mental health and 50 percent shall be expended to support data infrastructure development for [substance abuse] *substance use*.

Subpart II—Interim Maintenance Treatment of Narcotics Dependence

SEC. 1976. INTERIM MAINTENANCE TREATMENT.

(a) REQUIREMENT REGARDING SECRETARY.—Subject to the following subsections of this section, for the purpose of reducing the incidence of the transmission of HIV disease pursuant to the [intravenous abuse] *intravenous use* of heroin or other morphine-like drugs, the Secretary, in establishing conditions for the use of methadone in public or nonprofit private programs of treatment for dependence on such drugs, shall authorize such programs—

(1) to dispense methadone for treatment purposes to individuals who—

(A) meet the conditions for admission to such programs that dispense methadone as part of comprehensive treatment for such dependence; and

(B) are seeking admission to such programs that so dispense methadone, but as a result of the limited capacity of the programs, will not gain such admission until 14 or more days after seeking admission to the programs; and

(2) in dispensing methadone to such individuals, to provide only minimum ancillary services during the period in which the individuals are waiting for admission to programs of comprehensive treatment.

(b) INAPPLICABILITY OF REQUIREMENT IN CERTAIN CIRCUMSTANCES.—

(1) IN GENERAL.—The requirement established in subsection (a) for the Secretary does not apply if any or all of the following conditions are met:

(A) The preponderance of scientific research indicates that the risk of the transmission of HIV disease pursuant to the [intravenous abuse] *intravenous use* of drugs is minimal.

(B) The preponderance of scientific research indicates that the medically supervised dispensing of methadone is not an effective method of reducing the extent of dependence on heroin and other morphine-like drugs.

(C) The preponderance of available data indicates that, of treatment programs that dispense methadone as part of comprehensive treatment, a substantial majority admit all individuals seeking services to the programs not later than 14 days after the individuals seek admission to the programs.

(2) EVALUATION BY SECRETARY.—In evaluating whether any or all of the conditions described in paragraph (1) have been met, the Secretary shall consult with the National Commission on Acquired Immune Deficiency Syndrome.

(c) CONDITIONS FOR OBTAINING AUTHORIZATION FROM SECRETARY.—

(1) IN GENERAL.—In carrying out the requirement established in subsection (a), the Secretary shall, after consultation with the National Commission on Acquired Immune Deficiency Syndrome, by regulation issue such conditions for treatment programs to obtain authorization from the Secretary to provide interim maintenance treatment as may be necessary to carry out the purpose described in such subsection. Such conditions shall include conditions for preventing the unauthorized use of methadone.

(2) COUNSELING ON HIV DISEASE.—The regulations issued under paragraph (1) shall provide that an authorization described in such paragraph may not be issued to a treatment program unless the program provides to recipients of the treatment counseling on preventing exposure to and the transmission of HIV disease.

(3) PERMISSION OF RELEVANT STATE AS CONDITION OF AUTHORIZATION.—The regulations issued under paragraph (1) shall provide that the Secretary may not provide an authorization described in such paragraph to any treatment program in a State unless the chief public health officer of the State has certified to the Secretary that—

(A) such officer does not object to the provision of such authorizations to treatment programs in the State; and

(B) the provision of interim maintenance services in the State will not reduce the capacity of comprehensive treatment programs in the State to admit individuals to the programs (relative to the date on which such officer so certifies).

(4) DATE CERTAIN FOR ISSUANCE OF REGULATIONS; FAILURE OF SECRETARY.—The Secretary shall issue the final rule for purposes of the regulations required in paragraph (1), and such rule shall be effective, not later than the expiration of the 180-day period beginning on the date of the enactment of the ADAMHA Reorganization Act. If the Secretary fails to meet the requirement of the preceding sentence, the proposed rule issued on March 2, 1989, with respect to part 291 of title 21, Code of Federal Regulations (docket numbered 88N–0444; 54 Fed. Reg. 8973 et seq.) is deemed to take effect as a final rule upon the expiration of such period, and the provisions of paragraph (3) of this subsection are deemed to be incorporated into such rule.

(d) DEFINITIONS.—For purposes of this section:

(1) The term "interim maintenance services" means the provision of methadone in a treatment program under the circumstances described in paragraphs (1) and (2) of subsection (a).

(2) The term "HIV disease" means infection with the etiologic agent for acquired immune deficiency syndrome.

(3) The term "treatment program" means a public or nonprofit private program of treatment for dependence on heroin or other morphine-like drugs.

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TITLE XXVII—REQUIREMENTS RELATING TO HEALTH INSURANCE COVERAGE

PART A—INDIVIDUAL AND GROUP MARKET REFORMS

* * * * * * *

Subpart 2—Exclusion of Plans; Enforcement; Preemption

SEC. 2722. EXCLUSION OF CERTAIN PLANS.

(a) LIMITATION ON APPLICATION OF PROVISIONS RELATING TO GROUP HEALTH PLANS.—

(1) IN GENERAL.—The requirements of subparts 1 and 2 and part D shall apply with respect to group health plans only—

(A) subject to paragraph (2), in the case of a plan that is a nonfederal governmental plan, and

(B) with respect to health insurance coverage offered in connection with a group health plan (including such a plan that is a church plan or a governmental plan).

(2) TREATMENT OF NONFEDERAL GOVERNMENTAL PLANS.—

(A) ELECTION TO BE EXCLUDED.—Except as provided in subparagraph (D) or (E), if the plan sponsor of a non-

federal governmental plan which is a group health plan to which the provisions of subparts 1 and 2 otherwise apply makes an election under this subparagraph (in such form and manner as the Secretary may by regulations prescribe), then the requirements of such subparts insofar as they apply directly to group health plans (and not merely to group health insurance coverage) shall not apply to such governmental plans for such period except as provided in this paragraph.

(B) PERIOD OF ELECTION.—An election under subparagraph (A) shall apply—

(i) for a single specified plan year, or

(ii) in the case of a plan provided pursuant to a collective bargaining agreement, for the term of such agreement.

An election under clause (i) may be extended through subsequent elections under this paragraph.

(C) NOTICE TO ENROLLEES.—Under such an election, the plan shall provide for—

(i) notice to enrollees (on an annual basis and at the time of enrollment under the plan) of the fact and consequences of such election, and

(ii) certification and disclosure of creditable coverage under the plan with respect to enrollees in accordance with section 2701(e).

(D) ELECTION NOT APPLICABLE TO REQUIREMENTS CONCERNING GENETIC INFORMATION.—The election described in subparagraph (A) shall not be available with respect to the provisions of subsections (a)(1)(F), (b)(3), (c), and (d) of section 2702 and the provisions of sections 2701 and 2702(b) to the extent that such provisions apply to genetic information.

(E) ELECTION NOT APPLICABLE.—The election described in subparagraph (A) shall not be available with respect to the provisions of subparts I and II.

(F) SUNSET OF ELECTION OPTION.—

(i) IN GENERAL.—Notwithstanding the preceding provisions of this paragraph—

(I) no election described in subparagraph (A) with respect to section 2726 may be made on or after the date of the enactment of this subparagraph; and

(II) except as provided in clause (ii), no such election with respect to section 2726 expiring on or after the date that is 180 days after the date of such enactment may be renewed.

(ii) EXCEPTION FOR CERTAIN COLLECTIVELY BARGAINED PLANS.—Notwithstanding clause (i)(II), a plan described in subparagraph (B)(ii) that is subject to multiple agreements described in such subparagraph of varying lengths and that has an election described in subparagraph (A) with respect to section 2726 in effect as of the date of the enactment of this subparagraph that expires on or after the date that is 180 days after the date of such enactment may extend such election

until the date on which the term of the last such agreement expires.

(b) EXCEPTION FOR CERTAIN BENEFITS.—The requirements of subparts 1 and 2 and part Dshall not apply to any individual coverage or any group health plan (or group health insurance coverage) in relation to its provision of excepted benefits described in section 2791(c)(1).

(c) EXCEPTION FOR CERTAIN BENEFITS IF CERTAIN CONDITIONS MET.—

(1) LIMITED, EXCEPTED BENEFITS.—The requirements of subparts 1 and 2 and part Dshall not apply to any individual coverage or any group health plan (and group health insurance coverage offered in connection with a group health plan) in relation to its provision of excepted benefits described in section 2791(c)(2) if the benefits—

(A) are provided under a separate policy, certificate, or contract of insurance; or

(B) are otherwise not an integral part of the plan.

(2) NONCOORDINATED, EXCEPTED BENEFITS.—The requirements of subparts 1 and 2 and part Dshall not apply to any individual coverage or any group health plan (and group health insurance coverage offered in connection with a group health plan) in relation to its provision of excepted benefits described in section 2791(c)(3) if all of the following conditions are met:

(A) The benefits are provided under a separate policy, certificate, or contract of insurance.

(B) There is no coordination between the provision of such benefits and any exclusion of benefits under any group health plan maintained by the same plan sponsor.

(C) Such benefits are paid with respect to an event without regard to whether benefits are provided with respect to such an event under any group health plan maintained by the same plan sponsor or, with respect to individual coverage, under any health insurance coverage maintained by the same health insurance issuer.

(3) SUPPLEMENTAL EXCEPTED BENEFITS.—The requirements of this part and part Dshall not apply to any individual coverage or any group health plan (and group health insurance coverage) in relation to its provision of excepted benefits described in section 27971(c)(4) if the benefits are provided under a separate policy, certificate, or contract of insurance.

(d) TREATMENT OF PARTNERSHIPS.—For purposes of this part and part D—

(1) TREATMENT AS A GROUP HEALTH PLAN.—Any plan, fund, or program which would not be (but for this subsection) an employee welfare benefit plan and which is established or maintained by a partnership, to the extent that such plan, fund, or program provides medical care (including items and services paid for as medical care) to present or former partners in the partnership or to their dependents (as defined under the terms of the plan, fund, or program), directly or through insurance, reimbursement, or otherwise, shall be treated (subject to paragraph (2)) as an employee welfare benefit plan which is a group health plan.

(2) EMPLOYER.—In the case of a group health plan, the term "employer" also includes the partnership in relation to any partner.

(3) PARTICIPANTS OF GROUP HEALTH PLANS.—In the case of a group health plan, the term "participant" also includes—

(A) in connection with a group health plan maintained by a partnership, an individual who is a partner in relation to the partnership, or

(B) in connection with a group health plan maintained by a self-employed individual (under which one or more employees are participants), the self-employed individual,

if such individual is, or may become, eligible to receive a benefit under the plan or such individual's beneficiaries may be eligible to receive any such benefit.

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PART C—DEFINITIONS; MISCELLANEOUS PROVISIONS

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SEC. 2794. ENSURING THAT CONSUMERS GET VALUE FOR THEIR DOLLARS.

(a) INITIAL PREMIUM REVIEW PROCESS.—

(1) IN GENERAL.—The Secretary, in conjunction with States, shall establish a process for the annual review, beginning with the 2010 plan year and subject to subsection (b)(2)(A), of unreasonable increases in premiums for health insurance coverage.

(2) JUSTIFICATION AND DISCLOSURE.—The process established under paragraph (1) shall require health insurance issuers to submit to the Secretary and the relevant State a justification for an unreasonable premium increase prior to the implementation of the increase. Such issuers shall prominently post such information on their Internet websites. The Secretary shall ensure the public disclosure of information on such increases and justifications for all health insurance issuers.

(b) CONTINUING PREMIUM REVIEW PROCESS.—

(1) INFORMING SECRETARY OF PREMIUM INCREASE PATTERNS.—As a condition of receiving a grant under subsection (c)(1), a State, through its Commissioner of Insurance, shall—

(A) provide the Secretary with information about trends in premium increases in health insurance coverage in premium rating areas in the State; and

(B) make recommendations, as appropriate, to the State Exchange about whether particular health insurance issuers should be excluded from participation in the Exchange based on a pattern or practice of excessive or unjustified premium increases.

(2) MONITORING BY SECRETARY OF PREMIUM INCREASES.—

(A) IN GENERAL.—Beginning with plan years beginning in 2014, the Secretary, in conjunction with the States and consistent with the provisions of subsection (a)(2), shall monitor premium increases of health insurance coverage offered through an Exchange and outside of an Exchange.

(B) CONSIDERATION IN OPENING EXCHANGE.—In determining under section 1312(f)(2)(B) of the Patient Protec-

tion and Affordable Care Act whether to offer qualified health plans in the large group market through an Exchange, the State shall take into account any excess of premium growth outside of the Exchange as compared to the rate of such growth inside the Exchange.

(c) GRANTS IN SUPPORT OF PROCESS.—

(1) PREMIUM REVIEW GRANTS DURING 2010 THROUGH 2014.—The Secretary shall carry out a program to award grants to States during the 5-year period beginning with fiscal year 2010 to assist such States in carrying out subsection (a), including—

(A) in reviewing and, if appropriate under State law, approving premium increases for health insurance coverage;

(B) in providing information and recommendations to the Secretary under subsection (b)(1); and

(C) in establishing centers (consistent with subsection (d)) at academic or other nonprofit institutions to collect medical reimbursement information from health insurance issuers, to analyze and organize such information, and to make such information available to such issuers, health care providers, health researchers, health care policy makers, and the general public.

(2) FUNDING.—

(A) IN GENERAL.—Out of all funds in the Treasury not otherwise appropriated, there are appropriated to the Secretary $250,000,000, to be available for expenditure for grants under paragraph (1) and subparagraph (B).

(B) FURTHER AVAILABILITY FOR INSURANCE REFORM AND CONSUMER PROTECTION.—If the amounts appropriated under subparagraph (A) are not fully obligated under grants under paragraph (1) by the end of fiscal year 2014, any remaining funds shall remain available to the Secretary for grants to States for planning and implementing the insurance reforms and consumer protections under part A.

(C) ALLOCATION.—The Secretary shall establish a formula for determining the amount of any grant to a State under this subsection. Under such formula—

(i) the Secretary shall consider the number of plans of health insurance coverage offered in each State and the population of the State; and

(ii) no State qualifying for a grant under paragraph (1) shall receive less than $1,000,000, or more than $5,000,000 for a grant year.

(3) PARITY IMPLEMENTATION.—

(A) IN GENERAL.—Beginning during the first fiscal year that begins after the date of enactment of this paragraph, the Secretary shall, out of funds made available pursuant to subparagraph (C), award grants to eligible States to enforce and ensure compliance with the mental health and substance use disorder parity provisions of section 2726.

(B) ELIGIBLE STATE.—A State shall be eligible for a grant awarded under this paragraph only if such State—

(i) submits to the Secretary an application for such grant at such time, in such manner, and containing such information as specified by the Secretary; and

(ii) agrees to request and review from health insurance issuers offering group or individual health insurance coverage the comparative analyses and other information required of such health insurance issuers under subsection (a)(8)(A) of section 2726 relating to the design and application of nonquantitative treatment limitations imposed on mental health or substance use disorder benefits.

(C) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated $10,000,000 for each of the first five fiscal years beginning after the date of the enactment of this paragraph, to remain available until expended, for purposes of awarding grants under subparagraph (A).

(d) MEDICAL REIMBURSEMENT DATA CENTERS.—

(1) FUNCTIONS.—A center established under subsection (c)(1)(C) shall—

(A) develop fee schedules and other database tools that fairly and accurately reflect market rates for medical services and the geographic differences in those rates;

(B) use the best available statistical methods and data processing technology to develop such fee schedules and other database tools;

(C) regularly update such fee schedules and other database tools to reflect changes in charges for medical services;

(D) make health care cost information readily available to the public through an Internet website that allows consumers to understand the amounts that health care providers in their area charge for particular medical services; and

(E) regularly publish information concerning the statistical methodologies used by the center to analyze health charge data and make such data available to researchers and policy makers.

(2) CONFLICTS OF INTEREST.—A center established under subsection (c)(1)(C) shall adopt by-laws that ensures that the center (and all members of the governing board of the center) is independent and free from all conflicts of interest. Such by-laws shall ensure that the center is not controlled or influenced by, and does not have any corporate relation to, any individual or entity that may make or receive payments for health care services based on the center's analysis of health care costs.

(3) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed to permit a center established under subsection (c)(1)(C) to compel health insurance issuers to provide data to the center.

SEC. 2794. UNIFORM FRAUD AND ABUSE REFERRAL FORMAT.

The Secretary shall request the National Association of Insurance Commissioners to develop a model uniform report form for private health insurance issuer seeking to refer suspected fraud and abuse to State insurance departments or other responsible State agencies for investigation. The Secretary shall request that

the National Association of Insurance Commissioners develop recommendations for uniform reporting standards for such referrals.

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HELPING FAMILIES IN MENTAL HEALTH CRISIS REFORM ACT OF 2016

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the "21st Century Cures Act".

(b) TABLE OF CONTENTS.—The table of contents for this Act is as follows:

Sec. 1. Short title; table of contents.

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DIVISION B—HELPING FAMILIES IN MENTAL HEALTH CRISIS

Sec. 6000. Short title.

TITLE VI—STRENGTHENING LEADERSHIP AND ACCOUNTABILITY

* * * * * * *

Subtitle C—Interdepartmental Serious Mental Illness Coordinating Committee

[Sec. 6031. Interdepartmental Serious Mental Illness Coordinating Committee.]

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DIVISION B—HELPING FAMILIES IN MENTAL HEALTH CRISIS

* * * * * * *

TITLE VI—STRENGTHENING LEADERSHIP AND ACCOUNTABILITY

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Subtitle C—Interdepartmental Serious Mental Illness Coordinating Committee

[SEC. 6031. INTERDEPARTMENTAL SERIOUS MENTAL ILLNESS COORDINATING COMMITTEE.

[(a) ESTABLISHMENT.—

[(1) IN GENERAL.—Not later than 3 months after the date of enactment of this Act, the Secretary of Health and Human Services, or the designee of the Secretary, shall establish a committee to be known as the Interdepartmental Serious Mental Illness Coordinating Committee (in this section referred to as the "Committee").

[(2) FEDERAL ADVISORY COMMITTEE ACT.—Except as provided in this section, the provisions of the Federal Advisory Committee Act (5 U.S.C. App.) shall apply to the Committee.

[(b) MEETINGS.—The Committee shall meet not fewer than 2 times each year.

[(c) RESPONSIBILITIES.—Not later than 1 year after the date of enactment of this Act, and 5 years after such date of enactment, the Committee shall submit to Congress and any other relevant Federal department or agency a report including—

[(1) a summary of advances in serious mental illness and serious emotional disturbance research related to the prevention of, diagnosis of, intervention in, and treatment and recovery of serious mental illnesses, serious emotional disturbances, and advances in access to services and support for adults with a serious mental illness or children with a serious emotional disturbance;

[(2) an evaluation of the effect Federal programs related to serious mental illness have on public health, including public health outcomes such as—

[(A) rates of suicide, suicide attempts, incidence and prevalence of serious mental illnesses, serious emotional disturbances, and substance use disorders, overdose, overdose deaths, emergency hospitalizations, emergency room boarding, preventable emergency room visits, interaction with the criminal justice system, homelessness, and unemployment;

[(B) increased rates of employment and enrollment in educational and vocational programs;

[(C) quality of mental and substance use disorders treatment services; or

[(D) any other criteria as may be determined by the Secretary; and

[(3) specific recommendations for actions that agencies can take to better coordinate the administration of mental health services for adults with a serious mental illness or children with a serious emotional disturbance.

[(d) COMMITTEE EXTENSION.—Upon the submission of the second report under subsection (c), the Secretary shall submit a recommendation to Congress on whether to extend the operation of the Committee.

[(e) MEMBERSHIP.—

[(1) FEDERAL MEMBERS.—The Committee shall be composed of the following Federal representatives, or the designees of such representatives—

[(A) the Secretary of Health and Human Services, who shall serve as the Chair of the Committee;

[(B) the Assistant Secretary for Mental Health and Substance Use;

[(C) the Attorney General;

[(D) the Secretary of Veterans Affairs;

[(E) the Secretary of Defense;

[(F) the Secretary of Housing and Urban Development;

[(G) the Secretary of Education;

[(H) the Secretary of Labor;

[(I) the Administrator of the Centers for Medicare & Medicaid Services; and

[(J) the Commissioner of Social Security.

[(2) NON-FEDERAL MEMBERS.—The Committee shall also include not less than 14 non-Federal public members appointed by the Secretary of Health and Human Services, of which—

[(A) at least 2 members shall be an individual who has received treatment for a diagnosis of a serious mental illness;

[(B) at least 1 member shall be a parent or legal guardian of an adult with a history of a serious mental illness or a child with a history of a serious emotional disturbance;

[(C) at least 1 member shall be a representative of a leading research, advocacy, or service organization for adults with a serious mental illness;

[(D) at least 2 members shall be—

[(i) a licensed psychiatrist with experience in treating serious mental illnesses;

[(ii) a licensed psychologist with experience in treating serious mental illnesses or serious emotional disturbances;

[(iii) a licensed clinical social worker with experience treating serious mental illnesses or serious emotional disturbances; or

[(iv) a licensed psychiatric nurse, nurse practitioner, or physician assistant with experience in treating serious mental illnesses or serious emotional disturbances;

[(E) at least 1 member shall be a licensed mental health professional with a specialty in treating children and adolescents with a serious emotional disturbance;

[(F) at least 1 member shall be a mental health professional who has research or clinical mental health experience in working with minorities;

[(G) at least 1 member shall be a mental health professional who has research or clinical mental health experience in working with medically underserved populations;

[(H) at least 1 member shall be a State certified mental health peer support specialist;

[(I) at least 1 member shall be a judge with experience in adjudicating cases related to criminal justice or serious mental illness;

[(J) at least 1 member shall be a law enforcement officer or corrections officer with extensive experience in interfacing with adults with a serious mental illness, children with a serious emotional disturbance, or individuals in a mental health crisis; and

[(K) at least 1 member shall have experience providing services for homeless individuals and working with adults with a serious mental illness, children with a serious emotional disturbance, or individuals in a mental health crisis.

[(3) TERMS.—A member of the Committee appointed under subsection (e)(2) shall serve for a term of 3 years, and may be reappointed for 1 or more additional 3-year terms. Any member appointed to fill a vacancy for an unexpired term shall be appointed for the remainder of such term. A member may serve after the expiration of the member's term until a successor has been appointed.

[(f) WORKING GROUPS.—In carrying out its functions, the Committee may establish working groups. Such working groups shall be composed of Committee members, or their designees, and may hold such meetings as are necessary.

[(g) SUNSET.—The Committee shall terminate on the date that is 6 years after the date on which the Committee is established under subsection (a)(1).]

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PROTECTING ACCESS TO MEDICARE ACT OF 2014

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TITLE II—OTHER HEALTH PROVISIONS

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[SEC. 224. ASSISTED OUTPATIENT TREATMENT GRANT PROGRAM FOR INDIVIDUALS WITH SERIOUS MENTAL ILLNESS.

[(a) IN GENERAL.—The Secretary shall establish a 4-year pilot program to award not more than 50 grants each year to eligible entities for assisted outpatient treatment programs for individuals with serious mental illness.

[(b) CONSULTATION.—The Secretary shall carry out this section in consultation with the Director of the National Institute of Mental Health, the Attorney General of the United States, the Administrator of the Administration for Community Living, and the Administrator of the Substance Abuse and Mental Health Services Administration.

[(c) SELECTING AMONG APPLICANTS.—The Secretary—

[(1) may only award grants under this section to applicants that have not previously implemented an assisted outpatient treatment program; and

[(2) shall evaluate applicants based on their potential to reduce hospitalization, homelessness, incarceration, and interaction with the criminal justice system while improving the health and social outcomes of the patient.

[(d) USE OF GRANT.—An assisted outpatient treatment program funded with a grant awarded under this section shall include—

[(1) evaluating the medical and social needs of the patients who are participating in the program;

[(2) preparing and executing treatment plans for such patients that—

[(A) include criteria for completion of court-ordered treatment; and

[(B) provide for monitoring of the patient's compliance with the treatment plan, including compliance with medication and other treatment regimens;

[(3) providing for such patients case management services that support the treatment plan;

[(4) ensuring appropriate referrals to medical and social service providers;

[(5) evaluating the process for implementing the program to ensure consistency with the patient's needs and State law; and

[(6) measuring treatment outcomes, including health and social outcomes such as rates of incarceration, health care utilization, and homelessness.

[(e) REPORT.—Not later than the end of each of fiscal years 2016, 2017, 2018, 2019, 2020, 2021, and 2022, the Secretary shall submit a report to the appropriate congressional committees on the grant program under this section. Each such report shall include an evaluation of the following:

[(1) Cost savings and public health outcomes such as mortality, suicide, substance abuse, hospitalization, and use of services.

[(2) Rates of incarceration by patients.

[(3) Rates of homelessness among patients.

[(4) Patient and family satisfaction with program participation.

[(f) DEFINITIONS.—In this section:

[(1) The term "assisted outpatient treatment" means medically prescribed mental health treatment that a patient receives while living in a community under the terms of a law authorizing a State or local court to order such treatment.

[(2) The term "eligible entity" means a county, city, mental health system, mental health court, or any other entity with authority under the law of the State in which the grantee is located to implement, monitor, and oversee assisted outpatient treatment programs.

[(3) The term "Secretary" means the Secretary of Health and Human Services.

[(g) FUNDING.—

[(1) AMOUNT OF GRANTS.—A grant under this section shall be in an amount that is not more than $1,000,000 for each of fiscal years 2015 through 2022. Subject to the preceding sentence, the Secretary shall determine the amount of each grant based on the population of the area, including estimated patients, to be served under the grant.

[(2) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section $15,000,000 for each of fiscal years 2015 through 2017, $20,000,000 for fiscal year 2018, $19,000,000 for each of fiscal years 2019 and 2020, and $18,000,000 for each of fiscal years 2021 and 2022.]

SEC. 224. ASSISTED OUTPATIENT TREATMENT GRANT PROGRAM FOR INDIVIDUALS WITH SERIOUS MENTAL ILLNESS.

(a) IN GENERAL.—The Secretary shall carry out a program to award grants to eligible entities for assisted outpatient treatment programs for individuals with serious mental illness.

(b) CONSULTATION.—The Secretary shall carry out this section in consultation with the Director of the National Institute of Mental Health, the Attorney General of the United States, the Administrator of the Administration for Community Living, and the Assistant Secretary for Mental Health and Substance Use.

(c) SELECTING AMONG APPLICANTS.—In awarding grants under this section, the Secretary—

(1) may give preference to applicants that have not previously implemented an assisted outpatient treatment program; and

(2) shall evaluate applicants based on their potential to reduce hospitalization, homelessness, incarceration, and inter-

action with the criminal justice system while improving the health and social outcomes of the patient.

(d) PROGRAM REQUIREMENTS.—An assisted outpatient treatment program funded with a grant awarded under this section shall include—

(1) evaluating the medical and social needs of the patients who are participating in the program;

(2) preparing and executing treatment plans for such patients that—

(A) include criteria for completion of court-ordered treatment if applicable; and

(B) provide for monitoring of the patient's compliance with the treatment plan, including compliance with medication and other treatment regimens;

(3) providing for case management services that support the treatment plan;

(4) ensuring appropriate referrals to medical and social services providers;

(5) evaluating the process for implementing the program to ensure consistency with the patient's needs and State law; and

(6) measuring treatment outcomes, including health and social outcomes such as rates of incarceration, health care utilization, and homelessness.

(e) REPORT.—Not later than the end of fiscal year 2027, the Secretary shall submit a report to the appropriate congressional committees on the grant program under this section. Such report shall include an evaluation of the following:

(1) Cost savings and public health outcomes such as mortality, suicide, substance abuse, hospitalization, and use of services.

(2) Rates of incarceration of patients.

(3) Rates of homelessness of patients.

(4) Patient and family satisfaction with program participation.

(5) Demographic information regarding participation of those served by the grant compared to demographic information in the population of the grant recipient.

(f) DEFINITIONS.—In this section:

(1) The term "assisted outpatient treatment" means medically prescribed mental health treatment that a patient receives while living in a community under the terms of a law authorizing a State or local civil court to order such treatment.

(2) The term "eligible entity" means a county, city, mental health system, mental health court, or any other entity with authority under the law of the State in which the entity is located to implement, monitor, and oversee an assisted outpatient treatment program.

(g) FUNDING.—

(1) AMOUNT OF GRANTS.—

(A) MAXIMUM AMOUNT.—The amount of a grant under this section shall not exceed $1,000,000 for any fiscal year.

(B) DETERMINATION.—Subject to subparagraph (A), the Secretary shall determine the amount of each grant under this section based on the population of the area to be served

through the grant and an estimate of the number of patients to be served.

(2) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section $22,000,000 for each of fiscal years 2023 through 2027.

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COMPREHENSIVE ADDICTION AND RECOVERY ACT OF 2016

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TITLE I—PREVENTION AND EDUCATION

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SEC. 107. IMPROVING ACCESS TO OVERDOSE TREATMENT.

(a) GRANTS FOR REDUCING OVERDOSE DEATHS.—[Omitted Amends other Act]".

[(b) IMPROVING ACCESS TO OVERDOSE TREATMENT.—

[(1) INFORMATION ON BEST PRACTICES.—Not later than 180 days after the date of enactment of this Act:

[(A) The Secretary of Health and Human Services may provide information to prescribers within Federally qualified health centers (as defined in paragraph (4) of section 1861(aa) of the Social Security Act (42 U.S.C. 1395x(aa))), and the health care facilities of the Indian Health Service, on best practices for prescribing or co-prescribing a drug or device approved or cleared under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) for emergency treatment of known or suspected opioid overdose, including for patients receiving chronic opioid therapy and patients being treated for opioid use disorders.

[(B) The Secretary of Defense may provide information to prescribers within Department of Defense medical facilities on best practices for prescribing or co-prescribing a drug or device approved or cleared under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) for emergency treatment of known or suspected opioid overdose, including for patients receiving chronic opioid therapy and patients being treated for opioid use disorders.

[(C) The Secretary of Veterans Affairs may provide information to prescribers within Department of Veterans Affairs medical facilities on best practices for prescribing or co-prescribing a drug or device approved or cleared under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) for emergency treatment of known or suspected opioid overdose, including for patients receiving chronic opioid therapy and patients being treated for opioid use disorders.

[(2) RULE OF CONSTRUCTION.—Nothing in this subsection should be construed to establish or contribute to a medical standard of care.]

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SUPPORT FOR PATIENTS AND COMMUNITIES ACT

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the "Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act" or the "SUPPORT for Patients and Communities Act".

(b) TABLE OF CONTENTS.—The table of contents of this Act is as follows:

Sec. 1. Short title; table of contents.

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Subtitle J—Alternatives to Opioids in the Emergency Department

Sec. 7091. Emergency department alternatives to opioids [demonstration] program.

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TITLE VII—PUBLIC HEALTH PROVISIONS

Subtitle J—Alternatives to Opioids in the Emergency Department

SEC. 7091. EMERGENCY DEPARTMENT ALTERNATIVES TO OPIOIDS [DEMONSTRATION] PROGRAM.

(a) [DEMONSTRATION PROGRAM GRANTS.—] *GRANT PROGRAM.*—

(1) IN GENERAL.—The Secretary of Health and Human Services (in this section referred to as the "Secretary") shall carry out a [demonstration] program for purposes of awarding grants to hospitals and emergency departments, including free-standing emergency departments, to develop, implement, enhance, or study alternatives to opioids for pain management in such settings.

(2) ELIGIBILITY.—To be eligible to receive a grant under paragraph (1), a hospital or emergency department shall submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may require.

(3) GEOGRAPHIC DISTRIBUTION.—In awarding grants under this section, the Secretary shall seek to ensure geographical distribution among grant recipients.

(4) USE OF FUNDS.—Grants under paragraph (1) shall be used to—

(A) target treatment approaches for painful conditions frequently treated in such settings;

(B) train providers and other hospital personnel on protocols or best practices related to the use and prescription

of opioids and alternatives to opioids for pain management in the emergency department; and

(C) develop or continue strategies to provide alternatives to opioids, as appropriate.

(b) ADDITIONAL [DEMONSTRATION] PROGRAM.—The Secretary may carry out a demonstration program similar to the program under subsection (a) for other acute care settings.

(c) CONSULTATION.—The Secretary shall implement a process for recipients of grants under subsection (a) or (b) to share evidence-based and best practices and promote consultation with persons having robust knowledge, including emergency departments and physicians that have successfully implemented programs that use alternatives to opioids for pain management, as appropriate, such as approaches studied through the National Center for Complimentary and Integrative Health or other institutes and centers at the National Institutes of Health, as appropriate. The Secretary shall offer to each recipient of a grant under subsection (a) or (b) technical assistance as necessary.

(d) TECHNICAL ASSISTANCE.—The Secretary shall identify or facilitate the development of best practices on alternatives to opioids for pain management and provide technical assistance to hospitals and other acute care settings on alternatives to opioids for pain management. The technical assistance provided shall be for the purpose of—

(1) utilizing information from recipients of a grant under subsection (a) or (b) that have successfully implemented alternatives to opioids programs;

(2) identifying or facilitating the development of best practices on the use of alternatives to opioids, which may include pain-management strategies that involve non-addictive medical products, non-pharmacologic treatments, and technologies or techniques to identify patients at risk for opioid use disorder;

(3) identifying or facilitating the development of best practices on the use of alternatives to opioids that target common painful conditions and include certain patient populations, such as geriatric patients, pregnant women, and children; and

(4) disseminating information on the use of alternatives to opioids to providers in acute care settings, which may include emergency departments, outpatient clinics, critical access hospitals, Federally qualified health centers, Indian Health Service health facilities, and [tribal] *Tribal* hospitals.

(e) REPORT TO THE SECRETARY.—Each recipient of a grant under this section shall submit to the Secretary (during the period of such grant) annual reports on the progress of the program funded through the grant. These reports shall include, in accordance with all applicable State and Federal privacy laws—

(1) a description of and specific information about the opioid alternative pain management programs, including the demographic characteristics of patients who were treated with an alternative pain management protocol, implemented in hospitals, emergency departments, and other acute care settings;

(2) data on the opioid alternative pain management strategies used, including the number of opioid prescriptions written—

(A) during a baseline period before the program began; or

(B) at various stages of the program; and

(3) data on patients who were eventually prescribed opioids after alternative pain management protocols and treatments were utilized; and

(4) any other information the Secretary determines appropriate.

(f) REPORT TO CONGRESS.—[Not later than 1 year after completion of the demonstration program under this section, the Secretary shall submit a report to the Congress on the results of the demonstration program] *Not later than the end of each of fiscal years 2024 and 2027, the Secretary shall submit to the Congress a report on the results of the program* and include in the report—

(1) the number of applications received and the number funded;

(2) a summary of the reports described in subsection (e), including data that allows for comparison of programs; and

(3) recommendations for broader implementation of pain management strategies that encourage the use of alternatives to opioids in hospitals, emergency departments, or other acute care settings.

(g) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there is authorized to be appropriated $10,000,000 for each of fiscal years [2019 through 2021] *2023 through 2027*.

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CONTROLLED SUBSTANCES ACT

TITLE II—CONTROL AND ENFORCEMENT

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PART C—REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, AND DISPENSERS OF CONTROLLED SUBSTANCES; PIPERIDINE REPORTING

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PERSONS REQUIRED TO REGISTER

SEC. 302. (a)(1) Every person who manufactures or distributes any controlled substance or list I chemical, or who proposes to engage in the manufacture or distribution of any controlled substance or list I chemical, shall obtain annually a registration issued by the Attorney General in accordance with the rules and regulations promulgated by him.

(2) Every person who dispenses, or who proposes to dispense, any controlled substance, shall obtain from the Attorney General a registration issued in accordance with the rules and regulations promulgated by him. The Attorney General shall, by regulation, determine the period of such registrations. In no event; however, shall such registrations be issued for less than one year nor for more than three years.

(3)(A) Except as provided in subparagraph (C), the registration of any registrant under this title to manufacture, distribute, or dis-

pense controlled substances or list I chemicals terminates if and when such registrant—

(i) dies;

(ii) ceases legal existence;

(iii) discontinues business or professional practice; or

(iv) surrenders such registration.

(B) In the case of such a registrant who ceases legal existence or discontinues business or professional practice, such registrant shall promptly notify the Attorney General in writing of such fact.

(C) No registration under this title to manufacture, distribute, or dispense controlled substances or list I chemicals, and no authority conferred thereby, may be assigned or otherwise transferred except upon such conditions as the Attorney General may specify and then only pursuant to written consent. A registrant to whom a registration is assigned or transferred pursuant to the preceding sentence may not manufacture, distribute, or dispense controlled substances or list I chemicals pursuant to such registration until the Attorney General receives such written consent.

(D) In the case of a registrant under this title to manufacture, distribute, or dispense controlled substances or list I chemicals desiring to discontinue business or professional practice altogether or with respect to controlled substances and list I chemicals (without assigning or transferring such business or professional practice to another entity), such registrant shall return to the Attorney General for cancellation—

(i) the registrant's certificate of registration;

(ii) any unexecuted order forms in the registrant's possession; and

(iii) any other documentation that the Attorney General may require.

(b) Persons registered by the Attorney General under this title to manufacture, distribute, or dispense controlled substances or list I chemicals are authorized to possess, manufacture, distribute, or dispense such substances or chemicals (including any such activity in the conduct of research) to the extent authorized by their registration and in conformity with the other provisions of this title.

(c) The following persons shall not be required to register and may lawfully possess any controlled substance or list I chemical under this title:

(1) An agent or employee of any registered manufacturer, distributor, or dispenser of any controlled substance or list I chemical if such agent or employee is acting in the usual course of his business or employment.

(2) A common or contract carrier or warehouseman, or an employee thereof, whose possession of the controlled substance or list I chemical is in the usual course of his business or employment.

(3) An ultimate user who possesses such substance for a purpose specified in section 102(25).

(d) The Attorney General may, by regulation, waive the requirement for registration of certain manufacturers, distributors, or dispensers if he finds it consistent with the public health and safety.

(e)(1) A separate registration shall be required at each principal place of business or professional practice where the applicant man-

ufactures, distributes, or dispenses controlled substances or list I chemicals.

(2) Notwithstanding paragraph (1), a registrant who is a veterinarian shall not be required to have a separate registration in order to transport and dispense controlled substances in the usual course of veterinary practice at a site other than the registrant's registered principal place of business or professional practice, so long as the site of transporting and dispensing is located in a State where the veterinarian is licensed to practice veterinary medicine and is not a principal place of business or professional practice.

(3) Notwithstanding paragraph (1), a registrant that is dispensing pursuant to section 303(g) narcotic drugs to individuals for maintenance treatment or detoxification treatment shall not be required to have a separate registration to incorporate one or more mobile medication units into the registrant's practice to dispense such narcotics at locations other than the registrant's principal place of business or professional practice described in paragraph (1), so long as the registrant meets such standards for operation of a mobile medication unit as the Attorney General may establish.

(f) The Attorney General is authorized to inspect the establishment of a registrant or applicant for registration in accordance with the rules and regulations promulgated by him.

(g)(1) An ultimate user who has lawfully obtained a controlled substance in accordance with this title may, without being registered, deliver the controlled substance to another person for the purpose of disposal of the controlled substance if—

(A) the person receiving the controlled substance is authorized under this title to engage in such activity; and

(B) the disposal takes place in accordance with regulations issued by the Attorney General to prevent diversion of controlled substances.

(2) In developing regulations under this subsection, the Attorney General shall take into consideration the public health and safety, as well as the ease and cost of program implementation and participation by various communities. Such regulations may not require any entity to establish or operate a delivery or disposal program.

(3) The Attorney General may, by regulation, authorize long-term care facilities, as defined by the Attorney General by regulation, to dispose of controlled substances on behalf of ultimate users who reside, or have resided, at such long-term care facilities in a manner that the Attorney General determines will provide effective controls against diversion and be consistent with the public health and safety.

(4) If a person dies while lawfully in possession of a controlled substance for personal use, any person lawfully entitled to dispose of the decedent's property may deliver the controlled substance to another person for the purpose of disposal under the same conditions as provided in paragraph (1) for an ultimate user.

(5)(A) In the case of a person receiving hospice care, an employee of a qualified hospice program, acting within the scope of employment, may handle, without being registered under this section, any controlled substance that was lawfully dispensed to the person receiving hospice care, for the purpose of disposal of the controlled

substance so long as such disposal occurs onsite in accordance with all applicable Federal, State, Tribal, and local law and—

(i) the disposal occurs after the death of a person receiving hospice care;

(ii) the controlled substance is expired; or

(iii)(I) the employee is—

(aa) the physician of the person receiving hospice care; and

(bb) registered under section 303(f); and

(II) the hospice patient no longer requires the controlled substance because the plan of care of the hospice patient has been modified.

(B) For the purposes of this paragraph:

(i) The terms "hospice care" and "hospice program" have the meanings given to those terms in section 1861(dd) of the Social Security Act.

(ii) The term "employee of a qualified hospice program" means a physician, physician assistant, nurse, or other person who—

(I) is employed by, or pursuant to arrangements made by, a qualified hospice program;

(II)(aa) is licensed to perform medical or nursing services by the jurisdiction in which the person receiving hospice care was located; and

(bb) is acting within the scope of such employment in accordance with applicable State law; and

(III) has completed training through the qualified hospice program regarding the disposal of controlled substances in a secure and responsible manner so as to discourage abuse, misuse, or diversion.

(iii) The term "qualified hospice program" means a hospice program that—

(I) has written policies and procedures for assisting in the disposal of the controlled substances of a person receiving hospice care after the person's death;

(II) at the time when the controlled substances are first ordered—

(aa) provides a copy of the written policies and procedures to the patient or patient representative and family;

(bb) discusses the policies and procedures with the patient or representative and the family in a language and manner that they understand to ensure that these parties are educated regarding the safe disposal of controlled substances; and

(cc) documents in the patient's clinical record that the written policies and procedures were provided and discussed; and

(III) at the time following the disposal of the controlled substances—

(aa) documents in the patient's clinical record the type of controlled substance, dosage, route of administration, and quantity so disposed; and

(bb) the time, date, and manner in which that disposal occurred.

REGISTRATION REQUIREMENTS

SEC. 303. (a) The Attorney General shall register an applicant to manufacture controlled substances in schedule I or II if he determines that such registration is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on the effective date of this part. In determining the public interest, the following factors shall be considered:

(1) maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule I or II compounded therefrom into other than legitimate medical, scientific, research, or industrial channels, by limiting the importation and bulk manufacture of such controlled substances to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes;

(2) compliance with applicable State and local law;

(3) promotion of technical advances in the art of manufacturing these substances and the development of new substances;

(4) prior conviction record of applicant under Federal and State laws relating to the manufacture, distribution, or dispensing of such substances;

(5) past experience in the manufacture of controlled substances, and the existence in the establishment of effective control against diversion; and

(6) such other factors as may be relevant to and consistent with the public health and safety.

(b) The Attorney General shall register an applicant to distribute a controlled substance in schedule I or II unless he determines that the issuance of such registration is inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

(1) maintenance of effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels;

(2) compliance with applicable State and local law;

(3) prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of such substances;

(4) past experience in the distribution of controlled substances; and

(5) such other factors as may be relevant to and consistent with the public health and safety.

(c) Registration granted under subsections (a) and (b) of this section shall not entitle a registrant to (1) manufacture or distribute controlled substances in schedule I or II other than those specified in the registration, or (2) manufacture any quantity of those controlled substances in excess of the quota assigned pursuant to section 306.

(d) The Attorney General shall register an applicant to manufacture controlled substances in schedule III, IV, or V, unless he determines that the issuance of such registration is inconsistent with

the public interest. In determining the public interest, the following factors shall be considered:

(1) maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule III, IV, or V compounded therefrom into other than legitimate medical, scientific, or industrial channels;

(2) compliance with applicable State and local law;

(3) promotion of technical advances in the art of manufacturing these substances and the development of new substances;

(4) prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of such substances;

(5) past experience in the manufacture, distribution, and dispensing of controlled substances, and the existence in the establishment of effective controls against diversion; and

(6) such other factors as may be relevant to and consistent with the public health and safety.

(e) The Attorney General shall register an applicant to distribute controlled substances in schedule III, IV, or V, unless he determines that the issuance of such registration is inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

(1) maintenance of effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels;

(2) compliance with applicable State and local law;

(3) prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of such substances;

(4) past experience in the distribution of controlled substances; and

(5) such other factors as may be relevant to and consistent with the public health and safety.

(f) The Attorney General shall register practitioners (including pharmacies, as distinguished from pharmacists) to dispense, or conduct research with, controlled substances in schedule II, III, IV, or V and shall modify the registrations of pharmacies so registered to authorize them to dispense controlled substances by means of the Internet, if the applicant is authorized to dispense, or conduct research with respect to, controlled substances under the laws of the State in which he practices. The Attorney General may deny an application for such registration or such modification of registration if the Attorney General determines that the issuance of such registration or modification would be inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

(1) The recommendation of the appropriate State licensing board or professional disciplinary authority.

(2) The applicant's experience in dispensing, or conducting research with respect to controlled substances.

(3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

(4) Compliance with applicable State, Federal, or local laws relating to controlled substances.

(5) Such other conduct which may threaten the public health and safety.

Separate registration under this part for practitioners engaging in research with controlled substances in schedule II, III, IV, or V, who are already registered under this part in another capacity, shall not be required. Registration applications by practitioners wishing to conduct research with controlled substances in schedule I shall be referred to the Secretary, who shall determine the qualifications and competency of each practitioner requesting registration, as well as the merits of the research protocol. The Secretary, in determining the merits of each research protocol, shall consult with the Attorney General as to effective procedures to adequately safeguard against diversion of such controlled substances from legitimate medical or scientific use. Registration for the purpose of bona fide research with controlled substances in schedule I by a practitioner deemed qualified by the Secretary may be denied by the Attorney General only on a ground specified in section 304(a). Article 7 of the Convention on Psychotrophic Substances shall not be construed to prohibit, or impose additional restrictions upon, research involving drugs or other substances scheduled under the convention which is conducted in conformity with this subsection and other applicable provisions of this title.

[(g)(1) Except as provided in paragraph (2), practitioners who dispense narcotic drugs to individuals for maintenance treatment or detoxification treatment**]** *(g) Practitioners who dispense narcotic drugs (other than narcotic drugs in schedule III, IV, or V) to individuals for maintenance treatment or detoxification treatment* shall obtain annually a separate registration for that purpose. The Attorney General shall register an applicant to dispense narcotic drugs to individuals for maintenance treatment or detoxification treatment (or both)—

[(A)**]** *(1)* if the applicant is a practitioner who is determined by the Secretary to be qualified (under standards established by the Secretary) to engage in the treatment with respect to which registration is sought;

[(B)**]** *(2)* if the Attorney General determines that the applicant will comply with standards established by the Attorney General respecting **[**(i)**]** *(A)* security of stocks of narcotic drugs for such treatment, and **[**(ii)**]** *(B)* the maintenance of records (in accordance with section 307) on such drugs; and

[(C)**]** *(3)* if the Secretary determines that the applicant will comply with standards established by the Secretary (after consultation with the Attorney General) respecting the quantities of narcotic drugs which may be provided for unsupervised use by individuals in such treatment.

[(2)(A) Subject to subparagraphs (D) and (J), the requirements of paragraph (1) are waived in the case of the dispensing (including the prescribing), by a practitioner, of narcotic drugs in schedule III, IV, or V or combinations of such drugs if the practitioner meets the conditions specified in subparagraph (B) and the narcotic drugs or combinations of such drugs meet the conditions specified in subparagraph (C).

[(B) For purposes of subparagraph (A), the conditions specified in this subparagraph with respect to a practitioner are that, before the initial dispensing of narcotic drugs in schedule III, IV, or V or combinations of such drugs to patients for maintenance or detoxification treatment, the practitioner submit to the Secretary a notification of the intent of the practitioner to begin dispensing the drugs or combinations for such purpose, and that the notification contain the following certifications by the practitioner:

[(i) The practitioner is a qualifying practitioner (as defined in subparagraph (G)).

[(ii) With respect to patients to whom the practitioner will provide such drugs or combinations of drugs, the practitioner has the capacity to provide directly, by referral, or in such other manner as determined by the Secretary—

[(I) all drugs approved by the Food and Drug Administration for the treatment of opioid use disorder, including for maintenance, detoxification, overdose reversal, and relapse prevention; and

[(II) appropriate counseling and other appropriate ancillary services.

[(iii)(I) The total number of such patients of the practitioner at any one time will not exceed the applicable number. Except as provided in subclause (II), the applicable number is 30.

[(II) The applicable number is—

[(aa) 100 if, not sooner than 1 year after the date on which the practitioner submitted the initial notification, the practitioner submits a second notification to the Secretary of the need and intent of the practitioner to treat up to 100 patients;

[(bb) 100 if the practitioner holds additional credentialing, as defined in section 8.2 of title 42, Code of Federal Regulations (or successor regulations);

[(cc) 100 if the practitioner provides medication-assisted treatment (MAT) using covered medications (as such terms are defined in section 8.2 of title 42, Code of Federal Regulations (or successor regulations)) in a qualified practice setting (as described in section 8.615 of title 42, Code of Federal Regulations (or successor regulations)); or

[(dd) 275 if the practitioner meets the requirements specified in sections 8.610 through 8.655 of title 42, Code of Federal Regulations (or successor regulations).

[(III) The Secretary may by regulation change such applicable number.

[(IV) The Secretary may exclude from the applicable number patients to whom such drugs or combinations of drugs are directly administered by the qualifying practitioner in the office setting.

[(C) For purposes of subparagraph (A), the conditions specified in this subparagraph with respect to narcotic drugs in schedule III, IV, or V or combinations of such drugs are as follows:

[(i) The drugs or combinations of drugs have, under the Federal Food, Drug, and Cosmetic Act or section 351 of the Public

Health Service Act, been approved for use in maintenance or detoxification treatment.

[(ii) The drugs or combinations of drugs have not been the subject of an adverse determination. For purposes of this clause, an adverse determination is a determination published in the Federal Register and made by the Secretary, after consultation with the Attorney General, that the use of the drugs or combinations of drugs for maintenance or detoxification treatment requires additional standards respecting the qualifications of practitioners to provide such treatment, or requires standards respecting the quantities of the drugs that may be provided for unsupervised use.

[(D)(i) A waiver under subparagraph (A) with respect to a practitioner is not in effect unless (in addition to conditions under subparagraphs (B) and (C)) the following conditions are met:

[(I) The notification under subparagraph (B) is in writing and states the name of the practitioner.

[(II) The notification identifies the registration issued for the practitioner pursuant to subsection (f).

[(III) If the practitioner is a member of a group practice, the notification states the names of the other practitioners in the practice and identifies the registrations issued for the other practitioners pursuant to subsection (f).

[(ii) Upon receiving a determination from the Secretary under clause (iii) finding that a practitioner meets all requirements for a waiver under subparagraph (B), the Attorney General shall assign the practitioner involved an identification number under this paragraph for inclusion with the registration issued for the practitioner pursuant to subsection (f). The identification number so assigned shall be appropriate to preserve the confidentiality of patients for whom the practitioner has dispensed narcotic drugs under a waiver under subparagraph (A).

[(iii) Not later than 45 days after the date on which the Secretary receives a notification under subparagraph (B), the Secretary shall make a determination of whether the practitioner involved meets all requirements for a waiver under subparagraph (B) and shall forward such determination to the Attorney General. If the Secretary fails to make such determination by the end of the such 45-day period, the Attorney General shall assign the practitioner an identification number described in clause (ii) at the end of such period.

[(E)(i) If a practitioner is not registered under paragraph (1) and, in violation of the conditions specified in subparagraphs (B) through (D), dispenses narcotic drugs in schedule III, IV, or V or combinations of such drugs for maintenance treatment or detoxification treatment, the Attorney General may, for purposes of section 304(a)(4), consider the practitioner to have committed an act that renders the registration of the practitioner pursuant to subsection (f) to be inconsistent with the public interest.

[(ii)(I) Upon the expiration of 45 days from the date on which the Secretary receives a notification under subparagraph (B), a practitioner who in good faith submits a notification under subparagraph (B) and reasonably believes that the conditions specified in subparagraphs (B) through (D) have been met shall, in dispensing narcotic drugs in schedule III, IV, or V or combinations of such drugs

for maintenance treatment or detoxification treatment, be considered to have a waiver under subparagraph (A) until notified otherwise by the Secretary, except that such a practitioner may commence to prescribe or dispense such narcotic drugs for such purposes prior to the expiration of such 45-day period if it facilitates the treatment of an individual patient and both the Secretary and the Attorney General are notified by the practitioner of the intent to commence prescribing or dispensing such narcotic drugs.

[(II) For purposes of subclause (I), the publication in the Federal Register of an adverse determination by the Secretary pursuant to subparagraph (C)(ii) shall (with respect to the narcotic drug or combination involved) be considered to be a notification provided by the Secretary to practitioners, effective upon the expiration of the 30-day period beginning on the date on which the adverse determination is so published.

[(F)(i) With respect to the dispensing of narcotic drugs in schedule III, IV, or V or combinations of such drugs to patients for maintenance or detoxification treatment, a practitioner may, in his or her discretion, dispense such drugs or combinations for such treatment under a registration under paragraph (1) or a waiver under subparagraph (A) (subject to meeting the applicable conditions).

[(ii) This paragraph may not be construed as having any legal effect on the conditions for obtaining a registration under paragraph (1), including with respect to the number of patients who may be served under such a registration.

[(G) For purposes of this paragraph:

[(i) The term "group practice" has the meaning given such term in section 1877(h)(4) of the Social Security Act.

[(ii) The term "qualifying physician" means a physician who is licensed under State law and who meets one or more of the following conditions:

[(I) The physician holds a board certification in addiction psychiatry or addiction medicine from the American Board of Medical Specialties.

[(II) The physician holds an addiction certification or board certification from the American Society of Addiction Medicine or the American Board of Addiction Medicine.

[(III) The physician holds a board certification in addiction medicine from the American Osteopathic Association.

[(IV) The physician has, with respect to the treatment and management of opiate-dependent patients, completed not less than 8 hours of training (through classroom situations, seminars at professional society meetings, electronic communications, or otherwise) that is provided by the American Society of Addiction Medicine, the American Academy of Addiction Psychiatry, the American Medical Association, the American Osteopathic Association, the American Psychiatric Association, or any other organization that the Secretary determines is appropriate for purposes of this subclause. Such training shall include—

[(aa) opioid maintenance and detoxification;

[(bb) appropriate clinical use of all drugs approved by the Food and Drug Administration for the treatment of opioid use disorder;

[(cc) initial and periodic patient assessments (including substance use monitoring);

[(dd) individualized treatment planning, overdose reversal, and relapse prevention;

[(ee) counseling and recovery support services;

[(ff) staffing roles and considerations;

[(gg) diversion control; and

[(hh) other best practices, as identified by the Secretary.

[(V) The physician has participated as an investigator in one or more clinical trials leading to the approval of a narcotic drug in schedule III, IV, or V for maintenance or detoxification treatment, as demonstrated by a statement submitted to the Secretary by the sponsor of such approved drug.

[(VI) The physician has such other training or experience as the State medical licensing board (of the State in which the physician will provide maintenance or detoxification treatment) considers to demonstrate the ability of the physician to treat and manage opiate-dependent patients.

[(VII) The physician has such other training or experience as the Secretary considers to demonstrate the ability of the physician to treat and manage opiate-dependent patients. Any criteria of the Secretary under this subclause shall be established by regulation. Any such criteria are effective only for 3 years after the date on which the criteria are promulgated, but may be extended for such additional discrete 3-year periods as the Secretary considers appropriate for purposes of this subclause. Such an extension of criteria may only be effectuated through a statement published in the Federal Register by the Secretary during the 30-day period preceding the end of the 3-year period involved.

[(VIII) The physician graduated in good standing from an accredited school of allopathic medicine or osteopathic medicine in the United States during the 5-year period immediately preceding the date on which the physician submits to the Secretary a written notification under subparagraph (B) and successfully completed a comprehensive allopathic or osteopathic medicine curriculum or accredited medical residency that—

[(aa) included not less than 8 hours of training on treating and managing opioid-dependent patients; and

[(bb) included, at a minimum—

[(AA) the training described in items (aa) through (gg) of subclause (IV); and

[(BB) training with respect to any other best practice the Secretary determines should be included in the curriculum, which may include training on pain management, including assessment and appropriate use of opioid and non-opioid alternatives.

[(iii) The term "qualifying practitioner" means—

[(I) a qualifying physician, as defined in clause (ii);

[(II) a qualifying other practitioner, as defined in clause (iv), who is a nurse practitioner or physician assistant; or

[(III) for the period beginning on October 1, 2018, and ending on October 1, 2023, a qualifying other practitioner, as defined in clause (iv), who is a clinical nurse specialist, certified registered nurse anesthetist, or certified nurse midwife.

[(iv) The term "qualifying other practitioner" means a nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse midwife, or physician assistant who satisfies each of the following:

[(I) The nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse midwife, or physician assistant is licensed under State law to prescribe schedule III, IV, or V medications for the treatment of pain.

[(II) The nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse midwife, or physician assistant has—

[(aa) completed not fewer than 24 hours of initial training addressing each of the topics listed in clause (ii)(IV) (through classroom situations, seminars at professional society meetings, electronic communications, or otherwise) provided by the American Society of Addiction Medicine, the American Academy of Addiction Psychiatry, the American Medical Association, the American Osteopathic Association, the American Nurses Credentialing Center, the American Psychiatric Association, the American Association of Nurse Practitioners, the American Academy of Physician Assistants, or any other organization that the Secretary determines is appropriate for purposes of this subclause; or

[(bb) has such other training or experience as the Secretary determines will demonstrate the ability of the nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse midwife, or physician assistant to treat and manage opiate-dependent patients.

[(III) The nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse midwife, or physician assistant is supervised by, or works in collaboration with, a qualifying physician, if the nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse midwife, or physician assistant is required by State law to prescribe medications for the treatment of opioid use disorder in collaboration with or under the supervision of a physician.

The Secretary may, by regulation, revise the requirements for being a qualifying other practitioner under this clause.

[(H)(i) In consultation with the Administrator of the Drug Enforcement Administration, the Administrator of the Substance Abuse and Mental Health Services Administration, the Director of the National Institute on Drug Abuse, and the Commissioner of Food and Drugs, the Secretary shall issue regulations (through notice and comment rulemaking) or issue practice guidelines to address the following:

[(I) Approval of additional credentialing bodies and the responsibilities of additional credentialing bodies.

[(II) Additional exemptions from the requirements of this paragraph and any regulations under this paragraph.

[(III) Such other elements of the requirements under this paragraph as the Secretary determines necessary for purposes of implementing such requirements.

Nothing in such regulations or practice guidelines may authorize any Federal official or employee to exercise supervision or control over the practice of medicine or the manner in which medical services are provided.

[(ii) Not later than 18 months after the date of enactment of the Opioid Use Disorder Treatment Expansion and Modernization Act, the Secretary shall update the treatment improvement protocol containing best practice guidelines for the treatment of opioid-dependent patients in office-based settings. The Secretary shall update such protocol in consultation with experts in opioid use disorder research and treatment.

[(I) Notwithstanding section 708, nothing in this paragraph shall be construed to preempt any State law that—

[(i) permits a qualifying practitioner to dispense narcotic drugs in schedule III, IV, or V, or combinations of such drugs, for maintenance or detoxification treatment in accordance with this paragraph to a total number of patients that is more than 30 or less than the total number applicable to the qualifying practitioner under subparagraph (B)(iii)(II) if a State enacts a law modifying such total number and the Attorney General is notified by the State of such modification; or

[(ii) requires a qualifying practitioner to comply with additional requirements relating to the dispensing of narcotic drugs in schedule III, IV, or V, or combinations of such drugs, including requirements relating to the practice setting in which the qualifying practitioner practices and education, training, and reporting requirements.]

(h) The Attorney General shall register an applicant to distribute a list I chemical unless the Attorney General determines that registration of the applicant is inconsistent with the public interest. Registration under this subsection shall not be required for the distribution of a drug product that is exempted under clause (iv) or (v) of section 102(39)(A). In determining the public interest for the purposes of this subsection, the Attorney General shall consider—

(1) maintenance by the applicant of effective controls against diversion of listed chemicals into other than legitimate channels;

(2) compliance by the applicant with applicable Federal, State, and local law;

(3) any prior conviction record of the applicant under Federal or State laws relating to controlled substances or to chemicals controlled under Federal or State law;

(4) any past experience of the applicant in the manufacture and distribution of chemicals; and

(5) such other factors as are relevant to and consistent with the public health and safety.

(i)(1) For purposes of registration to manufacture a controlled substance under subsection (d) for use only in a clinical trial, the

Attorney General shall register the applicant, or serve an order to show cause upon the applicant in accordance with section 304(c), not later than 180 days after the date on which the application is accepted for filing.

(2) For purposes of registration to manufacture a controlled substance under subsection (a) for use only in a clinical trial, the Attorney General shall, in accordance with the regulations issued by the Attorney General, issue a notice of application not later than 90 days after the application is accepted for filing. Not later than 90 days after the date on which the period for comment pursuant to such notice ends, the Attorney General shall register the applicant, or serve an order to show cause upon the applicant in accordance with section 304(c), unless the Attorney General has granted a hearing on the application under section 1008(i) of the Controlled Substances Import and Export Act.

(j) EMERGENCY MEDICAL SERVICES THAT ADMINISTER CONTROLLED SUBSTANCES.—

(1) REGISTRATION.—For the purpose of enabling emergency medical services professionals to administer controlled substances in schedule II, III, IV, or V to ultimate users receiving emergency medical services in accordance with the requirements of this subsection, the Attorney General—

(A) shall register an emergency medical services agency if the agency submits an application demonstrating it is authorized to conduct such activity under the laws of each State in which the agency practices; and

(B) may deny an application for such registration if the Attorney General determines that the issuance of such registration would be inconsistent with the requirements of this subsection or the public interest based on the factors listed in subsection (f).

(2) OPTION FOR SINGLE REGISTRATION.—In registering an emergency medical services agency pursuant to paragraph (1), the Attorney General shall allow such agency the option of a single registration in each State where the agency administers controlled substances in lieu of requiring a separate registration for each location of the emergency medical services agency.

(3) HOSPITAL-BASED AGENCY.—If a hospital-based emergency medical services agency is registered under subsection (f), the agency may use the registration of the hospital to administer controlled substances in accordance with this subsection without being registered under this subsection.

(4) ADMINISTRATION OUTSIDE PHYSICAL PRESENCE OF MEDICAL DIRECTOR OR AUTHORIZING MEDICAL PROFESSIONAL.—Emergency medical services professionals of a registered emergency medical services agency may administer controlled substances in schedule II, III, IV, or V outside the physical presence of a medical director or authorizing medical professional in the course of providing emergency medical services if the administration is—

(A) authorized by the law of the State in which it occurs; and

(B) pursuant to—

(i) a standing order that is issued and adopted by one or more medical directors of the agency, including any such order that may be developed by a specific State authority; or

(ii) a verbal order that is—

(I) issued in accordance with a policy of the agency; and

(II) provided by a medical director or authorizing medical professional in response to a request by the emergency medical services professional with respect to a specific patient—

(aa) in the case of a mass casualty incident; or

(bb) to ensure the proper care and treatment of a specific patient.

(5) DELIVERY.—A registered emergency medical services agency may deliver controlled substances from a registered location of the agency to an unregistered location of the agency only if the agency—

(A) designates the unregistered location for such delivery; and

(B) notifies the Attorney General at least 30 days prior to first delivering controlled substances to the unregistered location.

(6) STORAGE.—A registered emergency medical services agency may store controlled substances—

(A) at a registered location of the agency;

(B) at any designated location of the agency or in an emergency services vehicle situated at a registered or designated location of the agency; or

(C) in an emergency medical services vehicle used by the agency that is—

(i) traveling from, or returning to, a registered or designated location of the agency in the course of responding to an emergency; or

(ii) otherwise actively in use by the agency under circumstances that provide for security of the controlled substances consistent with the requirements established by regulations of the Attorney General.

(7) NO TREATMENT AS DISTRIBUTION.—The delivery of controlled substances by a registered emergency medical services agency pursuant to this subsection shall not be treated as distribution for purposes of section 308.

(8) RESTOCKING OF EMERGENCY MEDICAL SERVICES VEHICLES AT A HOSPITAL.—Notwithstanding paragraph (13)(J), a registered emergency medical services agency may receive controlled substances from a hospital for purposes of restocking an emergency medical services vehicle following an emergency response, and without being subject to the requirements of section 308, provided all of the following conditions are satisfied:

(A) The registered or designated location of the agency where the vehicle is primarily situated maintains a record of such receipt in accordance with paragraph (9).

(B) The hospital maintains a record of such delivery to the agency in accordance with section 307.

(C) If the vehicle is primarily situated at a designated location, such location notifies the registered location of the agency within 72 hours of the vehicle receiving the controlled substances.

(9) MAINTENANCE OF RECORDS.—

(A) IN GENERAL.—A registered emergency medical services agency shall maintain records in accordance with subsections (a) and (b) of section 307 of all controlled substances that are received, administered, or otherwise disposed of pursuant to the agency's registration, without regard to subsection 307(c)(1)(B).

(B) REQUIREMENTS.—Such records—

(i) shall include records of deliveries of controlled substances between all locations of the agency; and

(ii) shall be maintained, whether electronically or otherwise, at each registered and designated location of the agency where the controlled substances involved are received, administered, or otherwise disposed of.

(10) OTHER REQUIREMENTS.—A registered emergency medical services agency, under the supervision of a medical director, shall be responsible for ensuring that—

(A) all emergency medical services professionals who administer controlled substances using the agency's registration act in accordance with the requirements of this subsection;

(B) the recordkeeping requirements of paragraph (9) are met with respect to a registered location and each designated location of the agency;

(C) the applicable physical security requirements established by regulation of the Attorney General are complied with wherever controlled substances are stored by the agency in accordance with paragraph (6); and

(D) the agency maintains, at a registered location of the agency, a record of the standing orders issued or adopted in accordance with paragraph (9).

(11) REGULATIONS.—The Attorney General may issue regulations—

(A) specifying, with regard to delivery of controlled substances under paragraph (5)—

(i) the types of locations that may be designated under such paragraph; and

(ii) the manner in which a notification under paragraph (5)(B) must be made;

(B) specifying, with regard to the storage of controlled substances under paragraph (6), the manner in which such substances must be stored at registered and designated locations, including in emergency medical service vehicles; and

(C) addressing the ability of hospitals, emergency medical services agencies, registered locations, and designated locations to deliver controlled substances to each other in the event of—

(i) shortages of such substances;

(ii) a public health emergency; or

(iii) a mass casualty event.

(12) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed—

(A) to limit the authority vested in the Attorney General by other provisions of this title to take measures to prevent diversion of controlled substances; or

(B) to override the authority of any State to regulate the provision of emergency medical services consistent with this subsection.

(13) DEFINITIONS.—In this section:

(A) The term "authorizing medical professional" means an emergency or other physician, or another medical professional (including an advanced practice registered nurse or physician assistant)—

(i) who is registered under this Act;

(ii) who is acting within the scope of the registration; and

(iii) whose scope of practice under a State license or certification includes the ability to provide verbal orders.

(B) The term "designated location" means a location designated by an emergency medical services agency under paragraph (5).

(C) The term "emergency medical services" means emergency medical response and emergency mobile medical services provided outside of a fixed medical facility.

(D) The term "emergency medical services agency" means an organization providing emergency medical services, including such an organization that—

(i) is governmental (including fire-based and hospital-based agencies), nongovernmental (including hospital-based agencies), private, or volunteer-based;

(ii) provides emergency medical services by ground, air, or otherwise; and

(iii) is authorized by the State in which the organization is providing such services to provide emergency medical care, including the administering of controlled substances, to members of the general public on an emergency basis.

(E) The term "emergency medical services professional" means a health care professional (including a nurse, paramedic, or emergency medical technician) licensed or certified by the State in which the professional practices and credentialed by a medical director of the respective emergency medical services agency to provide emergency medical services within the scope of the professional's State license or certification.

(F) The term "emergency medical services vehicle" means an ambulance, fire apparatus, supervisor truck, or other vehicle used by an emergency medical services agency for the purpose of providing or facilitating emergency medical care and transport or transporting controlled substances to and from the registered and designated locations.

(G) The term "hospital-based" means, with respect to an agency, owned or operated by a hospital.

(H) The term "medical director" means a physician who is registered under subsection (f) and provides medical oversight for an emergency medical services agency.

(I) The term "medical oversight" means supervision of the provision of medical care by an emergency medical services agency.

(J) The term "registered emergency medical services agency" means—

(i) an emergency medical services agency that is registered pursuant to this subsection; or

(ii) a hospital-based emergency medical services agency that is covered by the registration of the hospital under subsection (f).

(K) The term "registered location" means a location that appears on the certificate of registration issued to an emergency medical services agency under this subsection or subsection (f), which shall be where the agency receives controlled substances from distributors.

(L) The term "specific State authority" means a governmental agency or other such authority, including a regional oversight and coordinating body, that, pursuant to State law or regulation, develops clinical protocols regarding the delivery of emergency medical services in the geographic jurisdiction of such agency or authority within the State that may be adopted by medical directors.

(M) The term "standing order" means a written medical protocol in which a medical director determines in advance the medical criteria that must be met before administering controlled substances to individuals in need of emergency medical services.

(N) The term "verbal order" means an oral directive that is given through any method of communication including by radio or telephone, directly to an emergency medical services professional, to contemporaneously administer a controlled substance to individuals in need of emergency medical services outside the physical presence of the medical director or authorizing medical professional.

(k) In this section, the phrase "factors as may be relevant to and consistent with the public health and safety" means factors that are relevant to and consistent with the findings contained in section 101.

(l) REQUIRED TRAINING FOR PRESCRIBERS.—

(1) TRAINING REQUIRED.—As a condition on registration under this section to dispense controlled substances in schedule II, III, IV, or V, the Attorney General shall require any qualified practitioner, beginning with the first applicable registration for the practitioner, to meet the following:

(A) If the practitioner is a physician, the practitioner meets one or more of the following conditions:

(i) The physician holds a board certification in addiction psychiatry or addiction medicine from the American Board of Medical Specialties.

(ii) The physician holds a board certification from the American Board of Addiction Medicine.

(iii) The physician holds a board certification in addiction medicine from the American Osteopathic Association.

(iv) The physician has, with respect to the treatment and management of patients with opioid or other substance use disorders, completed not less than 8 hours of training (through classroom situations, seminars at professional society meetings, electronic communications, or otherwise) that is provided by—

(I) the American Society of Addiction Medicine, the American Academy of Addiction Psychiatry, the American Medical Association, the American Osteopathic Association, the American Psychiatric Association, or any other organization accredited by the Accreditation Council for Continuing Medical Education (commonly known as the "ACCME");

(II) any organization accredited by a State medical society accreditor that is recognized by the ACCME;

(III) any organization accredited by the American Osteopathic Association to provide continuing medical education; or

(IV) any organization approved by the Assistant Secretary for Mental Health and Substance Abuse or the ACCME.

(v) The physician graduated in good standing from an accredited school of allopathic medicine or osteopathic medicine in the United States during the 5-year period immediately preceding the date on which the physician first registers or renews under this section and has successfully completed a comprehensive allopathic or osteopathic medicine curriculum or accredited medical residency that included not less than 8 hours of training on treating and managing patients with opioid and other substance use disorders, including the appropriate clinical use of all drugs approved by the Food and Drug Administration for the treatment of a substance use disorder.

(B) If the practitioner is not a physician, the practitioner meets one or more of the following conditions:

(i) The practitioner has completed not fewer than 8 hours of training with respect to the treatment and management of patients with opioid or other substance use disorders (through classroom situations, seminars at professional society meetings, electronic communications, or otherwise) provided by the American Society of Addiction Medicine, the American Academy of Addiction Psychiatry, the American Medical Association, the American Osteopathic Association, the American Nurses Credentialing Center, the American Psychiatric Association, the American Association of Nurse Practitioners, the American Academy of Physician Associates, or any other organization approved or accredited by the Assistant Secretary for Mental Health and Substance

Abuse or the or the Accreditation Council for Continuing Medical Education.

(ii) The practitioner has graduated in good standing from an accredited physician assistant school or accredited school of advanced practice nursing in the United States during the 5-year period immediately preceding the date on which the practitioner first registers or renews under this section and has successfully completed a comprehensive physician assistant or advanced practice nursing curriculum that included not fewer than 8 hours of training on treating and managing patients with opioid and other substance use disorders, including the appropriate clinical use of all drugs approved by the Food and Drug Administration for the treatment of a substance use disorder.

(2) ONE-TIME TRAINING.—The Attorney General shall not require any qualified practitioner to complete the training described in clause (iv) or (v) of paragraph (1)(A) or clause (i) or (ii) of paragraph (1)(B) more than once.

(3) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed to preclude the use, by a qualified practitioner, of training received pursuant to this subsection to satisfy registration requirements of a State or for some other lawful purpose.

(4) DEFINITIONS.—In this section:

(A) FIRST APPLICABLE REGISTRATION.—The term "first applicable registration" means the first registration or renewal of registration by a qualified practitioner under this section that occurs on or after the date that is 180 days after the date of enactment of the Restoring Hope for Mental Health and Well-Being Act of 2022.

(B) QUALIFIED PRACTITIONER.—In this subsection, the term "qualified practitioner" means a practitioner who—

(i) is licensed under State law to prescribe controlled substances; and

(ii) is not solely a veterinarian.

DENIAL, REVOCATION, OR SUSPENSION OF REGISTRATION

SEC. 304. (a) A registration pursuant to section 303 to manufacture, distribute, or dispense a controlled substance or a list I chemical may be suspended or revoked by the Attorney General upon a finding that the registrant—

(1) has materially falsified any application filed pursuant to or required by this title or title III;

(2) has been convicted of a felony under this title or title III or any other law of the United States, or of any State, relating to any substance defined in this title as a controlled substance or a list I chemical;

(3) has had his State license or registration suspended, revoked, or denied by competent State authority and is no longer authorized by State law to engage in the manufacturing, distribution, or dispensing of controlled substances or list I chemicals or has had the suspension, revocation, or denial of his registration recommended by competent State authority;

(4) has committed such acts as would render his registration under section 303 inconsistent with the public interest as determined under such section; or

(5) has been excluded (or directed to be excluded) from participation in a program pursuant to section 1128(a) of the Social Security Act.

A registration pursuant to section [303(g)(1)] *303(g)* to dispense a narcotic drug for maintenance treatment or detoxification treatment may be suspended or revoked by the Attorney General upon a finding that the registrant has failed to comply with any standard referred to in section [303(g)(1)] *303(g)*.

(b) The Attorney General may limit revocation or suspension of a registration to the particular controlled substance or list I chemical with respect to which grounds for revocation or suspension exist.

(c)(1) Before taking action pursuant to this section, or pursuant to a denial of registration under section 303, the Attorney General shall serve upon the applicant or registrant an order to show cause why registration should not be denied, revoked, or suspended.

(2) An order to show cause under paragraph (1) shall—

(A) contain a statement of the basis for the denial, revocation, or suspension, including specific citations to any laws or regulations alleged to be violated by the applicant or registrant;

(B) direct the applicant or registrant to appear before the Attorney General at a time and place stated in the order, but not less than 30 days after the date of receipt of the order; and

(C) notify the applicant or registrant of the opportunity to submit a corrective action plan on or before the date of appearance.

(3) Upon review of any corrective action plan submitted by an applicant or registrant pursuant to paragraph (2), the Attorney General shall determine whether denial, revocation, or suspension proceedings should be discontinued, or deferred for the purposes of modification, amendment, or clarification to such plan.

(4) Proceedings to deny, revoke, or suspend shall be conducted pursuant to this section in accordance with subchapter II of chapter 5 of title 5, United States Code. Such proceedings shall be independent of, and not in lieu of, criminal prosecutions or other proceedings under this title or any other law of the United States.

(5) The requirements of this subsection shall not apply to the issuance of an immediate suspension order under subsection (d).

(d)(1) The Attorney General may, in his discretion, suspend any registration simultaneously with the institution of proceedings under this section, in cases where he finds that there is an imminent danger to the public health or safety. A failure to comply with a standard referred to in section [303(g)(1)] *303(g)* may be treated under this subsection as grounds for immediate suspension of a registration granted under such section. A suspension under this subsection shall continue in effect until the conclusion of such proceedings, including judicial review thereof, unless sooner withdrawn by the Attorney General or dissolved by a court of competent jurisdiction.

(2) In this subsection, the phrase "imminent danger to the public health or safety" means that, due to the failure of the registrant

to maintain effective controls against diversion or otherwise comply with the obligations of a registrant under this title or title III, there is a substantial likelihood of an immediate threat that death, serious bodily harm, or abuse of a controlled substance will occur in the absence of an immediate suspension of the registration.

(e) The suspension or revocation of a registration under this section shall operate to suspend or revoke any quota applicable under section 306.

(f) In the event the Attorney General suspends or revokes a registration granted under section 303, all controlled substances or list I chemicals owned or possessed by the registrant pursuant to such registration at the time of suspension or the effective date of the revocation order, as the case may be, may, in the discretion of the Attorney General, be placed under seal. No disposition may be made of any controlled substances or list I chemicals under seal until the time for taking an appeal has elapsed or until all appeals have been concluded except that a court, upon application therefor, may at any time order the sale of perishable controlled substances or list I chemicals. Any such order shall require the deposit of the proceeds of the sale with the court. Upon a revocation order becoming final, all such controlled substances or list I chemicals (or proceeds of sale deposited in court) shall be forfeited to the United States; and the Attorney General shall dispose of such controlled substances or list I chemicals in accordance with section 511(e). All right, title, and interest in such controlled substances or list I chemicals shall vest in the United States upon a revocation order becoming final.

(g) The Attorney General may, in his discretion, seize or place under seal any controlled substances or list I chemicals owned or possesed by a registrant whose registration has expired or who has ceased to practice or do business in the manner contemplated by his registration. Such controlled substances or list I chemicals shall be held for the benefit of the registrant, or his successor in interest. The Attorney General shall notify a registrant, or his successor in interest, who has any controlled substances or list I chemicals seized or placed under seal of the procedures to be followed to secure the return of the controlled substance or list I chemical and the conditions under which it will be returned. The Attorney General may not dispose of any controlled substance or list I chemical seized or placed under seal under this subsection until the expiration of one hundred and eighty days from the date such substance or chemical was seized or placed under seal.

(h) The Attorney General may issue an order to prohibit, conditionally or unconditionally, and permanently or for such period as the Attorney General may determine, any person from being registered under this title to manufacture, distribute, or dispense a controlled substance or a list I chemical, if the Attorney General finds that—

(1) such person meets or has met any of the conditions for suspension or revocation of registration under subsection (a); and

(2) such person has a history of prior suspensions or revocations of registration.

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DELIVERY OF A CONTROLLED SUBSTANCE BY A PHARMACY TO AN ADMINISTERING PRACTITIONER

SEC. 309A. (a) IN GENERAL.—Notwithstanding section 102(10), a pharmacy may deliver a controlled substance to a practitioner in accordance with a prescription that meets the requirements of this title and the regulations issued by the Attorney General under this title, for the purpose of administering the controlled substance by the practitioner if—

(1) the controlled substance is delivered by the pharmacy to the prescribing practitioner or the practitioner administering the controlled substance, as applicable, at the location listed on the practitioner's certificate of registration issued under this title;

(2) ❚the controlled substance is to be administered for the purpose of maintenance or detoxification treatment under section 303(g)(2)❚ *the controlled substance is a narcotic drug in schedule III, IV, or V to be administered for the purpose of maintenance or detoxification treatment* ❚and—❚

❚(A) the practitioner who issued the prescription is a qualifying practitioner authorized under, and acting within the scope of that section; and❚

❚(B) the controlled substance is to be administered by injection or implantation;❚ *and is to be administered by injection or implantation;*

(3) the pharmacy and the practitioner are authorized to conduct the activities specified in this section under the law of the State in which such activities take place;

(4) the prescription is not issued to supply any practitioner with a stock of controlled substances for the purpose of general dispensing to patients;

(5) except as provided in subsection (b), the controlled substance is to be administered only to the patient named on the prescription not later than 14 days after the date of receipt of the controlled substance by the practitioner; and

(6) notwithstanding any exceptions under section 307, the prescribing practitioner, and the practitioner administering the controlled substance, as applicable, maintain complete and accurate records of all controlled substances delivered, received, administered, or otherwise disposed of under this section, including the persons to whom controlled substances were delivered and such other information as may be required by regulations of the Attorney General.

(b) MODIFICATION OF NUMBER OF DAYS BEFORE WHICH CONTROLLED SUBSTANCE SHALL BE ADMINISTERED.—

(1) INITIAL 2-YEAR PERIOD.—During the 2-year period beginning on the date of enactment of this section, the Attorney General, in coordination with the Secretary, may reduce the number of days described in subsection (a)(5) if the Attorney General determines that such reduction will—

(A) reduce the risk of diversion; or

(B) protect the public health.

(2) MODIFICATIONS AFTER SUBMISSION OF REPORT.—After the date on which the report described in section 3204(b) of the SUPPORT for Patients and Communities Act is submitted, the

Attorney General, in coordination with the Secretary, may modify the number of days described in subsection (a)(5).

(3) MINIMUM NUMBER OF DAYS.—Any modification under this subsection shall be for a period of not less than 7 days.

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SOCIAL SECURITY ACT

TITLE XVIII—HEALTH INSURANCE FOR THE AGED AND DISABLED

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PART B—SUPPLEMENTARY MEDICAL INSURANCE BENEFITS FOR THE AGED AND DISABLED

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PAYMENT OF BENEFITS

SEC. 1833. (a) Except as provided in section 1876, and subject to the succeeding provisions of this section, there shall be paid from the Federal Supplementary Medical Insurance Trust Fund, in the case of each individual who is covered under the insurance program established by this part and incurs expenses for services with respect to which benefits are payable under this part, amounts equal to—(1) in the case of services described in section 1832(a)(1)—80 percent of the reasonable charges for the services; except that (A) an organization which provides medical and other health services (or arranges for their availability) on a prepayment basis (and either is sponsored by a union or employer, or does not provide, or arrange for the provision of, any inpatient hospital services) may elect to be paid 80 percent of the reasonable cost of services for which payment may be made under this part on behalf of individuals enrolled in such organization in lieu of 80 percent of the reasonable charges for such services if the organization undertakes to charge such individuals no more than 20 percent of such reasonable cost plus any amounts payable by them as a result of subsection (b), (B) with respect to items and services described in section 1861(s)(10)(A), the amounts paid shall be 100 percent of the reasonable charges for such items and services, (C) with respect to expenses incurred for those physicians' services for which payment may be made under this part that are described in section 1862(a)(4), the amounts paid shall be subject to such limitations as may be prescribed by regulations, (D) with respect to clinical diagnostic laboratory tests for which payment is made under this part (i)(I) on the basis of a fee schedule under subsection (h)(1) (for tests furnished before January 1, 2017) or section 1834(d)(1), the amount paid shall be equal to 80 percent (or 100 percent, in the case of such tests for which payment is made on an assignment-related basis) of the lesser of the amount determined under such fee schedule, the limitation amount for that test determined under subsection (h)(4)(B), or the amount of the charges billed for the tests, or (II) undersection 1834A (for tests furnished on or after January1, 2017), the amount paid shall be equal to 80 percent(or 100 percent, in the case of such tests for whichpayment is made on

an assignment-related basis) ofthe lesser of the amount determined under such sectionor the amount of the charges billed for the tests, or (ii) for tests furnished before January 1, 2017,on the basis of a negotiated rate established under subsection (h)(6), the amount paid shall be equal to 100 percent of such negotiated rate,,(E) with respect to services furnished to individuals who have been determined to have end stage renal disease, the amounts paid shall be determined subject to the provisions of section 1881,(F) with respect to clinical social worker services under section 1861(s)(2)(N), the amounts paid shall be 80 percent of the lesser of (i) the actual charge for the services or (ii) 75 percent of the amount determined for payment of a psychologist under clause (L),

(G) with respect to facility services furnished in connection with a surgical procedure specified pursuant to subsection (i)(1)(A) and furnished to an individual in an ambulatory surgical center described in such subsection, for services furnished beginning with the implementation date of a revised payment system for such services in such facilities specified in subsection (i)(2)(D), the amounts paid shall be 80 percent of the lesser of the actual charge for the services or the amount determined by the Secretary under such revised payment system,

(H) with respect to services of a certified registered nurse anesthetist under section 1861(s)(11), the amounts paid shall be 80 percent of the least of the actual charge, the prevailing charge that would be recognized (or, for services furnished on or after January 1, 1992, the fee schedule amount provided under section 1848) if the services had been performed by an anesthesiologist, or the fee schedule for such services established by the Secretary in accordance with subsection (l), (I) with respect to covered items (described in section 1834(a)(13)), the amounts paid shall be the amounts described in section 1834(a)(1), and(J) with respect to expenses incurred for radiologist services (as defined in section 1834(b)(6)), subject to section 1848, the amounts paid shall be 80 percent of the lesser of the actual charge for the services or the amount provided under the fee schedule established under section 1834(b), (K) with respect to certified nurse-midwife services under section 1861(s)(2)(L), the amounts paid shall be 80 percent of the lesser of the actual charge for the services or the amount determined by a fee schedule established by the Secretary for the purposes of this subparagraph (but in no event shall such fee schedule exceed 65 percent of the prevailing charge that would be allowed for the same service performed by a physician, or, for services furnished on or after January 1, 1992, 65 percent (or 100 percent for services furnished on or after January 1, 2011) of the fee schedule amount provided under section 1848 for the same service performed by a physician), (L) with respect to qualified psychologist services under section 1861(s)(2)(M), the amounts paid shall be 80 percent of the lesser of the actual charge for the services or the amount determined by a fee schedule established by the Secretary for the purposes of this subparagraph, (M) with respect to prosthetic devices and orthotics and prosthetics (as defined in section 1834(h)(4)), the amounts paid shall be the amounts described

in section 1834(h)(1), (N) with respect to expenses incurred for physicians' services (as defined in section 1848(j)(3)) other than personalized prevention plan services (as defined in section 1861(hhh)(1)), the amounts paid shall be 80 percent of the payment basis determined under section 1848(a)(1), (O) with respect to services described in section 1861(s)(2)(K) (relating to services furnished by physician assistants, nurse practitioners, or clinic nurse specialists), the amounts paid shall be equal to 80 percent of (i) the lesser of the actual charge or 85 percent of the fee schedule amount provided under section 1848, or (ii) in the case of services as an assistant at surgery, the lesser of the actual charge or 85 percent of the amount that would otherwise be recognized if performed by a physician who is serving as an assistant at surgery, (P) with respect to surgical dressings, the amounts paid shall be the amounts determined under section 1834(i), (Q) with respect to items or services for which fee schedules are established pursuant to section 1842(s), the amounts paid shall be 80 percent of the lesser of the actual charge or the fee schedule established in such section, (R) with respect to ambulance services, (i) the amounts paid shall be 80 percent of the lesser of the actual charge for the services or the amount determined by a fee schedule established by the Secretary under section 1834(l) and (ii) with respect to ambulance services described in section 1834(l)(8), the amounts paid shall be the amounts determined under section 1834(g) for outpatient critical access hospital services, (S) with respect to drugs and biologicals (including intravenous immune globulin (as defined in section 1861(zz))) not paid on a cost or prospective payment basis as otherwise provided in this part (other than items and services described in subparagraph (B)), the amounts paid shall be 80 percent of the lesser of the actual charge or the payment amount established in section 1842(o) (or, if applicable, under section 1847, 1847A, or 1847B), (T) with respect to medical nutrition therapy services (as defined in section 1861(vv)), the amount paid shall be 80 percent (or 100 percent if such services are recommended with a grade of A or B by the United States Preventive Services Task Force for any indication or population and are appropriate for the individual) of the lesser of the actual charge for the services or 85 percent of the amount determined under the fee schedule established under section 1848(b) for the same services if furnished by a physician, (U) with respect to facility fees described in section 1834(m)(2)(B), the amounts paid shall be 80 percent of the lesser of the actual charge or the amounts specified in such section, (V) notwithstanding subparagraphs (I) (relating to durable medical equipment), (M) (relating to prosthetic devices and orthotics and prosthetics), and (Q) (relating to 1842(s) items), with respect to competitively priced items and services (described in section 1847(a)(2)) that are furnished in a competitive area, the amounts paid shall be the amounts described in section 1847(b)(5), (W) with respect to additional preventive services (as defined in section 1861(ddd)(1)), the amount paid shall be (i) in the case of such services which are clinical diagnostic laboratory tests, the amount determined under subparagraph (D) (if such subpara-

graph were applied, by substituting "100 percent" for "80 percent"), and (ii) in the case of all other such services, 100 percent of the lesser of the actual charge for the service or the amount determined under a fee schedule established by the Secretary for purposes of this subparagraph, (X) with respect to personalized prevention plan services (as defined in section 1861(hhh)(1)), the amount paid shall be 100 percent of the lesser of the actual charge for the services or the amount determined under the payment basis determined under section 1848, (Y) subject to subsection (dd), with respect to preventive services described in subparagraphs (A) and (B) of section 1861(ddd)(3) that are appropriate for the individual and, in the case of such services described in subparagraph (A), are recommended with a grade of A or B by the United States Preventive Services Task Force for any indication or population, the amount paid shall be 100 percent of (i) except as provided in clause (ii), the lesser of the actual charge for the services or the amount determined under the fee schedule that applies to such services under this part, and (ii) in the case of such services that are covered OPD services (as defined in subsection (t)(1)(B)), the amount determined under subsection (t), (Z) with respect to Federally qualified health center services for which payment is made under section 1834(o), the amounts paid shall be 80 percent of the lesser of the actual charge or the amount determined under such section, (AA) with respect to an applicable disposable device (as defined in paragraph (2) of section 1834(s)) furnished to an individual pursuant to paragraph (1) of such section, the amount paid shall be equal to 80 percent of the lesser of the actual charge or the amount determined under paragraph (3) of such section, (BB) with respect to home infusion therapy, the amount paid shall be an amount equal to 80 percent of the lesser of the actual charge for the services or the amount determined under section 1834(u), (CC) with respect to opioid use disorder treatment services furnished during an episode of care, the amount paid shall be equal to the amount payable under section 1834(w) less any copayment required as specified by the Secretary, and (DD) with respect to a specified COVID–19 testing-related service described in paragraph (1) of subsection (cc) for which payment may be made under a specified outpatient payment provision described in paragraph (2) of such subsection, the amounts paid shall be 100 percent of the payment amount otherwise recognized under such respective specified outpatient payment provision for such service,;

(2) in the case of services described in section 1832(a)(2) (except those services described in subparagraphs (C), (D), (E), (F), (G), (H), and (I) of such section and unless otherwise specified in section 1881)—

(A) with respect to home health services (other than a covered osteoporosis drug) (as defined in section 1861(kk)), the amount determined under the prospective payment system under section 1895;

(B) with respect to other items and services (except those described in subparagraph (C), (D), or (E) of this para-

graph and except as may be provided in section 1886 or section 1888(e)(9))—

(i) furnished before January 1, 1999, the lesser of—

(I) the reasonable cost of such services, as determined under section 1861(v), or

(II) the customary charges with respect to such services,—less the amount a provider may charge as described in clause (ii) of section 1866(a)(2)(A), but in no case may the payment for such other services exceed 80 percent of such reasonable cost, or

(ii) if such services are furnished before January 1, 1999, by a public provider of services, or by another provider which demonstrates to the satisfaction of the Secretary that a significant portion of its patients are low-income (and requests that payment be made under this clause), free of charge or at nominal charges to the public, 80 percent of the amount determined in accordance with section 1814(b)(2), or

(iii) if such services are furnished on or after January 1, 1999, the amount determined under subsection (t), or

(iv) if (and for so long as) the conditions described in section 1814(b)(3) are met, the amounts determined under the reimbursement system described in such section;

(C) with respect to services described in the second sentence of section 1861(p), 80 percent of the reasonable charges for such services;

(D) with respect to clinical diagnostic laboratory tests for which payment is made under this part (i)(I)on the basis of a fee schedule determined under subsection(h)(1) (for tests furnished before January 1, 2017) or section 1834(d)(1), the amount paid shall be equal to 80 percent (or 100 percent, in the case of such tests for which payment is made on an assignment-related basis or to a provider having an agreement under section 1866) of the lesser of the amount determined under such fee schedule, the limitation amount for that test determined under subsection (h)(4)(B), or the amount of the charges billed for the tests, or (II) under section 1834A (for tests furnished on or after January 1, 2017), the amount paid shall be equal to 80 percent (or 100 percent, in the case of such tests for which payment is made on an assignment-related basis or to a provider having an agreement under section 1866) of the lesser of the amount determined under such section or the amount of the charges billed for the tests, or (ii) for tests furnished before January 1, 2017, on the basis of a negotiated rate established under subsection (h)(6), the amount paid shall be equal to 100 percent of such negotiated rate for such tests;

(E) with respect to—

(i) outpatient hospital radiology services (including diagnostic and therapeutic radiology, nuclear medicine and CAT scan procedures, magnetic resonance imag-

ing, and ultrasound and other imaging services, but excluding screening mammography and, for services furnished on or after January 1, 2005, diagnostic mammography), and

(ii) effective for procedures performed on or after October 1, 1989, diagnostic procedures (as defined by the Secretary) described in section 1861(s)(3) (other than diagnostic x-ray tests and diagnostic laboratory tests),

the amount determined under subsection (n) or, for services or procedures performed on or after January 1, 1999, subsection (t);

(F) with respect to a covered osteoporosis drug (as defined in section 1861(kk)) furnished by a home health agency, 80 percent of the reasonable cost of such service, as determined under section 1861(v);

(G) with respect to items and services described in section 1861(s)(10)(A), the lesser of—

(i) the reasonable cost of such services, as determined under section 1861(v), or

(ii) the customary charges with respect to such services; and

(H) with respect to personalized prevention plan services (as defined in section 1861(hhh)(1)) furnished by an outpatient department of a hospital, the amount determined under paragraph (1)(X),

or, if such services are furnished by a public provider of services, or by another provider which demonstrates to the satisfaction of the Secretary that a significant portion of its patients are low-income (and requests that payment be made under this provision), free of charge or at nominal charges to the public, the amount determined in accordance with section 1814(b)(2);

(3) in the case of services described in section 1832(a)(2)(D)—

(A) except as provided in subparagraph (B), the costs which are reasonable and related to the cost of furnishing such services or which are based on such other tests of reasonableness as the Secretary may prescribe in regulations, including those authorized under section 1861(v)(1)(A), less the amount a provider may charge as described in clause (ii) of section 1866(a)(2)(A), but in no case may the payment for such services (other than for items and services described in section 1861(s)(10)(A)) exceed 80 percent of such costs; or

(B) with respect to the services described in clause (ii) of section 1832(a)(2)(D) that are furnished to an individual enrolled with a MA plan under part C pursuant to a written agreement described in section 1853(a)(4), the amount (if any) by which—

(i) the amount of payment that would have otherwise been provided (I) under subparagraph (A) (calculated as if "100 percent" were substituted for "80 percent" in such subparagraph) for such services if the individual had not been so enrolled, or (II) in the case of such services furnished on or after the implementation date of the prospective payment system under

section 1834(o), under such section (calculated as if "100 percent" were substituted for "80 percent" in such section) for such services if the individual had not been so enrolled; exceeds

(ii) the amount of the payments received under such written agreement for such services (not including any financial incentives provided for in such agreement such as risk pool payments, bonuses, or withholds),

less the amount the federally qualified health center may charge as described in section 1857(e)(3)(B);

(4) in the case of facility services described in section 1832(a)(2)(F), and outpatient hospital facility services furnished in connection with surgical procedures specified by the Secretary pursuant to section 1833(i)(1)(A), the applicable amount as determined under paragraph (2) or (3) of subsection (i) or subsection (t);

(5) in the case of covered items (described in section 1834(a)(13)) the amounts described in section 1834(a)(1);

(6) in the case of outpatient critical access hospital services, the amounts described in section 1834(g);

(7) in the case of prosthetic devices and orthotics and prosthetics (as described in section 1834(h)(4)), the amounts described in section 1834(h);

(8) in the case of—

(A) outpatient physical therapy services, outpatient speech-language pathology services, and outpatient occupational therapy services furnished—

(i) by a rehabilitation agency, public health agency, clinic, comprehensive outpatient rehabilitation facility, or skilled nursing facility,

(ii) by a home health agency to an individual who is not homebound, or

(iii) by another entity under an arrangement with an entity described in clause (i) or (ii); and

(B) outpatient physical therapy services, outpatient speech-language pathology services, and outpatient occupational therapy services furnished—

(i) by a hospital to an outpatient or to a hospital inpatient who is entitled to benefits under part A but has exhausted benefits for inpatient hospital services during a spell of illness or is not so entitled to benefits under part A, or

(ii) by another entity under an arrangement with a hospital described in clause (i),

the amounts described in section 1834(k);

(9) in the case of services described in section 1832(a)(2)(E) that are not described in paragraph (8), the amounts described in section 1834(k); and

(10) with respect to rural emergency hospital services furnished on or after January 1, 2023, the amounts determined under section 1834(x).

Paragraph (3)(A) shall not apply to Federally qualified health center services furnished on or after the implementation date of the prospective payment system under section 1834(o). For services furnished on or after January 1, 2022, paragraph (1)(Y) shall apply

with respect to a colorectal cancer screening test regardless of the code that is billed for the establishment of a diagnosis as a result of the test, or for the removal of tissue or other matter or other procedure that is furnished in connection with, as a result of, and in the same clinical encounter as the screening test.

(b) Before applying subsection (a) with respect to expenses incurred by an individual during any calendar year, the total amount of the expenses incurred by such individual during such year (which would, except for this subsection, constitute incurred expenses from which benefits payable under subsection (a) are determinable) shall be reduced by a deductible of $75 for calendar years before 1991, $100 for 1991 through 2004, $110 for 2005, and for a subsequent year the amount of such deductible for the previous year increased by the annual percentage increase in the monthly actuarial rate under section 1839(a)(1) ending with such subsequent year (rounded to the nearest $1); except that (1) such total amount shall not include expenses incurred for preventive services described in subparagraph (A) of section 1861(ddd)(3) that are recommended with a grade of A or B by the United States Preventive Services Task Force for any indication or population and are appropriate for the individual., (2) such deductible shall not apply with respect to home health services (other than a covered osteoporosis drug (as defined in section 1861(kk))), (3) such deductible shall not apply with respect to clinical diagnostic laboratory tests for which payment is made under this part (A) under subsection (a)(1)(D)(i) or (a)(2)(D)(i) on an assignment-related basis, or to a provider having an agreement under section 1866, or (B) for tests furnished before January 1, 2017,on the basis of a negotiated rate determined under subsection (h)(6), (4) such deductible shall not apply to Federally qualified health center services, (5) such deductible shall not apply with respect to screening mammography (as described in section 1861(jj)), (6) such deductible shall not apply with respect to screening pap smear and screening pelvic exam (as described in section 1861(nn)), (7) such deductible shall not apply with respect to ultrasound screening for abdominal aortic aneurysm (as defined in section 1861(bbb)), (8) such deductible shall not apply with respect to colorectal cancer screening tests (as described in section 1861(pp)(1)), (9) such deductible shall not apply with respect to an initial preventive physical examination (as defined in section 1861(ww)), (10) such deductible shall not apply with respect to personalized prevention plan services (as defined in section 1861(hhh)(1)), (11) such deductible shall not apply with respect to any specified COVID–19 testing-related service described in paragraph (1) of subsection (cc) for which payment may be made under a specified outpatient payment provision described in paragraph (2) of such subsection, and (12) such deductible shall not apply withrespect a COVID–19 vaccine and its administration describedin section 1861(s)(10)(A). The total amount of the expenses incurred by an individual as determined under the preceding sentence shall, after the reduction specified in such sentence, be further reduced by an amount equal to the expenses incurred for the first three pints of whole blood (or equivalent quantities of packed red blood cells, as defined under regulations) furnished to the individual during the calendar year, except that such deductible for such blood shall in accordance with regulations be

appropriately reduced to the extent that there has been a replacement of such blood (or equivalent quantities of packed red blood cells, as so defined); and for such purposes blood (or equivalent quantities of packed red blood cells, as so defined) furnished such individual shall be deemed replaced when the institution or other person furnishing such blood (or such equivalent quantities of packed red blood cells, as so defined) is given one pint of blood for each pint of blood (or equivalent quantities of packed red blood cells, as so defined) furnished such individual with respect to which a deduction is made under this sentence. The deductible under the previous sentence for blood or blood cells furnished an individual in a year shall be reduced to the extent that a deductible has been imposed under section 1813(a)(2) to blood or blood cells furnished the individual in the year. Paragraph (1) of the first sentence of this subsection shall apply with respect to a colorectal cancer screening test regardless of the code that is billed for the establishment of a diagnosis as a result of the test, or for the removal of tissue or other matter or other procedure that is furnished in connection with, as a result of, and in the same clinical encounter as the screening test.

(c)(1) Notwithstanding any other provision of this part, with respect to expenses incurred in a calendar year in connection with the treatment of mental, psychoneurotic, and personality disorders of an individual who is not an inpatient of a hospital at the time such expenses are incurred, there shall be considered as incurred expenses for purposes of subsections (a) and (b)—

(A) for expenses incurred in years prior to 2010, only 62½ percent of such expenses;

(B) for expenses incurred in 2010 or 2011, only 68¾ percent of such expenses;

(C) for expenses incurred in 2012, only 75 percent of such expenses;

(D) for expenses incurred in 2013, only 81¼ percent of such expenses; and

(E) for expenses incurred in 2014 or any subsequent calendar year, 100 percent of such expenses.

(2) For purposes of subparagraphs (A) through (D) of paragraph (1), the term "treatment" does not include brief office visits (as defined by the Secretary) for the sole purpose of monitoring or changing drug prescriptions used in the treatment of such disorders or partial hospitalization services that are not directly provided by a physician

(d) No payment may be made under this part with respect to any services furnished an individual to the extent that such individual is entitled (or would be entitled except for section 1813) to have payment made with respect to such services under part A.

(e) No payment shall be made to any provider of services or other person under this part unless there has been furnished such information as may be necessary in order to determine the amounts due such provider or other person under this part for the period with respect to which the amounts are being paid or for any prior period.

(f)(1) In establishing limits under subsection (a) on payment for rural health clinic services provided by rural health clinics (other than such clinics in hospitals with less than 50 beds), the Secretary

shall establish such limit, for services provided prior to April 1, 2021—

(A) in 1988, after March 31, at $46 per visit, and

(B) in a subsequent year (before April 1, 2021), at the limit established under this paragraph for the previous year increased by the percentage increase in the MEI (as defined in section 1842(i)(3)) applicable to primary care services (as defined in section 1842(i)(4)) furnished as of the first day of that year.

(2) In establishing limits under subsection (a) on payment for rural health clinic services furnished on or after April 1, 2021, by a rural health clinic (other than a rural health clinic described in paragraph (3)(B)), the Secretary shall establish such limit, for services provided—

(A) in 2021, after March 31, at $100 per visit;

(B) in 2022, at $113 per visit;

(C) in 2023, at $126 per visit;

(D) in 2024, at $139 per visit;

(E) in 2025, at $152 per visit;

(F) in 2026, at $165 per visit;

(G) in 2027, at $178 per visit;

(H) in 2028, at $190 per visit; and

(I) in a subsequent year, at the limit established under this paragraph for the previous year increased by the percentage increase in the MEI applicable to primary care services furnished as of the first day of such subsequent year.

(3)(A) In establishing limits under subsection (a) on payment for rural health clinic services furnished on or after April 1, 2021, by a rural health clinic described in subparagraph (B), the Secretary shall establish such limit, with respect to each such rural health clinic, for services provided—

(i) in 2021, after March 31, at an amount equal to the greater of—

(I) with respect to a rural health clinic that had a per visit payment amount established for services furnished in 2020—

(aa) the per visit payment amount applicable to such rural health clinic for rural health clinic services furnished in 2020, increased by the percentage increase in the MEI applicable to primary care services furnished as of the first day of 2021; or

(bb) the limit described in paragraph (2)(A); and

(II) with respect to a rural health clinic that did not have a per visit payment amount established for services furnished in 2020—

(aa) the per visit payment amount applicable to such rural health clinic for rural health clinic services furnished in 2021; or

(bb) the limit described in paragraph (2)(A); and

(ii) in a subsequent year, at an amount equal to the greater of—

(I) the amount established under subclause (I) or (II) of clause (i), as applicable, or this subclause for the previous year with respect to such rural health clinic, increased by

the percentage increase in the MEI applicable to primary care services furnished as of the first day of such subsequent year; or

(II) the limit established under paragraph (2) for such subsequent year.

(B) A rural health clinic described in this subparagraph is a rural health clinic that—

(i) as of December 31, 2020, was in a hospital with less than 50 beds and after such date such hospital continues to have less than 50 beds (not taking into account any increase in the number of beds pursuant to a waiver under subsection (b)(1)(A) of section 1135 during the emergency period described in subsection (g)(1)(B) of such section); and

(ii)(I) as of December 31, 2020, was enrolled under section 1866(j) (including temporary enrollment during such emergency period for such emergency period); or

(II) submitted an application for enrollment under section 1866(j) (or a request for such a temporary enrollment for such emergency period) that was received not later than December 31, 2020.

(g)(1)(A) Subject to paragraphs (4) and (5), in the case of physical therapy services of the type described in section 1861(p) and speech-language pathology services of the type described in such section through the application of section 1861(ll)(2), but (except as provided in paragraph (6)) not described in subsection (a)(8)(B), and physical therapy services and speech-language pathology services of such type which are furnished by a physician or as incident to physicians' services, with respect to expenses incurred in any calendar year, no more than the amount specified in paragraph (2) for the year shall be considered as incurred expenses for purposes of subsections (a) and (b). The preceding sentence shall not apply to expenses incurred with respect to services furnished after December 31, 2017.

(B) With respect to services furnished during 2018 or a subsequent year, in the case of physical therapy services of the type described in section 1861(p), speech-language pathology services of the type described in such section through the application of section 1861(ll)(2), and physical therapy services and speech-language pathology services of such type which are furnished by a physician or as incident to physicians' services, with respect to expenses incurred in any calendar year, any amount that is more than the amount specified in paragraph (2) for the year shall not be considered as incurred expenses for purposes of subsections (a) and (b) unless the applicable requirements of paragraph (7) are met.

(2) The amount specified in this paragraph—

(A) for 1999, 2000, and 2001, is $1,500, and

(B) for a subsequent year is the amount specified in this paragraph for the preceding year increased by the percentage increase in the MEI (as defined in section 1842(i)(3)) for such subsequent year;

except that if an increase under subparagraph (B) for a year is not a multiple of $10, it shall be rounded to the nearest multiple of $10.

(3)(A) Subject to paragraphs (4) and (5), in the case of occupational therapy services (of the type that are described in section

1861(p) (but (except as provided in paragraph (6)) not described in subsection (a)(8)(B)) through the operation of section 1861(g) and of such type which are furnished by a physician or as incident to physicians' services), with respect to expenses incurred in any calendar year, no more than the amount specified in paragraph (2) for the year shall be considered as incurred expenses for purposes of subsections (a) and (b). The preceding sentence shall not apply to expenses incurred with respect to services furnished after December 31, 2017.

(B) With respect to services furnished during 2018 or a subsequent year, in the case of occupational therapy services (of the type that are described in section 1861(p) through the operation of section 1861(g) and of such type which are furnished by a physician or as incident to physicians' services), with respect to expenses incurred in any calendar year, any amount that is more than the amount specified in paragraph (2) for the year shall not be considered as incurred expenses for purposes of subsections (a) and (b) unless the applicable requirements of paragraph (7) are met.

(4) This subsection shall not apply to expenses incurred with respect to services furnished during 2000, 2001, 2002, 2004, and 2005.

(5)(A) With respect to expenses incurred during the period beginning on January 1, 2006, and ending on December 31, 2017, for services, the Secretary shall implement a process under which an individual enrolled under this part may, upon request of the individual or a person on behalf of the individual, obtain an exception from the uniform dollar limitation specified in paragraph (2), for services described in paragraphs (1) and (3) if the provision of such services is determined to be medically necessary and if the requirement of subparagraph (B) is met. Under such process, if the Secretary does not make a decision on such a request for an exception within 10 business days of the date of the Secretary's receipt of the request made in accordance with such requirement, the Secretary shall be deemed to have found the services to be medically necessary.

(B) In the case of outpatient therapy services for which an exception is requested under the first sentence of subparagraph (A), the claim for such services shall contain an appropriate modifier (such as the KX modifier used as of the date of the enactment of this subparagraph) indicating that such services are medically necessary as justified by appropriate documentation in the medical record involved.

(C)(i) In applying this paragraph with respect to a request for an exception with respect to expenses that would be incurred for outpatient therapy services (including services described in subsection (a)(8)(B)) that would exceed the threshold described in clause (ii) for a year, the request for such an exception, for services furnished on or after October 1, 2012, shall be subject to a manual medical review process that, subject to subparagraph (E), is similar to the manual medical review process used for certain exceptions under this paragraph in 2006.

(ii) The threshold under this clause for a year is $3,700. Such threshold shall be applied separately—

(I) for physical therapy services and speech-language pathology services; and

(II) for occupational therapy services.

(E)(i) In place of the manual medical review process under subparagraph (C)(i), the Secretary shall implement a process for medical review under this subparagraph under which the Secretary shall identify and conduct medical review for services described in subparagraph (C)(i) furnished by a provider of services or supplier (in this subparagraph referred to as a "therapy provider") using such factors as the Secretary determines to be appropriate.

(ii) Such factors may include the following:

(I) The therapy provider has had a high claims denial percentage for therapy services under this part or is less compliant with applicable requirements under this title.

(II) The therapy provider has a pattern of billing for therapy services under this part that is aberrant compared to peers or otherwise has questionable billing practices for such services, such as billing medically unlikely units of services in a day.

(III) The therapy provider is newly enrolled under this title or has not previously furnished therapy services under this part.

(IV) The services are furnished to treat a type of medical condition.

(V) The therapy provider is part of group that includes another therapy provider identified using the factors determined under this subparagraph.

(iii) For purposes of carrying out this subparagraph, the Secretary shall provide for the transfer, from the Federal Supplementary Medical Insurance Trust Fund under section 1841, of $5,000,000 to the Centers for Medicare & Medicaid Services Program Management Account for fiscal years 2015 and 2016, to remain available until expended. Such funds may not be used by a contractor under section 1893(h) for medical reviews under this subparagraph.

(iv) The targeted review process under this subparagraph shall not apply to services for which expenses are incurred beyond the period for which the exceptions process under subparagraph (A) is implemented, except as such process is applied under paragraph (7)(B).

(6)(A) In applying paragraphs (1) and (3) to services furnished during the period beginning not later than October 1, 2012, and ending on December 31, 2017, the exclusion of services described in subsection (a)(8)(B) from the uniform dollar limitation specified in paragraph (2) shall not apply to such services furnished during 2012 through 2017.

(B)(i) With respect to outpatient therapy services furnished beginning on or after January 1, 2013, and before January 1, 2014, for which payment is made under section 1834(g), the Secretary shall count toward the uniform dollar limitations described in paragraphs (1) and (3) and the threshold described in paragraph (5)(C) the amount that would be payable under this part if such services were paid under section 1834(k)(1)(B) instead of being paid under section 1834(g).

(ii) Nothing in clause (i) shall be construed as changing the method of payment for outpatient therapy services under section 1834(g).

(7) For purposes of paragraphs (1)(B) and (3)(B), with respect to services described in such paragraphs, the requirements described in this paragraph are as follows:

(A) INCLUSION OF APPROPRIATE MODIFIER.—The claim for such services contains an appropriate modifier (such as the KX modifier described in paragraph (5)(B)) indicating that such services are medically necessary as justified by appropriate documentation in the medical record involved.

(B) TARGETED MEDICAL REVIEW FOR CERTAIN SERVICES ABOVE THRESHOLD.—

(i) IN GENERAL.—In the case where expenses that would be incurred for such services would exceed the threshold described in clause (ii) for the year, such services shall be subject to the process for medical review implemented under paragraph (5)(E).

(ii) THRESHOLD.—The threshold under this clause for—

(I) a year before 2028, is $3,000;

(II) 2028, is the amount specified in subclause (I) increased by the percentage increase in the MEI (as defined in section 1842(i)(3)) for 2028; and

(III) a subsequent year, is the amount specified in this clause for the preceding year increased by the percentage increase in the MEI (as defined in section 1842(i)(3)) for such subsequent year;

except that if an increase under subclause (II) or (III) for a year is not a multiple of $10, it shall be rounded to the nearest multiple of $10.

(iii) APPLICATION.—The threshold under clause (ii) shall be applied separately—

(I) for physical therapy services and speech-language pathology services; and

(II) for occupational therapy services.

(iv) FUNDING.—For purposes of carrying out this subparagraph, the Secretary shall provide for the transfer, from the Federal Supplementary Medical Insurance Trust Fund under section 1841 to the Centers for Medicare & Medicaid Services Program Management Account, of $5,000,000 for each fiscal year beginning with fiscal year 2018, to remain available until expended. Such funds may not be used by a contractor under section 1893(h) for medical reviews under this subparagraph.

(8) With respect to services furnished on or after January 1, 2013, where payment may not be made as a result of application of paragraphs (1) and (3), section 1879 shall apply in the same manner as such section applies to a denial that is made by reason of section 1862(a)(1).

(h)(1)(A) Subject to section 1834(d)(1), the Secretary shall establish fee schedules for clinical diagnostic laboratory tests (including prostate cancer screening tests under section 1861(oo) consisting of prostate-specific antigen blood tests) for which payment is made under this part, other than such tests performed by a provider of services for an inpatient of such provider.

(B) In the case of clinical diagnostic laboratory tests performed by a physician or by a laboratory (other than tests performed by a qualified hospital laboratory (as defined in subparagraph (D)) for

outpatients of such hospital), the fee schedules established under subparagraph (A) shall be established on a regional, statewide, or carrier service area basis (as the Secretary may determine to be appropriate) for tests furnished on or after July 1, 1984.

(C) In the case of clinical diagnostic laboratory tests performed by a qualified hospital laboratory (as defined in subparagraph (D)) for outpatients of such hospital, the fee schedules established under subparagraph (A) shall be established on a regional, statewide, or carrier service area basis (as the Secretary may determine to be appropriate) for tests furnished on or after July 1, 1984.

(D) In this subsection, the term "qualified hospital laboratory" means a hospital laboratory, in a sole community hospital (as defined in section 1886(d)(5)(D)(iii)), which provides some clinical diagnostic laboratory tests 24 hours a day in order to serve a hospital emergency room which is available to provide services 24 hours a day and 7 days a week.

(2)(A)(i) Except as provided in clause (v), subparagraph (B), and paragraph (4), the Secretary shall set the fee schedules at 60 percent (or, in the case of a test performed by a qualified hospital laboratory (as defined in paragraph (1)(D)) for outpatients of such hospital, 62 percent) of the prevailing charge level determined pursuant to the third and fourth sentences of section 1842(b)(3) for similar clinical diagnostic laboratory tests for the applicable region, State, or area for the 12-month period beginning July 1, 1984, adjusted annually (to become effective on January 1 of each year) by, subject to clause (iv), a percentage increase or decrease equal to the percentage increase or decrease in the Consumer Price Index for All Urban Consumers (United States city average) minus, for each of the years 2009 and 2010, 0.5 percentage points, and, for tests furnished before the dateof enactment of section 1834A, subject to such other adjustments as the Secretary determines are justified by technological changes.

(ii) Notwithstanding clause (i)—

(I) any change in the fee schedules which would have become effective under this subsection for tests furnished on or after January 1, 1988, shall not be effective for tests furnished during the 3-month period beginning on January 1, 1988,

(II) the Secretary shall not adjust the fee schedules under clause (i) to take into account any increase in the consumer price index for 1988,

(III) the annual adjustment in the fee schedules determined under clause (i) for each of the years 1991, 1992, and 1993 shall be 2 percent, and

(IV) the annual adjustment in the fee schedules determined under clause (i) for each of the years 1994 and 1995, 1998 through 2002, and 2004 through 2008 shall be 0 percent.

(iii) In establishing fee schedules under clause (i) with respect to automated tests and tests (other than cytopathology tests) which before July 1, 1984, the Secretary made subject to a limit based on lowest charge levels under the sixth sentence of section 1842(b)(3) performed after March 31, 1988, the Secretary shall reduce by 8.3 percent the fee schedules otherwise established for 1988, and such reduced fee schedules shall serve as the base for 1989 and subsequent years.

(iv) After determining the adjustment to the fee schedules under clause (i), the Secretary shall reduce such adjustment—

(I) for 2011 and each subsequent year, by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II); and

(II) for each of 2011 through 2015, by 1.75 percentage points.

Subclause (I) shall not apply in a year where the adjustment to the fee schedules determined under clause (i) is 0.0 or a percentage decrease for a year. The application of the productivity adjustment under subclause (I) shall not result in an adjustment to the fee schedules under clause (i) being less than 0.0 for a year. The application of subclause (II) may result in an adjustment to the fee schedules under clause (i) being less than 0.0 for a year, and may result in payment rates for a year being less than such payment rates for the preceding year.

(v) The Secretary shall reduce by 2 percent the fee schedules otherwise determined under clause (i) for 2013, and such reduced fee schedules shall serve as the base for 2014 and subsequent years.

(B) The Secretary may make further adjustments or exceptions to the fee schedules to assure adequate reimbursement of (i) emergency laboratory tests needed for the provision of bona fide emergency services, and (ii) certain low volume high-cost tests where highly sophisticated equipment or extremely skilled personnel are necessary to assure quality.

(3) In addition to the amounts provided under the fee schedules (for tests furnished before January 1, 2017)or under section 1834A (for tests furnished on or afterJanuary 1, 2017), subject to subsection (b)(5) of such section, the Secretary shall provide for and establish (A) a nominal fee to cover the appropriate costs in collecting the sample on which a clinical diagnostic laboratory test was performed and for which payment is made under this part, except that not more than one such fee may be provided under this paragraph with respect to samples collected in the same encounter, and (B) a fee to cover the transportation and personnel expenses for trained personnel to travel to the location of an individual to collect the sample, except that such a fee may be provided only with respect to an individual who is homebound or an inpatient in an inpatient facility (other than a hospital). In establishing a fee to cover the transportation and personnel expenses for trained personnel to travel to the location of an individual to collect a sample, the Secretary shall provide a method for computing the fee based on the number of miles traveled and the personnel costs associated with the collection of each individual sample, but the Secretary shall only be required to apply such method in the case of tests furnished during the period beginning on April 1, 1989, and ending on December 31, 1990, by a laboratory that establishes to the satisfaction of the Secretary (based on data for the 12-month period ending June 30, 1988) that (i) the laboratory is dependent upon payments under this title for at least 80 percent of its collected revenues for clinical diagnostic laboratory tests, (ii) at least 85 percent of its gross revenues for such tests are attributable to tests performed with respect to individuals who are homebound or who are residents in a nursing facility, and (iii) the laboratory provided such tests for residents in nursing facilities representing at least 20 percent of the number of such facilities in the State in which the laboratory is located.

(4)(A) In establishing any fee schedule under this subsection, the Secretary may provide for an adjustment to take into account, with respect to the portion of the expenses of clinical diagnostic laboratory tests attributable to wages, the relative difference between a region's or local area's wage rates and the wage rate presumed in the data on which the schedule is based.

(B) For purposes of subsections (a)(1)(D)(i) and (a)(2)(D)(i), the limitation amount for a clinical diagnostic laboratory test performed—

(i) on or after July 1, 1986, and before April 1, 1988, is equal to 115 percent of the median of all the fee schedules established for that test for that laboratory setting under paragraph (1),

(ii) after March 31, 1988, and before January 1, 1990, is equal to the median of all the fee schedules established for that test for that laboratory setting under paragraph (1),

(iii) after December 31, 1989, and before January 1, 1991, is equal to 93 percent of the median of all the fee schedules established for that test for that laboratory setting under paragraph (1),

(iv) after December 31, 1990, and before January 1, 1994, is equal to 88 percent of such median,

(v) after December 31, 1993, and before January 1, 1995, is equal to 84 percent of such median,

(vi) after December 31, 1994, and before January 1, 1996, is equal to 80 percent of such median,

(vii) after December 31, 1995, and before January 1, 1998, is equal to 76 percent of such median, and

(viii) after December 31, 1997, is equal to 74 percent of such median (or 100 percent of such median in the case of a clinical diagnostic laboratory test performed on or after January 1, 2001, that the Secretary determines is a new test for which no limitation amount has previously been established under this subparagraph).

(5)(A) In the case of a bill or request for payment for a clinical diagnostic laboratory test for which payment may otherwise be made under this part on an assignment-related basis or under a provider agreement under section 1866, payment may be made only to the person or entity which performed or supervised the performance of such test; except that—

(i) if a physician performed or supervised the performance of such test, payment may be made to another physician with whom he shares his practice,

(ii) in the case of a test performed at the request of a laboratory by another laboratory, payment may be made to the referring laboratory but only if—

(I) the referring laboratory is located in, or is part of, a rural hospital,

(II) the referring laboratory is wholly owned by the entity performing such test, the referring laboratory wholly owns the entity performing such test, or both the referring laboratory and the entity performing such test are wholly-owned by a third entity, or

(III) not more than 30 percent of the clinical diagnostic laboratory tests for which such referring laboratory (but

not including a laboratory described in subclause (II)), receives requests for testing during the year in which the test is performed are performed by another laboratory, and

(iii) in the case of a clinical diagnostic laboratory test provided under an arrangement (as defined in section 1861(w)(1)) made by a hospital, critical access hospital, or skilled nursing facility, payment shall be made to the hospital or skilled nursing facility.

(B) In the case of such a bill or request for payment for a clinical diagnostic laboratory test for which payment may otherwise be made under this part, and which is not described in subparagraph (A), payment may be made to the beneficiary only on the basis of the itemized bill of the person or entity which performed or supervised the performance of the test.

(C) Payment for a clinical diagnostic laboratory test, including a test performed in a physician's office but excluding a test performed by a rural health clinic may only be made on an assignment-related basis or to a provider of services with an agreement in effect under section 1866.

(D) A person may not bill for a clinical diagnostic laboratory test, including a test performed in a physician's office but excluding a test performed by a rural health clinic, other than on an assignment-related basis. If a person knowingly and willfully and on a repeated basis bills for a clinical diagnostic laboratory test in violation of the previous sentence, the Secretary may apply sanctions against the person in the same manner as the Secretary may apply sanctions against a physician in accordance with paragraph (2) of section 1842(j) in the same manner such paragraphs apply with respect to a physician. Paragraph (4) of such section shall apply in this subparagraph in the same manner as such paragraph applies to such section.

(6) For tests furnished before January 1, 2017, inthe case of any diagnostic laboratory test payment for which is not made on the basis of a fee schedule under paragraph (1), the Secretary may establish a payment rate which is acceptable to the person or entity performing the test and which would be considered the full charge for such tests. Such negotiated rate shall be limited to an amount not in excess of the total payment that would have been made for the services in the absence of such rate.

(7) Notwithstanding paragraphs (1) and (4)and section 1834A, the Secretary shall establish a national minimum payment amount under this part for a diagnostic or screening pap smear laboratory test (including all cervical cancer screening technologies that have been approved by the Food and Drug Administration as a primary screening method for detection of cervical cancer) equal to $14.60 for tests furnished in 2000. For such tests furnished in subsequent years, such national minimum payment amount shall be adjusted annually as provided in paragraph (2).

(8)(A) The Secretary shall establish by regulation procedures for determining the basis for, and amount of, payment under this subsection for any clinical diagnostic laboratory test with respect to which a new or substantially revised HCPCS code is assigned on or after January 1, 2005 (in this paragraph referred to as "new tests").

(B) Determinations under subparagraph (A) shall be made only after the Secretary—

(i) makes available to the public (through an Internet website and other appropriate mechanisms) a list that includes any such test for which establishment of a payment amount under this subsection is being considered for a year;

(ii) on the same day such list is made available, causes to have published in the Federal Register notice of a meeting to receive comments and recommendations (and data on which recommendations are based) from the public on the appropriate basis under this subsection for establishing payment amounts for the tests on such list;

(iii) not less than 30 days after publication of such notice convenes a meeting, that includes representatives of officials of the Centers for Medicare & Medicaid Services involved in determining payment amounts, to receive such comments and recommendations (and data on which the recommendations are based);

(iv) taking into account the comments and recommendations (and accompanying data) received at such meeting, develops and makes available to the public (through an Internet website and other appropriate mechanisms) a list of proposed determinations with respect to the appropriate basis for establishing a payment amount under this subsection for each such code, together with an explanation of the reasons for each such determination, the data on which the determinations are based, and a request for public written comments on the proposed determination; and

(v) taking into account the comments received during the public comment period, develops and makes available to the public (through an Internet website and other appropriate mechanisms) a list of final determinations of the payment amounts for such tests under this subsection, together with the rationale for each such determination, the data on which the determinations are based, and responses to comments and suggestions received from the public.

(C) Under the procedures established pursuant to subparagraph (A), the Secretary shall—

(i) set forth the criteria for making determinations under subparagraph (A); and

(ii) make available to the public the data (other than proprietary data) considered in making such determinations.

(D) The Secretary may convene such further public meetings to receive public comments on payment amounts for new tests under this subsection as the Secretary deems appropriate.

(E) For purposes of this paragraph:

(i) The term "HCPCS" refers to the Health Care Procedure Coding System.

(ii) A code shall be considered to be "substantially revised" if there is a substantive change to the definition of the test or procedure to which the code applies (such as a new analyte or a new methodology for measuring an existing analyte-specific test).

(9) Notwithstanding any other provision in this part, in the case of any diagnostic laboratory test for HbA1c that is labeled by the

Food and Drug Administration for home use and is furnished on or after April 1, 2008, the payment rate for such test shall be the payment rate established under this part for a glycated hemoglobin test (identified as of October 1, 2007, by HCPCS code 83036 (and any succeeding codes)).

(i)(1) The Secretary shall, in consultation with appropriate medical organizations—

(A) specify those surgical procedures which are appropriately (when considered in terms of the proper utilization of hospital inpatient facilities) performed on an inpatient basis in a hospital but which also can be performed safely on an ambulatory basis in an ambulatory surgical center (meeting the standards specified under section 1832(a)(2)(F)(i)), critical access hospital, or hospital outpatient department, and

(B) specify those surgical procedures which are appropriately (when considered in terms of the proper utilization of hospital inpatient facilities) performed on an inpatient basis in a hospital but which also can be performed safely on an ambulatory basis in a physician's office.

The lists of procedures established under subparagraphs (A) and (B) shall be reviewed and updated not less often than every 2 years, in consultation with appropriate trade and professional organizations.

(2)(A) For services furnished prior to the implementation of the system described in subparagraph (D), subject to subparagraph (E), the amount of payment to be made for facility services furnished in connection with a surgical procedure specified pursuant to paragraph (1)(A) and furnished to an individual in an ambulatory surgical center described in such paragraph shall be equal to 80 percent of a standard overhead amount established by the Secretary (with respect to each such procedure) on the basis of the Secretary's estimate of a fair fee which—

(i) takes into account the costs incurred by such centers, or classes of centers, generally in providing services furnished in connection with the performance of such procedure, as determined in accordance with a survey (based upon a representative sample of procedures and facilities) of the actual audited costs incurred by such centers in providing such services,

(ii) takes such costs into account in such a manner as will assure that the performance of the procedure in such a center will result in substantially less amounts paid under this title than would have been paid if the procedure had been performed on an inpatient basis in a hospital, and

(iii) in the case of insertion of an intraocular lens during or subsequent to cataract surgery includes payment which is reasonable and related to the cost of acquiring the class of lens involved.

Each amount so established shall be reviewed and updated not later than July 1, 1987, and annually thereafter to take account of varying conditions in different areas.

(B) The amount of payment to be made under this part for facility services furnished, in connection with a surgical procedure specified pursuant to paragraph (1)(B), in a physician's office shall be equal to 80 percent of a standard overhead amount established by

the Secretary (with respect to each such procedure) on the basis of the Secretary's estimate of a fair fee which—

(i) takes into account additional costs, not usually included in the professional fee, incurred by physicians in securing, maintaining, and staffing the facilities and ancillary services appropriate for the performance of such procedure in the physician's office, and

(ii) takes such items into account in such a manner which will assure that the performance of such procedure in the physician's office will result in substantially less amounts paid under this title than would have been paid if the services had been furnished on an inpatient basis in a hospital.

Each amount so established shall be reviewed and updated not later than July 1, 1987, and annually thereafter to take account of varying conditions in different areas.

(C)(i) Notwithstanding the second sentence of each of subparagraphs (A) and (B), except as otherwise specified in clauses (ii), (iii), and (iv), if the Secretary has not updated amounts established under such subparagraphs or under subparagraph (D), with respect to facility services furnished during a fiscal year (beginning with fiscal year 1986 or a calendar year (beginning with 2006)), such amounts shall be increased by the percentage increase in the Consumer Price Index for all urban consumers (U.S. city average) as estimated by the Secretary for the 12-month period ending with the midpoint of the year involved.

(ii) In each of the fiscal years 1998 through 2002, the increase under this subparagraph shall be reduced (but not below zero) by 2.0 percentage points.

(iii) In fiscal year 2004, beginning with April 1, 2004, the increase under this subparagraph shall be the Consumer Price Index for all urban consumers (U.S. city average) as estimated by the Secretary for the 12-month period ending with March 31, 2003, minus 3.0 percentage points.

(iv) In fiscal year 2005, the last quarter of calendar year 2005, and each of calendar years 2006 through 2009, the increase under this subparagraph shall be 0 percent.

(D)(i) Taking into account the recommendations in the report under section 626(d) of Medicare Prescription Drug, Improvement, and Modernization Act of 2003, the Secretary shall implement a revised payment system for payment of surgical services furnished in ambulatory surgical centers.

(ii) In the year the system described in clause (i) is implemented, such system shall be designed to result in the same aggregate amount of expenditures for such services as would be made if this subparagraph did not apply, as estimated by the Secretary and taking into account reduced expenditures that would apply if subparagraph (E) were to continue to apply, as estimated by the Secretary.

(iii) The Secretary shall implement the system described in clause (i) for periods in a manner so that it is first effective beginning on or after January 1, 2006, and not later than January 1, 2008.

(iv) The Secretary may implement such system in a manner so as to provide for a reduction in any annual update for failure to report on quality measures in accordance with paragraph (7).

(v) In implementing the system described in clause (i) for 2011 and each subsequent year, any annual update under such system for the year, after application of clause (iv), shall be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II). The application of the preceding sentence may result in such update being less than 0.0 for a year, and may result in payment rates under the system described in clause (i) for a year being less than such payment rates for the preceding year.

(vi) There shall be no administrative or judicial review under section 1869, 1878, or otherwise, of the classification system, the relative weights, payment amounts, and the geographic adjustment factor, if any, under this subparagraph.

(E) With respect to surgical procedures furnished on or after January 1, 2007, and before the effective date of the implementation of a revised payment system under subparagraph (D), if—

(i) the standard overhead amount under subparagraph (A) for a facility service for such procedure, without the application of any geographic adjustment, exceeds

(ii) the Medicare OPD fee schedule amount established under the prospective payment system for hospital outpatient department services under paragraph (3)(D) of section 1833(t) for such service for such year, determined without regard to geographic adjustment under paragraph (2)(D) of such section,

the Secretary shall substitute under subparagraph (A) the amount described in clause (ii) for the standard overhead amount for such service referred to in clause (i).

(3)(A) The aggregate amount of the payments to be made under this part for outpatient hospital facility services or critical access hospital services furnished before January 1, 1999, in connection with surgical procedures specified under paragraph (1)(A) shall be equal to the lesser of—

(i) the amount determined with respect to such services under subsection (a)(2)(B); or

(ii) the blend amount (described in subparagraph (B)).

(B)(i) The blend amount for a cost reporting period is the sum of—

(I) the cost proportion (as defined in clause (ii)(I)) of the amount described in subparagraph (A)(i), and

(II) the ASC proportion (as defined in clause (ii)(II)) of the standard overhead amount payable with respect to the same surgical procedure as if it were provided in an ambulatory surgical center in the same area, as determined under paragraph (2)(A), less the amount a provider may charge as described in clause (ii) of section 1866(a)(2)(A).

(ii) Subject to paragraph (4), in this paragraph:

(I) The term "cost proportion" means 75 percent for cost reporting periods beginning in fiscal year 1988, 50 percent for portions of cost reporting periods beginning on or after October 1, 1988, and ending on or before December 31, 1990, and 42 percent for portions of cost reporting periods beginning on or after January 1, 1991.

(II) The term "ASC proportion" means 25 percent for cost reporting periods beginning in fiscal year 1988, 50 percent for portions of cost reporting periods beginning on or after October

1, 1988, and ending on or before December 31, 1990, and 58 percent for portions of cost reporting periods beginning on or after January 1, 1991.

(4)(A) In the case of a hospital that—

(i) makes application to the Secretary and demonstrates that it specializes in eye services or eye and ear services (as determined by the Secretary),

(ii) receives more than 30 percent of its total revenues from outpatient services, and

(iii) on October 1, 1987—

(I) was an eye specialty hospital or an eye and ear specialty hospital, or

(II) was operated as an eye or eye and ear unit (as defined in subparagraph (B)) of a general acute care hospital which, on the date of the application described in clause (i), operates less than 20 percent of the beds that the hospital operated on October 1, 1987, and has sold or otherwise disposed of a substantial portion of the hospital's other acute care operations,

the cost proportion and ASC proportion in effect under subclauses (I) and (II) of paragraph (3)(B)(ii) for cost reporting periods beginning in fiscal year 1988 shall remain in effect for cost reporting periods beginning on or after October 1, 1988, and before January 1, 1995.

(B) For purposes of this subparagraph (A)(iii)(II), the term "eye or eye and ear unit" means a physically separate or distinct unit containing separate surgical suites devoted solely to eye or eye and ear services.

(5)(A) The Secretary is authorized to provide by regulations that in the case of a surgical procedure, specified by the Secretary pursuant to paragraph (1)(A), performed in an ambulatory surgical center described in such paragraph, there shall be paid (in lieu of any amounts otherwise payable under this part) with respect to the facility services furnished by such center and with respect to all related services (including physicians' services, laboratory, X-ray, and diagnostic services) a single all-inclusive fee established pursuant to subparagraph (B), if all parties furnishing all such services agree to accept such fee (to be divided among the parties involved in such manner as they shall have previously agreed upon) as full payment for the services furnished.

(B) In implementing this paragraph, the Secretary shall establish with respect to each surgical procedure specified pursuant to paragraph (1)(A) the amount of the all-inclusive fee for such procedure, taking into account such factors as may be appropriate. The amount so established with respect to any surgical procedure shall be reviewed periodically and may be adjusted by the Secretary, when appropriate, to take account of varying conditions in different areas.

(6) Any person, including a facility having an agreement under section 1832(a)(2)(F)(i), who knowingly and willfully presents, or causes to be presented, a bill or request for payment, for an intraocular lens inserted during or subsequent to cataract surgery for which payment may be made under paragraph (2)(A)(iii), is subject to a civil money penalty of not to exceed $2,000. The provisions of section 1128A (other than subsections (a) and (b)) shall apply to a

civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

(7)(A) For purposes of paragraph (2)(D)(iv), the Secretary may provide, in the case of an ambulatory surgical center that does not submit, to the Secretary in accordance with this paragraph, data required to be submitted on measures selected under this paragraph with respect to a year, any annual increase provided under the system established under paragraph (2)(D) for such year shall be reduced by 2.0 percentage points. A reduction under this subparagraph shall apply only with respect to the year involved and the Secretary shall not take into account such reduction in computing any annual increase factor for a subsequent year.

(B) Except as the Secretary may otherwise provide, the provisions of subparagraphs (B), (C), (D), and (E) of paragraph (17) of section 1833(t) shall apply with respect to services of ambulatory surgical centers under this paragraph in a similar manner to the manner in which they apply under such paragraph and, for purposes of this subparagraph, any reference to a hospital, outpatient setting, or outpatient hospital services is deemed a reference to an ambulatory surgical center, the setting of such a center, or services of such a center, respectively.

(8) The Secretary shall conduct a similar type of review as required under paragraph (22) of section 1833(t)), including the second sentence of subparagraph (C) of such paragraph, to payment for services under this subsection, and make such revisions under this paragraph, in an appropriate manner (as determined by the Secretary).

(j) Whenever a final determination is made that the amount of payment made under this part either to a provider of services or to another person pursuant to an assignment under section 1842(b)(3)(B)(ii) was in excess of or less than the amount of payment that is due, and payment of such excess or deficit is not made (or effected by offset) within 30 days of the date of the determination, interest shall accrue on the balance of such excess or deficit not paid or offset (to the extent that the balance is owed by or owing to the provider) at a rate determined in accordance with the regulations of the Secretary of the Treasury applicable to charges for late payments (or, in the case of such a determination made with respect to a payment made on or after the date of the enactment of the CARES Act and during the period at the end of the emergency sentence described in section 1135(g)(1)(B) under the program described in section 421.214 of title 42, Code of Federal Regulations (or any successor regulation), at a rate of 4 percent).

(k) With respect to services described in section 1861(s)(10)(B), the Secretary may provide, instead of the amount of payment otherwise provided under this part, for payment of such an amount or amounts as reasonably reflects the general cost of efficiently providing such services.

(l)(1)(A) The Secretary shall establish a fee schedule for services of certified registered nurse anesthetists under section 1861(s)(11).

(B) In establishing the fee schedule under this paragraph the Secretary may utilize a system of time units, a system of base and time units, or any appropriate methodology.

(C) The provisions of this subsection shall not apply to certain services furnished in certain hospitals in rural areas under the provisions of section 9320(k) of the Omnibus Budget Reconciliation Act of 1986, as amended by section 6132 of the Omnibus Budget Reconciliation Act of 1989.

(2) Except as provided in paragraph (3), the fee schedule established under paragraph (1) shall be initially based on audited data from cost reporting periods ending in fiscal year 1985 and such other data as the Secretary determines necessary.

(3)(A) In establishing the initial fee schedule for those services, the Secretary shall adjust the fee schedule to the extent necessary to ensure that the estimated total amount which will be paid under this title for those services plus applicable coinsurance in 1989 will equal the estimated total amount which would be paid under this title for those services in 1989 if the services were included as inpatient hospital services and payment for such services was made under part A in the same manner as payment was made in fiscal year 1987, adjusted to take into account changes in prices and technology relating to the administration of anesthesia.

(B) The Secretary shall also reduce the prevailing charge of physicians for medical direction of a certified registered nurse anesthetist, or the fee schedule for services of certified registered nurse anesthetists, or both, to the extent necessary to ensure that the estimated total amount which will be paid under this title plus applicable coinsurance for such medical direction and such services in 1989 and 1990 will not exceed the estimated total amount which would have been paid plus applicable coinsurance but for the enactment of the amendments made by section 9320 of the Omnibus Budget Reconciliation Act of 1986. A reduced prevailing charge under this subparagraph shall become the prevailing charge but for subsequent years for purposes of applying the economic index under the fourth sentence of section 1842(b)(3).

(4)(A) Except as provided in subparagraphs (C) and (D), in determining the amount paid under the fee schedule under this subsection for services furnished on or after January 1, 1991, by a certified registered nurse anesthetist who is not medically directed—

(i) the conversion factor shall be—

(I) for services furnished in 1991, $15.50,

(II) for services furnished in 1992, $15.75,

(III) for services furnished in 1993, $16.00,

(IV) for services furnished in 1994, $16.25,

(V) for services furnished in 1995, $16.50,

(VI) for services furnished in 1996, $16.75, and

(VII) for services furnished in calendar years after 1996, the previous year's conversion factor increased by the update determined under section 1848(d) for physician anesthesia services for that year;

(ii) the payment areas to be used shall be the fee schedule areas used under section 1848 (or, in the case of services furnished during 1991, the localities used under section 1842(b)) for purposes of computing payments for physicians' services that are anesthesia services;

(iii) the geographic adjustment factors to be applied to the conversion factor under clause (i) for services in a fee schedule area or locality is—

(I) in the case of services furnished in 1991, the geographic work index value and the geographic practice cost index value specified in section 1842(q)(1)(B) for physicians' services that are anesthesia services furnished in the area or locality, and

(II) in the case of services furnished after 1991, the geographic work index value, the geographic practice cost index value, and the geographic malpractice index value used for determining payments for physicians' services that are anesthesia services under section 1848,

with 70 percent of the conversion factor treated as attributable to work and 30 percent as attributable to overhead for services furnished in 1991 (and the portions attributable to work, practice expenses, and malpractice expenses in 1992 and thereafter being the same as is applied under section 1848).

(B)(i) Except as provided in clause (ii) and subparagraph (D), in determining the amount paid under the fee schedule under this subsection for services furnished on or after January 1, 1991, and before January 1, 1994, by a certified registered nurse anesthetist who is medically directed, the Secretary shall apply the same methodology specified in subparagraph (A).

(ii) The conversion factor used under clause (i) shall be—

(I) for services furnished in 1991, $10.50,

(II) for services furnished in 1992, $10.75, and

(III) for services furnished in 1993, $11.00.

(iii) In the case of services of a certified registered nurse anesthetist who is medically directed or medically supervised by a physician which are furnished on or after January 1, 1994, the fee schedule amount shall be one-half of the amount described in section 1848(a)(5)(B) with respect to the physician.

(C) Notwithstanding subclauses (I) through (V) of subparagraph (A)(i)—

(i) in the case of a 1990 conversion factor that is greater than $16.50, the conversion factor for a calendar year after 1990 and before 1996 shall be the 1990 conversion factor reduced by the product of the last digit of the calendar year and one-fifth of the amount by which the 1990 conversion factor exceeds $16.50; and

(ii) in the case of a 1990 conversion factor that is greater than $15.49 but less than $16.51, the conversion factor for a calendar year after 1990 and before 1996 shall be the greater of—

(I) the 1990 conversion factor, or

(II) the conversion factor specified in subparagraph (A)(i) for the year involved.

(D) Notwithstanding subparagraph (C), in no case may the conversion factor used to determine payment for services in a fee schedule area or locality under this subsection, as adjusted by the adjustment factors specified in subparagraphs (A)(iii), exceed the conversion factor used to determine the amount paid for physicians' services that are anesthesia services in the area or locality.

(5)(A) Payment for the services of a certified registered nurse anesthetist (for which payment may otherwise be made under this part) may be made on the basis of a claim or request for payment presented by the certified registered nurse anesthetist furnishing

such services, or by a hospital, critical access hospital, physician, group practice, or ambulatory surgical center with which the certified registered nurse anesthetist furnishing such services has an employment or contractual relationship that provides for payment to be made under this part for such services to such hospital, critical access hospital, physician, group practice, or ambulatory surgical center.

(B) No hospital or critical access hospital that presents a claim or request for payment for services of a certified nurse anesthetist under this part may treat any uncollected coinsurance amount imposed under this part with respect to such services as a bad debt of such hospital or critical access hospital for purposes of this title.

(6) If an adjustment under paragraph (3)(B) results in a reduction in the reasonable charge for a physicians' service and a nonparticipating physician furnishes the service to an individual entitled to benefits under this part after the effective date of the reduction, the physician's actual charge is subject to a limit under section 1842(j)(1)(D).

(m)(1) In the case of physicians' services furnished in a year to an individual, who is covered under the insurance program established by this part and who incurs expenses for such services, in an area that is designated (under section 332(a)(1)(A) of the Public Health Service Act) as a health professional shortage area as identified by the Secretary prior to the beginning of such year, in addition to the amount otherwise paid under this part, there also shall be paid to the physician (or to an employer or facility in the cases described in clause (A) of section 1842(b)(6)) (on a monthly or quarterly basis) from the Federal Supplementary Medical Insurance Trust Fund an amount equal to 10 percent of the payment amount for the service under this part.

(2) For each health professional shortage area identified in paragraph (1) that consists of an entire county, the Secretary shall provide for the additional payment under paragraph (1) without any requirement on the physician to identify the health professional shortage area involved. The Secretary may implement the previous sentence using the method specified in subsection (u)(4)(C).

(3) The Secretary shall post on the Internet website of the Centers for Medicare & Medicaid Services a list of the health professional shortage areas identified in paragraph (1) that consist of a partial county to facilitate the additional payment under paragraph (1) in such areas.

(4) There shall be no administrative or judicial review under section 1869, section 1878, or otherwise, respecting—

(A) the identification of a county or area;

(B) the assignment of a specialty of any physician under this paragraph;

(C) the assignment of a physician to a county under this subsection; or

(D) the assignment of a postal ZIP Code to a county or other area under this subsection.

(n)(1)(A) The aggregate amount of the payments to be made for all or part of a cost reporting period for services described in subsection (a)(2)(E)(i) furnished under this part on or after October 1, 1988, and before January 1, 1999, and for services described in subsection (a)(2)(E)(ii) furnished under this part on or after October

1, 1989, and before January 1, 1999, shall be equal to the lesser of—

(i) the amount determined with respect to such services under subsection (a)(2)(B), or

(ii) the blend amount for radiology services and diagnostic procedures determined in accordance with subparagraph (B).

(B)(i) The blend amount for radiology services and diagnostic procedures for a cost reporting period is the sum of—

(I) the cost proportion (as defined in clause (ii)) of the amount described in subparagraph (A)(i); and

(II) the charge proportion (as defined in clause (ii)(II)) of 62 percent (for services described in subsection (a)(2)(E)(i)), or (for procedures described in subsection (a)(2)(E)(ii)), 42 percent or such other percent established by the Secretary (or carriers acting pursuant to guidelines issued by the Secretary) based on prevailing charges established with actual charge data, of the prevailing charge or (for services described in subsection (a)(2)(E)(i) furnished on or after January 1, 1989) the fee schedule amount established for participating physicians for the same services as if they were furnished in a physician's office in the same locality as determined under section 1842(b), less the amount a provider may charge as described in clause (ii) of section 1866(a)(2)(A).

(ii) In this subparagraph:

(I) The term "cost proportion" means 50 percent, except that such term means 65 percent in the case of outpatient radiology services for portions of cost reporting periods which occur in fiscal year 1989 and in the case of diagnostic procedures described in subsection (a)(2)(E)(ii) for portions of cost reporting periods which occur in fiscal year 1990, and such term means 42 percent in the case of outpatient radiology services for portions of cost reporting periods beginning on or after January 1, 1991.

(II) The term "charge proportion" means 100 percent minus the cost proportion.

(o)(1) In the case of shoes described in section 1861(s)(12)—

(A) no payment may be made under this part, with respect to any individual for any year, for the furnishing of—

(i) more than one pair of custom molded shoes (including inserts provided with such shoes) and 2 additional pairs of inserts for such shoes, or

(ii) more than one pair of extra-depth shoes (not including inserts provided with such shoes) and 3 pairs of inserts for such shoes, and

(B) with respect to expenses incurred in any calendar year, no more than the amount of payment applicable under paragraph (2) shall be considered as incurred expenses for purposes of subsections (a) and (b).

Payment for shoes (or inserts) under this part shall be considered to include payment for any expenses for the fitting of such shoes (or inserts).

(2)(A) Except as provided by the Secretary under subparagraphs (B) and (C), the amount of payment under this paragraph for custom molded shoes, extra-depth shoes, and inserts shall be the

amount determined for such items by the Secretary under section 1834(h).

(B) The Secretary may establish payment amounts for shoes and inserts that are lower than the amount established under section 1834(h) if the Secretary finds that shoes and inserts of an appropriate quality are readily available at or below the amount established under such section.

(C) In accordance with procedures established by the Secretary, an individual entitled to benefits with respect to shoes described in section 1861(s)(12) may substitute modification of such shoes instead of obtaining one (or more, as specified by the Secretary) pair of inserts (other than the original pair of inserts with respect to such shoes). In such case, the Secretary shall substitute, for the payment amount established under section 1834(h), a payment amount that the Secretary estimates will assure that there is no net increase in expenditures under this subsection as a result of this subparagraph.

(3) In this title, the term "shoes" includes, except for purposes of subparagraphs (A)(ii) and (B) of paragraph (2), inserts for extra-depth shoes.

(q)(1) Each request for payment, or bill submitted, for an item or service furnished by an entity for which payment may be made under this part and for which the entity knows or has reason to believe there has been a referral by a referring physician (within the meaning of section 1877) shall include the name and unique physician identification number for the referring physician.

(2)(A) In the case of a request for payment for an item or service furnished by an entity under this part on an assignment-related basis and for which information is required to be provided under paragraph (1) but not included, payment may be denied under this part.

(B) In the case of a request for payment for an item or service furnished by an entity under this part not submitted on an assignment-related basis and for which information is required to be provided under paragraph (1) but not included—

(i) if the entity knowingly and willfully fails to provide such information promptly upon request of the Secretary or a carrier, the entity may be subject to a civil money penalty in an amount not to exceed $2,000, and

(ii) if the entity knowingly, willfully, and in repeated cases fails, after being notified by the Secretary of the obligations and requirements of this subsection to provide the information required under paragraph (1), the entity may be subject to exclusion from participation in the programs under this Act for a period not to exceed 5 years, in accordance with the procedures of subsections (c), (f), and (g) of section 1128.

The provisions of section 1128A (other than subsections (a) and (b)) shall apply to civil money penalties under clause (i) in the same manner as they apply to a penalty or proceeding under section 1128A(a).

(r)(1) With respect to services described in section 1861(s)(2)(K)(ii) (relating to nurse practitioner or clinical nurse specialist services), payment may be made on the basis of a claim or request for payment presented by the nurse practitioner or clinical nurse specialist furnishing such services, or by a hospital, critical

access hospital, skilled nursing facility or nursing facility (as defined in section 1919(a)), physician, group practice, or ambulatory surgical center with which the nurse practitioner or clinical nurse specialist has an employment or contractual relationship that provides for payment to be made under this part for such services to such hospital, physician, group practice, or ambulatory surgical center.

(2) No hospital or critical access hospital that presents a claim or request for payment under this part for services described in section 1861(s)(2)(K)(ii) may treat any uncollected coinsurance amount imposed under this part with respect to such services as a bad debt of such hospital for purposes of this title.

(s) The Secretary may not provide for payment under subsection (a)(1)(A) with respect to an organization unless the organization provides assurances satisfactory to the Secretary that the organization meets the requirement of section 1866(f) (relating to maintaining written policies and procedures respecting advance directives).

(t) PROSPECTIVE PAYMENT SYSTEM FOR HOSPITAL OUTPATIENT DEPARTMENT SERVICES.—

(1) AMOUNT OF PAYMENT.—

(A) IN GENERAL.—With respect to covered OPD services (as defined in subparagraph (B)) furnished during a year beginning with 1999, the amount of payment under this part shall be determined under a prospective payment system established by the Secretary in accordance with this subsection.

(B) DEFINITION OF COVERED OPD SERVICES.—For purposes of this subsection, the term "covered OPD services"—

(i) means hospital outpatient services designated by the Secretary;

(ii) subject to clause (iv), includes inpatient hospital services designated by the Secretary that are covered under this part and furnished to a hospital inpatient who (I) is entitled to benefits under part A but has exhausted benefits for inpatient hospital services during a spell of illness, or (II) is not so entitled;

(iii) includes implantable items described in paragraph (3), (6), or (8) of section 1861(s);

(iv) does not include any therapy services described in subsection (a)(8) or ambulance services, for which payment is made under a fee schedule described in section 1834(k) or section 1834(l) and does not include screening mammography (as defined in section 1861(jj)), diagnostic mammography, or personalized prevention plan services (as defined in section 1861(hhh)(1)); and

(v) does not include applicable items and services (as defined in subparagraph (A) of paragraph (21)) that are furnished on or after January 1, 2017, by an off-campus outpatient department of a provider (as defined in subparagraph (B) of such paragraph).

(2) SYSTEM REQUIREMENTS.—Under the payment system—

(A) the Secretary shall develop a classification system for covered OPD services;

(B) the Secretary may establish groups of covered OPD services, within the classification system described in subparagraph (A), so that services classified within each group are comparable clinically and with respect to the use of resources and so that an implantable item is classified to the group that includes the service to which the item relates;

(C) the Secretary shall, using data on claims from 1996 and using data from the most recent available cost reports, establish relative payment weights for covered OPD services (and any groups of such services described in subparagraph (B)) based on median (or, at the election of the Secretary, mean) hospital costs and shall determine projections of the frequency of utilization of each such service (or group of services) in 1999;

(D) subject to paragraph (19), the Secretary shall determine a wage adjustment factor to adjust the portion of payment and coinsurance attributable to labor-related costs for relative differences in labor and labor-related costs across geographic regions in a budget neutral manner;

(E) the Secretary shall establish, in a budget neutral manner, outlier adjustments under paragraph (5) and transitional pass-through payments under paragraph (6) and other adjustments as determined to be necessary to ensure equitable payments, such as adjustments for certain classes of hospitals;

(F) the Secretary shall develop a method for controlling unnecessary increases in the volume of covered OPD services;

(G) the Secretary shall create additional groups of covered OPD services that classify separately those procedures that utilize contrast agents from those that do not; and

(H) with respect to devices of brachytherapy consisting of a seed or seeds (or radioactive source), the Secretary shall create additional groups of covered OPD services that classify such devices separately from the other services (or group of services) paid for under this subsection in a manner reflecting the number, isotope, and radioactive intensity of such devices furnished, including separate groups for palladium-103 and iodine-125 devices and for stranded and non-stranded devices furnished on or after July 1, 2007.

For purposes of subparagraph (B), items and services within a group shall not be treated as "comparable with respect to the use of resources" if the highest median cost (or mean cost, if elected by the Secretary under subparagraph (C)) for an item or service within the group is more than 2 times greater than the lowest median cost (or mean cost, if so elected) for an item or service within the group; except that the Secretary may make exceptions in unusual cases, such as low volume items and services, but may not make such an exception in the case of a drug or biological that has been designated as an orphan

drug under section 526 of the Federal Food, Drug and Cosmetic Act.

(3) CALCULATION OF BASE AMOUNTS.—

(A) AGGREGATE AMOUNTS THAT WOULD BE PAYABLE IF DEDUCTIBLES WERE DISREGARDED.—The Secretary shall estimate the sum of—

(i) the total amounts that would be payable from the Trust Fund under this part for covered OPD services in 1999, determined without regard to this subsection, as though the deductible under section 1833(b) did not apply, and

(ii) the total amounts of copayments estimated to be paid under this subsection by beneficiaries to hospitals for covered OPD services in 1999, as though the deductible under section 1833(b) did not apply.

(B) UNADJUSTED COPAYMENT AMOUNT.—

(i) IN GENERAL.—For purposes of this subsection, subject to clause (ii), the "unadjusted copayment amount" applicable to a covered OPD service (or group of such services) is 20 percent of the national median of the charges for the service (or services within the group) furnished during 1996, updated to 1999 using the Secretary's estimate of charge growth during the period.

(ii) ADJUSTED TO BE 20 PERCENT WHEN FULLY PHASED IN.—If the pre-deductible payment percentage for a covered OPD service (or group of such services) furnished in a year would be equal to or exceed 80 percent, then the unadjusted copayment amount shall be 20 percent of amount determined under subparagraph (D).

(iii) RULES FOR NEW SERVICES.—The Secretary shall establish rules for establishment of an unadjusted copayment amount for a covered OPD service not furnished during 1996, based upon its classification within a group of such services.

(C) CALCULATION OF CONVERSION FACTORS.—

(i) FOR 1999.—

(I) IN GENERAL.—The Secretary shall establish a 1999 conversion factor for determining the medicare OPD fee schedule amounts for each covered OPD service (or group of such services) furnished in 1999. Such conversion factor shall be established on the basis of the weights and frequencies described in paragraph (2)(C) and in such a manner that the sum for all services and groups of the products (described in subclause (II) for each such service or group) equals the total projected amount described in subparagraph (A).

(II) PRODUCT DESCRIBED.—The Secretary shall determine for each service or group the product of the medicare OPD fee schedule amounts (taking into account appropriate adjustments described in paragraphs (2)(D) and (2)(E)) and the estimated frequencies for such service or group.

(ii) SUBSEQUENT YEARS.—Subject to paragraph (8)(B), the Secretary shall establish a conversion factor for covered OPD services furnished in subsequent years in an amount equal to the conversion factor established under this subparagraph and applicable to such services furnished in the previous year increased by the OPD fee schedule increase factor specified under clause (iv) for the year involved.

(iii) ADJUSTMENT FOR SERVICE MIX CHANGES.—Insofar as the Secretary determines that the adjustments for service mix under paragraph (2) for a previous year (or estimates that such adjustments for a future year) did (or are likely to) result in a change in aggregate payments under this subsection during the year that are a result of changes in the coding or classification of covered OPD services that do not reflect real changes in service mix, the Secretary may adjust the conversion factor computed under this subparagraph for subsequent years so as to eliminate the effect of such coding or classification changes.

(iv) OPD FEE SCHEDULE INCREASE FACTOR.—For purposes of this subparagraph, subject to paragraph (17) and subparagraph (F) of this paragraph, the "OPD fee schedule increase factor" for services furnished in a year is equal to the market basket percentage increase applicable under section 1886(b)(3)(B)(iii) to hospital discharges occurring during the fiscal year ending in such year, reduced by 1 percentage point for such factor for services furnished in each of 2000 and 2002. In applying the previous sentence for years beginning with 2000, the Secretary may substitute for the market basket percentage increase an annual percentage increase that is computed and applied with respect to covered OPD services furnished in a year in the same manner as the market basket percentage increase is determined and applied to inpatient hospital services for discharges occurring in a fiscal year.

(D) CALCULATION OF MEDICARE OPD FEE SCHEDULE AMOUNTS.—The Secretary shall compute a medicare OPD fee schedule amount for each covered OPD service (or group of such services) furnished in a year, in an amount equal to the product of—

(i) the conversion factor computed under subparagraph (C) for the year, and

(ii) the relative payment weight (determined under paragraph (2)(C)) for the service or group.

(E) PRE-DEDUCTIBLE PAYMENT PERCENTAGE.—The pre-deductible payment percentage for a covered OPD service (or group of such services) furnished in a year is equal to the ratio of—

(i) the medicare OPD fee schedule amount established under subparagraph (D) for the year, minus the unadjusted copayment amount determined under subparagraph (B) for the service or group, to

(ii) the medicare OPD fee schedule amount determined under subparagraph (D) for the year for such service or group.

(F) PRODUCTIVITY AND OTHER ADJUSTMENT.—After determining the OPD fee schedule increase factor under subparagraph (C)(iv), the Secretary shall reduce such increase factor—

(i) for 2012 and subsequent years, by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II); and

(ii) for each of 2010 through 2019, by the adjustment described in subparagraph (G).

The application of this subparagraph may result in the increase factor under subparagraph (C)(iv) being less than 0.0 for a year, and may result in payment rates under the payment system under this subsection for a year being less than such payment rates for the preceding year.

(G) OTHER ADJUSTMENT.—For purposes of subparagraph (F)(ii), the adjustment described in this subparagraph is—

(i) for each of 2010 and 2011, 0.25 percentage point;

(ii) for each of 2012 and 2013, 0.1 percentage point;

(iii) for 2014, 0.3 percentage point;

(iv) for each of 2015 and 2016, 0.2 percentage point; and

(v) for each of 2017, 2018, and 2019, 0.75 percentage point.

(4) MEDICARE PAYMENT AMOUNT.—The amount of payment made from the Trust Fund under this part for a covered OPD service (and such services classified within a group) furnished in a year is determined, subject to paragraph (7), as follows:

(A) FEE SCHEDULE ADJUSTMENTS.—The medicare OPD fee schedule amount (computed under paragraph (3)(D)) for the service or group and year is adjusted for relative differences in the cost of labor and other factors determined by the Secretary, as computed under paragraphs (2)(D) and (2)(E).

(B) SUBTRACT APPLICABLE DEDUCTIBLE.—Reduce the adjusted amount determined under subparagraph (A) by the amount of the deductible under section 1833(b), to the extent applicable.

(C) APPLY PAYMENT PROPORTION TO REMAINDER.—The amount of payment is the amount so determined under subparagraph (B) multiplied by the pre-deductible payment percentage (as determined under paragraph (3)(E)) for the service or group and year involved, plus the amount of any reduction in the copayment amount attributable to paragraph (8)(C).

(5) OUTLIER ADJUSTMENT.—

(A) IN GENERAL.—Subject to subparagraph (D), the Secretary shall provide for an additional payment for each covered OPD service (or group of services) for which a hospital's charges, adjusted to cost, exceed—

(i) a fixed multiple of the sum of—

(I) the applicable medicare OPD fee schedule amount determined under paragraph (3)(D), as

adjusted under paragraph (4)(A) (other than for adjustments under this paragraph or paragraph (6)); and

(II) any transitional pass-through payment under paragraph (6); and

(ii) at the option of the Secretary, such fixed dollar amount as the Secretary may establish.

(B) AMOUNT OF ADJUSTMENT.—The amount of the additional payment under subparagraph (A) shall be determined by the Secretary and shall approximate the marginal cost of care beyond the applicable cutoff point under such subparagraph.

(C) LIMIT ON AGGREGATE OUTLIER ADJUSTMENTS.—

(i) IN GENERAL.—The total of the additional payments made under this paragraph for covered OPD services furnished in a year (as estimated by the Secretary before the beginning of the year) may not exceed the applicable percentage (specified in clause (ii)) of the total program payments estimated to be made under this subsection for all covered OPD services furnished in that year. If this paragraph is first applied to less than a full year, the previous sentence shall apply only to the portion of such year.

(ii) APPLICABLE PERCENTAGE.—For purposes of clause (i), the term "applicable percentage" means a percentage specified by the Secretary up to (but not to exceed)—

(I) for a year (or portion of a year) before 2004, 2.5 percent; and

(II) for 2004 and thereafter, 3.0 percent.

(D) TRANSITIONAL AUTHORITY.—In applying subparagraph (A) for covered OPD services furnished before January 1, 2002, the Secretary may—

(i) apply such subparagraph to a bill for such services related to an outpatient encounter (rather than for a specific service or group of services) using OPD fee schedule amounts and transitional pass-through payments covered under the bill; and

(ii) use an appropriate cost-to-charge ratio for the hospital involved (as determined by the Secretary), rather than for specific departments within the hospital.

(E) EXCLUSION OF SEPARATE DRUG AND BIOLOGICAL APCS FROM OUTLIER PAYMENTS.—No additional payment shall be made under subparagraph (A) in the case of ambulatory payment classification groups established separately for drugs or biologicals.

(6) TRANSITIONAL PASS-THROUGH FOR ADDITIONAL COSTS OF INNOVATIVE MEDICAL DEVICES, DRUGS, AND BIOLOGICALS.—

(A) IN GENERAL.—The Secretary shall provide for an additional payment under this paragraph for any of the following that are provided as part of a covered OPD service (or group of services):

(i) CURRENT ORPHAN DRUGS.—A drug or biological that is used for a rare disease or condition with re-

spect to which the drug or biological has been designated as an orphan drug under section 526 of the Federal Food, Drug and Cosmetic Act if payment for the drug or biological as an outpatient hospital service under this part was being made on the first date that the system under this subsection is implemented.

(ii) CURRENT CANCER THERAPY DRUGS AND BIOLOGICALS AND BRACHYTHERAPY.—A drug or biological that is used in cancer therapy, including (but not limited to) a chemotherapeutic agent, an antiemetic, a hematopoietic growth factor, a colony stimulating factor, a biological response modifier, a bisphosphonate, and a device of brachytherapy or temperature monitored cryoablation, if payment for such drug, biological, or device as an outpatient hospital service under this part was being made on such first date.

(iii) CURRENT RADIOPHARMACEUTICAL DRUGS AND BIOLOGICAL PRODUCTS.—A radiopharmaceutical drug or biological product used in diagnostic, monitoring, and therapeutic nuclear medicine procedures if payment for the drug or biological as an outpatient hospital service under this part was being made on such first date.

(iv) NEW MEDICAL DEVICES, DRUGS, AND BIOLOGICALS.—A medical device, drug, or biological not described in clause (i), (ii), or (iii) if—

(I) payment for the device, drug, or biological as an outpatient hospital service under this part was not being made as of December 31, 1996; and

(II) the cost of the drug or biological or the average cost of the category of devices is not insignificant in relation to the OPD fee schedule amount (as calculated under paragraph (3)(D)) payable for the service (or group of services) involved.

(B) USE OF CATEGORIES IN DETERMINING ELIGIBILITY OF A DEVICE FOR PASS-THROUGH PAYMENTS.—The following provisions apply for purposes of determining whether a medical device qualifies for additional payments under clause (ii) or (iv) of subparagraph (A):

(i) ESTABLISHMENT OF INITIAL CATEGORIES.—

(I) IN GENERAL.—The Secretary shall initially establish under this clause categories of medical devices based on type of device by April 1, 2001. Such categories shall be established in a manner such that each medical device that meets the requirements of clause (ii) or (iv) of subparagraph (A) as of January 1, 2001, is included in such a category and no such device is included in more than one category. For purposes of the preceding sentence, whether a medical device meets such requirements as of such date shall be determined on the basis of the program memoranda issued before such date.

(II) AUTHORIZATION OF IMPLEMENTATION OTHER THAN THROUGH REGULATIONS.—The categories

may be established under this clause by program memorandum or otherwise, after consultation with groups representing hospitals, manufacturers of medical devices, and other affected parties.

(ii) ESTABLISHING CRITERIA FOR ADDITIONAL CATEGORIES.—

(I) IN GENERAL.—The Secretary shall establish criteria that will be used for creation of additional categories (other than those established under clause (i)) through rulemaking (which may include use of an interim final rule with comment period).

(II) STANDARD.—Such categories shall be established under this clause in a manner such that no medical device is described by more than one category. Such criteria shall include a test of whether the average cost of devices that would be included in a category and are in use at the time the category is established is not insignificant, as described in subparagraph (A)(iv)(II).

(III) DEADLINE.—Criteria shall first be established under this clause by July 1, 2001. The Secretary may establish in compelling circumstances categories under this clause before the date such criteria are established.

(IV) ADDING CATEGORIES.—The Secretary shall promptly establish a new category of medical devices under this clause for any medical device that meets the requirements of subparagraph (A)(iv) and for which none of the categories in effect (or that were previously in effect) is appropriate.

(iii) PERIOD FOR WHICH CATEGORY IS IN EFFECT.—A category of medical devices established under clause (i) or (ii) shall be in effect for a period of at least 2 years, but not more than 3 years, that begins—

(I) in the case of a category established under clause (i), on the first date on which payment was made under this paragraph for any device described by such category (including payments made during the period before April 1, 2001); and

(II) in the case of any other category, on the first date on which payment is made under this paragraph for any medical device that is described by such category.

(iv) REQUIREMENTS TREATED AS MET.—A medical device shall be treated as meeting the requirements of subparagraph (A)(iv), regardless of whether the device meets the requirement of subclause (I) of such subparagraph, if—

(I) the device is described by a category established and in effect under clause (i); or

(II) the device is described by a category established and in effect under clause (ii) and an application under section 515 of the Federal Food, Drug, and Cosmetic Act has been approved with respect to the device, or the device has been

cleared for market under section 510(k) of such Act, or the device is exempt from the requirements of section 510(k) of such Act pursuant to subsection (l) or (m) of section 510 of such Act or section 520(g) of such Act.

Nothing in this clause shall be construed as requiring an application or prior approval (other than that described in subclause (II)) in order for a covered device described by a category to qualify for payment under this paragraph.

(C) LIMITED PERIOD OF PAYMENT.—

(i) DRUGS AND BIOLOGICALS.—Subject to subparagraph (G), the payment under this paragraph with respect to a drug or biological shall only apply during a period of at least 2 years, but not more than 3 years, that begins—

(I) on the first date this subsection is implemented in the case of a drug or biological described in clause (i), (ii), or (iii) of subparagraph (A) and in the case of a drug or biological described in subparagraph (A)(iv) and for which payment under this part is made as an outpatient hospital service before such first date; or

(II) in the case of a drug or biological described in subparagraph (A)(iv) not described in subclause (I), on the first date on which payment is made under this part for the drug or biological as an outpatient hospital service.

(ii) MEDICAL DEVICES.—Payment shall be made under this paragraph with respect to a medical device only if such device—

(I) is described by a category of medical devices established and in effect under subparagraph (B); and

(II) is provided as part of a service (or group of services) paid for under this subsection and provided during the period for which such category is in effect under such subparagraph.

(D) AMOUNT OF ADDITIONAL PAYMENT.—Subject to subparagraph (E)(iii), the amount of the payment under this paragraph with respect to a device, drug, or biological provided as part of a covered OPD service is—

(i) subject to subparagraph (H), in the case of a drug or biological, the amount by which the amount determined under section 1842(o) (or if the drug or biological is covered under a competitive acquisition contract under section 1847B, an amount determined by the Secretary equal to the average price for the drug or biological for all competitive acquisition areas and year established under such section as calculated and adjusted by the Secretary for purposes of this paragraph) for the drug or biological exceeds the portion of the otherwise applicable medicare OPD fee schedule that the Secretary determines is associated with the drug or biological; or

(ii) in the case of a medical device, the amount by which the hospital's charges for the device, adjusted to cost, exceeds the portion of the otherwise applicable medicare OPD fee schedule that the Secretary determines is associated with the device.

(E) LIMIT ON AGGREGATE ANNUAL ADJUSTMENT.—

(i) IN GENERAL.—The total of the additional payments made under this paragraph for covered OPD services furnished in a year (as estimated by the Secretary before the beginning of the year) may not exceed the applicable percentage (specified in clause (ii)) of the total program payments estimated to be made under this subsection for all covered OPD services furnished in that year. If this paragraph is first applied to less than a full year, the previous sentence shall apply only to the portion of such year. This clause shall not apply for 2018 or 2020.

(ii) APPLICABLE PERCENTAGE.—For purposes of clause (i), the term "applicable percentage" means—

(I) for a year (or portion of a year) before 2004, 2.5 percent; and

(II) for 2004 and thereafter, a percentage specified by the Secretary up to (but not to exceed) 2.0 percent.

(iii) UNIFORM PROSPECTIVE REDUCTION IF AGGREGATE LIMIT PROJECTED TO BE EXCEEDED.—If the Secretary estimates before the beginning of a year that the amount of the additional payments under this paragraph for the year (or portion thereof) as determined under clause (i) without regard to this clause will exceed the limit established under such clause, the Secretary shall reduce pro rata the amount of each of the additional payments under this paragraph for that year (or portion thereof) in order to ensure that the aggregate additional payments under this paragraph (as so estimated) do not exceed such limit.

(F) LIMITATION OF APPLICATION OF FUNCTIONAL EQUIVALENCE STANDARD.—

(i) IN GENERAL.—The Secretary may not publish regulations that apply a functional equivalence standard to a drug or biological under this paragraph.

(ii) APPLICATION.—Clause (i) shall apply to the application of a functional equivalence standard to a drug or biological on or after the date of enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 unless—

(I) such application was being made to such drug or biological prior to such date of enactment; and

(II) the Secretary applies such standard to such drug or biological only for the purpose of determining eligibility of such drug or biological for additional payments under this paragraph and not for the purpose of any other payments under this title.

(iii) RULE OF CONSTRUCTION.—Nothing in this subparagraph shall be construed to effect the Secretary's authority to deem a particular drug to be identical to another drug if the 2 products are pharmaceutically equivalent and bioequivalent, as determined by the Commissioner of Food and Drugs.

(G) PASS-THROUGH EXTENSION FOR CERTAIN DRUGS AND BIOLOGICALS.—In the case of a drug or biological whose period of pass-through status under this paragraph ended on December 31, 2017, and for which payment under this subsection was packaged into a payment for a covered OPD service (or group of services) furnished beginning January 1, 2018, such pass-through status shall be extended for a 2-year period beginning on October 1, 2018.

(H) TEMPORARY PAYMENT RULE FOR CERTAIN DRUGS AND BIOLOGICALS.—In the case of a drug or biological whose period of pass-through status under this paragraph ended on December 31, 2017, and for which payment under this subsection was packaged into a payment for a covered OPD service (or group of services) furnished beginning January 1, 2018, the payment amount for such drug or biological under this subsection that is furnished during the period beginning on October 1, 2018, and ending on March 31, 2019, shall be the greater of—

(i) the payment amount that would otherwise apply under subparagraph (D)(i) for such drug or biological during such period; or

(ii) the payment amount that applied under such subparagraph (D)(i) for such drug or biological on December 31, 2017.

(I) SPECIAL PAYMENT ADJUSTMENT RULES FOR LAST QUARTER OF 2018.—In the case of a drug or biological whose period of pass-through status under this paragraph ended on December 31, 2017, and for which payment under this subsection was packaged into a payment amount for a covered OPD service (or group of services) beginning January 1, 2018, the following rules shall apply with respect to payment amounts under this subsection for covered a OPD service (or group of services) furnished during the period beginning on October 1, 2018, and ending on December 31, 2018:

(i) The Secretary shall remove the packaged costs of such drug or biological (as determined by the Secretary) from the payment amount under this subsection for the covered OPD service (or group of services) with which it is packaged.

(ii) The Secretary shall not make any adjustments to payment amounts under this subsection for a covered OPD service (or group of services) for which no costs were removed under clause (i).

(J) ADDITIONAL PASS-THROUGH EXTENSION AND SPECIAL PAYMENT ADJUSTMENT RULE FOR CERTAIN DIAGNOSTIC RADIOPHARMACEUTICALS.—In the case of a drug or biological furnished in the context of a clinical study on diagnostic imaging tests approved under a coverage with evi-

dence development determination whose period of pass-through status under this paragraph concluded on December 31, 2018, and for which payment under this subsection was packaged into a payment for a covered OPD service (or group of services) furnished beginning January 1, 2019, the Secretary shall—

(i) extend such pass-through status for such drug or biological for the 9-month period beginning on January 1, 2020;

(ii) remove, during such period, the packaged costs of such drug or biological (as determined by the Secretary) from the payment amount under this subsection for the covered OPD service (or group of services) with which it is packaged; and

(iii) not make any adjustments to payment amounts under this subsection for a covered OPD service (or group of services) for which no costs were removed under clause (ii).

(7) TRANSITIONAL ADJUSTMENT TO LIMIT DECLINE IN PAYMENT.—

(A) BEFORE 2002.—Subject to subparagraph (D), for covered OPD services furnished before January 1, 2002, for which the PPS amount (as defined in subparagraph (E)) is—

(i) at least 90 percent, but less than 100 percent, of the pre-BBA amount (as defined in subparagraph (F)), the amount of payment under this subsection shall be increased by 80 percent of the amount of such difference;

(ii) at least 80 percent, but less than 90 percent, of the pre-BBA amount, the amount of payment under this subsection shall be increased by the amount by which (I) the product of 0.71 and the pre-BBA amount, exceeds (II) the product of 0.70 and the PPS amount;

(iii) at least 70 percent, but less than 80 percent, of the pre-BBA amount, the amount of payment under this subsection shall be increased by the amount by which (I) the product of 0.63 and the pre-BBA amount, exceeds (II) the product of 0.60 and the PPS amount; or

(iv) less than 70 percent of the pre-BBA amount, the amount of payment under this subsection shall be increased by 21 percent of the pre-BBA amount.

(B) 2002.—Subject to subparagraph (D), for covered OPD services furnished during 2002, for which the PPS amount is—

(i) at least 90 percent, but less than 100 percent, of the pre-BBA amount, the amount of payment under this subsection shall be increased by 70 percent of the amount of such difference;

(ii) at least 80 percent, but less than 90 percent, of the pre-BBA amount, the amount of payment under this subsection shall be increased by the amount by which (I) the product of 0.61 and the pre-BBA amount,

exceeds (II) the product of 0.60 and the PPS amount; or

(iii) less than 80 percent of the pre-BBA amount, the amount of payment under this subsection shall be increased by 13 percent of the pre-BBA amount.

(C) 2003.—Subject to subparagraph (D), for covered OPD services furnished during 2003, for which the PPS amount is—

(i) at least 90 percent, but less than 100 percent, of the pre-BBA amount, the amount of payment under this subsection shall be increased by 60 percent of the amount of such difference; or

(ii) less than 90 percent of the pre-BBA amount, the amount of payment under this subsection shall be increased by 6 percent of the pre-BBA amount.

(D) HOLD HARMLESS PROVISIONS.—

(i) TEMPORARY TREATMENT FOR CERTAIN RURAL HOSPITALS.—(I) In the case of a hospital located in a rural area and that has not more than 100 beds or a sole community hospital (as defined in section 1886(d)(5)(D)(iii)) located in a rural area, for covered OPD services furnished before January 1, 2006, for which the PPS amount is less than the pre-BBA amount, the amount of payment under this subsection shall be increased by the amount of such difference.

(II) In the case of a hospital located in a rural area and that has not more than 100 beds and that is not a sole community hospital (as defined in section 1886(d)(5)(D)(iii)), for covered OPD services furnished on or after January 1, 2006, and before January 1, 2013, for which the PPS amount is less than the pre-BBA amount, the amount of payment under this subsection shall be increased by the applicable percentage of the amount of such difference. For purposes of the preceding sentence, the applicable percentage shall be 95 percent with respect to covered OPD services furnished in 2006, 90 percent with respect to such services furnished in 2007, and 85 percent with respect to such services furnished in 2008, 2009, 2010, 2011, or 2012.

(III) In the case of a sole community hospital (as defined in section 1886(d)(5)(D)(iii)) that has not more than 100 beds, for covered OPD services furnished on or after January 1, 2009, and before January 1, 2013, for which the PPS amount is less than the pre-BBA amount, the amount of payment under this subsection shall be increased by 85 percent of the amount of such difference. In the case of covered OPD services furnished on or after January 1, 2010, and before March 1, 2012, the preceding sentence shall be applied without regard to the 100-bed limitation.

(ii) PERMANENT TREATMENT FOR CANCER HOSPITALS AND CHILDREN'S HOSPITALS.—In the case of a hospital described in clause (iii) or (v) of section 1886(d)(1)(B), for covered OPD services for which the PPS amount is

less than the pre-BBA amount, the amount of payment under this subsection shall be increased by the amount of such difference.

(E) PPS AMOUNT DEFINED.—In this paragraph, the term "PPS amount" means, with respect to covered OPD services, the amount payable under this title for such services (determined without regard to this paragraph), including amounts payable as copayment under paragraph (8), coinsurance under section 1866(a)(2)(A)(ii), and the deductible under section 1833(b).

(F) PRE-BBA AMOUNT DEFINED.—

(i) IN GENERAL.—In this paragraph, the "pre-BBA amount" means, with respect to covered OPD services furnished by a hospital in a year, an amount equal to the product of the reasonable cost of the hospital for such services for the portions of the hospital's cost reporting period (or periods) occurring in the year and the base OPD payment-to-cost ratio for the hospital (as defined in clause (ii)).

(ii) BASE PAYMENT-TO-COST-RATIO DEFINED.—For purposes of this subparagraph, the "base payment-to-cost ratio" for a hospital means the ratio of—

(I) the hospital's reimbursement under this part for covered OPD services furnished during the cost reporting period ending in 1996 (or in the case of a hospital that did not submit a cost report for such period, during the first subsequent cost reporting period ending before 2001 for which the hospital submitted a cost report), including any reimbursement for such services through cost-sharing described in subparagraph (E), to

(II) the reasonable cost of such services for such period.

The Secretary shall determine such ratios as if the amendments made by section 4521 of the Balanced Budget Act of 1997 were in effect in 1996.

(G) INTERIM PAYMENTS.—The Secretary shall make payments under this paragraph to hospitals on an interim basis, subject to retrospective adjustments based on settled cost reports.

(H) NO EFFECT ON COPAYMENTS.—Nothing in this paragraph shall be construed to affect the unadjusted copayment amount described in paragraph (3)(B) or the copayment amount under paragraph (8).

(I) APPLICATION WITHOUT REGARD TO BUDGET NEUTRALITY.—The additional payments made under this paragraph—

(i) shall not be considered an adjustment under paragraph (2)(E); and

(ii) shall not be implemented in a budget neutral manner.

(8) COPAYMENT AMOUNT.—

(A) IN GENERAL.—Except as provided in subparagraphs (B) and (C), the copayment amount under this subsection is the amount by which the amount described in para-

graph (4)(B) exceeds the amount of payment determined under paragraph (4)(C).

(B) ELECTION TO OFFER REDUCED COPAYMENT AMOUNT.—The Secretary shall establish a procedure under which a hospital, before the beginning of a year (beginning with 1999), may elect to reduce the copayment amount otherwise established under subparagraph (A) for some or all covered OPD services to an amount that is not less than 20 percent of the medicare OPD fee schedule amount (computed under paragraph (3)(D)) for the service involved. Under such procedures, such reduced copayment amount may not be further reduced or increased during the year involved and the hospital may disseminate information on the reduction of copayment amount effected under this subparagraph.

(C) LIMITATION ON COPAYMENT AMOUNT.—

(i) TO INPATIENT HOSPITAL DEDUCTIBLE AMOUNT.—In no case shall the copayment amount for a procedure performed in a year exceed the amount of the inpatient hospital deductible established under section 1813(b) for that year.

(ii) TO SPECIFIED PERCENTAGE.—The Secretary shall reduce the national unadjusted copayment amount for a covered OPD service (or group of such services) furnished in a year in a manner so that the effective copayment rate (determined on a national unadjusted basis) for that service in the year does not exceed the following percentage:

(I) For procedures performed in 2001, on or after April 1, 2001, 57 percent.

(II) For procedures performed in 2002 or 2003, 55 percent.

(III) For procedures performed in 2004, 50 percent.

(IV) For procedures performed in 2005, 45 percent.

(V) For procedures performed in 2006 and thereafter, 40 percent.

(D) NO IMPACT ON DEDUCTIBLES.—Nothing in this paragraph shall be construed as affecting a hospital's authority to waive the charging of a deductible under section 1833(b).

(E) COMPUTATION IGNORING OUTLIER AND PASS-THROUGH ADJUSTMENTS.—The copayment amount shall be computed under subparagraph (A) as if the adjustments under paragraphs (5) and (6) (and any adjustment made under paragraph (2)(E) in relation to such adjustments) had not occurred.

(9) PERIODIC REVIEW AND ADJUSTMENTS COMPONENTS OF PROSPECTIVE PAYMENT SYSTEM.—

(A) PERIODIC REVIEW.—The Secretary shall review not less often than annually and revise the groups, the relative payment weights, and the wage and other adjustments described in paragraph (2) to take into account changes in medical practice, changes in technology, the addition of

new services, new cost data, and other relevant information and factors. The Secretary shall consult with an expert outside advisory panel composed of an appropriate selection of representatives of providers to review (and advise the Secretary concerning) the clinical integrity of the groups and weights. Such panel may use data collected or developed by entities and organizations (other than the Department of Health and Human Services) in conducting such review.

(B) BUDGET NEUTRALITY ADJUSTMENT.—If the Secretary makes adjustments under subparagraph (A), then the adjustments for a year may not cause the estimated amount of expenditures under this part for the year to increase or decrease from the estimated amount of expenditures under this part that would have been made if the adjustments had not been made. In determining adjustments under the preceding sentence for 2004 and 2005, the Secretary shall not take into account under this subparagraph or paragraph (2)(E) any expenditures that would not have been made but for the application of paragraph (14).

(C) UPDATE FACTOR.—If the Secretary determines under methodologies described in paragraph (2)(F) that the volume of services paid for under this subsection increased beyond amounts established through those methodologies, the Secretary may appropriately adjust the update to the conversion factor otherwise applicable in a subsequent year.

(10) SPECIAL RULE FOR AMBULANCE SERVICES.—The Secretary shall pay for hospital outpatient services that are ambulance services on the basis described in section 1861(v)(1)(U), or, if applicable, the fee schedule established under section 1834(l).

(11) SPECIAL RULES FOR CERTAIN HOSPITALS.—In the case of hospitals described in clause (iii) or (v) of section 1886(d)(1)(B)—

(A) the system under this subsection shall not apply to covered OPD services furnished before January 1, 2000; and

(B) the Secretary may establish a separate conversion factor for such services in a manner that specifically takes into account the unique costs incurred by such hospitals by virtue of their patient population and service intensity.

(12) LIMITATION ON REVIEW.—There shall be no administrative or judicial review under section 1869, 1878, or otherwise of—

(A) the development of the classification system under paragraph (2), including the establishment of groups and relative payment weights for covered OPD services, of wage adjustment factors, other adjustments, and methods described in paragraph (2)(F);

(B) the calculation of base amounts under paragraph (3);

(C) periodic adjustments made under paragraph (6);

(D) the establishment of a separate conversion factor under paragraph (8)(B); and

(E) the determination of the fixed multiple, or a fixed dollar cutoff amount, the marginal cost of care, or applica-

ble percentage under paragraph (5) or the determination of insignificance of cost, the duration of the additional payments, the determination and deletion of initial and new categories (consistent with subparagraphs (B) and (C) of paragraph (6)), the portion of the medicare OPD fee schedule amount associated with particular devices, drugs, or biologicals, and the application of any pro rata reduction under paragraph (6).

(13) AUTHORIZATION OF ADJUSTMENT FOR RURAL HOSPITALS.—

(A) STUDY.—The Secretary shall conduct a study to determine if, under the system under this subsection, costs incurred by hospitals located in rural areas by ambulatory payment classification groups (APCs) exceed those costs incurred by hospitals located in urban areas.

(B) AUTHORIZATION OF ADJUSTMENT.—Insofar as the Secretary determines under subparagraph (A) that costs incurred by hospitals located in rural areas exceed those costs incurred by hospitals located in urban areas, the Secretary shall provide for an appropriate adjustment under paragraph (2)(E) to reflect those higher costs by January 1, 2006.

(14) DRUG APC PAYMENT RATES.—

(A) IN GENERAL.—The amount of payment under this subsection for a specified covered outpatient drug (defined in subparagraph (B)) that is furnished as part of a covered OPD service (or group of services)—

(i) in 2004, in the case of—

(I) a sole source drug shall in no case be less than 88 percent, or exceed 95 percent, of the reference average wholesale price for the drug;

(II) an innovator multiple source drug shall in no case exceed 68 percent of the reference average wholesale price for the drug; or

(III) a noninnovator multiple source drug shall in no case exceed 46 percent of the reference average wholesale price for the drug;

(ii) in 2005, in the case of—

(I) a sole source drug shall in no case be less than 83 percent, or exceed 95 percent, of the reference average wholesale price for the drug;

(II) an innovator multiple source drug shall in no case exceed 68 percent of the reference average wholesale price for the drug; or

(III) a noninnovator multiple source drug shall in no case exceed 46 percent of the reference average wholesale price for the drug; or

(iii) in a subsequent year, shall be equal, subject to subparagraph (E)—

(I) to the average acquisition cost for the drug for that year (which, at the option of the Secretary, may vary by hospital group (as defined by the Secretary based on volume of covered OPD services or other relevant characteristics)), as determined by the Secretary taking into account the

hospital acquisition cost survey data under subparagraph (D); or

(II) if hospital acquisition cost data are not available, the average price for the drug in the year established under section 1842(o), section 1847A, or section 1847B, as the case may be, as calculated and adjusted by the Secretary as necessary for purposes of this paragraph.

(B) SPECIFIED COVERED OUTPATIENT DRUG DEFINED.—

(i) IN GENERAL.—In this paragraph, the term "specified covered outpatient drug" means, subject to clause (ii), a covered outpatient drug (as defined in section 1927(k)(2)) for which a separate ambulatory payment classification group (APC) has been established and that is—

(I) a radiopharmaceutical; or

(II) a drug or biological for which payment was made under paragraph (6) (relating to pass-through payments) on or before December 31, 2002.

(ii) EXCEPTION.—Such term does not include—

(I) a drug or biological for which payment is first made on or after January 1, 2003, under paragraph (6);

(II) a drug or biological for which a temporary HCPCS code has not been assigned; or

(III) during 2004 and 2005, an orphan drug (as designated by the Secretary).

(C) PAYMENT FOR DESIGNATED ORPHAN DRUGS DURING 2004 AND 2005.—The amount of payment under this subsection for an orphan drug designated by the Secretary under subparagraph (B)(ii)(III) that is furnished as part of a covered OPD service (or group of services) during 2004 and 2005 shall equal such amount as the Secretary may specify.

(D) ACQUISITION COST SURVEY FOR HOSPITAL OUTPATIENT DRUGS.—

(i) ANNUAL GAO SURVEYS IN 2004 AND 2005.—

(I) IN GENERAL.—The Comptroller General of the United States shall conduct a survey in each of 2004 and 2005 to determine the hospital acquisition cost for each specified covered outpatient drug. Not later than April 1, 2005, the Comptroller General shall furnish data from such surveys to the Secretary for use in setting the payment rates under subparagraph (A) for 2006.

(II) RECOMMENDATIONS.—Upon the completion of such surveys, the Comptroller General shall recommend to the Secretary the frequency and methodology of subsequent surveys to be conducted by the Secretary under clause (ii).

(ii) SUBSEQUENT SECRETARIAL SURVEYS.—The Secretary, taking into account such recommendations, shall conduct periodic subsequent surveys to determine the hospital acquisition cost for each specified

covered outpatient drug for use in setting the payment rates under subparagraph (A).

(iii) SURVEY REQUIREMENTS.—The surveys conducted under clauses (i) and (ii) shall have a large sample of hospitals that is sufficient to generate a statistically significant estimate of the average hospital acquisition cost for each specified covered outpatient drug. With respect to the surveys conducted under clause (i), the Comptroller General shall report to Congress on the justification for the size of the sample used in order to assure the validity of such estimates.

(iv) DIFFERENTIATION IN COST.—In conducting surveys under clause (i), the Comptroller General shall determine and report to Congress if there is (and the extent of any) variation in hospital acquisition costs for drugs among hospitals based on the volume of covered OPD services performed by such hospitals or other relevant characteristics of such hospitals (as defined by the Comptroller General).

(v) COMMENT ON PROPOSED RATES.—Not later than 30 days after the date the Secretary promulgated proposed rules setting forth the payment rates under subparagraph (A) for 2006, the Comptroller General shall evaluate such proposed rates and submit to Congress a report regarding the appropriateness of such rates based on the surveys the Comptroller General has conducted under clause (i).

(E) ADJUSTMENT IN PAYMENT RATES FOR OVERHEAD COSTS.—

(i) MEDPAC REPORT ON DRUG APC DESIGN.—The Medicare Payment Advisory Commission shall submit to the Secretary, not later than July 1, 2005, a report on adjustment of payment for ambulatory payment classifications for specified covered outpatient drugs to take into account overhead and related expenses, such as pharmacy services and handling costs. Such report shall include—

(I) a description and analysis of the data available with regard to such expenses;

(II) a recommendation as to whether such a payment adjustment should be made; and

(III) if such adjustment should be made, a recommendation regarding the methodology for making such an adjustment.

(ii) ADJUSTMENT AUTHORIZED.—The Secretary may adjust the weights for ambulatory payment classifications for specified covered outpatient drugs to take into account the recommendations contained in the report submitted under clause (i).

(F) CLASSES OF DRUGS.—For purposes of this paragraph:

(i) SOLE SOURCE DRUGS.—The term "sole source drug" means—

(I) a biological product (as defined under section 1861(t)(1)); or

(II) a single source drug (as defined in section 1927(k)(7)(A)(iv)).

(ii) INNOVATOR MULTIPLE SOURCE DRUGS.—The term "innovator multiple source drug" has the meaning given such term in section 1927(k)(7)(A)(ii).

(iii) NONINNOVATOR MULTIPLE SOURCE DRUGS.—The term "noninnovator multiple source drug" has the meaning given such term in section 1927(k)(7)(A)(iii).

(G) REFERENCE AVERAGE WHOLESALE PRICE.—The term "reference average wholesale price" means, with respect to a specified covered outpatient drug, the average wholesale price for the drug as determined under section 1842(o) as of May 1, 2003.

(H) INAPPLICABILITY OF EXPENDITURES IN DETERMINING CONVERSION, WEIGHTING, AND OTHER ADJUSTMENT FACTORS.—Additional expenditures resulting from this paragraph shall not be taken into account in establishing the conversion, weighting, and other adjustment factors for 2004 and 2005 under paragraph (9), but shall be taken into account for subsequent years.

(15) PAYMENT FOR NEW DRUGS AND BIOLOGICALS UNTIL HCPCS CODE ASSIGNED.—With respect to payment under this part for an outpatient drug or biological that is covered under this part and is furnished as part of covered OPD services for which a HCPCS code has not been assigned, the amount provided for payment for such drug or biological under this part shall be equal to 95 percent of the average wholesale price for the drug or biological.

(16) MISCELLANEOUS PROVISIONS.—

(A) APPLICATION OF RECLASSIFICATION OF CERTAIN HOSPITALS.—If a hospital is being treated as being located in a rural area under section 1886(d)(8)(E), that hospital shall be treated under this subsection as being located in that rural area.

(B) THRESHOLD FOR ESTABLISHMENT OF SEPARATE APCS FOR DRUGS.—The Secretary shall reduce the threshold for the establishment of separate ambulatory payment classification groups (APCs) with respect to drugs or biologicals to $50 per administration for drugs and biologicals furnished in 2005 and 2006.

(C) PAYMENT FOR DEVICES OF BRACHYTHERAPY AND THERAPEUTIC RADIOPHARMACEUTICALS AT CHARGES ADJUSTED TO COST.—Notwithstanding the preceding provisions of this subsection, for a device of brachytherapy consisting of a seed or seeds (or radioactive source) furnished on or after January 1, 2004, and before January 1, 2010, and for therapeutic radiopharmaceuticals furnished on or after January 1, 2008, and before January 1, 2010, the payment basis for the device or therapeutic radiopharmaceutical under this subsection shall be equal to the hospital's charges for each device or therapeutic radiopharmaceutical furnished, adjusted to cost. Charges for such devices or therapeutic radiopharmaceuticals shall not be included in determining any outlier payment under this subsection.

(D) SPECIAL PAYMENT RULE.—

(i) IN GENERAL.—In the case of covered OPD services furnished on or after April 1, 2013, in a hospital described in clause (ii), if—

(I) the payment rate that would otherwise apply under this subsection for stereotactic radiosurgery, complete course of treatment of cranial lesion(s) consisting of 1 session that is multisource Cobalt 60 based (identified as of January 1, 2013, by HCPCS code 77371 (and any succeeding code) and reimbursed as of such date under APC 0127 (and any succeeding classification group)); exceeds

(II) the payment rate that would otherwise apply under this subsection for linear accelerator based stereotactic radiosurgery, complete course of therapy in one session (identified as of January 1, 2013, by HCPCS code G0173 (and any succeeding code) and reimbursed as of such date under APC 0067 (and any succeeding classification group)),

the payment rate for the service described in subclause (I) shall be reduced to an amount equal to the payment rate for the service described in subclause (II).

(ii) HOSPITAL DESCRIBED.—A hospital described in this clause is a hospital that is not—

(I) located in a rural area (as defined in section 1886(d)(2)(D));

(II) classified as a rural referral center under section 1886(d)(5)(C); or

(III) a sole community hospital (as defined in section 1886(d)(5)(D)(iii)).

(iii) NOT BUDGET NEUTRAL.—In making any budget neutrality adjustments under this subsection for 2013 (with respect to covered OPD services furnished on or after April 1, 2013, and before January 1, 2014) or a subsequent year, the Secretary shall not take into account the reduced expenditures that result from the application of this subparagraph.

(E) APPLICATION OF APPROPRIATE USE CRITERIA FOR CERTAIN IMAGING SERVICES.—For provisions relating to the application of appropriate use criteria for certain imaging services, see section 1834(q).

(F) PAYMENT INCENTIVE FOR THE TRANSITION FROM TRADITIONAL X-RAY IMAGING TO DIGITAL RADIOGRAPHY.—Notwithstanding the previous provisions of this subsection:

(i) LIMITATION ON PAYMENT FOR FILM X-RAY IMAGING SERVICES.—In the case of an imaging service that is an X-ray taken using film and that is furnished during 2017 or a subsequent year, the payment amount for such service (including the X-ray component of a packaged service) that would otherwise be determined under this section (without application of this paragraph and before application of any other adjustment

under this subsection) for such year shall be reduced by 20 percent.

(ii) PHASED-IN LIMITATION ON PAYMENT FOR COMPUTED RADIOGRAPHY IMAGING SERVICES.—In the case of an imaging service that is an X-ray taken using computed radiography technology (as defined in section 1848(b)(9)(C))—

(I) in the case of such a service furnished during 2018, 2019, 2020, 2021, or 2022, the payment amount for such service (including the X-ray component of a packaged service) that would otherwise be determined under this section (without application of this paragraph and before application of any other adjustment under this subsection) for such year shall be reduced by 7 percent; and

(II) in the case of such a service furnished during 2023 or a subsequent year, the payment amount for such service (including the X-ray component of a packaged service) that would otherwise be determined under this section (without application of this paragraph and before application of any other adjustment under this subsection) for such year shall be reduced by 10 percent.

(iii) APPLICATION WITHOUT REGARD TO BUDGET NEUTRALITY.—The reductions made under this subparagraph—

(I) shall not be considered an adjustment under paragraph (2)(E); and

(II) shall not be implemented in a budget neutral manner.

(iv) IMPLEMENTATION.—In order to implement this subparagraph, the Secretary shall adopt appropriate mechanisms which may include use of modifiers.

(17) QUALITY REPORTING.—

(A) REDUCTION IN UPDATE FOR FAILURE TO REPORT.—

(i) IN GENERAL.—For purposes of paragraph (3)(C)(iv) for 2009 and each subsequent year, in the case of a subsection (d) hospital (as defined in section 1886(d)(1)(B)) that does not submit, to the Secretary in accordance with this paragraph, data required to be submitted on measures selected under this paragraph with respect to such a year, the OPD fee schedule increase factor under paragraph (3)(C)(iv) for such year shall be reduced by 2.0 percentage points.

(ii) NON-CUMULATIVE APPLICATION.—A reduction under this subparagraph shall apply only with respect to the year involved and the Secretary shall not take into account such reduction in computing the OPD fee schedule increase factor for a subsequent year.

(B) FORM AND MANNER OF SUBMISSION.—Each subsection (d) hospital shall submit data on measures selected under this paragraph to the Secretary in a form and manner, and

at a time, specified by the Secretary for purposes of this paragraph.

(C) DEVELOPMENT OF OUTPATIENT MEASURES.—

(i) IN GENERAL.—The Secretary shall develop measures that the Secretary determines to be appropriate for the measurement of the quality of care (including medication errors) furnished by hospitals in outpatient settings and that reflect consensus among affected parties and, to the extent feasible and practicable, shall include measures set forth by one or more national consensus building entities.

(ii) CONSTRUCTION.—Nothing in this paragraph shall be construed as preventing the Secretary from selecting measures that are the same as (or a subset of) the measures for which data are required to be submitted under section 1886(b)(3)(B)(viii).

(D) REPLACEMENT OF MEASURES.—For purposes of this paragraph, the Secretary may replace any measures or indicators in appropriate cases, such as where all hospitals are effectively in compliance or the measures or indicators have been subsequently shown not to represent the best clinical practice.

(E) AVAILABILITY OF DATA.—The Secretary shall establish procedures for making data submitted under this paragraph available to the public. Such procedures shall ensure that a hospital has the opportunity to review the data that are to be made public with respect to the hospital prior to such data being made public. The Secretary shall report quality measures of process, structure, outcome, patients' perspectives on care, efficiency, and costs of care that relate to services furnished in outpatient settings in hospitals on the Internet website of the Centers for Medicare & Medicaid Services.

(18) AUTHORIZATION OF ADJUSTMENT FOR CANCER HOSPITALS.—

(A) STUDY.—The Secretary shall conduct a study to determine if, under the system under this subsection, costs incurred by hospitals described in section 1886(d)(1)(B)(v) with respect to ambulatory payment classification groups exceed those costs incurred by other hospitals furnishing services under this subsection (as determined appropriate by the Secretary). In conducting the study under this subparagraph, the Secretary shall take into consideration the cost of drugs and biologicals incurred by such hospitals.

(B) AUTHORIZATION OF ADJUSTMENT.—Insofar as the Secretary determines under subparagraph (A) that costs incurred by hospitals described in section 1886(d)(1)(B)(v) exceed those costs incurred by other hospitals furnishing services under this subsection, the Secretary shall, subject to subparagraph (C), provide for an appropriate adjustment under paragraph (2)(E) to reflect those higher costs effective for services furnished on or after January 1, 2011.

(C) TARGET PCR ADJUSTMENT.—In applying section 419.43(i) of title 42 of the Code of Federal Regulations to implement the appropriate adjustment under this para-

graph for services furnished on or after January 1, 2018, the Secretary shall use a target PCR that is 1.0 percentage points less than the target PCR that would otherwise apply. In addition to the percentage point reduction under the previous sentence, the Secretary may consider making an additional percentage point reduction to such target PCR that takes into account payment rates for applicable items and services described in paragraph (21)(C) other than for services furnished by hospitals described in section 1886(d)(1)(B)(v). In making any budget neutrality adjustments under this subsection for 2018 or a subsequent year, the Secretary shall not take into account the reduced expenditures that result from the application of this subparagraph.

(19) FLOOR ON AREA WAGE ADJUSTMENT FACTOR FOR HOSPITAL OUTPATIENT DEPARTMENT SERVICES IN FRONTIER STATES.—

(A) IN GENERAL.—Subject to subparagraph (B), with respect to covered OPD services furnished on or after January 1, 2011, the area wage adjustment factor applicable under the payment system established under this subsection to any hospital outpatient department which is located in a frontier State (as defined in section 1886(d)(3)(E)(iii)(II)) may not be less than 1.00. The preceding sentence shall not be applied in a budget neutral manner.

(B) LIMITATION.—This paragraph shall not apply to any hospital outpatient department located in a State that receives a non-labor related share adjustment under section 1886(d)(5)(H).

(20) NOT BUDGET NEUTRAL APPLICATION OF REDUCED EXPENDITURES RESULTING FROM QUALITY INCENTIVES FOR COMPUTED TOMOGRAPHY.—The Secretary shall not take into account the reduced expenditures that result from the application of section 1834(p) in making any budget neutrality adjustments this subsection.

(21) SERVICES FURNISHED BY AN OFF-CAMPUS OUTPATIENT DEPARTMENT OF A PROVIDER.—

(A) APPLICABLE ITEMS AND SERVICES.—For purposes of paragraph (1)(B)(v) and this paragraph, the term "applicable items and services" means items and services other than items and services furnished by a dedicated emergency department (as defined in section 489.24(b) of title 42 of the Code of Federal Regulations).

(B) OFF-CAMPUS OUTPATIENT DEPARTMENT OF A PROVIDER.—

(i) IN GENERAL.—For purposes of paragraph (1)(B)(v) and this paragraph, subject to the subsequent provisions of this subparagraph, the term "off-campus outpatient department of a provider" means a department of a provider (as defined in section 413.65(a)(2) of title 42 of the Code of Federal Regulations, as in effect as of the date of the enactment of this paragraph) that is not located—

(I) on the campus (as defined in such section 413.65(a)(2)) of such provider; or

(II) within the distance (described in such definition of campus) from a remote location of a hospital facility (as defined in such section 413.65(a)(2)).

(ii) EXCEPTION.—For purposes of paragraph (1)(B)(v) and this paragraph, the term "off-campus outpatient department of a provider" shall not include a department of a provider (as so defined) that was billing under this subsection with respect to covered OPD services furnished prior to the date of the enactment of this paragraph.

(iii) DEEMED TREATMENT FOR 2017.—For purposes of applying clause (ii) with respect to applicable items and services furnished during 2017, a department of a provider (as so defined) not described in such clause is deemed to be billing under this subsection with respect to covered OPD services furnished prior to November 2, 2015, if the Secretary received from the provider prior to December 2, 2015, an attestation (pursuant to section 413.65(b)(3) of title 42 of the Code of Federal Regulations) that such department was a department of a provider (as so defined).

(iv) ALTERNATIVE EXCEPTION BEGINNING WITH 2018.—For purposes of paragraph (1)(B)(v) and this paragraph with respect to applicable items and services furnished during 2018 or a subsequent year, the term "off-campus outpatient department of a provider" also shall not include a department of a provider (as so defined) that is not described in clause (ii) if—

(I) the Secretary receives from the provider an attestation (pursuant to such section 413.65(b)(3)) not later than December 31, 2016 (or, if later, 60 days after the date of the enactment of this clause), that such department met the requirements of a department of a provider specified in section 413.65 of title 42 of the Code of Federal Regulations;

(II) the provider includes such department as part of the provider on its enrollment form in accordance with the enrollment process under section 1866(j); and

(III) the department met the mid-build requirement of clause (v) and the Secretary receives, not later than 60 days after the date of the enactment of this clause, from the chief executive officer or chief operating officer of the provider a written certification that the department met such requirement.

(v) MID-BUILD REQUIREMENT DESCRIBED.—The mid-build requirement of this clause is, with respect to a department of a provider, that before November 2, 2015, the provider had a binding written agreement

with an outside unrelated party for the actual construction of such department.

(vi) EXCLUSION FOR CERTAIN CANCER HOSPITALS.—For purposes of paragraph (1)(B)(v) and this paragraph with respect to applicable items and services furnished during 2017 or a subsequent year, the term "off-campus outpatient department of a provider" also shall not include a department of a provider (as so defined) that is not described in clause (ii) if the provider is a hospital described in section 1886(d)(1)(B)(v) and—

(I) in the case of a department that met the requirements of section 413.65 of title 42 of the Code of Federal Regulations after November 1, 2015, and before the date of the enactment of this clause, the Secretary receives from the provider an attestation that such department met such requirements not later than 60 days after such date of enactment; or

(II) in the case of a department that meets such requirements after such date of enactment, the Secretary receives from the provider an attestation that such department meets such requirements not later than 60 days after the date such requirements are first met with respect to such department.

(vii) AUDIT.—Not later than December 31, 2018, the Secretary shall audit the compliance with requirements of clause (iv) with respect to each department of a provider to which such clause applies. Not later than 2 years after the date the Secretary receives an attestation under clause (vi) relating to compliance of a department of a provider with requirements referred to in such clause, the Secretary shall audit the compliance with such requirements with respect to the department. If the Secretary finds as a result of an audit under this clause that the applicable requirements were not met with respect to such department, the department shall not be excluded from the term "off-campus outpatient department of a provider" under such clause.

(viii) IMPLEMENTATION.—For purposes of implementing clauses (iii) through (vii):

(I) Notwithstanding any other provision of law, the Secretary may implement such clauses by program instruction or otherwise.

(II) Subchapter I of chapter 35 of title 44, United States Code, shall not apply.

(III) For purposes of carrying out this subparagraph with respect to clauses (iii) and (iv) (and clause (vii) insofar as it relates to clause (iv)), $10,000,000 shall be available from the Federal Supplementary Medical Insurance Trust Fund under section 1841, to remain available until December 31, 2018. For purposes of carrying out this

subparagraph with respect to clause (vi) (and clause (vii) insofar as it relates to such clause), $2,000,000 shall be available from the Federal Supplementary Medical Insurance Trust Fund under section 1841, to remain available until expended.

(C) AVAILABILITY OF PAYMENT UNDER OTHER PAYMENT SYSTEMS.—Payments for applicable items and services furnished by an off-campus outpatient department of a provider that are described in paragraph (1)(B)(v) shall be made under the applicable payment system under this part (other than under this subsection) if the requirements for such payment are otherwise met.

(D) INFORMATION NEEDED FOR IMPLEMENTATION.—Each hospital shall provide to the Secretary such information as the Secretary determines appropriate to implement this paragraph and paragraph (1)(B)(v) (which may include reporting of information on a hospital claim using a code or modifier and reporting information about off-campus outpatient departments of a provider on the enrollment form described in section 1866(j)).

(E) LIMITATIONS.—There shall be no administrative or judicial review under section 1869, section 1878, or otherwise of the following:

(i) The determination of the applicable items and services under subparagraph (A) and applicable payment systems under subparagraph (C).

(ii) The determination of whether a department of a provider meets the term described in subparagraph (B).

(iii) Any information that hospitals are required to report pursuant to subparagraph (D).

(iv) The determination of an audit under subparagraph (B)(vii).

(22) REVIEW AND REVISIONS OF PAYMENTS FOR NON-OPIOID ALTERNATIVE TREATMENTS.—

(A) IN GENERAL.—With respect to payments made under this subsection for covered OPD services (or groups of services), including covered OPD services assigned to a comprehensive ambulatory payment classification, the Secretary—

(i) shall, as soon as practicable, conduct a review (part of which may include a request for information) of payments for opioids and evidence-based non-opioid alternatives for pain management (including drugs and devices, nerve blocks, surgical injections, and neuromodulation) with a goal of ensuring that there are not financial incentives to use opioids instead of non-opioid alternatives;

(ii) may, as the Secretary determines appropriate, conduct subsequent reviews of such payments; and

(iii) shall consider the extent to which revisions under this subsection to such payments (such as the creation of additional groups of covered OPD services to classify separately those procedures that utilize

opioids and non-opioid alternatives for pain management) would reduce payment incentives to use opioids instead of non-opioid alternatives for pain management.

(B) PRIORITY.—In conducting the review under clause (i) of subparagraph (A) and considering revisions under clause (iii) of such subparagraph, the Secretary shall focus on covered OPD services (or groups of services) assigned to a comprehensive ambulatory payment classification, ambulatory payment classifications that primarily include surgical services, and other services determined by the Secretary which generally involve treatment for pain management.

(C) REVISIONS.—If the Secretary identifies revisions to payments pursuant to subparagraph (A)(iii), the Secretary shall, as determined appropriate, begin making such revisions for services furnished on or after January 1, 2020. Revisions under the previous sentence shall be treated as adjustments for purposes of application of paragraph (9)(B).

(D) RULES OF CONSTRUCTION.—Nothing in this paragraph shall be construed to preclude the Secretary—

(i) from conducting a demonstration before making the revisions described in subparagraph (C); or

(ii) prior to implementation of this paragraph, from changing payments under this subsection for covered OPD services (or groups of services) which include opioids or non-opioid alternatives for pain management.

(u) INCENTIVE PAYMENTS FOR PHYSICIAN SCARCITY AREAS.—

(1) IN GENERAL.—In the case of physicians' services furnished on or after January 1, 2005, and before July 1, 2008—

(A) by a primary care physician in a primary care scarcity county (identified under paragraph (4)); or

(B) by a physician who is not a primary care physician in a specialist care scarcity county (as so identified),

in addition to the amount of payment that would otherwise be made for such services under this part, there also shall be paid an amount equal to 5 percent of the payment amount for the service under this part.

(2) DETERMINATION OF RATIOS OF PHYSICIANS TO MEDICARE BENEFICIARIES IN AREA.—Based upon available data, the Secretary shall establish for each county or equivalent area in the United States, the following:

(A) NUMBER OF PHYSICIANS PRACTICING IN THE AREA.—The number of physicians who furnish physicians' services in the active practice of medicine or osteopathy in that county or area, other than physicians whose practice is exclusively for the Federal Government, physicians who are retired, or physicians who only provide administrative services. Of such number, the number of such physicians who are—

(i) primary care physicians; or

(ii) physicians who are not primary care physicians.

(B) NUMBER OF MEDICARE BENEFICIARIES RESIDING IN THE AREA.—The number of individuals who are residing in the county and are entitled to benefits under part A or enrolled under this part, or both (in this subsection referred to as "individuals").

(C) DETERMINATION OF RATIOS.—

(i) PRIMARY CARE RATIO.—The ratio (in this paragraph referred to as the "primary care ratio") of the number of primary care physicians (determined under subparagraph (A)(i)), to the number of individuals determined under subparagraph (B).

(ii) SPECIALIST CARE RATIO.—The ratio (in this paragraph referred to as the "specialist care ratio") of the number of other physicians (determined under subparagraph (A)(ii)), to the number of individuals determined under subparagraph (B).

(3) RANKING OF COUNTIES.—The Secretary shall rank each such county or area based separately on its primary care ratio and its specialist care ratio.

(4) IDENTIFICATION OF COUNTIES.—

(A) IN GENERAL.—The Secretary shall identify—

(i) those counties and areas (in this paragraph referred to as "primary care scarcity counties") with the lowest primary care ratios that represent, if each such county or area were weighted by the number of individuals determined under paragraph (2)(B), an aggregate total of 20 percent of the total of the individuals determined under such paragraph; and

(ii) those counties and areas (in this subsection referred to as "specialist care scarcity counties") with the lowest specialist care ratios that represent, if each such county or area were weighted by the number of individuals determined under paragraph (2)(B), an aggregate total of 20 percent of the total of the individuals determined under such paragraph.

(B) PERIODIC REVISIONS.—The Secretary shall periodically revise the counties or areas identified in subparagraph (A) (but not less often than once every three years) unless the Secretary determines that there is no new data available on the number of physicians practicing in the county or area or the number of individuals residing in the county or area, as identified in paragraph (2).

(C) IDENTIFICATION OF COUNTIES WHERE SERVICE IS FURNISHED.—For purposes of paying the additional amount specified in paragraph (1), if the Secretary uses the 5-digit postal ZIP Code where the service is furnished, the dominant county of the postal ZIP Code (as determined by the United States Postal Service, or otherwise) shall be used to determine whether the postal ZIP Code is in a scarcity county identified in subparagraph (A) or revised in subparagraph (B).

(D) SPECIAL RULE.—With respect to physicians' services furnished on or after January 1, 2008, and before July 1, 2008, for purposes of this subsection, the Secretary shall use the primary care scarcity counties and the specialty

care scarcity counties (as identified under the preceding provisions of this paragraph) that the Secretary was using under this subsection with respect to physicians' services furnished on December 31, 2007.

(E) JUDICIAL REVIEW.—There shall be no administrative or judicial review under section 1869, 1878, or otherwise, respecting—

116.(i) the identification of a county or area;

(ii) the assignment of a specialty of any physician under this paragraph;

(iii) the assignment of a physician to a county under paragraph (2); or

(iv) the assignment of a postal ZIP Code to a county or other area under this subsection.

(5) RURAL CENSUS TRACTS.—To the extent feasible, the Secretary shall treat a rural census tract of a metropolitan statistical area (as determined under the most recent modification of the Goldsmith Modification, originally published in the Federal Register on February 27, 1992 (57 Fed. Reg. 6725)), as an equivalent area for purposes of qualifying as a primary care scarcity county or specialist care scarcity county under this subsection.

(6) PHYSICIAN DEFINED.—For purposes of this paragraph, the term "physician" means a physician described in section 1861(r)(1) and the term "primary care physician" means a physician who is identified in the available data as a general practitioner, family practice practitioner, general internist, or obstetrician or gynecologist.

(7) PUBLICATION OF LIST OF COUNTIES; POSTING ON WEBSITE.—With respect to a year for which a county or area is identified or revised under paragraph (4), the Secretary shall identify such counties or areas as part of the proposed and final rule to implement the physician fee schedule under section 1848 for the applicable year. The Secretary shall post the list of counties identified or revised under paragraph (4) on the Internet website of the Centers for Medicare & Medicaid Services.

(v) INCREASE OF FQHC PAYMENT LIMITS.—In the case of services furnished by Federally qualified health centers (as defined in section 1861(aa)(4)), the Secretary shall establish payment limits with respect to such services under this part for services furnished—

(1) in 2010, at the limits otherwise established under this part for such year increased by $5; and

(2) in a subsequent year, at the limits established under this subsection for the previous year increased by the percentage increase in the MEI (as defined in section 1842(i)(3)) for such subsequent year.

(w) METHODS OF PAYMENT.—The Secretary may develop alternative methods of payment for items and services provided under clinical trials and comparative effectiveness studies sponsored or supported by an agency of the Department of Health and Human Services, as determined by the Secretary, to those that would otherwise apply under this section, to the extent such alternative methods are necessary to preserve the scientific validity of such trials or studies, such as in the case where masking the identity

of interventions from patients and investigators is necessary to comply with the particular trial or study design.

(x) INCENTIVE PAYMENTS FOR PRIMARY CARE SERVICES.—

(1) IN GENERAL.—In the case of primary care services furnished on or after January 1, 2011, and before January 1, 2016, by a primary care practitioner, in addition to the amount of payment that would otherwise be made for such services under this part, there also shall be paid (on a monthly or quarterly basis) an amount equal to 10 percent of the payment amount for the service under this part.

(2) DEFINITIONS.—In this subsection:

(A) PRIMARY CARE PRACTITIONER.—The term "primary care practitioner" means an individual—

(i) who—

(I) is a physician (as described in section 1861(r)(1)) who has a primary specialty designation of family medicine, internal medicine, geriatric medicine, or pediatric medicine; or

(II) is a nurse practitioner, clinical nurse specialist, or physician assistant (as those terms are defined in section 1861(aa)(5)); and

(ii) for whom primary care services accounted for at least 60 percent of the allowed charges under this part for such physician or practitioner in a prior period as determined appropriate by the Secretary.

(B) PRIMARY CARE SERVICES.—The term "primary care services" means services identified, as of January 1, 2009, by the following HCPCS codes (and as subsequently modified by the Secretary):

(i) 99201 through 99215.

(ii) 99304 through 99340.

(iii) 99341 through 99350.

(3) COORDINATION WITH OTHER PAYMENTS.—The amount of the additional payment for a service under this subsection and subsection (m) shall be determined without regard to any additional payment for the service under subsection (m) and this subsection, respectively. The amount of the additional payment for a service under this subsection and subsection (z) shall be determined without regard to any additional payment for the service under subsection (z) and this subsection, respectively.

(4) LIMITATION ON REVIEW.—There shall be no administrative or judicial review under section 1869, 1878, or otherwise, respecting the identification of primary care practitioners under this subsection.

(y) INCENTIVE PAYMENTS FOR MAJOR SURGICAL PROCEDURES FURNISHED IN HEALTH PROFESSIONAL SHORTAGE AREAS.—

(1) IN GENERAL.—In the case of major surgical procedures furnished on or after January 1, 2011, and before January 1, 2016, by a general surgeon in an area that is designated (under section 332(a)(1)(A) of the Public Health Service Act) as a health professional shortage area as identified by the Secretary prior to the beginning of the year involved, in addition to the amount of payment that would otherwise be made for such services under this part, there also shall be paid (on a

monthly or quarterly basis) an amount equal to 10 percent of the payment amount for the service under this part.

(2) DEFINITIONS.—In this subsection:

(A) GENERAL SURGEON.—In this subsection, the term "general surgeon" means a physician (as described in section 1861(r)(1)) who has designated CMS specialty code 02–General Surgery as their primary specialty code in the physician's enrollment under section 1866(j).

(B) MAJOR SURGICAL PROCEDURES.—The term "major surgical procedures" means physicians' services which are surgical procedures for which a 10-day or 90-day global period is used for payment under the fee schedule under section 1848(b).

(3) COORDINATION WITH OTHER PAYMENTS.—The amount of the additional payment for a service under this subsection and subsection (m) shall be determined without regard to any additional payment for the service under subsection (m) and this subsection, respectively. The amount of the additional payment for a service under this subsection and subsection (z) shall be determined without regard to any additional payment for the service under subsection (z) and this subsection, respectively.

(4) APPLICATION.—The provisions of paragraph (2) and (4) of subsection (m) shall apply to the determination of additional payments under this subsection in the same manner as such provisions apply to the determination of additional payments under subsection (m).

(z) INCENTIVE PAYMENTS FOR PARTICIPATION IN ELIGIBLE ALTERNATIVE PAYMENT MODELS.—

(1) PAYMENT INCENTIVE.—

(A) IN GENERAL.—In the case of covered professional services furnished by an eligible professional during a year that is in the period beginning with 2019 and ending with 2024 and for which the professional is a qualifying APM participant with respect to such year, in addition to the amount of payment that would otherwise be made for such covered professional services under this part for such year, there also shall be paid to such professional an amount equal to 5 percent of the estimated aggregate payment amounts for such covered professional services under this part for the preceding year. For purposes of the previous sentence, the payment amount for the preceding year may be an estimation for the full preceding year based on a period of such preceding year that is less than the full year. The Secretary shall establish policies to implement this subparagraph in cases in which payment for covered professional services furnished by a qualifying APM participant in an alternative payment model—

(i) is made to an eligible alternative payment entity rather than directly to the qualifying APM participant; or

(ii) is made on a basis other than a fee-for-service basis (such as payment on a capitated basis).

(B) FORM OF PAYMENT.—Payments under this subsection shall be made in a lump sum, on an annual basis, as soon as practicable.

(C) TREATMENT OF PAYMENT INCENTIVE.—Payments under this subsection shall not be taken into account for purposes of determining actual expenditures under an alternative payment model and for purposes of determining or rebasing any benchmarks used under the alternative payment model.

(D) COORDINATION.—The amount of the additional payment under this subsection or subsection (m) shall be determined without regard to any additional payment under subsection (m) and this subsection, respectively. The amount of the additional payment under this subsection or subsection (x) shall be determined without regard to any additional payment under subsection (x) and this subsection, respectively. The amount of the additional payment under this subsection or subsection (y) shall be determined without regard to any additional payment under subsection (y) and this subsection, respectively.

(2) QUALIFYING APM PARTICIPANT.—For purposes of this subsection, the term "qualifying APM participant" means the following:

(A) 2019 AND 2020.—With respect to 2019 and 2020, an eligible professional for whom the Secretary determines that at least 25 percent of payments under this part for covered professional services furnished by such professional during the most recent period for which data are available (which may be less than a year) were attributable to such services furnished under this part through an eligible alternative payment entity.

(B) 2021 THROUGH 2024.—With respect to each of 2021 through 2024, an eligible professional described in either of the following clauses:

(i) MEDICARE PAYMENT THRESHOLD OPTION.—An eligible professional for whom the Secretary determines that at least 50 percent of payments under this part for covered professional services furnished by such professional during the most recent period for which data are available (which may be less than a year) were attributable to such services furnished under this part through an eligible alternative payment entity.

(ii) COMBINATION ALL-PAYER AND MEDICARE PAYMENT THRESHOLD OPTION.—An eligible professional—

(I) for whom the Secretary determines, with respect to items and services furnished by such professional during the most recent period for which data are available (which may be less than a year), that at least 50 percent of the sum of—

(aa) payments described in clause (i); and

(bb) all other payments, regardless of payer (other than payments made by the Secretary of Defense or the Secretary of Veterans Affairs and other than payments made under title XIX in a State in which no medical home or alternative payment model is available under the State program under that title),

meet the requirement described in clause (iii)(I) with respect to payments described in item (aa) and meet the requirement described in clause (iii)(II) with respect to payments described in item (bb);

(II) for whom the Secretary determines at least 25 percent of payments under this part for covered professional services furnished by such professional during the most recent period for which data are available (which may be less than a year) were attributable to such services furnished under this part through an eligible alternative payment entity; and

(III) who provides to the Secretary such information as is necessary for the Secretary to make a determination under subclause (I), with respect to such professional.

(iii) REQUIREMENT.—For purposes of clause (ii)(I)—

(I) the requirement described in this subclause, with respect to payments described in item (aa) of such clause, is that such payments are made to an eligible alternative payment entity; and

(II) the requirement described in this subclause, with respect to payments described in item (bb) of such clause, is that such payments are made under arrangements in which—

(aa) quality measures comparable to measures under the performance category described in section 1848(q)(2)(B)(i) apply;

(bb) certified EHR technology is used; and

(cc) the eligible professional participates in an entity that—

(AA) bears more than nominal financial risk if actual aggregate expenditures exceeds expected aggregate expenditures; or

(BB) with respect to beneficiaries under title XIX, is a medical home that meets criteria comparable to medical homes expanded under section 1115A(c).

(C) BEGINNING IN 2025.—With respect to 2025 and each subsequent year, an eligible professional described in either of the following clauses:

(i) MEDICARE PAYMENT THRESHOLD OPTION.—An eligible professional for whom the Secretary determines that at least 75 percent of payments under this part for covered professional services furnished by such professional during the most recent period for which data are available (which may be less than a year) were attributable to such services furnished under this part through an eligible alternative payment entity.

(ii) COMBINATION ALL-PAYER AND MEDICARE PAYMENT THRESHOLD OPTION.—An eligible professional—

(I) for whom the Secretary determines, with respect to items and services furnished by such professional during the most recent period for which

data are available (which may be less than a year), that at least 75 percent of the sum of—

(aa) payments described in clause (i); and

(bb) all other payments, regardless of payer (other than payments made by the Secretary of Defense or the Secretary of Veterans Affairs and other than payments made under title XIX in a State in which no medical home or alternative payment model is available under the State program under that title),

meet the requirement described in clause (iii)(I) with respect to payments described in item (aa) and meet the requirement described in clause (iii)(II) with respect to payments described in item (bb);

(II) for whom the Secretary determines at least 25 percent of payments under this part for covered professional services furnished by such professional during the most recent period for which data are available (which may be less than a year) were attributable to such services furnished under this part through an eligible alternative payment entity; and

(III) who provides to the Secretary such information as is necessary for the Secretary to make a determination under subclause (I), with respect to such professional.

(iii) REQUIREMENT.—For purposes of clause (ii)(I)—

(I) the requirement described in this subclause, with respect to payments described in item (aa) of such clause, is that such payments are made to an eligible alternative payment entity; and

(II) the requirement described in this subclause, with respect to payments described in item (bb) of such clause, is that such payments are made under arrangements in which—

(aa) quality measures comparable to measures under the performance category described in section 1848(q)(2)(B)(i) apply;

(bb) certified EHR technology is used; and

(cc) the eligible professional participates in an entity that—

(AA) bears more than nominal financial risk if actual aggregate expenditures exceeds expected aggregate expenditures; or

(BB) with respect to beneficiaries under title XIX, is a medical home that meets criteria comparable to medical homes expanded under section 1115A(c).

(D) USE OF PATIENT APPROACH.—The Secretary may base the determination of whether an eligible professional is a qualifying APM participant under this subsection and the determination of whether an eligible professional is a partial qualifying APM participant under section 1848(q)(1)(C)(iii) by using counts of patients in lieu of

using payments and using the same or similar percentage criteria (as specified in this subsection and such section, respectively), as the Secretary determines appropriate. With respect to 2023 and 2024, the Secretary shall use the same percentage criteria for counts of patients that are used in 2022.

(3) ADDITIONAL DEFINITIONS.—In this subsection:

(A) COVERED PROFESSIONAL SERVICES.—The term "covered professional services" has the meaning given that term in section 1848(k)(3)(A).

(B) ELIGIBLE PROFESSIONAL.—The term "eligible professional" has the meaning given that term in section 1848(k)(3)(B) and includes a group that includes such professionals.

(C) ALTERNATIVE PAYMENT MODEL (APM).—The term "alternative payment model" means, other than for purposes of subparagraphs (B)(ii)(I)(bb) and (C)(ii)(I)(bb) of paragraph (2), any of the following:

(i) A model under section 1115A (other than a health care innovation award).

(ii) The shared savings program under section 1899.

(iii) A demonstration under section 1866C.

(iv) A demonstration required by Federal law.

(D) ELIGIBLE ALTERNATIVE PAYMENT ENTITY.—The term "eligible alternative payment entity" means, with respect to a year, an entity that—

(i) participates in an alternative payment model that—

(I) requires participants in such model to use certified EHR technology (as defined in subsection (o)(4)); and

(II) provides for payment for covered professional services based on quality measures comparable to measures under the performance category described in section 1848(q)(2)(B)(i); and

(ii)(I) bears financial risk for monetary losses under such alternative payment model that are in excess of a nominal amount; or

(II) is a medical home expanded under section 1115A(c).

(4) LIMITATION.—There shall be no administrative or judicial review under section 1869, 1878, or otherwise, of the following:

(A) The determination that an eligible professional is a qualifying APM participant under paragraph (2) and the determination that an entity is an eligible alternative payment entity under paragraph (3)(D).

(B) The determination of the amount of the 5 percent payment incentive under paragraph (1)(A), including any estimation as part of such determination.

(aa) MEDICAL REVIEW OF SPINAL SUBLUXATION SERVICES.—

(1) IN GENERAL.—The Secretary shall implement a process for the medical review (as described in paragraph (2)) of treatment by a chiropractor described in section 1861(r)(5) by means of manual manipulation of the spine to correct a subluxation (as described in such section) of an individual who is

enrolled under this part and apply such process to such services furnished on or after January 1, 2017, focusing on services such as—

(A) services furnished by a such a chiropractor whose pattern of billing is aberrant compared to peers; and

(B) services furnished by such a chiropractor who, in a prior period, has a services denial percentage in the 85th percentile or greater, taking into consideration the extent that service denials are overturned on appeal.

(2) MEDICAL REVIEW.—

(A) PRIOR AUTHORIZATION MEDICAL REVIEW.—

(i) IN GENERAL.—Subject to clause (ii), the Secretary shall use prior authorization medical review for services described in paragraph (1) that are furnished to an individual by a chiropractor described in section 1861(r)(5) that are part of an episode of treatment that includes more than 12 services. For purposes of the preceding sentence, an episode of treatment shall be determined by the underlying cause that justifies the need for services, such as a diagnosis code.

(ii) ENDING APPLICATION OF PRIOR AUTHORIZATION MEDICAL REVIEW.—The Secretary shall end the application of prior authorization medical review under clause (i) to services described in paragraph (1) by such a chiropractor if the Secretary determines that the chiropractor has a low denial rate under such prior authorization medical review. The Secretary may subsequently reapply prior authorization medical review to such chiropractor if the Secretary determines it to be appropriate and the chiropractor has, in the time period subsequent to the determination by the Secretary of a low denial rate with respect to the chiropractor, furnished such services described in paragraph (1).

(iii) EARLY REQUEST FOR PRIOR AUTHORIZATION REVIEW PERMITTED.—Nothing in this subsection shall be construed to prevent such a chiropractor from requesting prior authorization for services described in paragraph (1) that are to be furnished to an individual before the chiropractor furnishes the twelfth such service to such individual for an episode of treatment.

(B) TYPE OF REVIEW.—The Secretary may use pre-payment review or post-payment review of services described in section 1861(r)(5) that are not subject to prior authorization medical review under subparagraph (A).

(C) RELATIONSHIP TO LAW ENFORCEMENT ACTIVITIES.—The Secretary may determine that medical review under this subsection does not apply in the case where potential fraud may be involved.

(3) NO PAYMENT WITHOUT PRIOR AUTHORIZATION.—With respect to a service described in paragraph (1) for which prior authorization medical review under this subsection applies, the following shall apply:

(A) PRIOR AUTHORIZATION DETERMINATION.—The Secretary shall make a determination, prior to the service

being furnished, of whether the service would or would not meet the applicable requirements of section 1862(a)(1)(A).

(B) DENIAL OF PAYMENT.—Subject to paragraph (5), no payment may be made under this part for the service unless the Secretary determines pursuant to subparagraph (A) that the service would meet the applicable requirements of such section 1862(a)(1)(A).

(4) SUBMISSION OF INFORMATION.—A chiropractor described in section 1861(r)(5) may submit the information necessary for medical review by fax, by mail, or by electronic means. The Secretary shall make available the electronic means described in the preceding sentence as soon as practicable.

(5) TIMELINESS.—If the Secretary does not make a prior authorization determination under paragraph (3)(A) within 14 business days of the date of the receipt of medical documentation needed to make such determination, paragraph (3)(B) shall not apply.

(6) APPLICATION OF LIMITATION ON BENEFICIARY LIABILITY.—Where payment may not be made as a result of the application of paragraph (2)(B), section 1879 shall apply in the same manner as such section applies to a denial that is made by reason of section 1862(a)(1).

(7) REVIEW BY CONTRACTORS.—The medical review described in paragraph (2) may be conducted by medicare administrative contractors pursuant to section 1874A(a)(4)(G) or by any other contractor determined appropriate by the Secretary that is not a recovery audit contractor.

(8) MULTIPLE SERVICES.—The Secretary shall, where practicable, apply the medical review under this subsection in a manner so as to allow an individual described in paragraph (1) to obtain, at a single time rather than on a service-by-service basis, an authorization in accordance with paragraph (3)(A) for multiple services.

(9) CONSTRUCTION.—With respect to a service described in paragraph (1) that has been affirmed by medical review under this subsection, nothing in this subsection shall be construed to preclude the subsequent denial of a claim for such service that does not meet other applicable requirements under this Act.

(10) IMPLEMENTATION.—

(A) AUTHORITY.—The Secretary may implement the provisions of this subsection by interim final rule with comment period.

(B) ADMINISTRATION.—Chapter 35 of title 44, United States Code, shall not apply to medical review under this subsection.

(bb) ADDITIONAL PAYMENTS FOR CERTAIN RURAL HEALTH CLINICS WITH PHYSICIANS OR PRACTITIONERS RECEIVING DATA 2000 WAIVERS.—

(1) IN GENERAL.—In the case of a rural health clinic with respect to which, beginning on or after January 1, 2019, rural health clinic services (as defined in section 1861(aa)(1)) are furnished for the treatment of opioid use disorder by a physician or practitioner who meets the requirements described in paragraph (3), the Secretary shall, subject to availability of funds

under paragraph (4), make a payment (at such time and in such manner as specified by the Secretary) to such rural health clinic after receiving and approving an application described in paragraph (2). Such payment shall be in an amount determined by the Secretary, based on an estimate of the average costs of training for purposes of receiving a waiver described in paragraph (3)(B). Such payment may be made only one time with respect to each such physician or practitioner.

(2) APPLICATION.—In order to receive a payment described in paragraph (1), a rural health clinic shall submit to the Secretary an application for such a payment at such time, in such manner, and containing such information as specified by the Secretary. A rural health clinic may apply for such a payment for each physician or practitioner described in paragraph (1) furnishing services described in such paragraph at such clinic.

(3) REQUIREMENTS.—For purposes of paragraph (1), the requirements described in this paragraph, with respect to a physician or practitioner, are the following:

(A) The physician or practitioner is employed by or working under contract with a rural health clinic described in paragraph (1) that submits an application under paragraph (2).

(B) The physician or practitioner [first receives a waiver under section 303(g) of the Controlled Substances Act on or after January 1, 2019] *first begins prescribing narcotic drugs in schedule III, IV, or V of section 202 of the Controlled Substances Act for the purpose of maintenance or detoxification treatment on or after January 1, 2021.*

(4) FUNDING.—For purposes of making payments under this subsection, there are appropriated, out of amounts in the Treasury not otherwise appropriated, $2,000,000, which shall remain available until expended.

(cc) SPECIFIED COVID–19 TESTING-RELATED SERVICES.—For purposes of subsection (a)(1)(DD):

(1) DESCRIPTION.—

(A) IN GENERAL.—A specified COVID–19 testing-related service described in this paragraph is a medical visit that—

(i) is in any of the categories of HCPCS evaluation and management service codes described in subparagraph (B);

(ii) is furnished during any portion of the emergency period (as defined in section 1135(g)(1)(B)) (beginning on or after the date of enactment of this subsection);

(iii) results in an order for or administration of a clinical diagnostic laboratory test described in section 1852(a)(1)(B)(iv)(IV); and

(iv) relates to the furnishing or administration of such test or to the evaluation of such individual for purposes of determining the need of such individual for such test.

(B) CATEGORIES OF HCPCS CODES.—For purposes of subparagraph (A), the categories of HCPCS evaluation and management services codes are the following:

(i) Office and other outpatient services.

(ii) Hospital observation services.
(iii) Emergency department services.
(iv) Nursing facility services.
(v) Domiciliary, rest home, or custodial care services.
(vi) Home services.
(vii) Online digital evaluation and management services.

(2) SPECIFIED OUTPATIENT PAYMENT PROVISION.—A specified outpatient payment provision described in this paragraph is any of the following:

(A) The hospital outpatient prospective payment system under subsection (t).
(B) The physician fee schedule under section 1848.
(C) The prospective payment system developed under section 1834(o).
(D) Section 1834(g), with respect to an outpatient critical access hospital service.
(E) The payment basis determined in regulations pursuant to section 1833(a)(3) for rural health clinic services.

(dd) SPECIAL COINSURANCE RULE FOR CERTAIN COLORECTAL CANCER SCREENING TESTS.—

(1) IN GENERAL.—In the case of a colorectal cancer screening test to which paragraph (1)(Y) of subsection (a) would not apply but for the third sentence of such subsection that is furnished during a year beginning on or after January 1, 2022, and before January 1, 2030, the amount paid shall be equal to the specified percent (as defined in paragraph (2)) for such year of the lesser of the actual charge for the service or the amount determined under the fee schedule that applies to such test under this part (or, in the case such test is a covered OPD service (as defined in subsection (t)(1)(B)), the amount determined under subsection (t)).

(2) SPECIFIED PERCENT DEFINED.—For purposes of paragraph (1), the term "specified percent" means—

(A) for 2022, 80 percent;
(B) for 2023 through 2026, 85 percent; and
(C) for 2027 through 2029, 90 percent.

SPECIAL PAYMENT RULES FOR PARTICULAR ITEMS AND SERVICES

SEC. 1834. (a) PAYMENT FOR DURABLE MEDICAL EQUIPMENT.—

(1) GENERAL RULE FOR PAYMENT.—

(A) IN GENERAL.—With respect to a covered item (as defined in paragraph (13)) for which payment is determined under this subsection, payment shall be made in the frequency specified in paragraphs (2) through (7) and in an amount equal to 80 percent of the payment basis described in subparagraph (B).

(B) PAYMENT BASIS.—Subject to subparagraph (F)(i), the payment basis described in this subparagraph is the lesser of—

(i) the actual charge for the item, or
(ii) the payment amount recognized under paragraphs (2) through (7) of this subsection for the item;

except that clause (i) shall not apply if the covered item is furnished by a public home health agency (or by another

home health agency which demonstrates to the satisfaction of the Secretary that a significant portion of its patients are low income) free of charge or at nominal charges to the public.

(C) EXCLUSIVE PAYMENT RULE.—Subject to subparagraph (F)(ii), this subsection shall constitute the exclusive provision of this title for payment for covered items under this part or under part A to a home health agency.

(D) REDUCTION IN FEE SCHEDULES FOR CERTAIN ITEMS.—With respect to a seat-lift chair or transcutaneous electrical nerve stimulator furnished on or after April 1, 1990, the Secretary shall reduce the payment amount applied under subparagraph (B)(ii) for such an item by 15 percent, and, in the case of a transcutaneous electrical nerve stimulator furnished on or after January 1, 1991, the Secretary shall further reduce such payment amount (as previously reduced) by 45 percent.

(E) CLINICAL CONDITIONS FOR COVERAGE.—

(i) IN GENERAL.—The Secretary shall establish standards for clinical conditions for payment for covered items under this subsection.

(ii) REQUIREMENTS.—The standards established under clause (i) shall include the specification of types or classes of covered items that require, as a condition of payment under this subsection, a face-to-face examination of the individual by a physician (as defined in section 1861(r)), a physician assistant, nurse practitioner, or a clinical nurse specialist (as those terms are defined in section 1861(aa)(5)) and a prescription for the item.

(iii) PRIORITY OF ESTABLISHMENT OF STANDARDS.—In establishing the standards under this subparagraph, the Secretary shall first establish standards for those covered items for which the Secretary determines there has been a proliferation of use, consistent findings of charges for covered items that are not delivered, or consistent findings of falsification of documentation to provide for payment of such covered items under this part.

(iv) STANDARDS FOR POWER WHEELCHAIRS.—Effective on the date of the enactment of this subparagraph, in the case of a covered item consisting of a motorized or power wheelchair for an individual, payment may not be made for such covered item unless a physician (as defined in section 1861(r)(1)), a physician assistant, nurse practitioner, or a clinical nurse specialist (as those terms are defined in section 1861(aa)(5)) has conducted a face-to-face examination of the individual and written a prescription for the item.

(v) LIMITATION ON PAYMENT FOR COVERED ITEMS.—Payment may not be made for a covered item under this subsection unless the item meets any standards established under this subparagraph for clinical condition of coverage.

(F) APPLICATION OF COMPETITIVE ACQUISITION; LIMITATION OF INHERENT REASONABLENESS AUTHORITY.—In the case of covered items furnished on or after January 1, 2011, subject to subparagraphs (G) and (H), that are included in a competitive acquisition program in a competitive acquisition area under section 1847(a)—

(i) the payment basis under this subsection for such items and services furnished in such area shall be the payment basis determined under such competitive acquisition program;

(ii) the Secretary may (and, in the case of covered items furnished on or after January 1, 2016, subject to clause (iii), shall) use information on the payment determined under such competitive acquisition programs to adjust the payment amount otherwise recognized under subparagraph (B)(ii) for an area that is not a competitive acquisition area under section 1847 and in the case of such adjustment, paragraph (10)(B) shall not be applied; and

(iii) in the case of covered items furnished on or after January 1, 2016, the Secretary shall continue to make such adjustments described in clause (ii) as, under such competitive acquisition programs, additional covered items are phased in or information is updated as contracts under section 1847 are recompeted in accordance with section 1847(b)(3)(B).

(G) USE OF INFORMATION ON COMPETITIVE BID RATES.—The Secretary shall specify by regulation the methodology to be used in applying the provisions of subparagraph (F)(ii) and subsection (h)(1)(H)(ii). In promulgating such regulation, the Secretary shall consider the costs of items and services in areas in which such provisions would be applied compared to the payment rates for such items and services in competitive acquisition areas.In the case of items and services furnished on or after January 1, 2019, in making any adjustments under clause (ii) or (iii) of subparagraph (F), under subsection (h)(1)(H)(ii), or under section 1842(s)(3)(B), the Secretary shall—

(i) solicit and take into account stakeholder input; and

(ii) take into account the highest amount bid by a winning supplier in a competitive acquisition area and a comparison of each of the following with respect to non-competitive acquisition areas and competitive acquisition areas:

(I) The average travel distance and cost associated with furnishing items and services in the area.

(II) The average volume of items and services furnished by suppliers in the area.

(III) The number of suppliers in the area.

(H) DIABETIC SUPPLIES.—

(i) IN GENERAL.—On or after the date described in clause (ii), the payment amount under this part for diabetic supplies, including testing strips, that are non-

mail order items (as defined by the Secretary) shall be equal to the single payment amounts established under the national mail order competition for diabetic supplies under section 1847.

(ii) DATE DESCRIBED.—The date described in this clause is the date of the implementation of the single payment amounts under the national mail order competition for diabetic supplies under section 1847.

(I) TREATMENT OF VACUUM ERECTION SYSTEMS.—Effective for items and services furnished on and after July 1, 2015, vacuum erection systems described as prosthetic devices described in section 1861(s)(8) shall be treated in the same manner as erectile dysfunction drugs are treated for purposes of section 1860D-2(e)(2)(A).

(2) PAYMENT FOR INEXPENSIVE AND OTHER ROUTINELY PURCHASED DURABLE MEDICAL EQUIPMENT.—

(A) IN GENERAL.—Payment for an item of durable medical equipment (as defined in paragraph (13))—

(i) the purchase price of which does not exceed $150,

(ii) which the Secretary determines is acquired at least 75 percent of the time by purchase,

(iii) which is an accessory used in conjunction with a nebulizer, aspirator, or a ventilator excluded under paragraph (3)(A), or

(iv) in the case of devices furnished on or after October 1, 2015, which serves as a speech generating device or which is an accessory that is needed for the individual to effectively utilize such a device,

shall be made on a rental basis or in a lump-sum amount for the purchase of the item. The payment amount recognized for purchase or rental of such equipment is the amount specified in subparagraph (B) for purchase or rental, except that the total amount of payments with respect to an item may not exceed the payment amount specified in subparagraph (B) with respect to the purchase of the item.

(B) PAYMENT AMOUNT.—For purposes of subparagraph (A), the amount specified in this subparagraph, with respect to the purchase or rental of an item furnished in a carrier service area—

(i) in 1989 and in 1990 is the average reasonable charge in the area for the purchase or rental, respectively, of the item for the 12-month period ending on June 30, 1987, increased by the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 6-month period ending with December 1987;

(ii) in 1991 is the sum of (I) 67 percent of the local payment amount for the item or device computed under subparagraph (C)(i)(I) for 1991, and (II) 33 percent of the national limited payment amount for the item or device computed under subparagraph (C)(ii) for 1991;

(iii) in 1992 is the sum of (I) 33 percent of the local payment amount for the item or device computed

under subparagraph (C)(i)(II) for 1992, and (II) 67 percent of the national limited payment amount for the item or device computed under subparagraph (C)(ii) for 1992; and

(iv) in 1993 and each subsequent year is the national limited payment amount for the item or device computed under subparagraph (C)(ii) for that year (reduced by 10 percent, in the case of a blood glucose testing strip furnished after 1997 for an individual with diabetes).

(C) COMPUTATION OF LOCAL PAYMENT AMOUNT AND NATIONAL LIMITED PAYMENT AMOUNT.—For purposes of subparagraph (B)—

(i) the local payment amount for an item or device for a year is equal to—

(I) for 1991, the amount specified in subparagraph (B)(i) for 1990 increased by the covered item update for 1991, and

(II) for 1992, 1993, and 1994 the amount determined under this clause for the preceding year increased by the covered item update for the year; and

(ii) the national limited payment amount for an item or device for a year is equal to—

(I) for 1991, the local payment amount determined under clause (i) for such item or device for that year, except that the national limited payment amount may not exceed 100 percent of the weighted average of all local payment amounts determined under such clause for such item for that year and may not be less than 85 percent of the weighted average of all local payment amounts determined under such clause for such item,

(II) for 1992 and 1993, the amount determined under this clause for the preceding year increased by the covered item update for such subsequent year,

(III) for 1994, the local payment amount determined under clause (i) for such item or device for that year, except that the national limited payment amount may not exceed 100 percent of the median of all local payment amounts determined under such clause for such item for that year and may not be less than 85 percent of the median of all local payment amounts determined under such clause for such item or device for that year, and

(IV) for each subsequent year, the amount determined under this clause for the preceding year increased by the covered item update for such subsequent year.

(3) PAYMENT FOR ITEMS REQUIRING FREQUENT AND SUBSTANTIAL SERVICING.—

(A) IN GENERAL.—Payment for a covered item (such as IPPB machines and ventilators, excluding ventilators that are either continuous airway pressure devices or intermit-

tent assist devices with continuous airway pressure devices) for which there must be frequent and substantial servicing in order to avoid risk to the patient's health shall be made on a monthly basis for the rental of the item and the amount recognized is the amount specified in subparagraph (B).

(B) PAYMENT AMOUNT.—For purposes of subparagraph (A), the amount specified in this subparagraph, with respect to an item or device furnished in a carrier service area—

(i) in 1989 and in 1990 is the average reasonable charge in the area for the rental of the item or device for the 12-month period ending with June 1987, increased by the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 6-month period ending with December 1987;

(ii) in 1991 is the sum of (I) 67 percent of the local payment amount for the item or device computed under subparagraph (C)(i)(I) for 1991, and (II) 33 percent of the national limited payment amount for the item or device computed under subparagraph (C)(ii) for 1991;

(iii) in 1992 is the sum of (I) 33 percent of the local payment amount for the item or device computed under subparagraph (C)(i)(II) for 1992, and (II) 67 percent of the national limited payment amount for the item or device computed under subparagraph (C)(ii) for 1992; and

(iv) in 1993 and each subsequent year is the national limited payment amount for the item or device computed under subparagraph (C)(ii) for that year.

(C) COMPUTATION OF LOCAL PAYMENT AMOUNT AND NATIONAL LIMITED PAYMENT AMOUNT.—For purposes of subparagraph (B)—

(i) the local payment amount for an item or device for a year is equal to—

(I) for 1991, the amount specified in subparagraph (B)(i) for 1990 increased by the covered item update for 1991, and

(II) for 1992, 1993, and 1994 the amount determined under this clause for the preceding year increased by the covered item update for the year; and

(ii) the national limited payment amount for an item or device for a year is equal to—

(I) for 1991, the local payment amount determined under clause (i) for such item or device for that year, except that the national limited payment amount may not exceed 100 percent of the weighted average of all local payment amounts determined under such clause for such item for that year and may not be less than 85 percent of the weighted average of all local payment amounts determined under such clause for such item,

(II) for 1992 and 1993, the amount determined under this clause for the preceding year increased by the covered item update for such subsequent year,

(III) for 1994, the local payment amount determined under clause (i) for such item or device for that year, except that the national limited payment amount may not exceed 100 percent of the median of all local payment amounts determined under such clause for such item for that year and may not be less than 85 percent of the median of all local payment amounts determined under such clause for such item or device for that year, and

(IV) for each subsequent year, the amount determined under this clause for the preceding year increased by the covered item update for such subsequent year.

(4) PAYMENT FOR CERTAIN CUSTOMIZED ITEMS.—Payment with respect to a covered item that is uniquely constructed or substantially modified to meet the specific needs of an individual patient, and for that reason cannot be grouped with similar items for purposes of payment under this title, shall be made in a lump-sum amount (A) for the purchase of the item in a payment amount based upon the carrier's individual consideration for that item, and (B) for the reasonable and necessary maintenance and servicing for parts and labor not covered by the supplier's or manufacturer's warranty, when necessary during the period of medical need, and the amount recognized for such maintenance and servicing shall be paid on a lump-sum, as needed basis based upon the carrier's individual consideration for that item. In the case of a wheelchair furnished on or after January 1, 1992, the wheelchair shall be treated as a customized item for purposes of this paragraph if the wheelchair has been measured, fitted, or adapted in consideration of the patient's body size, disability, period of need, or intended use, and has been assembled by a supplier or ordered from a manufacturer who makes available customized features, modifications, or components for wheelchairs that are intended for an individual patient's use in accordance with instructions from the patient's physician.

(5) PAYMENT FOR OXYGEN AND OXYGEN EQUIPMENT.—

(A) IN GENERAL.—Payment for oxygen and oxygen equipment shall be made on a monthly basis in the monthly payment amount recognized under paragraph (9) for oxygen and oxygen equipment (other than portable oxygen equipment), subject to subparagraphs (B), (C), (E), and (F).

(B) ADD-ON FOR PORTABLE OXYGEN EQUIPMENT.—When portable oxygen equipment is used, but subject to subparagraph (D), the payment amount recognized under subparagraph (A) shall be increased by the monthly payment amount recognized under paragraph (9) for portable oxygen equipment.

(C) VOLUME ADJUSTMENT.—When the attending physician prescribes an oxygen flow rate—

(i) exceeding 4 liters per minute, the payment amount recognized under subparagraph (A), subject to subparagraph (D), shall be increased by 50 percent, or

(ii) of less than 1 liter per minute, the payment amount recognized under subparagraph (A) shall be decreased by 50 percent.

(D) LIMIT ON ADJUSTMENT.—When portable oxygen equipment is used and the attending physician prescribes an oxygen flow rate exceeding 4 liters per minute, there shall only be an increase under either subparagraph (B) or (C), whichever increase is larger, and not under both such subparagraphs.

(E) RECERTIFICATION FOR PATIENTS RECEIVING HOME OXYGEN THERAPY.—In the case of a patient receiving home oxygen therapy services who, at the time such services are initiated, has an initial arterial blood gas value at or above a partial pressure of 56 or an arterial oxygen saturation at or above 89 percent (or such other values, pressures, or criteria as the Secretary may specify) no payment may be made under this part for such services after the expiration of the 90-day period that begins on the date the patient first receives such services unless the patient's attending physician certifies that, on the basis of a follow-up test of the patient's arterial blood gas value or arterial oxygen saturation conducted during the final 30 days of such 90-day period, there is a medical need for the patient to continue to receive such services.

(F) RENTAL CAP.—

(i) IN GENERAL.—Payment for oxygen equipment (including portable oxygen equipment) under this paragraph may not extend over a period of continuous use (as determined by the Secretary) of longer than 36 months.

(ii) PAYMENTS AND RULES AFTER RENTAL CAP.—After the 36th continuous month during which payment is made for the equipment under this paragraph—

(I) the supplier furnishing such equipment under this subsection shall continue to furnish the equipment during any period of medical need for the remainder of the reasonable useful lifetime of the equipment, as determined by the Secretary;

(II) payments for oxygen shall continue to be made in the amount recognized for oxygen under paragraph (9) for the period of medical need; and

(III) maintenance and servicing payments shall, if the Secretary determines such payments are reasonable and necessary, be made (for parts and labor not covered by the supplier's or manufacturer's warranty, as determined by the Secretary to be appropriate for the equipment), and such payments shall be in an amount determined to be appropriate by the Secretary.

(6) PAYMENT FOR OTHER COVERED ITEMS (OTHER THAN DURABLE MEDICAL EQUIPMENT).—Payment for other covered items (other than durable medical equipment and other covered

items described in paragraph (3), (4), or (5)) shall be made in a lump-sum amount for the purchase of the item in the amount of the purchase price recognized under paragraph (8).

(7) PAYMENT FOR OTHER ITEMS OF DURABLE MEDICAL EQUIPMENT.—

(A) PAYMENT.—In the case of an item of durable medical equipment not described in paragraphs (2) through (6), the following rules shall apply:

(i) RENTAL.—

(I) IN GENERAL.—Except as provided in clause (iii), payment for the item shall be made on a monthly basis for the rental of the item during the period of medical need (but payments under this clause may not extend over a period of continuous use (as determined by the Secretary) of longer than 13 months).

(II) PAYMENT AMOUNT.—Subject to subclause (III) and subparagraph (B), the amount recognized for the item, for each of the first 3 months of such period, is 10 percent of the purchase price recognized under paragraph (8) with respect to the item, and, for each of the remaining months of such period, is 7.5 percent of such purchase price.

(III) SPECIAL RULE FOR POWER-DRIVEN WHEELCHAIRS.—For purposes of payment for power-driven wheelchairs, subclause (II) shall be applied by substituting "15 percent" and "6 percent" for "10 percent" and "7.5 percent", respectively.

(ii) OWNERSHIP AFTER RENTAL.—On the first day that begins after the 13th continuous month during which payment is made for the rental of an item under clause (i), the supplier of the item shall transfer title to the item to the individual.

(iii) PURCHASE AGREEMENT OPTION FOR COMPLEX, REHABILITATIVE POWER-DRIVEN WHEELCHAIRS.—In the case of a complex, rehabilitative power-driven wheelchair, at the time the supplier furnishes the item, the supplier shall offer the individual the option to purchase the item, and payment for such item shall be made on a lump-sum basis if the individual exercises such option.

(iv) MAINTENANCE AND SERVICING.—After the supplier transfers title to the item under clause (ii) or in the case of a power-driven wheelchair for which a purchase agreement has been entered into under clause (iii), maintenance and servicing payments shall, if the Secretary determines such payments are reasonable and necessary, be made (for parts and labor not covered by the supplier's or manufacturer's warranty, as determined by the Secretary to be appropriate for the particular type of durable medical equipment), and such payments shall be in an amount determined to be appropriate by the Secretary.

(B) RANGE FOR RENTAL AMOUNTS.—

(i) FOR 1989.—For items furnished during 1989, the payment amount recognized under subparagraph (A)(i) shall not be more than 115 percent, and shall not be less than 85 percent, of the prevailing charge established for rental of the item in January 1987, increased by the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 6-month period ending with December 1987.

(ii) FOR 1990.—For items furnished during 1990, clause (i) shall apply in the same manner as it applies to items furnished during 1989.

(C) REPLACEMENT OF ITEMS.—

(i) ESTABLISHMENT OF REASONABLE USEFUL LIFETIME.—In accordance with clause (iii), the Secretary shall determine and establish a reasonable useful lifetime for items of durable medical equipment for which payment may be made under this paragraph.

(ii) PAYMENT FOR REPLACEMENT ITEMS.—If the reasonable lifetime of such an item, as so established, has been reached during a continuous period of medical need, or the carrier determines that the item is lost or irreparably damaged, the patient may elect to have payment for an item serving as a replacement for such item made—

(I) on a monthly basis for the rental of the replacement item in accordance with subparagraph (A); or

(II) in the case of an item for which a purchase agreement has been entered into under subparagraph (A)(iii), in a lump-sum amount for the purchase of the item.

(iii) LENGTH OF REASONABLE USEFUL LIFETIME.—The reasonable useful lifetime of an item of durable medical equipment under this subparagraph shall be equal to 5 years, except that, if the Secretary determines that, on the basis of prior experience in making payments for such an item under this title, a reasonable useful lifetime of 5 years is not appropriate with respect to a particular item, the Secretary shall establish an alternative reasonable lifetime for such item.

(8) PURCHASE PRICE RECOGNIZED FOR MISCELLANEOUS DEVICES AND ITEMS.—For purposes of paragraphs (6) and (7), the amount that is recognized under this paragraph as the purchase price for a covered item is the amount described in subparagraph (C) of this paragraph, determined as follows:

(A) COMPUTATION OF LOCAL PURCHASE PRICE.—Each carrier under section 1842 shall compute a base local purchase price for the item as follows:

(i) The carrier shall compute a base local purchase price, for each item described—

(I) in paragraph (6) equal to the average reasonable charge in the locality for the purchase of the item for the 12-month period ending with June 1987, or

(II) in paragraph (7) equal to the average of the purchase prices on the claims submitted on an assignment-related basis for the unused item supplied during the 6-month period ending with December 1986.

(ii) The carrier shall compute a local purchase price, with respect to the furnishing of each particular item—

(I) in 1989 and 1990, equal to the base local purchase price computed under clause (i) increased by the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 6-month period ending with December 1987,

(II) in 1991, equal to the local purchase price computed under this clause for the previous year, increased by the covered item update for 1991, and decreased by the percentage by which the average of the reasonable charges for claims paid for all items described in paragraph (7) is lower than the average of the purchase prices submitted for such items during the final 9 months of 1988; or

(III) in 1992, 1993, and 1994 equal to the local purchase price computed under this clause for the previous year increased by the covered item update for the year.

(B) COMPUTATION OF NATIONAL LIMITED PURCHASE PRICE.—With respect to the furnishing of a particular item in a year, the Secretary shall compute a national limited purchase price—

(i) for 1991, equal to the local purchase price computed under subparagraph (A)(ii) for the item for the year, except that such national limited purchase price may not exceed 100 percent of the weighted average of all local purchase prices for the item computed under such subparagraph for the year, and may not be less than 85 percent of the weighted average of all local purchase prices for the item computed under such subparagraph for the year;

(ii) for 1992 and 1993, the amount determined under this subparagraph for the preceding year increased by the covered item update for such subsequent year;

(iii) for 1994, the local purchase price computed under subparagraph (A)(ii) for the item for the year, except that such national limited purchase price may not exceed 100 percent of the median of all local purchase prices computed for the item under such subparagraph for the year and may not be less than 85 percent of the median of all local purchase prices computed under such subparagraph for the item for the year; and

(iv) for each subsequent year, equal to the amount determined under this subparagraph for the preceding year increased by the covered item update for such subsequent year.

(C) PURCHASE PRICE RECOGNIZED.—For purposes of paragraphs (6) and (7), the amount that is recognized under this paragraph as the purchase price for each item furnished—

(i) in 1989 or 1990, is 100 percent of the local purchase price computed under subparagraph (A)(ii)(I);

(ii) in 1991, is the sum of (I) 67 percent of the local purchase price computed under subparagraph (A)(ii)(II) for 1991, and (II) 33 percent of the national limited purchase price computed under subparagraph (B) for 1991;

(iii) in 1992, is the sum of (I) 33 percent of the local purchase price computed under subparagraph (A)(ii)(III) for 1992, and (II) 67 percent of the national limited purchase price computed under subparagraph (B) for 1992; and

(iv) in 1993 or a subsequent year, is the national limited purchase price computed under subparagraph (B) for that year.

(9) MONTHLY PAYMENT AMOUNT RECOGNIZED WITH RESPECT TO OXYGEN AND OXYGEN EQUIPMENT.—For purposes of paragraph (5), the amount that is recognized under this paragraph for payment for oxygen and oxygen equipment is the monthly payment amount described in subparagraph (C) of this paragraph. Such amount shall be computed separately (i) for all items of oxygen and oxygen equipment (other than portable oxygen equipment) and (ii) for portable oxygen equipment (each such group referred to in this paragraph as an "item").

(A) COMPUTATION OF LOCAL MONTHLY PAYMENT RATE.—Each carrier under this section shall compute a base local payment rate for each item as follows:

(i) The carrier shall compute a base local average monthly payment rate per beneficiary as an amount equal to (I) the total reasonable charges for the item during the 12-month period ending with December 1986, divided by (II) the total number of months for all beneficiaries receiving the item in the area during the 12-month period for which the carrier made payment for the item under this title.

(ii) The carrier shall compute a local average monthly payment rate for the item applicable—

(I) to 1989 and 1990, equal to 95 percent of the base local average monthly payment rate computed under clause (i) for the item increased by the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 6-month period ending with December 1987, or

(II) to 1991, 1992, 1993, and 1994 equal to the local average monthly payment rate computed under this clause for the item for the previous year increased by the covered item increase for the year.

(B) COMPUTATION OF NATIONAL LIMITED MONTHLY PAYMENT RATE.—With respect to the furnishing of an item in

a year, the Secretary shall compute a national limited monthly payment rate equal to—

(i) for 1991, the local monthly payment rate computed under subparagraph (A)(ii)(II) for the item for the year, except that such national limited monthly payment rate may not exceed 100 percent of the weighted average of all local monthly payment rates computed for the item under such subparagraph for the year, and may not be less than 85 percent of the weighted average of all local monthly payment rates computed for the item under such subparagraph for the year;

(ii) for 1992 and 1993, the amount determined under this subparagraph for the preceding year increased by the covered item update for such subsequent year;

(iii) for 1994, the local monthly payment rate computed under subparagraph (A)(ii) for the item for the year, except that such national limited monthly payment rate may not exceed 100 percent of the median of all local monthly payment rates computed for the item under such subparagraph for the year and may not be less than 85 percent of the median of all local monthly payment rates computed for the item under such subparagraph for the year;

(iv) for 1995, 1996, and 1997, equal to the amount determined under this subparagraph for the preceding year increased by the covered item update for such subsequent year;

(v) for 1998, 75 percent of the amount determined under this subparagraph for 1997; and

(vi) for 1999 and each subsequent year, 70 percent of the amount determined under this subparagraph for 1997.

(C) MONTHLY PAYMENT AMOUNT RECOGNIZED.—For purposes of paragraph (5), the amount that is recognized under this paragraph as the base monthly payment amount for each item furnished—

(i) in 1989 and in 1990, is 100 percent of the local average monthly payment rate computed under subparagraph (A)(ii) for the item;

(ii) in 1991, is the sum of (I) 67 percent of the local average monthly payment rate computed under subparagraph (A)(ii)(II) for the item for 1991, and (II) 33 percent of the national limited monthly payment rate computed under subparagraph (B)(i) for the item for 1991;

(iii) in 1992, is the sum of (I) 33 percent of the local average monthly payment rate computed under subparagraph (A)(ii)(II) for the item for 1992, and (II) 67 percent of the national limited monthly payment rate computed under subparagraph (B)(ii) for the item for 1992; and

(iv) in a subsequent year, is the national limited monthly payment rate computed under subparagraph (B) for the item for that year.

(D) AUTHORITY TO CREATE CLASSES.—

(i) IN GENERAL.—Subject to clause (ii), the Secretary may establish separate classes for any item of oxygen and oxygen equipment and separate national limited monthly payment rates for each of such classes.

(ii) BUDGET NEUTRALITY.—The Secretary may take actions under clause (i) only to the extent such actions do not result in expenditures for any year to be more or less than the expenditures which would have been made if such actions had not been taken. The requirement of the preceding sentence shall not apply beginning with the second calendar quarter beginning on or after the date of the enactment of this sentence.

(10) EXCEPTIONS AND ADJUSTMENTS.—

(A) AREAS OUTSIDE CONTINENTAL UNITED STATES.—Exceptions to the amounts recognized under the previous provisions of this subsection shall be made to take into account the unique circumstances of covered items furnished in Alaska, Hawaii, or Puerto Rico.

(B) ADJUSTMENT FOR INHERENT REASONABLENESS.—The Secretary is authorized to apply the provisions of paragraphs (8) and (9) of section 1842(b) to covered items and suppliers of such items and payments under this subsection in an area and with respect to covered items and services for which the Secretary does not make a payment amount adjustment under paragraph (1)(F).

(C) TRANSCUTANEOUS ELECTRICAL NERVE STIMULATOR (TENS).—In order to permit an attending physician time to determine whether the purchase of a transcutaneous electrical nerve stimulator is medically appropriate for a particular patient, the Secretary may determine an appropriate payment amount for the initial rental of such item for a period of not more than 2 months. If such item is subsequently purchased, the payment amount with respect to such purchase is the payment amount determined under paragraph (2).

(11) IMPROPER BILLING AND REQUIREMENT OF PHYSICIAN ORDER.—

(A) IMPROPER BILLING FOR CERTAIN RENTAL ITEMS.—Notwithstanding any other provision of this title, a supplier of a covered item for which payment is made under this subsection and which is furnished on a rental basis shall continue to supply the item without charge (other than a charge provided under this subsection for the maintenance and servicing of the item) after rental payments may no longer be made under this subsection. If a supplier knowingly and willfully violates the previous sentence, the Secretary may apply sanctions against the supplier under section 1842(j)(2) in the same manner such sanctions may apply with respect to a physician.

(B) REQUIREMENT OF PHYSICIAN ORDER.—

(i) IN GENERAL.—The Secretary is authorized to require, for specified covered items, that payment may be made under this subsection with respect to the item only if a physician enrolled under section 1866(j) or an

eligible professional under section 1848(k)(3)(B) that is enrolled under section 1866(j) has communicated to the supplier, before delivery of the item, a written order for the item.

(ii) REQUIREMENT FOR FACE TO FACE ENCOUNTER.—The Secretary shall require that such an order be written pursuant to a physician, a physician assistant, a nurse practitioner, or a clinical nurse specialist (as those terms are defined in section 1861(aa)(5)) documenting such physician, physician assistant, practitioner, or specialist has had a face-to-face encounter (including through use of telehealth under subsection (m) and other than with respect to encounters that are incident to services involved) with the individual involved during the 6-month period preceding such written order, or other reasonable timeframe as determined by the Secretary.

(12) REGIONAL CARRIERS.—The Secretary may designate, by regulation under section 1842, one carrier for one or more entire regions to process all claims within the region for covered items under this section.

(13) COVERED ITEM.—In this subsection, the term "covered item" means durable medical equipment (as defined in section 1861(n)), including such equipment described in section 1861(m)(5), but not including implantable items for which payment may be made under section 1833(t).

(14) COVERED ITEM UPDATE.—In this subsection, the term "covered item update" means, with respect to a year—

(A) for 1991 and 1992, the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 12-month period ending with June of the previous year reduced by 1 percentage point;

(B) for 1993, 1994, 1995, 1996, and 1997, the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 12-month period ending with June of the previous year;

(C) for each of the years 1998 through 2000, 0 percentage points;

(D) for 2001, the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 12-month period ending with June 2000;

(E) for 2002, 0 percentage points;

(F) for 2003, the percentage increase in the consumer price index for all urban consumers (U.S. urban average) for the 12-month period ending with June of 2002;

(G) for 2004 through 2006—

(i) subject to clause (ii), in the case of class III medical devices described in section 513(a)(1)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(c)(1)(C)), the percentage increase described in subparagraph (B) for the year involved; and

(ii) in the case of covered items not described in clause (i), 0 percentage points;

(H) for 2007—

(i) subject to clause (ii), in the case of class III medical devices described in section 513(a)(1)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(c)(1)(C)), the percentage change determined by the Secretary to be appropriate taking into account recommendations contained in the report of the Comptroller General of the United States under section 302(c)(1)(B) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003; and

(ii) in the case of covered items not described in clause (i), 0 percentage points;

(I) for 2008—

(i) subject to clause (ii), in the case of class III medical devices described in section 513(a)(1)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(c)(1)(C)), the percentage increase described in subparagraph (B) (as applied to the payment amount for 2007 determined after the application of the percentage change under subparagraph (H)(i)); and

(ii) in the case of covered items not described in clause (i), 0 percentage points;

(J) for 2009—

(i) in the case of items and services furnished in any geographic area, if such items or services were selected for competitive acquisition in any area under the competitive acquisition program under section 1847(a)(1)(B)(i)(I) before July 1, 2008, including related accessories but only if furnished with such items and services selected for such competition and diabetic supplies but only if furnished through mail order, - 9.5 percent; or

(ii) in the case of other items and services, the percentage increase in the consumer price index for all urban consumers (U.S. urban average) for the 12-month period ending with June 2008;

(K) for 2010, the percentage increase in the consumer price index for all urban consumers (U.S. urban average) for the 12-month period ending with June of the previous year; and

(L) for 2011 and each subsequent year—

(i) the percentage increase in the consumer price index for all urban consumers (United States city average) for the 12-month period ending with June of the previous year, reduced by—

(ii) the productivity adjustment described in section 1886(b)(3)(B)(xi)(II).

The application of subparagraph (L)(ii) may result in the covered item update under this paragraph being less than 0.0 for a year, and may result in payment rates under this subsection for a year being less than such payment rates for the preceding year.

(15) ADVANCE DETERMINATIONS OF COVERAGE FOR CERTAIN ITEMS.—

(A) DEVELOPMENT OF LISTS OF ITEMS BY SECRETARY.—The Secretary may develop and periodically update a list

of items for which payment may be made under this subsection that the Secretary determines, on the basis of prior payment experience, are frequently subject to unnecessary utilization throughout a carrier's entire service area or a portion of such area.

(B) DEVELOPMENT OF LISTS OF SUPPLIERS BY SECRETARY.—The Secretary may develop and periodically update a list of suppliers of items for which payment may be made under this subsection with respect to whom—

(i) the Secretary has found that a substantial number of claims for payment under this part for items furnished by the supplier have been denied on the basis of the application of section 1862(a)(1); or

(ii) the Secretary has identified a pattern of overutilization resulting from the business practice of the supplier.

(C) DETERMINATIONS OF COVERAGE IN ADVANCE.—A carrier shall determine in advance of delivery of an item whether payment for the item may not be made because the item is not covered or because of the application of section 1862(a)(1) if—

(i) the item is included on the list developed by the Secretary under subparagraph (A);

(ii) the item is furnished by a supplier included on the list developed by the Secretary under subparagraph (B); or

(iii) the item is a customized item (other than inexpensive items specified by the Secretary) and the patient to whom the item is to be furnished or the supplier requests that such advance determination be made.

(16) DISCLOSURE OF INFORMATION AND SURETY BOND.—The Secretary shall not provide for the issuance (or renewal) of a provider number for a supplier of durable medical equipment, for purposes of payment under this part for durable medical equipment furnished by the supplier, unless the supplier provides the Secretary on a continuing basis—

(A) with—

(i) full and complete information as to the identity of each person with an ownership or control interest (as defined in section 1124(a)(3)) in the supplier or in any subcontractor (as defined by the Secretary in regulations) in which the supplier directly or indirectly has a 5 percent or more ownership interest; and

(ii) to the extent determined to be feasible under regulations of the Secretary, the name of any disclosing entity (as defined in section 1124(a)(2)) with respect to which a person with such an ownership or control interest in the supplier is a person with such an ownership or control interest in the disclosing entity; and

(B) with a surety bond in a form specified by the Secretary and in an amount that is not less than $50,000 that the Secretary determines is commensurate with the volume of the billing of the supplier.

The Secretary may waive the requirement of a bond under subparagraph (B) in the case of a supplier that provides a comparable surety bond under State law. The Secretary, at the Secretary's discretion, may impose the requirements of the first sentence with respect to some or all providers of items or services under part A or some or all suppliers or other persons (other than physicians or other practitioners, as defined in section 1842(b)(18)(C)) who furnish items or services under this part.

(17) PROHIBITION AGAINST UNSOLICITED TELEPHONE CONTACTS BY SUPPLIERS.—

(A) IN GENERAL.—A supplier of a covered item under this subsection may not contact an individual enrolled under this part by telephone regarding the furnishing of a covered item to the individual unless 1 of the following applies:

(i) The individual has given written permission to the supplier to make contact by telephone regarding the furnishing of a covered item.

(ii) The supplier has furnished a covered item to the individual and the supplier is contacting the individual only regarding the furnishing of such covered item.

(iii) If the contact is regarding the furnishing of a covered item other than a covered item already furnished to the individual, the supplier has furnished at least 1 covered item to the individual during the 15-month period preceding the date on which the supplier makes such contact.

(B) PROHIBITING PAYMENT FOR ITEMS FURNISHED SUBSEQUENT TO UNSOLICITED CONTACTS.—If a supplier knowingly contacts an individual in violation of subparagraph (A), no payment may be made under this part for any item subsequently furnished to the individual by the supplier.

(C) EXCLUSION FROM PROGRAM FOR SUPPLIERS ENGAGING IN PATTERN OF UNSOLICITED CONTACTS.—If a supplier knowingly contacts individuals in violation of subparagraph (A) to such an extent that the supplier's conduct establishes a pattern of contacts in violation of such subparagraph, the Secretary shall exclude the supplier from participation in the programs under this Act, in accordance with the procedures set forth in subsections (c), (f), and (g) of section 1128.

(18) REFUND OF AMOUNTS COLLECTED FOR CERTAIN DISALLOWED ITEMS.—

(A) IN GENERAL.—If a nonparticipating supplier furnishes to an individual enrolled under this part a covered item for which no payment may be made under this part by reason of paragraph (17)(B), the supplier shall refund on a timely basis to the patient (and shall be liable to the patient for) any amounts collected from the patient for the item, unless—

(i) the supplier establishes that the supplier did not know and could not reasonably have been expected to

know that payment may not be made for the item by reason of paragraph (17)(B), or

(ii) before the item was furnished, the patient was informed that payment under this part may not be made for that item and the patient has agreed to pay for that item.

(B) SANCTIONS.—If a supplier knowingly and willfully fails to make refunds in violation of subparagraph (A), the Secretary may apply sanctions against the supplier in accordance with section 1842(j)(2).

(C) NOTICE.—Each carrier with a contract in effect under this part with respect to suppliers of covered items shall send any notice of denial of payment for covered items by reason of paragraph (17)(B) and for which payment is not requested on an assignment-related basis to the supplier and the patient involved.

(D) TIMELY BASIS DEFINED.—A refund under subparagraph (A) is considered to be on a timely basis only if—

(i) in the case of a supplier who does not request reconsideration or seek appeal on a timely basis, the refund is made within 30 days after the date the supplier receives a denial notice under subparagraph (C), or

(ii) in the case in which such a reconsideration or appeal is taken, the refund is made within 15 days after the date the supplier receives notice of an adverse determination on reconsideration or appeal.

(19) CERTAIN UPGRADED ITEMS.—

(A) INDIVIDUAL'S RIGHT TO CHOOSE UPGRADED ITEM.—Notwithstanding any other provision of this title, the Secretary may issue regulations under which an individual may purchase or rent from a supplier an item of upgraded durable medical equipment for which payment would be made under this subsection if the item were a standard item.

(B) PAYMENTS TO SUPPLIER.—In the case of the purchase or rental of an upgraded item under subparagraph (A)—

(i) the supplier shall receive payment under this subsection with respect to such item as if such item were a standard item; and

(ii) the individual purchasing or renting the item shall pay the supplier an amount equal to the difference between the supplier's charge and the amount under clause (i).

In no event may the supplier's charge for an upgraded item exceed the applicable fee schedule amount (if any) for such item.

(C) CONSUMER PROTECTION SAFEGUARDS.—Any regulations under subparagraph (A) shall provide for consumer protection standards with respect to the furnishing of upgraded equipment under subparagraph (A). Such regulations shall provide for—

(i) determination of fair market prices with respect to an upgraded item;

(ii) full disclosure of the availability and price of standard items and proof of receipt of such disclosure information by the beneficiary before the furnishing of the upgraded item;

(iii) conditions of participation for suppliers in the billing arrangement;

(iv) sanctions of suppliers who are determined to engage in coercive or abusive practices, including exclusion; and

(v) such other safeguards as the Secretary determines are necessary.

(20) IDENTIFICATION OF QUALITY STANDARDS.—

(A) IN GENERAL.—Subject to subparagraph (C), the Secretary shall establish and implement quality standards for suppliers of items and services described in subparagraph (D) to be applied by recognized independent accreditation organizations (as designated under subparagraph (B)) and with which such suppliers shall be required to comply in order to—

(i) furnish any such item or service for which payment is made under this part; and

(ii) receive or retain a provider or supplier number used to submit claims for reimbursement for any such item or service for which payment may be made under this title.

(B) DESIGNATION OF INDEPENDENT ACCREDITATION ORGANIZATIONS.—Not later than the date that is 1 year after the date on which the Secretary implements the quality standards under subparagraph (A), notwithstanding section 1865(a), the Secretary shall designate and approve one or more independent accreditation organizations for purposes of such subparagraph.

(C) QUALITY STANDARDS.—The quality standards described in subparagraph (A) may not be less stringent than the quality standards that would otherwise apply if this paragraph did not apply and shall include consumer services standards.

(D) ITEMS AND SERVICES DESCRIBED.—The items and services described in this subparagraph are the following items and services, as the Secretary determines appropriate:

(i) Covered items (as defined in paragraph (13)) for which payment may otherwise be made under this subsection.

(ii) Prosthetic devices and orthotics and prosthetics described in section 1834(h)(4).

(iii) Items and services described in section 1842(s)(2).

(E) IMPLEMENTATION.—The Secretary may establish by program instruction or otherwise the quality standards under this paragraph, including subparagraph (F), after consultation with representatives of relevant parties. Such standards shall be applied prospectively and shall be published on the Internet website of the Centers for Medicare & Medicaid Services.

(F) APPLICATION OF ACCREDITATION REQUIREMENT.—In implementing quality standards under this paragraph—

(i) subject to clause (ii) and subparagraph (G), the Secretary shall require suppliers furnishing items and services described in subparagraph (D) on or after October 1, 2009, directly or as a subcontractor for another entity, to have submitted to the Secretary evidence of accreditation by an accreditation organization designated under subparagraph (B) as meeting applicable quality standards, except that the Secretary shall not require under this clause pharmacies to obtain such accreditation before January 1, 2010, except that the Secretary shall not require a pharmacy to have submitted to the Secretary such evidence of accreditation prior to January 1, 2011; and

(ii) in applying such standards and the accreditation requirement of clause (i) with respect to eligible professionals (as defined in section 1848(k)(3)(B)), and including such other persons, such as orthotists and prosthetists, as specified by the Secretary, furnishing such items and services—

(I) such standards and accreditation requirement shall not apply to such professionals and persons unless the Secretary determines that the standards being applied are designed specifically to be applied to such professionals and persons; and

(II) the Secretary may exempt such professionals and persons from such standards and requirement if the Secretary determines that licensing, accreditation, or other mandatory quality requirements apply to such professionals and persons with respect to the furnishing of such items and services.

(G) APPLICATION OF ACCREDITATION REQUIREMENT TO CERTAIN PHARMACIES.—

(i) IN GENERAL.—With respect to items and services furnished on or after January 1, 2011, in implementing quality standards under this paragraph—

(I) subject to subclause (II), in applying such standards and the accreditation requirement of subparagraph (F)(i) with respect to pharmacies described in clause (ii) furnishing such items and services, such standards and accreditation requirement shall not apply to such pharmacies; and

(II) the Secretary may apply to such pharmacies an alternative accreditation requirement established by the Secretary if the Secretary determines such alternative accreditation requirement is more appropriate for such pharmacies.

(ii) PHARMACIES DESCRIBED.—A pharmacy described in this clause is a pharmacy that meets each of the following criteria:

(I) The total billings by the pharmacy for such items and services under this title are less than 5 percent of total pharmacy sales, as determined based on the average total pharmacy sales for the previous 3 calendar years, 3 fiscal years, or other yearly period specified by the Secretary.

(II) The pharmacy has been enrolled under section 1866(j) as a supplier of durable medical equipment, prosthetics, orthotics, and supplies, has been issued (which may include the renewal of) a provider number for at least 5 years, and for which a final adverse action (as defined in section 424.57(a) of title 42, Code of Federal Regulations) has not been imposed in the past 5 years.

(III) The pharmacy submits to the Secretary an attestation, in a form and manner, and at a time, specified by the Secretary, that the pharmacy meets the criteria described in subclauses (I) and (II). Such attestation shall be subject to section 1001 of title 18, United States Code.

(IV) The pharmacy agrees to submit materials as requested by the Secretary, or during the course of an audit conducted on a random sample of pharmacies selected annually, to verify that the pharmacy meets the criteria described in subclauses (I) and (II). Materials submitted under the preceding sentence shall include a certification by an accountant on behalf of the pharmacy or the submission of tax returns filed by the pharmacy during the relevant periods, as requested by the Secretary.

(21) SPECIAL PAYMENT RULE FOR SPECIFIED ITEMS AND SUPPLIES.—

(A) IN GENERAL.—Notwithstanding the preceding provisions of this subsection, for specified items and supplies (described in subparagraph (B)) furnished during 2005, the payment amount otherwise determined under this subsection for such specified items and supplies shall be reduced by the percentage difference between—

(i) the amount of payment otherwise determined for the specified item or supply under this subsection for 2002, and

(ii) the amount of payment for the specified item or supply under chapter 89 of title 5, United States Code, as identified in the column entitled "Median FEHP Price" in the table entitled "SUMMARY OF MEDICARE PRICES COMPARED TO VA, MEDICAID, RETAIL, AND FEHP PRICES FOR 16 ITEMS" included in the Testimony of the Inspector General before the Senate Committee on Appropriations, June 12, 2002, or any subsequent report by the Inspector General.

(B) SPECIFIED ITEM OR SUPPLY DESCRIBED.—For purposes of subparagraph (A), a specified item or supply means oxygen and oxygen equipment, standard wheelchairs (including standard power wheelchairs), nebulizers, diabetic sup-

plies consisting of lancets and testing strips, hospital beds, and air mattresses, but only if the HCPCS code for the item or supply is identified in a table referred to in subparagraph (A)(ii).

(C) APPLICATION OF UPDATE TO SPECIAL PAYMENT AMOUNT.—The covered item update under paragraph (14) for specified items and supplies for 2006 and each subsequent year shall be applied to the payment amount under subparagraph (A) unless payment is made for such items and supplies under section 1847.

(22) SPECIAL PAYMENT RULE FOR DIABETIC SUPPLIES.—Notwithstanding the preceding provisions of this subsection, for purposes of determining the payment amount under this subsection for diabetic supplies furnished on or after the first day of the calendar quarter during 2013 that is at least 30 days after the date of the enactment of this paragraph and before the date described in paragraph (1)(H)(ii), the Secretary shall recalculate and apply the covered item update under paragraph (14) as if subparagraph (J)(i) of such paragraph was amended by striking "but only if furnished through mail order".

(b) FEE SCHEDULES FOR RADIOLOGIST SERVICES.—

(1) DEVELOPMENT.—The Secretary shall develop—

(A) a relative value scale to serve as the basis for the payment for radiologist services under this part, and

(B) using such scale and appropriate conversion factors and subject to subsection (c)(1)(A), fee schedules (on a regional, statewide, locality, or carrier service area basis) for payment for radiologist services under this part, to be implemented for such services furnished during 1989.

(2) CONSULTATION.—In carrying out paragraph (1), the Secretary shall regularly consult closely with the Physician Payment Review Commission, the American College of Radiology, and other organizations representing physicians or suppliers who furnish radiologist services and shall share with them the data and data analysis being used to make the determinations under paragraph (1), including data on variations in current medicare payments by geographic area, and by service and physician specialty.

(3) CONSIDERATIONS.—In developing the relative value scale and fee schedules under paragraph (1), the Secretary—

(A) shall take into consideration variations in the cost of furnishing such services among geographic areas and among different sites where services are furnished, and

(B) may also take into consideration such other factors respecting the manner in which physicians in different specialties furnish such services as may be appropriate to assure that payment amounts are equitable and designed to promote effective and efficient provision of radiologist services by physicians in the different specialties.

(4) SAVINGS.—

(A) BUDGET NEUTRAL FEE SCHEDULES.—The Secretary shall develop preliminary fee schedules for 1989, which are designed to result in the same amount of aggregate payments (net of any coinsurance and deductibles under sec-

tions 1833(a)(1)(J) and 1833(b)) for radiologist services furnished in 1989 as would have been made if this subsection had not been enacted.

(B) INITIAL SAVINGS.—The fee schedules established for payment purposes under this subsection for services furnished in 1989 shall be 97 percent of the amounts permitted under these preliminary fee schedules developed under subparagraph (A).

(C) 1990 FEE SCHEDULES.—For radiologist services (other than portable X-ray services) furnished under this part during 1990, after March 31 of such year, the conversion factors used under this subsection shall be 96 percent of the conversion factors that applied under this subsection as of December 31, 1989.

(D) 1991 FEE SCHEDULES.—For radiologist services (other than portable X-ray services) furnished under this part during 1991, the conversion factors used in a locality under this subsection shall, subject to clause (vii), be reduced to the adjusted conversion factor for the locality determined as follows:

(i) NATIONAL WEIGHTED AVERAGE CONVERSION FACTOR.—The Secretary shall estimate the national weighted average of the conversion factors used under this subsection for services furnished during 1990 beginning on April 1, using the best available data.

(ii) REDUCED NATIONAL WEIGHTED AVERAGE.—The national weighted average estimated under clause (i) shall be reduced by 13 percent.

(iii) COMPUTATION OF 1990 LOCALITY INDEX RELATIVE TO NATIONAL AVERAGE.—The Secretary shall establish an index which reflects, for each locality, the ratio of the conversion factor used in the locality under this subsection to the national weighted average estimated under clause (i).

(iv) ADJUSTED CONVERSION FACTOR.—The adjusted conversion factor for the professional or technical component of a service in a locality is the sum of ½ of the locally-adjusted amount determined under clause (v) and ½ of the GPCI-adjusted amount determined under clause (vi).

(v) LOCALLY-ADJUSTED AMOUNT.—For purposes of clause (iv), the locally adjusted amount determined under this clause is the product of (I) the national weighted average conversion factor computed under clause (ii), and (II) the index value established under clause (iii) for the locality.

(vi) GPCI-ADJUSTED AMOUNT.—For purposes of clause (iv), the GPCI-adjusted amount determined under this clause is the sum of—

(I) the product of (a) the portion of the reduced national weighted average conversion factor computed under clause (ii) which is attributable to physician work and (b) the geographic work index value for the locality (specified in Addendum C to the Model Fee Schedule for Physician Services

(published on September 4, 1990, 55 Federal Register pp. 36238–36243)); and

(II) the product of (a) the remaining portion of the reduced national weighted average conversion factor computed under clause (ii), and (b) the geographic practice cost index value specified in section 1842(b)(14)(C)(iv) for the locality.

In applying this clause with respect to the professional component of a service, 80 percent of the conversion factor shall be considered to be attributable to physician work and with respect to the technical component of the service, 0 percent shall be considered to be attributable to physician work.

(vii) LIMITS ON CONVERSION FACTOR.—The conversion factor to be applied to a locality to the professional or technical component of a service shall not be reduced under this subparagraph by more than 9.5 percent below the conversion factor applied in the locality under subparagraph (C) to such component, but in no case shall the conversion factor be less than 60 percent of the national weighted average of the conversion factors (computed under clause (i)).

(E) RULE FOR CERTAIN SCANNING SERVICES.—In the case of the technical components of magnetic resonance imaging (MRI) services and computer assisted tomography (CAT) services furnished after December 31, 1990, the amount otherwise payable shall be reduced by 10 percent.

(F) SUBSEQUENT UPDATING.—For radiologist services furnished in subsequent years, the fee schedules shall be the schedules for the previous year updated by the percentage increase in the MEI (as defined in section 1842(i)(3)) for the year.

(G) NONPARTICIPATING PHYSICIANS AND SUPPLIERS.—Each fee schedule so established shall provide that the payment rate recognized for nonparticipating physicians and suppliers is equal to the appropriate percent (as defined in section 1842(b)(4)(A)(iv)) of the payment rate recognized for participating physicians and suppliers.

(5) LIMITING CHARGES OF NONPARTICIPATING PHYSICIANS AND SUPPLIERS.—

(A) IN GENERAL.—In the case of radiologist services furnished after January 1, 1989, for which payment is made under a fee schedule under this subsection, if a nonparticipating physician or supplier furnishes the service to an individual entitled to benefits under this part, the physician or supplier may not charge the individual more than the limiting charge (as defined in subparagraph (B)).

(B) LIMITING CHARGE DEFINED.—In subparagraph (A), the term "limiting charge" means, with respect to a service furnished—

(i) in 1989, 125 percent of the amount specified for the service in the appropriate fee schedule established under paragraph (1),

(ii) in 1990, 120 percent of the amount specified for the service in the appropriate fee schedule established under paragraph (1), and

(iii) after 1990, 115 percent of the amount specified for the service in the appropriate fee schedule established under paragraph (1).

(C) ENFORCEMENT.—If a physician or supplier knowingly and willfully bills in violation of subparagraph (A), the Secretary may apply sanctions against such physician or supplier in accordance with section 1842(j)(2) in the same manner as such sanctions may apply to a physician.

(6) RADIOLOGIST SERVICES DEFINED.—For the purposes of this subsection and section 1833(a)(1)(J), the term "radiologist services" only includes radiology services performed by, or under the direction or supervision of, a physician—

(A) who is certified, or eligible to be certified, by the American Board of Radiology, or

(B) for whom radiology services account for at least 50 percent of the total amount of charges made under this part.

(c) PAYMENT AND STANDARDS FOR SCREENING MAMMOGRAPHY.—

(1) IN GENERAL.—With respect to expenses incurred for screening mammography (as defined in section 1861(jj)), payment may be made only—

(A) for screening mammography conducted consistent with the frequency permitted under paragraph (2); and

(B) if the screening mammography is conducted by a facility that has a certificate (or provisional certificate) issued under section 354 of the Public Health Service Act.

(2) FREQUENCY COVERED.—

(A) IN GENERAL.—Subject to revision by the Secretary under subparagraph (B)—

(i) no payment may be made under this part for screening mammography performed on a woman under 35 years of age;

(ii) payment may be made under this part for only one screening mammography performed on a woman over 34 years of age, but under 40 years of age; and

(iii) in the case of a woman over 39 years of age, payment may not be made under this part for screening mammography performed within 11 months following the month in which a previous screening mammography was performed.

(B) REVISION OF FREQUENCY.—

(i) REVIEW.—The Secretary, in consultation with the Director of the National Cancer Institute, shall review periodically the appropriate frequency for performing screening mammography, based on age and such other factors as the Secretary believes to be pertinent.

(ii) REVISION OF FREQUENCY.—The Secretary, taking into consideration the review made under clause (i), may revise from time to time the frequency with which screening mammography may be paid for under this subsection.

(d) FREQUENCY LIMITS AND PAYMENT FOR COLORECTAL CANCER SCREENING TESTS.—

(1) SCREENING FECAL-OCCULT BLOOD TESTS.—

(A) PAYMENT AMOUNT.—The payment amount for colorectal cancer screening tests consisting of screening fecal-occult blood tests is equal to the payment amount established for diagnostic fecal-occult blood tests under section 1833(h).

(B) FREQUENCY LIMIT.—No payment may be made under this part for a colorectal cancer screening test consisting of a screening fecal-occult blood test—

(i) if the individual is under 50 years of age; or

(ii) if the test is performed within the 11 months after a previous screening fecal-occult blood test.

(2) SCREENING FLEXIBLE SIGMOIDOSCOPIES.—

(A) FEE SCHEDULE.—With respect to colorectal cancer screening tests consisting of screening flexible sigmoidoscopies, payment under section 1848 shall be consistent with payment under such section for similar or related services.

(B) PAYMENT LIMIT.—In the case of screening flexible sigmoidoscopy services, payment under this part shall not exceed such amount as the Secretary specifies, based upon the rates recognized for diagnostic flexible sigmoidoscopy services.

(C) FACILITY PAYMENT LIMIT.—

(i) IN GENERAL.—Notwithstanding subsections (i)(2)(A) and (t) of section 1833, in the case of screening flexible sigmoidoscopy services furnished on or after January 1, 1999, that—

(I) in accordance with regulations, may be performed in an ambulatory surgical center and for which the Secretary permits ambulatory surgical center payments under this part, and

(II) are performed in an ambulatory surgical center or hospital outpatient department,

payment under this part shall be based on the lesser of the amount under the fee schedule that would apply to such services if they were performed in a hospital outpatient department in an area or the amount under the fee schedule that would apply to such services if they were performed in an ambulatory surgical center in the same area.

(ii) LIMITATION ON COINSURANCE.—Subject to section 1833(a)(1)(Y), but notwithstanding any other provision of this title, in the case of a beneficiary who receives the services described in clause (i)—

(I) in computing the amount of any applicable copayment, the computation of such coinsurance shall be based upon the fee schedule under which payment is made for the services, and

(II) the amount of such coinsurance is equal to 25 percent of the payment amount under the fee schedule described in subclause (I).

(D) SPECIAL RULE FOR DETECTED LESIONS.—Subject to section 1833(a)(1)(Y), if during the course of such screening flexible sigmoidoscopy, a lesion or growth is detected which results in a biopsy or removal of the lesion or growth, payment under this part shall not be made for the screening flexible sigmoidoscopy but shall be made for the procedure classified as a flexible sigmoidoscopy with such biopsy or removal.

(E) FREQUENCY LIMIT.—No payment may be made under this part for a colorectal cancer screening test consisting of a screening flexible sigmoidoscopy—

(i) if the individual is under 50 years of age; or

(ii) if the procedure is performed within the 47 months after a previous screening flexible sigmoidoscopy or, in the case of an individual who is not at high risk for colorectal cancer, if the procedure is performed within the 119 months after a previous screening colonoscopy.

(3) SCREENING COLONOSCOPY.—

(A) FEE SCHEDULE.—With respect to colorectal cancer screening test consisting of a screening colonoscopy, payment under section 1848 shall be consistent with payment amounts under such section for similar or related services.

(B) PAYMENT LIMIT.—In the case of screening colonoscopy services, payment under this part shall not exceed such amount as the Secretary specifies, based upon the rates recognized for diagnostic colonoscopy services.

(C) FACILITY PAYMENT LIMIT.—

(i) IN GENERAL.—Notwithstanding subsections (i)(2)(A) and (t) of section 1833, in the case of screening colonoscopy services furnished on or after January 1, 1999, that are performed in an ambulatory surgical center or a hospital outpatient department, payment under this part shall be based on the lesser of the amount under the fee schedule that would apply to such services if they were performed in a hospital outpatient department in an area or the amount under the fee schedule that would apply to such services if they were performed in an ambulatory surgical center in the same area.

(ii) LIMITATION ON COINSURANCE.—Subject to section 1833(a)(1)(Y), but notwithstanding any other provision of this title, in the case of a beneficiary who receives the services described in clause (i)—

(I) in computing the amount of any applicable coinsurance, the computation of such coinsurance shall be based upon the fee schedule under which payment is made for the services, and

(II) the amount of such coinsurance is equal to 25 percent of the payment amount under the fee schedule described in subclause (I).

(D) SPECIAL RULE FOR DETECTED LESIONS.—Subject to section 1833(a)(1)(Y), if during the course of such screening colonoscopy, a lesion or growth is detected which results in a biopsy or removal of the lesion or growth, payment under

this part shall not be made for the screening colonoscopy but shall be made for the procedure classified as a colonoscopy with such biopsy or removal.

(E) FREQUENCY LIMIT.—No payment may be made under this part for a colorectal cancer screening test consisting of a screening colonoscopy for individuals at high risk for colorectal cancer if the procedure is performed within the 23 months after a previous screening colonoscopy or for other individuals if the procedure is performed within the 119 months after a previous screening colonoscopy or within 47 months after a previous screening flexible sigmoidoscopy.

(e) ACCREDITATION REQUIREMENT FOR ADVANCED DIAGNOSTIC IMAGING SERVICES.—

(1) IN GENERAL.—

(A) IN GENERAL.—Beginning with January 1, 2012, with respect to the technical component of advanced diagnostic imaging services for which payment is made under the fee schedule established under section 1848(b) and that are furnished by a supplier, payment may only be made if such supplier is accredited by an accreditation organization designated by the Secretary under paragraph (2)(B)(i).

(B) ADVANCED DIAGNOSTIC IMAGING SERVICES DEFINED.—In this subsection, the term "advanced diagnostic imaging services" includes—

(i) diagnostic magnetic resonance imaging, computed tomography, and nuclear medicine (including positron emission tomography); and

(ii) such other diagnostic imaging services, including services described in section 1848(b)(4)(B) (excluding X-ray, ultrasound, and fluoroscopy), as specified by the Secretary in consultation with physician specialty organizations and other stakeholders.

(C) SUPPLIER DEFINED.—In this subsection, the term "supplier" has the meaning given such term in section 1861(d).

(2) ACCREDITATION ORGANIZATIONS.—

(A) FACTORS FOR DESIGNATION OF ACCREDITATION ORGANIZATIONS.—The Secretary shall consider the following factors in designating accreditation organizations under subparagraph (B)(i) and in reviewing and modifying the list of accreditation organizations designated pursuant to subparagraph (C):

(i) The ability of the organization to conduct timely reviews of accreditation applications.

(ii) Whether the organization has established a process for the timely integration of new advanced diagnostic imaging services into the organization's accreditation program.

(iii) Whether the organization uses random site visits, site audits, or other strategies for ensuring accredited suppliers maintain adherence to the criteria described in paragraph (3).

(iv) The ability of the organization to take into account the capacities of suppliers located in a rural area (as defined in section 1886(d)(2)(D)).

(v) Whether the organization has established reasonable fees to be charged to suppliers applying for accreditation.

(vi) Such other factors as the Secretary determines appropriate.

(B) DESIGNATION.—Not later than January 1, 2010, the Secretary shall designate organizations to accredit suppliers furnishing the technical component of advanced diagnostic imaging services. The list of accreditation organizations so designated may be modified pursuant to subparagraph (C).

(C) REVIEW AND MODIFICATION OF LIST OF ACCREDITATION ORGANIZATIONS.—

(i) IN GENERAL.—The Secretary shall review the list of accreditation organizations designated under subparagraph (B) taking into account the factors under subparagraph (A). Taking into account the results of such review, the Secretary may, by regulation, modify the list of accreditation organizations designated under subparagraph (B).

(ii) SPECIAL RULE FOR ACCREDITATIONS DONE PRIOR TO REMOVAL FROM LIST OF DESIGNATED ACCREDITATION ORGANIZATIONS.—In the case where the Secretary removes an organization from the list of accreditation organizations designated under subparagraph (B), any supplier that is accredited by the organization during the period beginning on the date on which the organization is designated as an accreditation organization under subparagraph (B) and ending on the date on which the organization is removed from such list shall be considered to have been accredited by an organization designated by the Secretary under subparagraph (B) for the remaining period such accreditation is in effect.

(3) CRITERIA FOR ACCREDITATION.—The Secretary shall establish procedures to ensure that the criteria used by an accreditation organization designated under paragraph (2)(B) to evaluate a supplier that furnishes the technical component of advanced diagnostic imaging services for the purpose of accreditation of such supplier is specific to each imaging modality. Such criteria shall include—

(A) standards for qualifications of medical personnel who are not physicians and who furnish the technical component of advanced diagnostic imaging services;

(B) standards for qualifications and responsibilities of medical directors and supervising physicians, including standards that recognize the considerations described in paragraph (4);

(C) procedures to ensure that equipment used in furnishing the technical component of advanced diagnostic imaging services meets performance specifications;

(D) standards that require the supplier have procedures in place to ensure the safety of persons who furnish the technical component of advanced diagnostic imaging services and individuals to whom such services are furnished;

(E) standards that require the establishment and maintenance of a quality assurance and quality control program by the supplier that is adequate and appropriate to ensure the reliability, clarity, and accuracy of the technical quality of diagnostic images produced by such supplier; and

(F) any other standards or procedures the Secretary determines appropriate.

(4) RECOGNITION IN STANDARDS FOR THE EVALUATION OF MEDICAL DIRECTORS AND SUPERVISING PHYSICIANS.—The standards described in paragraph (3)(B) shall recognize whether a medical director or supervising physician—

(A) in a particular specialty receives training in advanced diagnostic imaging services in a residency program;

(B) has attained, through experience, the necessary expertise to be a medical director or a supervising physician;

(C) has completed any continuing medical education courses relating to such services; or

(D) has met such other standards as the Secretary determines appropriate.

(5) RULE FOR ACCREDITATIONS MADE PRIOR TO DESIGNATION.—In the case of a supplier that is accredited before January 1, 2010, by an accreditation organization designated by the Secretary under paragraph (2)(B) as of January 1, 2010, such supplier shall be considered to have been accredited by an organization designated by the Secretary under such paragraph as of January 1, 2012, for the remaining period such accreditation is in effect.

(f) REDUCTION IN PAYMENTS FOR PHYSICIAN PATHOLOGY SERVICES DURING 1991.—

(1) IN GENERAL.—For physician pathology services furnished under this part during 1991, the prevailing charges used in a locality under this part shall be 7 percent below the prevailing charges used in the locality under this part in 1990 after March 31.

(2) LIMITATION.—The prevailing charge for the technical and professional components of an physician pathology service furnished by a physician through an independent laboratory shall not be reduced pursuant to paragraph (1) to the extent that such reduction would reduce such prevailing charge below 115 percent of the prevailing charge for the professional component of such service when furnished by a hospital-based physician in the same locality. For purposes of the preceding sentence, an independent laboratory is a laboratory that is independent of a hospital and separate from the attending or consulting physicians' office.

(g) PAYMENT FOR OUTPATIENT CRITICAL ACCESS HOSPITAL SERVICES.—

(1) IN GENERAL.—The amount of payment for outpatient critical access hospital services of a critical access hospital is equal to 101 percent of the reasonable costs of the hospital in pro-

viding such services, unless the hospital makes the election under paragraph (2).

(2) ELECTION OF COST-BASED HOSPITAL OUTPATIENT SERVICE PAYMENT PLUS FEE SCHEDULE FOR PROFESSIONAL SERVICES.—A critical access hospital may elect to be paid for outpatient critical access hospital services amounts equal to the sum of the following, less the amount that such hospital may charge as described in section 1866(a)(2)(A):

(A) FACILITY FEE.—With respect to facility services, not including any services for which payment may be made under subparagraph (B), 101 percent of the reasonable costs of the critical access hospital in providing such services.

(B) FEE SCHEDULE FOR PROFESSIONAL SERVICES.—With respect to professional services otherwise included within outpatient critical access hospital services, 115 percent of such amounts as would otherwise be paid under this part if such services were not included in outpatient critical access hospital services. Subsections (x) and (y) of section 1833 shall not be taken into account in determining the amounts that would otherwise be paid pursuant to the preceding sentence.

The Secretary may not require, as a condition for applying subparagraph (B) with respect to a critical access hospital, that each physician or other practitioner providing professional services in the hospital must assign billing rights with respect to such services, except that such subparagraph shall not apply to those physicians and practitioners who have not assigned such billing rights.

(3) DISREGARDING CHARGES.—The payment amounts under this subsection shall be determined without regard to the amount of the customary or other charge.

(4) TREATMENT OF CLINICAL DIAGNOSTIC LABORATORY SERVICES.—No coinsurance, deductible, copayment, or other cost-sharing otherwise applicable under this part shall apply with respect to clinical diagnostic laboratory services furnished as an outpatient critical access hospital service. Nothing in this title shall be construed as providing for payment for clinical diagnostic laboratory services furnished as part of outpatient critical access hospital services, other than on the basis described in this subsection. For purposes of the preceding sentence and section 1861(mm)(3), clinical diagnostic laboratory services furnished by a critical access hospital shall be treated as being furnished as part of outpatient critical access services without regard to whether the individual with respect to whom such services are furnished is physically present in the critical access hospital, or in a skilled nursing facility or a clinic (including a rural health clinic) that is operated by a critical access hospital, at the time the specimen is collected.

(5) COVERAGE OF COSTS FOR CERTAIN EMERGENCY ROOM ON-CALL PROVIDERS.—In determining the reasonable costs of outpatient critical access hospital services under paragraphs (1) and (2)(A), the Secretary shall recognize as allowable costs, amounts (as defined by the Secretary) for reasonable compensation and related costs for physicians, physician assist-

ants, nurse practitioners, and clinical nurse specialists who are on-call (as defined by the Secretary) to provide emergency services but who are not present on the premises of the critical access hospital involved, and are not otherwise furnishing services covered under this title and are not on-call at any other provider or facility.

(h) PAYMENT FOR PROSTHETIC DEVICES AND ORTHOTICS AND PROSTHETICS.—

(1) GENERAL RULE FOR PAYMENT.—

(A) IN GENERAL.—Payment under this subsection for prosthetic devices and orthotics and prosthetics shall be made in a lump-sum amount for the purchase of the item in an amount equal to 80 percent of the payment basis described in subparagraph (B).

(B) PAYMENT BASIS.—Except as provided in subparagraphs (C), (E), and (H)(i), the payment basis described in this subparagraph is the lesser of—

(i) the actual charge for the item; or

(ii) the amount recognized under paragraph (2) as the purchase price for the item.

(C) EXCEPTION FOR CERTAIN PUBLIC HOME HEALTH AGENCIES.—Subparagraph (B)(i) shall not apply to an item furnished by a public home health agency (or by another home health agency which demonstrates to the satisfaction of the Secretary that a significant portion of its patients are low income) free of charge or at nominal charges to the public.

(D) EXCLUSIVE PAYMENT RULE.—Subject to subparagraph (H)(ii), this subsection shall constitute the exclusive provision of this title for payment for prosthetic devices, orthotics, and prosthetics under this part or under part A to a home health agency.

(E) EXCEPTION FOR CERTAIN ITEMS.—Payment for ostomy supplies, tracheostomy supplies, and urologicals shall be made in accordance with subparagraphs (B) and (C) of section 1834(a)(2).

(F) SPECIAL PAYMENT RULES FOR CERTAIN PROSTHETICS AND CUSTOM-FABRICATED ORTHOTICS.—

(i) IN GENERAL.—No payment shall be made under this subsection for an item of custom-fabricated orthotics described in clause (ii) or for an item of prosthetics unless such item is—

(I) furnished by a qualified practitioner; and

(II) fabricated by a qualified practitioner or a qualified supplier at a facility that meets such criteria as the Secretary determines appropriate.

(ii) DESCRIPTION OF CUSTOM-FABRICATED ITEM.—

(I) IN GENERAL.—An item described in this clause is an item of custom-fabricated orthotics that requires education, training, and experience to custom-fabricate and that is included in a list established by the Secretary in subclause (II). Such an item does not include shoes and shoe inserts.

(II) LIST OF ITEMS.—The Secretary, in consultation with appropriate experts in orthotics (including national organizations representing manufacturers of orthotics), shall establish and update as appropriate a list of items to which this subparagraph applies. No item may be included in such list unless the item is individually fabricated for the patient over a positive model of the patient.

(iii) QUALIFIED PRACTITIONER DEFINED.—In this subparagraph, the term "qualified practitioner" means a physician or other individual who—

(I) is a qualified physical therapist or a qualified occupational therapist;

(II) in the case of a State that provides for the licensing of orthotics and prosthetics, is licensed in orthotics or prosthetics by the State in which the item is supplied; or

(III) in the case of a State that does not provide for the licensing of orthotics and prosthetics, is specifically trained and educated to provide or manage the provision of prosthetics and custom-designed or -fabricated orthotics, and is certified by the American Board for Certification in Orthotics and Prosthetics, Inc. or by the Board for Orthotist/Prosthetist Certification, or is credentialed and approved by a program that the Secretary determines, in consultation with appropriate experts in orthotics and prosthetics, has training and education standards that are necessary to provide such prosthetics and orthotics.

(iv) QUALIFIED SUPPLIER DEFINED.—In this subparagraph, the term "qualified supplier" means any entity that is accredited by the American Board for Certification in Orthotics and Prosthetics, Inc. or by the Board for Orthotist/Prosthetist Certification, or accredited and approved by a program that the Secretary determines has accreditation and approval standards that are essentially equivalent to those of such Board.

(G) REPLACEMENT OF PROSTHETIC DEVICES AND PARTS.—

(i) IN GENERAL.—Payment shall be made for the replacement of prosthetic devices which are artificial limbs, or for the replacement of any part of such devices, without regard to continuous use or useful lifetime restrictions if an ordering physician determines that the provision of a replacement device, or a replacement part of such a device, is necessary because of any of the following:

(I) A change in the physiological condition of the patient.

(II) An irreparable change in the condition of the device, or in a part of the device.

(III) The condition of the device, or the part of the device, requires repairs and the cost of such repairs would be more than 60 percent of the cost

of a replacement device, or, as the case may be, of the part being replaced.

(ii) CONFIRMATION MAY BE REQUIRED IF DEVICE OR PART BEING REPLACED IS LESS THAN 3 YEARS OLD.—If a physician determines that a replacement device, or a replacement part, is necessary pursuant to clause (i)—

(I) such determination shall be controlling; and

(II) such replacement device or part shall be deemed to be reasonable and necessary for purposes of section 1862(a)(1)(A);

except that if the device, or part, being replaced is less than 3 years old (calculated from the date on which the beneficiary began to use the device or part), the Secretary may also require confirmation of necessity of the replacement device or replacement part, as the case may be.

(H) APPLICATION OF COMPETITIVE ACQUISITION TO ORTHOTICS; LIMITATION OF INHERENT REASONABLENESS AUTHORITY.—In the case of orthotics described in paragraph (2)(C) of section 1847(a) furnished on or after January 1, 2011, subject to subsection (a)(1)(G), that are included in a competitive acquisition program in a competitive acquisition area under such section—

(i) the payment basis under this subsection for such orthotics furnished in such area shall be the payment basis determined under such competitive acquisition program; and

(ii) subject to subsection (a)(1)(G), the Secretary may use information on the payment determined under such competitive acquisition programs to adjust the payment amount otherwise recognized under subparagraph (B)(ii) for an area that is not a competitive acquisition area under section 1847, and in the case of such adjustment, paragraphs (8) and (9) of section 1842(b) shall not be applied.

(2) PURCHASE PRICE RECOGNIZED.—For purposes of paragraph (1), the amount that is recognized under this paragraph as the purchase price for prosthetic devices, orthotics, and prosthetics is the amount described in subparagraph (C) of this paragraph, determined as follows:

(A) COMPUTATION OF LOCAL PURCHASE PRICE.—Each carrier under section 1842 shall compute a base local purchase price for the item as follows:

(i) The carrier shall compute a base local purchase price for each item equal to the average reasonable charge in the locality for the purchase of the item for the 12-month period ending with June 1987.

(ii) The carrier shall compute a local purchase price, with respect to the furnishing of each particular item—

(I) in 1989 and 1990, equal to the base local purchase price computed under clause (i) increased by the percentage increase in the consumer price index for all urban consumers (United

States city average) for the 6-month period ending with December 1987, or

(II) in 1991, 1992 or 1993, equal to the local purchase price computed under this clause for the previous year increased by the applicable percentage increase for the year.

(B) COMPUTATION OF REGIONAL PURCHASE PRICE.—With respect to the furnishing of a particular item in each region (as defined by the Secretary), the Secretary shall compute a regional purchase price—

(i) for 1992, equal to the average (weighted by relative volume of all claims among carriers) of the local purchase prices for the carriers in the region computed under subparagraph (A)(ii)(II) for the year, and

(ii) for each subsequent year, equal to the regional purchase price computed under this subparagraph for the previous year increased by the applicable percentage increase for the year.

(C) PURCHASE PRICE RECOGNIZED.—For purposes of paragraph (1) and subject to subparagraph (D), the amount that is recognized under this paragraph as the purchase price for each item furnished—

(i) in 1989, 1990, or 1991, is 100 percent of the local purchase price computed under subparagraph (A)(ii);

(ii) in 1992, is the sum of (I) 75 percent of the local purchase price computed under subparagraph (A)(ii)(II) for 1992, and (II) 25 percent of the regional purchase price computed under subparagraph (B) for 1992;

(iii) in 1993, is the sum of (I) 50 percent of the local purchase price computed under subparagraph (A)(ii)(II) for 1993, and (II) 50 percent of the regional purchase price computed under subparagraph (B) for 1993; and

(iv) in 1994 or a subsequent year, is the regional purchase price computed under subparagraph (B) for that year.

(D) RANGE ON AMOUNT RECOGNIZED.—The amount that is recognized under subparagraph (C) as the purchase price for an item furnished—

(i) in 1992, may not exceed 125 percent, and may not be lower than 85 percent, of the average of the purchase prices recognized under such subparagraph for all the carrier service areas in the United States in that year; and

(ii) in a subsequent year, may not exceed 120 percent, and may not be lower than 90 percent, of the average of the purchase prices recognized under such subparagraph for all the carrier service areas in the United States in that year.

(3) APPLICABILITY OF CERTAIN PROVISIONS RELATING TO DURABLE MEDICAL EQUIPMENT.—Paragraphs (12) and (17) and subparagraphs (A) and (B) of paragraph (10) and paragraph (11) of subsection (a) shall apply to prosthetic devices, orthotics,

and prosthetics in the same manner as such provisions apply to covered items under such subsection.

(4) DEFINITIONS.—In this subsection—

(A) the term "applicable percentage increase" means—

(i) for 1991, 0 percent;

(ii) for 1992 and 1993, the percentage increase in the consumer price index for all urban consumers (United States city average) for the 12-month period ending with June of the previous year;

(iii) for 1994 and 1995, 0 percent;

(iv) for 1996 and 1997, the percentage increase in the consumer price index for all urban consumers (United States city average) for the 12-month period ending with June of the previous year;

(v) for each of the years 1998 through 2000, 1 percent;

(vi) for 2001, the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 12-month period ending with June 2000;

(vii) for 2002, 1 percent;

(viii) for 2003, the percentage increase in the consumer price index for all urban consumers (United States city average) for the 12-month period ending with June of the previous year;

(ix) for 2004, 2005, and 2006, 0 percent;

(x) for for each of 2007 through 2010, the percentage increase in the consumer price index for all urban consumers (United States city average) for the 12-month period ending with June of the previous year; and

(xi) for 2011 and each subsequent year—

(I) the percentage increase in the consumer price index for all urban consumers (United States city average) for the 12-month period ending with June of the previous year, reduced by—

(II) the productivity adjustment described in section 1886(b)(3)(B)(xi)(II).

(B) the term "prosthetic devices" has the meaning given such term in section 1861(s)(8), except that such term does not include parenteral and enteral nutrition nutrients, supplies, and equipment and does not include an implantable item for which payment may be made under section 1833(t); and

(C) the term "orthotics and prosthetics" has the meaning given such term in section 1861(s)(9) (and includes shoes described in section 1861(s)(12)), but does not include intraocular lenses or medical supplies (including catheters, catheter supplies, ostomy bags, and supplies related to ostomy care) furnished by a home health agency under section 1861(m)(5).

The application of subparagraph (A)(xi)(II) may result in the applicable percentage increase under subparagraph (A) being less than 0.0 for a year, and may result in payment rates under this subsection for a year being less than such payment rates for the preceding year.

(5) DOCUMENTATION CREATED BY ORTHOTISTS AND PROSTHETISTS.—For purposes of determining the reasonableness and medical necessity of orthotics and prosthetics, documentation created by an orthotist or prosthetist shall be considered part of the individual's medical record to support documentation created by eligible professionals described in section 1848(k)(3)(B).

(i) PAYMENT FOR SURGICAL DRESSINGS.—

(1) IN GENERAL.—Payment under this subsection for surgical dressings (described in section 1861(s)(5)) shall be made in a lump sum amount for the purchase of the item in an amount equal to 80 percent of the lesser of—

(A) the actual charge for the item; or

(B) a payment amount determined in accordance with the methodology described in subparagraphs (B) and (C) of subsection (a)(2) (except that in applying such methodology, the national limited payment amount referred to in such subparagraphs shall be initially computed based on local payment amounts using average reasonable charges for the 12-month period ending December 31, 1992, increased by the covered item updates described in such subsection for 1993 and 1994).

(2) EXCEPTIONS.—Paragraph (1) shall not apply to surgical dressings that are—

(A) furnished as an incident to a physician's professional service; or

(B) furnished by a home health agency.

(j) REQUIREMENTS FOR SUPPLIERS OF MEDICAL EQUIPMENT AND SUPPLIES.—

(1) ISSUANCE AND RENEWAL OF SUPPLIER NUMBER.—

(A) PAYMENT.—Except as provided in subparagraph (C), no payment may be made under this part after the date of the enactment of the Social Security Act Amendments of 1994 for items furnished by a supplier of medical equipment and supplies unless such supplier obtains (and renews at such intervals as the Secretary may require) a supplier number.

(B) STANDARDS FOR POSSESSING A SUPPLIER NUMBER.—A supplier may not obtain a supplier number unless—

(i) for medical equipment and supplies furnished on or after the date of the enactment of the Social Security Act Amendments of 1994 and before January 1, 1996, the supplier meets standards prescribed by the Secretary in regulations issued on June 18, 1992; and

(ii) for medical equipment and supplies furnished on or after January 1, 1996, the supplier meets revised standards prescribed by the Secretary (in consultation with representatives of suppliers of medical equipment and supplies, carriers, and consumers) that shall include requirements that the supplier—

(I) comply with all applicable State and Federal licensure and regulatory requirements;

(II) maintain a physical facility on an appropriate site;

(III) have proof of appropriate liability insurance; and

(IV) meet such other requirements as the Secretary may specify.

(C) EXCEPTION FOR ITEMS FURNISHED AS INCIDENT TO A PHYSICIAN'S SERVICE.—Subparagraph (A) shall not apply with respect to medical equipment and supplies furnished incident to a physician's service.

(D) PROHIBITION AGAINST MULTIPLE SUPPLIER NUMBERS.—The Secretary may not issue more than one supplier number to any supplier of medical equipment and supplies unless the issuance of more than one number is appropriate to identify subsidiary or regional entities under the supplier's ownership or control.

(E) PROHIBITION AGAINST DELEGATION OF SUPPLIER DETERMINATIONS.—The Secretary may not delegate (other than by contract under section 1842) the responsibility to determine whether suppliers meet the standards necessary to obtain a supplier number.

(2) CERTIFICATES OF MEDICAL NECESSITY.—

(A) LIMITATION ON INFORMATION PROVIDED BY SUPPLIERS ON CERTIFICATES OF MEDICAL NECESSITY.—

(i) IN GENERAL.—Effective 60 days after the date of the enactment of the Social Security Act Amendments of 1994, a supplier of medical equipment and supplies may distribute to physicians, or to individuals entitled to benefits under this part, a certificate of medical necessity for commercial purposes which contains no more than the following information completed by the supplier:

(I) An identification of the supplier and the beneficiary to whom such medical equipment and supplies are furnished.

(II) A description of such medical equipment and supplies.

(III) Any product code identifying such medical equipment and supplies.

(IV) Any other administrative information (other than information relating to the beneficiary's medical condition) identified by the Secretary.

(ii) INFORMATION ON PAYMENT AMOUNT AND CHARGES.—If a supplier distributes a certificate of medical necessity containing any of the information permitted to be supplied under clause (i), the supplier shall also list on the certificate of medical necessity the fee schedule amount and the supplier's charge for the medical equipment or supplies being furnished prior to distribution of such certificate to the physician.

(iii) PENALTY.—Any supplier of medical equipment and supplies who knowingly and willfully distributes a certificate of medical necessity in violation of clause (i) or fails to provide the information required under clause (ii) is subject to a civil money penalty in an

amount not to exceed $1,000 for each such certificate of medical necessity so distributed. The provisions of section 1128A (other than subsections (a) and (b)) shall apply to civil money penalties under this subparagraph in the same manner as they apply to a penalty or proceeding under section 1128A(a).

(B) DEFINITION.—For purposes of this paragraph, the term "certificate of medical necessity" means a form or other document containing information required by the carrier to be submitted to show that an item is reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

(3) COVERAGE AND REVIEW CRITERIA.—The Secretary shall annually review the coverage and utilization of items of medical equipment and supplies to determine whether such items should be made subject to coverage and utilization review criteria, and if appropriate, shall develop and apply such criteria to such items.

(4) LIMITATION ON PATIENT LIABILITY.—If a supplier of medical equipment and supplies (as defined in paragraph (5))—

(A) furnishes an item or service to a beneficiary for which no payment may be made by reason of paragraph (1);

(B) furnishes an item or service to a beneficiary for which payment is denied in advance under subsection (a)(15); or

(C) furnishes an item or service to a beneficiary for which payment is denied under section 1862(a)(1);

any expenses incurred for items and services furnished to an individual by such a supplier not on an assigned basis shall be the responsibility of such supplier. The individual shall have no financial responsibility for such expenses and the supplier shall refund on a timely basis to the individual (and shall be liable to the individual for) any amounts collected from the individual for such items or services. The provisions of subsection (a)(18) shall apply to refunds required under the previous sentence in the same manner as such provisions apply to refunds under such subsection.

(5) DEFINITION.—The term "medical equipment and supplies" means—

(A) durable medical equipment (as defined in section 1861(n));

(B) prosthetic devices (as described in section 1861(s)(8));

(C) orthotics and prosthetics (as described in section 1861(s)(9));

(D) surgical dressings (as described in section 1861(s)(5));

(E) such other items as the Secretary may determine; and

(F) for purposes of paragraphs (1) and (3)—

(i) home dialysis supplies and equipment (as described in section 1861(s)(2)(F)),

(ii) immunosuppressive drugs (as described in section 1861(s)(2)(J)),

(iii) therapeutic shoes for diabetics (as described in section 1861(s)(12)),

(iv) oral drugs prescribed for use as an anticancer therapeutic agent (as described in section 1861(s)(2)(Q)), and

(v) self-administered erythropoetin (as described in section 1861(s)(2)(P)).

(k) PAYMENT FOR OUTPATIENT THERAPY SERVICES AND COMPREHENSIVE OUTPATIENT REHABILITATION SERVICES.—

(1) IN GENERAL.—With respect to services described in section 1833(a)(8) or 1833(a)(9) for which payment is determined under this subsection, the payment basis shall be—

(A) for services furnished during 1998, the amount determined under paragraph (2); or

(B) for services furnished during a subsequent year, 80 percent of the lesser of—

(i) the actual charge for the services, or

(ii) the applicable fee schedule amount (as defined in paragraph (3)) for the services.

(2) PAYMENT IN 1998 BASED UPON ADJUSTED REASONABLE COSTS.—The amount under this paragraph for services is the lesser of—

(A) the charges imposed for the services, or

(B) the adjusted reasonable costs (as defined in paragraph (4)) for the services,

less 20 percent of the amount of the charges imposed for such services.

(3) APPLICABLE FEE SCHEDULE AMOUNT.—In this subsection, the term "applicable fee schedule amount" means, with respect to services furnished in a year, the amount determined under the fee schedule established under section 1848 for such services furnished during the year or, if there is no such fee schedule established for such services, the amount determined under the fee schedule established for such comparable services as the Secretary specifies.

(4) ADJUSTED REASONABLE COSTS.—In paragraph (2), the term "adjusted reasonable costs" means, with respect to any services, reasonable costs determined for such services, reduced by 10 percent. The 10-percent reduction shall not apply to services described in section 1833(a)(8)(B) (relating to services provided by hospitals).

(5) UNIFORM CODING.—For claims for services submitted on or after April 1, 1998, for which the amount of payment is determined under this subsection, the claim shall include a code (or codes) under a uniform coding system specified by the Secretary that identifies the services furnished.

(6) RESTRAINT ON BILLING.—The provisions of subparagraphs (A) and (B) of section 1842(b)(18) shall apply to therapy services for which payment is made under this subsection in the same manner as they apply to services provided by a practitioner described in section 1842(b)(18)(C).

(7) ADJUSTMENT IN DISCOUNT FOR CERTAIN MULTIPLE THERAPY SERVICES.—In the case of therapy services furnished on or after April 1, 2013, and for which payment is made under this subsection pursuant to the applicable fee schedule amount (as

defined in paragraph (3)), instead of the 25 percent multiple procedure payment reduction specified in the final rule published by the Secretary in the Federal Register on November 29, 2010, the reduction percentage shall be 50 percent.

(l) ESTABLISHMENT OF FEE SCHEDULE FOR AMBULANCE SERVICES.—

(1) IN GENERAL.—The Secretary shall establish a fee schedule for payment for ambulance services whether provided directly by a supplier or provider or under arrangement with a provider under this part through a negotiated rulemaking process described in title 5, United States Code, and in accordance with the requirements of this subsection.

(2) CONSIDERATIONS.—In establishing such fee schedule, the Secretary shall—

(A) establish mechanisms to control increases in expenditures for ambulance services under this part;

(B) establish definitions for ambulance services which link payments to the type of services provided;

(C) consider appropriate regional and operational differences;

(D) consider adjustments to payment rates to account for inflation and other relevant factors; and

(E) phase in the application of the payment rates under the fee schedule in an efficient and fair manner consistent with paragraph (11), except that such phase-in shall provide for full payment of any national mileage rate for ambulance services provided by suppliers that are paid by carriers in any of the 50 States where payment by a carrier for such services for all such suppliers in such State did not, prior to the implementation of the fee schedule, include a separate amount for all mileage within the county from which the beneficiary is transported.

(3) SAVINGS.—In establishing such fee schedule, the Secretary shall—

(A) ensure that the aggregate amount of payments made for ambulance services under this part during 2000 does not exceed the aggregate amount of payments which would have been made for such services under this part during such year if the amendments made by section 4531(a) of the Balanced Budget Act of 1997 continued in effect, except that in making such determination the Secretary shall assume an update in such payments for 2002 equal to percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 12-month period ending with June of the previous year reduced in the case of 2002 by 1.0 percentage points;

(B) set the payment amounts provided under the fee schedule for services furnished in 2001 and each subsequent year at amounts equal to the payment amounts under the fee schedule for services furnished during the previous year, increased, subject to subparagraph (C) and the succeeding sentence of this paragraph, by the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 12-month period ending

with June of the previous year reduced in the case of 2002 by 1.0 percentage points; and

(C) for 2011 and each subsequent year, after determining the percentage increase under subparagraph (B) for the year, reduce such percentage increase by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II).

The application of subparagraph (C) may result in the percentage increase under subparagraph (B) being less than 0.0 for a year, and may result in payment rates under the fee schedule under this subsection for a year being less than such payment rates for the preceding year.

(4) CONSULTATION.—In establishing the fee schedule for ambulance services under this subsection, the Secretary shall consult with various national organizations representing individuals and entities who furnish and regulate ambulance services and share with such organizations relevant data in establishing such schedule.

(5) LIMITATION ON REVIEW.—There shall be no administrative or judicial review under section 1869 or otherwise of the amounts established under the fee schedule for ambulance services under this subsection, including matters described in paragraph (2).

(6) RESTRAINT ON BILLING.—The provisions of subparagraphs (A) and (B) of section 1842(b)(18) shall apply to ambulance services for which payment is made under this subsection in the same manner as they apply to services provided by a practitioner described in section 1842(b)(18)(C).

(7) CODING SYSTEM.—The Secretary may require the claim for any services for which the amount of payment is determined under this subsection to include a code (or codes) under a uniform coding system specified by the Secretary that identifies the services furnished.

(8) SERVICES FURNISHED BY CRITICAL ACCESS HOSPITALS.—Notwithstanding any other provision of this subsection, the Secretary shall pay 101 percent of the reasonable costs incurred in furnishing ambulance services if such services are furnished—

(A) by a critical access hospital (as defined in section 1861(mm)(1)), or

(B) by an entity that is owned and operated by a critical access hospital,

but only if the critical access hospital or entity is the only provider or supplier of ambulance services that is located within a 35-mile drive of such critical access hospital.

(9) TRANSITIONAL ASSISTANCE FOR RURAL PROVIDERS.—In the case of ground ambulance services furnished on or after July 1, 2001, and before January 1, 2004, for which the transportation originates in a rural area (as defined in section 1886(d)(2)(D)) or in a rural census tract of a metropolitan statistical area (as determined under the most recent modification of the Goldsmith Modification, originally published in the Federal Register on February 27, 1992 (57 Fed. Reg. 6725)), the fee schedule established under this subsection shall provide that, with respect to the payment rate for mileage for a trip

above 17 miles, and up to 50 miles, the rate otherwise established shall be increased by not less than ½ of the additional payment per mile established for the first 17 miles of such a trip originating in a rural area.

(10) PHASE-IN PROVIDING FLOOR USING BLEND OF FEE SCHEDULE AND REGIONAL FEE SCHEDULES.—In carrying out the phase-in under paragraph (2)(E) for each level of ground service furnished in a year, the portion of the payment amount that is based on the fee schedule shall be the greater of the amount determined under such fee schedule (without regard to this paragraph) or the following blended rate of the fee schedule under paragraph (1) and of a regional fee schedule for the region involved:

(A) For 2004 (for services furnished on or after July 1, 2004), the blended rate shall be based 20 percent on the fee schedule under paragraph (1) and 80 percent on the regional fee schedule.

(B) For 2005, the blended rate shall be based 40 percent on the fee schedule under paragraph (1) and 60 percent on the regional fee schedule.

(C) For 2006, the blended rate shall be based 60 percent on the fee schedule under paragraph (1) and 40 percent on the regional fee schedule.

(D) For 2007, 2008, and 2009, the blended rate shall be based 80 percent on the fee schedule under paragraph (1) and 20 percent on the regional fee schedule.

(E) For 2010 and each succeeding year, the blended rate shall be based 100 percent on the fee schedule under paragraph (1).

For purposes of this paragraph, the Secretary shall establish a regional fee schedule for each of the nine census divisions (referred to in section 1886(d)(2)) using the methodology (used in establishing the fee schedule under paragraph (1)) to calculate a regional conversion factor and a regional mileage payment rate and using the same payment adjustments and the same relative value units as used in the fee schedule under such paragraph.

(11) ADJUSTMENT IN PAYMENT FOR CERTAIN LONG TRIPS.—In the case of ground ambulance services furnished on or after July 1, 2004, and before January 1, 2009, regardless of where the transportation originates, the fee schedule established under this subsection shall provide that, with respect to the payment rate for mileage for a trip above 50 miles the per mile rate otherwise established shall be increased by ¼ of the payment per mile otherwise applicable to miles in excess of 50 miles in such trip.

(12) ASSISTANCE FOR RURAL PROVIDERS FURNISHING SERVICES IN LOW POPULATION DENSITY AREAS.—

(A) IN GENERAL.—In the case of ground ambulance services furnished on or after July 1, 2004, and before January 1, 2023, for which the transportation originates in a qualified rural area (identified under subparagraph (B)(iii)), the Secretary shall provide for a percent increase in the base rate of the fee schedule for a trip established under this subsection. In establishing such percent increase, the Sec-

retary shall estimate the average cost per trip for such services (not taking into account mileage) in the lowest quartile as compared to the average cost per trip for such services (not taking into account mileage) in the highest quartile of all rural county populations.

(B) IDENTIFICATION OF QUALIFIED RURAL AREAS.—

(i) DETERMINATION OF POPULATION DENSITY IN AREA.—Based upon data from the United States decennial census for the year 2000, the Secretary shall determine, for each rural area, the population density for that area.

(ii) RANKING OF AREAS.—The Secretary shall rank each such area based on such population density.

(iii) IDENTIFICATION OF QUALIFIED RURAL AREAS.—The Secretary shall identify those areas (in subparagraph (A) referred to as "qualified rural areas") with the lowest population densities that represent, if each such area were weighted by the population of such area (as used in computing such population densities), an aggregate total of 25 percent of the total of the population of all such areas.

(iv) RURAL AREA.—For purposes of this paragraph, the term "rural area" has the meaning given such term in section 1886(d)(2)(D). If feasible, the Secretary shall treat a rural census tract of a metropolitan statistical area (as determined under the most recent modification of the Goldsmith Modification, originally published in the Federal Register on February 27, 1992 (57 Fed. Reg. 6725) as a rural area for purposes of this paragraph.

(v) JUDICIAL REVIEW.—There shall be no administrative or judicial review under section 1869, 1878, or otherwise, respecting the identification of an area under this subparagraph.

(13) TEMPORARY INCREASE FOR GROUND AMBULANCE SERVICES.—

(A) IN GENERAL.—After computing the rates with respect to ground ambulance services under the other applicable provisions of this subsection, in the case of such services furnished on or after July 1, 2004, and before January 1, 2007, and for such services furnished on or after July 1, 2008, and before January 1, 2023, for which the transportation originates in—

(i) a rural area described in paragraph (9) or in a rural census tract described in such paragraph, the fee schedule established under this section shall provide that the rate for the service otherwise established, after the application of any increase under paragraphs (11) and (12), shall be increased by 2 percent (or 3 percent if such service is furnished on or after July 1, 2008, and before January 1, 2023); and

(ii) an area not described in clause (i), the fee schedule established under this subsection shall provide that the rate for the service otherwise established, after the application of any increase under paragraph

(11), shall be increased by 1 percent (or 2 percent if such service is furnished on or after July 1, 2008, and before January 1, 2023).

(B) APPLICATION OF INCREASED PAYMENTS AFTER APPLICABLE PERIOD.—The increased payments under subparagraph (A) shall not be taken into account in calculating payments for services furnished after the applicable period specified in such subparagraph.

(14) PROVIDING APPROPRIATE COVERAGE OF RURAL AIR AMBULANCE SERVICES.—

(A) IN GENERAL.—The regulations described in section 1861(s)(7) shall provide, to the extent that any ambulance services (whether ground or air) may be covered under such section, that a rural air ambulance service (as defined in subparagraph (C)) is reimbursed under this subsection at the air ambulance rate if the air ambulance service—

(i) is reasonable and necessary based on the health condition of the individual being transported at or immediately prior to the time of the transport; and

(ii) complies with equipment and crew requirements established by the Secretary.

(B) SATISFACTION OF REQUIREMENT OF MEDICALLY NECESSARY.—The requirement of subparagraph (A)(i) is deemed to be met for a rural air ambulance service if—

(i) subject to subparagraph (D), such service is requested by a physician or other qualified medical personnel (as specified by the Secretary) who certifies or reasonably determines that the individual's condition is such that the time needed to transport the individual by land or the instability of transportation by land poses a threat to the individual's survival or seriously endangers the individual's health; or

(ii) such service is furnished pursuant to a protocol that is established by a State or regional emergency medical service (EMS) agency and recognized or approved by the Secretary under which the use of an air ambulance is recommended, if such agency does not have an ownership interest in the entity furnishing such service.

(C) RURAL AIR AMBULANCE SERVICE DEFINED.—For purposes of this paragraph, the term "rural air ambulance service" means fixed wing and rotary wing air ambulance service in which the point of pick up of the individual occurs in a rural area (as defined in section 1886(d)(2)(D)) or in a rural census tract of a metropolitan statistical area (as determined under the most recent modification of the Goldsmith Modification, originally published in the Federal Register on February 27, 1992 (57 Fed. Reg. 6725)).

(D) LIMITATION.—

(i) IN GENERAL.—Subparagraph (B)(i) shall not apply if there is a financial or employment relationship between the person requesting the rural air ambulance service and the entity furnishing the ambulance service, or an entity under common ownership with the entity furnishing the air ambulance service, or a finan-

cial relationship between an immediate family member of such requester and such an entity.

(ii) EXCEPTION.—Where a hospital and the entity furnishing rural air ambulance services are under common ownership, clause (i) shall not apply to remuneration (through employment or other relationship) by the hospital of the requester or immediate family member if the remuneration is for provider-based physician services furnished in a hospital (as described in section 1887) which are reimbursed under part A and the amount of the remuneration is unrelated directly or indirectly to the provision of rural air ambulance services.

(15) PAYMENT ADJUSTMENT FOR NON-EMERGENCY AMBULANCE TRANSPORTS FOR ESRD BENEFICIARIES.—The fee schedule amount otherwise applicable under the preceding provisions of this subsection shall be reduced by 10 percent for ambulance services furnished during the period beginning on October 1, 2013, and ending on September 30, 2018, and by 23 percent for such services furnished on or after October 1, 2018, consisting of non-emergency basic life support services involving transport of an individual with end-stage renal disease for renal dialysis services (as described in section 1881(b)(14)(B)) furnished other than on an emergency basis by a provider of services or a renal dialysis facility.

(16) PRIOR AUTHORIZATION FOR REPETITIVE SCHEDULED NON-EMERGENT AMBULANCE TRANSPORTS.—

(A) IN GENERAL.—Beginning January 1, 2017, if the expansion to all States of the model of prior authorization described in paragraph (2) of section 515(a) of the Medicare Access and CHIP Reauthorization Act of 2015 meets the requirements described in paragraphs (1) through (3) of section 1115A(c), then the Secretary shall expand such model to all States.

(B) FUNDING.—The Secretary shall use funds made available under section 1893(h)(10) to carry out this paragraph.

(C) CLARIFICATION REGARDING BUDGET NEUTRALITY.—Nothing in this paragraph may be construed to limit or modify the application of section 1115A(b)(3)(B) to models described in such section, including with respect to the model described in subparagraph (A) and expanded beginning on January 1, 2017, under such subparagraph.

(17) SUBMISSION OF COST AND OTHER INFORMATION.—

(A) DEVELOPMENT OF DATA COLLECTION SYSTEM.—The Secretary shall develop a data collection system (which may include use of a cost survey) to collect cost, revenue, utilization, and other information determined appropriate by the Secretary with respect to providers of services (in this paragraph referred to as "providers") and suppliers of ground ambulance services. Such system shall be designed to collect information—

(i) needed to evaluate the extent to which reported costs relate to payment rates under this subsection;

(ii) on the utilization of capital equipment and ambulance capacity, including information consistent with the type of information described in section 1121(a); and

(iii) on different types of ground ambulance services furnished in different geographic locations, including rural areas and low population density areas described in paragraph (12).

(B) SPECIFICATION OF DATA COLLECTION SYSTEM.—

(i) IN GENERAL.—The Secretary shall—

(I) not later than December 31, 2019, specify the data collection system under subparagraph (A); and

(II) identify the providers and suppliers of ground ambulance services that would be required to submit information under such data collection system, including the representative sample described in clause (ii).

(ii) DETERMINATION OF REPRESENTATIVE SAMPLE.—

(I) IN GENERAL.—Not later than December 31, 2019, with respect to the data collection for the first year under such system, and for each subsequent year through 2024, the Secretary shall determine a representative sample to submit information under the data collection system.

(II) REQUIREMENTS.—The sample under subclause (I) shall be representative of the different types of providers and suppliers of ground ambulance services (such as those providers and suppliers that are part of an emergency service or part of a government organization) and the geographic locations in which ground ambulance services are furnished (such as urban, rural, and low population density areas).

(III) LIMITATION.—The Secretary shall not include an individual provider or supplier of ground ambulance services in the sample under subclause (I) in 2 consecutive years, to the extent practicable.

(C) REPORTING OF COST INFORMATION.—For each year, a provider or supplier of ground ambulance services identified by the Secretary under subparagraph (B)(i)(II) as being required to submit information under the data collection system with respect to a period for the year shall submit to the Secretary information specified under the system. Such information shall be submitted in a form and manner, and at a time, specified by the Secretary for purposes of this subparagraph.

(D) PAYMENT REDUCTION FOR FAILURE TO REPORT.—

(i) IN GENERAL.—Beginning January 1, 2022, subject to clause (ii), a 10 percent reduction to payments under this subsection shall be made for the applicable period (as defined in clause (ii)) to a provider or supplier of ground ambulance services that—

(I) is required to submit information under the data collection system with respect to a period under subparagraph (C); and

(II) does not sufficiently submit such information, as determined by the Secretary.

(ii) APPLICABLE PERIOD DEFINED.—For purposes of clause (i), the term "applicable period" means, with respect to a provider or supplier of ground ambulance services, a year specified by the Secretary not more than 2 years after the end of the period with respect to which the Secretary has made a determination under clause (i)(II) that the provider or supplier of ground ambulance services failed to sufficiently submit information under the data collection system.

(iii) HARDSHIP EXEMPTION.—The Secretary may exempt a provider or supplier from the payment reduction under clause (i) with respect to an applicable period in the event of significant hardship, such as a natural disaster, bankruptcy, or other similar situation that the Secretary determines interfered with the ability of the provider or supplier of ground ambulance services to submit such information in a timely manner for the specified period.

(iv) INFORMAL REVIEW.—The Secretary shall establish a process under which a provider or supplier of ground ambulance services may seek an informal review of a determination that the provider or supplier is subject to the payment reduction under clause (i).

(E) ONGOING DATA COLLECTION.—

(i) REVISION OF DATA COLLECTION SYSTEM.—The Secretary may, as the Secretary determines appropriate and, if available, taking into consideration the report (or reports) under subparagraph (F), revise the data collection system under subparagraph (A).

(ii) SUBSEQUENT DATA COLLECTION.—In order to continue to evaluate the extent to which reported costs relate to payment rates under this subsection and for other purposes the Secretary deems appropriate, the Secretary shall require providers and suppliers of ground ambulance services to submit information for years after 2024 as the Secretary determines appropriate, but in no case less often than once every 3 years.

(F) GROUND AMBULANCE DATA COLLECTION SYSTEM STUDY.—

(i) IN GENERAL.—Not later than the second June 15th following the date on which the Secretary transmits data for the first representative sample of providers and suppliers of ground ambulance services to the Medicare Payment Advisory Commission, and as determined necessary by such Commission thereafter,, such Commission shall assess, and submit to Congress a report on, information submitted by providers and suppliers of ground ambulance services through the data collection system under subparagraph (A), the

adequacy of payments for ground ambulance services under this subsection, and geographic variations in the cost of furnishing such services.

(ii) CONTENTS.—A report under clause (i) shall contain the following:

(I) An analysis of information submitted through the data collection system.

(II) An analysis of any burden on providers and suppliers of ground ambulance services associated with the data collection system.

(III) A recommendation as to whether information should continue to be submitted through such data collection system or if such system should be revised under subparagraph (E)(i).

(IV) Other information determined appropriate by the Commission.

(G) PUBLIC AVAILABILITY.—The Secretary shall post information on the results of the data collection under this paragraph on the Internet website of the Centers for Medicare & Medicaid Services, as determined appropriate by the Secretary.

(H) IMPLEMENTATION.—The Secretary shall implement this paragraph through notice and comment rulemaking.

(I) ADMINISTRATION.—Chapter 35 of title 44, United States Code, shall not apply to the collection of information required under this subsection.

(J) LIMITATIONS ON REVIEW.—There shall be no administrative or judicial review under section 1869, section 1878, or otherwise of the data collection system or identification of respondents under this paragraph.

(K) FUNDING FOR IMPLEMENTATION.—For purposes of carrying out subparagraph (A), the Secretary shall provide for the transfer, from the Federal Supplementary Medical Insurance Trust Fund under section 1841, of $15,000,000 to the Centers for Medicare & Medicaid Services Program Management Account for fiscal year 2018. Amounts transferred under this subparagraph shall remain available until expended.

(m) PAYMENT FOR TELEHEALTH SERVICES.—

(1) IN GENERAL.—Subject to paragraphs (8) and (9), the Secretary shall pay for telehealth services that are furnished via a telecommunications system by a physician (as defined in section 1861(r)) or a practitioner (as defined in paragraph (4)(E)) to an eligible telehealth individual enrolled under this part notwithstanding that the individual physician or practitioner providing the telehealth service is not at the same location as the beneficiary. For purposes of the preceding sentence, in the case of any Federal telemedicine demonstration program conducted in Alaska or Hawaii, the term "telecommunications system" includes store-and-forward technologies that provide for the asynchronous transmission of health care information in single or multimedia formats.

(2) PAYMENT AMOUNT.—

(A) DISTANT SITE.—Subject to paragraph (8), the Secretary shall pay to a physician or practitioner located at a

distant site that furnishes a telehealth service to an eligible telehealth individual an amount equal to the amount that such physician or practitioner would have been paid under this title had such service been furnished without the use of a telecommunications system.

(B) FACILITY FEE FOR ORIGINATING SITE.—

(i) IN GENERAL.—Subject to clauses (ii) and (iii) and paragraph (6)(C), with respect to a telehealth service, subject to section 1833(a)(1)(U), there shall be paid to the originating site a facility fee equal to—

(I) for the period beginning on October 1, 2001, and ending on December 31, 2001, and for 2002, $20; and

(II) for a subsequent year, the facility fee specified in subclause (I) or this subclause for the preceding year increased by the percentage increase in the MEI (as defined in section 1842(i)(3)) for such subsequent year.

(ii) NO FACILITY FEE IF ORIGINATING SITE IS THE HOME.—No facility fee shall be paid under this subparagraph to an originating site described in paragraph (4)(C)(ii)(X).

(iii) NO FACILITY FEE FOR NEW SITES.—With respect to telehealth services identified in paragraph (4)(F)(i) as of the date of the enactment of this clause that are furnished during the 151-day period beginning on the first day after the end of the emergency period described in section 1135(g)(1)(B), a facility fee shall only be paid under this subparagraph to an originating site that is described in paragraph (4)(C)(ii) (other than subclause (X) of such paragraph).

(C) TELEPRESENTER NOT REQUIRED.—Nothing in this subsection shall be construed as requiring an eligible telehealth individual to be presented by a physician or practitioner at the originating site for the furnishing of a service via a telecommunications system, unless it is medically necessary (as determined by the physician or practitioner at the distant site).

(3) LIMITATION ON BENEFICIARY CHARGES.—

(A) PHYSICIAN AND PRACTITIONER.—The provisions of section 1848(g) and subparagraphs (A) and (B) of section 1842(b)(18) shall apply to a physician or practitioner receiving payment under this subsection in the same manner as they apply to physicians or practitioners under such sections.

(B) ORIGINATING SITE.—The provisions of section 1842(b)(18) shall apply to originating sites receiving a facility fee in the same manner as they apply to practitioners under such section.

(4) DEFINITIONS.—For purposes of this subsection:

(A) DISTANT SITE.—Subject to paragraph (8), the term"distant site" means the site at which the physician or practitioner is located at the time the service is provided via a telecommunications system.

(B) ELIGIBLE TELEHEALTH INDIVIDUAL.—The term "eligible telehealth individual" means an individual enrolled under this part who receives a telehealth service furnished at an originating site.

(C) ORIGINATING SITE.—

(i) IN GENERAL.—Except as provided in clause (iii) and paragraphs (5), (6), and (7), the term"originating site" means only those sites described in clause (ii) at which the eligible telehealth individual is located at the time the service is furnished via a telecommunications system and only if such site is located—

(I) in an area that is designated as a rural health professional shortage area under section 332(a)(1)(A) of the Public Health Service Act (42 U.S.C. 254e(a)(1)(A));

(II) in a county that is not included in a Metropolitan Statistical Area; or

(III) from an entity that participates in a Federal telemedicine demonstration project that has been approved by (or receives funding from) the Secretary of Health and Human Services as of December 31, 2000.

(ii) SITES DESCRIBED.—The sites referred to in clause (i) are the following sites:

(I) The office of a physician or practitioner.

(II) A critical access hospital (as defined in section 1861(mm)(1)).

(III) A rural health clinic (as defined in section 1861(aa)(2)).

(IV) A Federally qualified health center (as defined in section 1861(aa)(4)).

(V) A hospital (as defined in section 1861(e)).

(VI) A hospital-based or critical access hospital-based renal dialysis center (including satellites).

(VII) A skilled nursing facility (as defined in section 1819(a)).

(VIII) A community mental health center (as defined in section 1861(ff)(3)(B)).

(IX) A renal dialysis facility, but only for purposes of section 1881(b)(3)(B).

(X) The home of an individual, but only for purposes of section 1881(b)(3)(B) or telehealth services described in paragraph (7).

(XI) A rural emergency hospital (as defined in section 1861(kkk)(2)).

(iii) EXPANDING ACCESS TO TELEHEALTH SERVICES.—With respect to telehealth services identified in subparagraph (F)(i) as of the date of the enactment of this clause that are furnished during the 151-day period beginning on the first day after the end of the emergency period described in section 1135(g)(1)(B), the term "originating site" means any site in the United States at which the eligible telehealth individual is located at the time the service is furnished via a tele-

communications system, including the home of an individual.

(D) PHYSICIAN.—The term "physician" has the meaning given that term in section 1861(r).

(E) PRACTITIONER.—The term "practitioner" has the meaning given that term in section 1842(b)(18)(C) and, for the 151-day period beginning on the first day after the end of the period at the end of the emergency sentence described in section 1135(g)(1)(B), shall include a qualified occupational therapist (as such term is used in section 1861(g)), a qualified physical therapist (as such term is used in section 1861(p)), a qualified speech-language pathologist (as defined in section 1861(ll)(4)(A)), and a qualified audiologist (as defined in section 1861(ll)(4)(B)).

(F) TELEHEALTH SERVICE.—

(i) IN GENERAL.—Subject to paragraph (8), the term"telehealth service" means professional consultations, office visits, and office psychiatry services (identified as of July 1, 2000, by HCPCS codes 99241–99275, 99201–99215, 90804–90809, and 90862 (and as subsequently modified by the Secretary)), and any additional service specified by the Secretary.

(ii) YEARLY UPDATE.—The Secretary shall establish a process that provides, on an annual basis, for the addition or deletion of services (and HCPCS codes), as appropriate, to those specified in clause (i) for authorized payment under paragraph (1).

(5) TREATMENT OF HOME DIALYSIS MONTHLY ESRD-RELATED VISIT.—The geographic requirements described in paragraph (4)(C)(i) shall not apply with respect to telehealth services furnished on or after January 1, 2019, for purposes of section 1881(b)(3)(B), at an originating site described in subclause (VI), (IX), or (X) of paragraph (4)(C)(ii).

(6) TREATMENT OF STROKE TELEHEALTH SERVICES.—

(A) NON-APPLICATION OF ORIGINATING SITE REQUIREMENTS.—The requirements described in paragraph (4)(C) shall not apply with respect to telehealth services furnished on or after January 1, 2019, for purposes of diagnosis, evaluation, or treatment of symptoms of an acute stroke, as determined by the Secretary.

(B) INCLUSION OF CERTAIN SITES.—With respect to telehealth services described in subparagraph (A), the term "originating site" shall include any hospital (as defined in section 1861(e)) or critical access hospital (as defined in section 1861(mm)(1)), any mobile stroke unit (as defined by the Secretary), or any other site determined appropriate by the Secretary, at which the eligible telehealth individual is located at the time the service is furnished via a telecommunications system.

(C) NO ORIGINATING SITE FACILITY FEE FOR NEW SITES.—No facility fee shall be paid under paragraph (2)(B) to an originating site with respect to a telehealth service described in subparagraph (A) if the originating site does not otherwise meet the requirements for an originating site under paragraph (4)(C).

(7) TREATMENT OF SUBSTANCE USE DISORDER SERVICES AND MENTAL HEALTH SERVICES FURNISHED THROUGH TELEHEALTH.—

(A) IN GENERAL.—The geographic requirements described in paragraph (4)(C)(i) shall not apply with respect to telehealth services furnished on or after July 1, 2019, to an eligible telehealth individual with a substance use disorder diagnosis for purposes of treatment of such disorder or co-occurring mental health disorder, as determined by the Secretary, or, on or after the first day after the end of the emergency period described in section 1135(g)(1)(B), subject to subparagraph (B), to an eligible telehealth individual for purposes of diagnosis, evaluation, or treatment of a mental health disorder, as determined by the Secretary, at an originating site described in paragraph (4)(C)(ii) (other than an originating site described in subclause (IX) of such paragraph) or, for the period for which clause (iii) of paragraph (4)(C) applies, at any site described in such clause.

(B) REQUIREMENTS FOR MENTAL HEALTH SERVICES FURNISHED THROUGH TELEHEALTH.—

(i) IN GENERAL.—Payment may not be made under this paragraph for telehealth services furnished on or after the day that is the 152nd day after the end of the period at the end of the emergency sentence described in section 1135(g)(1)(B)) by a physician or practitioner to an eligible telehealth individual for purposes of diagnosis, evaluation, or treatment of a mental health disorder unless such physician or practitioner furnishes an item or service in person, without the use of telehealth, for which payment is made under this title (or would have been made under this title if such individual were entitled to, or enrolled for, benefits under this title at the time such item or service is furnished)—

(I) within the 6-month period prior to the first time such physician or practitioner furnishes such a telehealth service to the eligible telehealth individual; and

(II) during subsequent periods in which such physician or practitioner furnishes such telehealth services to the eligible telehealth individual, at such times as the Secretary determines appropriate.

(ii) CLARIFICATION.—This subparagraph shall not apply if payment would otherwise be allowed—

(I) under this paragraph (with respect to telehealth services furnished to an eligible telehealth individual with a substance use disorder diagnosis for purposes of treatment of such disorder or co-occurring mental health disorder); or

(II) under this subsection without application of this paragraph.

(8) ENHANCING TELEHEALTH SERVICES FOR FEDERALLY QUALIFIED HEALTH CENTERS AND RURAL HEALTH CLINICS.—

(A) IN GENERAL.—During the emergency period described in section 1135(g)(1)(B) and, during the 151-day period beginning on the first day after the end of such emergency period—

(i) the Secretary shall pay for telehealth services that are furnished via a telecommunications system by a Federally qualified health center or a rural health clinic to an eligible telehealth individual enrolled under this part notwithstanding that the Federally qualified health center or rural clinic providing the telehealth service is not at the same location as the beneficiary;

(ii) the amount of payment to a Federally qualified health center or rural health clinic that serves as a distant site for such a telehealth service shall be determined under subparagraph (B); and

(iii) for purposes of this subsection—

(I) the term "distant site" includes a Federally qualified health center or rural health clinic that furnishes a telehealth service to an eligible telehealth individual; and

(II) the term "telehealth services" includes a rural health clinic service or Federally qualified health center service that is furnished using telehealth to the extent that payment codes corresponding to services identified by the Secretary under clause (i) or (ii) of paragraph (4)(F) are listed on the corresponding claim for such rural health clinic service or Federally qualified health center service.

(B) SPECIAL PAYMENT RULE.—

(i) IN GENERAL.—The Secretary shall develop and implement payment methods that apply under this subsection to a Federally qualified health center or rural health clinic that serves as a distant site that furnishes a telehealth service to an eligible telehealth individual during the periods for which subparagraph (A) applies. Such payment methods shall be based on payment rates that are similar to the national average payment rates for comparable telehealth services under the physician fee schedule under section 1848. Notwithstanding any other provision of law, the Secretary may implement such payment methods through program instruction or otherwise.

(ii) EXCLUSION FROM FQHC PPS CALCULATION AND RHC AIR CALCULATION.—Costs associated with telehealth services shall not be used to determine the amount of payment for Federally qualified health center services under the prospective payment system under section 1834(o) or for rural health clinic services under the methodology for all-inclusive rates (established by the Secretary) under section 1833(a)(3).

(9) TREATMENT OF TELEHEALTH SERVICES FURNISHED USING AUDIO-ONLY TELECOMMUNICATIONS TECHNOLOGY.—The Secretary shall continue to provide coverage and payment under

this part for telehealth services identified in paragraph (4)(F)(i) as of the date of the enactment of this paragraph that are furnished via an audio-only telecommunications system during the 151-day period beginning on the first day after the end of the emergency period described in section 1135(g)(1)(B). For purposes of the previous sentence, the term "telehealth service" means a telehealth service identified as of the date of the enactment of this paragraph by a HCPCS code (and any succeeding codes) for which the Secretary has not applied the requirements of paragraph (1) and the first sentence of section 410.78(a)(3) of title 42, Code of Federal Regulations, during such emergency period.

(n) AUTHORITY TO MODIFY OR ELIMINATE COVERAGE OF CERTAIN PREVENTIVE SERVICES.—Notwithstanding any other provision of this title, effective beginning on January 1, 2010, if the Secretary determines appropriate, the Secretary may—

(1) modify—

(A) the coverage of any preventive service described in subparagraph (A) of section 1861(ddd)(3) to the extent that such modification is consistent with the recommendations of the United States Preventive Services Task Force; and

(B) the services included in the initial preventive physical examination described in subparagraph (B) of such section; and

(2) provide that no payment shall be made under this title for a preventive service described in subparagraph (A) of such section that has not received a grade of A, B, C, or I by such Task Force.

(o) DEVELOPMENT AND IMPLEMENTATION OF PROSPECTIVE PAYMENT SYSTEM.—

(1) DEVELOPMENT.—

(A) IN GENERAL.—The Secretary shall develop a prospective payment system for payment for Federally qualified health center services furnished by Federally qualified health centers under this title. Such system shall include a process for appropriately describing the services furnished by Federally qualified health centers and shall establish payment rates for specific payment codes based on such appropriate descriptions of services. Such system shall be established to take into account the type, intensity, and duration of services furnished by Federally qualified health centers. Such system may include adjustments, including geographic adjustments, determined appropriate by the Secretary.

(B) COLLECTION OF DATA AND EVALUATION.—By not later than January 1, 2011, the Secretary shall require Federally qualified health centers to submit to the Secretary such information as the Secretary may require in order to develop and implement the prospective payment system under this subsection, including the reporting of services using HCPCS codes.

(2) IMPLEMENTATION.—

(A) IN GENERAL.—Notwithstanding section 1833(a)(3)(A), the Secretary shall provide, for cost reporting periods beginning on or after October 1, 2014, for payments of pro-

spective payment rates for Federally qualified health center services furnished by Federally qualified health centers under this title in accordance with the prospective payment system developed by the Secretary under paragraph (1).

(B) PAYMENTS.—

(i) INITIAL PAYMENTS.—The Secretary shall implement such prospective payment system so that the estimated aggregate amount of prospective payment rates (determined prior to the application of section 1833(a)(1)(Z)) under this title for Federally qualified health center services in the first year that such system is implemented is equal to 100 percent of the estimated amount of reasonable costs (determined without the application of a per visit payment limit or productivity screen and prior to the application of section 1866(a)(2)(A)(ii)) that would have occurred for such services under this title in such year if the system had not been implemented.

(ii) PAYMENTS IN SUBSEQUENT YEARS.—Payment rates in years after the year of implementation of such system shall be the payment rates in the previous year increased—

(I) in the first year after implementation of such system, by the percentage increase in the MEI (as defined in section 1842(i)(3)) for the year involved; and

(II) in subsequent years, by the percentage increase in a market basket of Federally qualified health center goods and services as promulgated through regulations, or if such an index is not available, by the percentage increase in the MEI (as defined in section 1842(i)(3)) for the year involved.

(C) PREPARATION FOR PPS IMPLEMENTATION.—Notwithstanding any other provision of law, the Secretary may establish and implement by program instruction or otherwise the payment codes to be used under the prospective payment system under this section.

(3) ADDITIONAL PAYMENTS FOR CERTAIN FQHCS WITH PHYSICIANS OR OTHER PRACTITIONERS RECEIVING DATA 2000 WAIVERS.—

(A) IN GENERAL.—In the case of a Federally qualified health center with respect to which, beginning on or after January 1, 2019, Federally qualified health center services (as defined in section 1861(aa)(3)) are furnished for the treatment of opioid use disorder by a physician or practitioner who meets the requirements described in subparagraph (C), the Secretary shall, subject to availability of funds under subparagraph (D), make a payment (at such time and in such manner as specified by the Secretary) to such Federally qualified health center after receiving and approving an application submitted by such Federally qualified health center under subparagraph (B). Such a payment shall be in an amount determined by the Sec-

retary, based on an estimate of the average costs of training for purposes of receiving a waiver described in subparagraph (C)(ii). Such a payment may be made only one time with respect to each such physician or practitioner.

(B) APPLICATION.—In order to receive a payment described in subparagraph (A), a Federally qualified health center shall submit to the Secretary an application for such a payment at such time, in such manner, and containing such information as specified by the Secretary. A Federally qualified health center may apply for such a payment for each physician or practitioner described in subparagraph (A) furnishing services described in such subparagraph at such center.

(C) REQUIREMENTS.—For purposes of subparagraph (A), the requirements described in this subparagraph, with respect to a physician or practitioner, are the following:

(i) The physician or practitioner is employed by or working under contract with a Federally qualified health center described in subparagraph (A) that submits an application under subparagraph (B).

(ii) The physician or practitioner ⟦first receives a waiver under section 303(g) of the Controlled Substances Act on or after January 1, 2019⟧ *first begins prescribing narcotic drugs in schedule III, IV, or V of section 202 of the Controlled Substances Act for the purpose of maintenance or detoxification treatment on or after January 1, 2021.*

(D) FUNDING.—For purposes of making payments under this paragraph, there are appropriated, out of amounts in the Treasury not otherwise appropriated, $6,000,000, which shall remain available until expended.

(4) PAYMENT FOR CERTAIN SERVICES FURNISHED BY FEDERALLY QUALIFIED HEALTH CENTERS TO HOSPICE PATIENTS.—

(A) ATTENDING PHYSICIAN SERVICES FOR HOSPICE PATIENTS.—In the case of services described in section?1812(d)(2)(A)(ii) furnished on or after January 1, 2022, by an attending physician (as defined in section 1861(dd)(3)(B), other than a physician or practitioner who is employed by a hospice program) who is employed by or working under contract with a Federally qualified health center, a Federally qualified health center shall be paid for such services under the prospective payment system under this subsection.

(B) MENTAL HEALTH VISITS FURNISHED VIA TELECOMMUNICATIONS TECHNOLOGY.—In the case of mental health visits furnished via interactive, real-time, audio and video telecommunications technology or audio-only interactions, the in-person mental health visit requirements established under section 405.2463(b)(3) of title 42 of the Code of Federal Regulations (or a successor regulation) shall not apply prior to the day that is the 152nd day after the end of the emergency period described in section 1135(g)(1)(B)).

(p) QUALITY INCENTIVES TO PROMOTE PATIENT SAFETY AND PUBLIC HEALTH IN COMPUTED TOMOGRAPHY.—

(1) QUALITY INCENTIVES.—In the case of an applicable computed tomography service (as defined in paragraph (2)) for which payment is made under an applicable payment system (as defined in paragraph (3)) and that is furnished on or after January 1, 2016, using equipment that is not consistent with the CT equipment standard (described in paragraph (4)), the payment amount for such service shall be reduced by the applicable percentage (as defined in paragraph (5)).

(2) APPLICABLE COMPUTED TOMOGRAPHY SERVICES DEFINED.—In this subsection, the term "applicable computed tomography service" means a service billed using diagnostic radiological imaging codes for computed tomography (identified as of January 1, 2014, by HCPCS codes 70450–70498, 71250–71275, 72125–72133, 72191–72194, 73200–73206, 73700–73706, 74150–74178, 74261–74263, and 75571–75574 (and any succeeding codes).

(3) APPLICABLE PAYMENT SYSTEM DEFINED.—In this subsection, the term "applicable payment system" means the following:

(A) The technical component and the technical component of the global fee under the fee schedule established under section 1848(b).

(B) The prospective payment system for hospital outpatient department services under section 1833(t).

(4) CONSISTENCY WITH CT EQUIPMENT STANDARD.—In this subsection, the term "not consistent with the CT equipment standard" means, with respect to an applicable computed tomography service, that the service was furnished using equipment that does not meet each of the attributes of the National Electrical Manufacturers Association (NEMA) Standard XR–29–2013, entitled "Standard Attributes on CT Equipment Related to Dose Optimization and Management". Through rulemaking, the Secretary may apply successor standards.

(5) APPLICABLE PERCENTAGE DEFINED.—In this subsection, the term "applicable percentage" means—

(A) for 2016, 5 percent; and

(B) for 2017 and subsequent years, 15 percent.

(6) IMPLEMENTATION.—

(A) INFORMATION.—The Secretary shall require that information be provided and attested to by a supplier and a hospital outpatient department that indicates whether an applicable computed tomography service was furnished that was not consistent with the CT equipment standard (described in paragraph (4)). Such information may be included on a claim and may be a modifier. Such information shall be verified, as appropriate, as part of the periodic accreditation of suppliers under section 1834(e) and hospitals under section 1865(a).

(B) ADMINISTRATION.—Chapter 35 of title 44, United States Code, shall not apply to information described in subparagraph (A).

(q) RECOGNIZING APPROPRIATE USE CRITERIA FOR CERTAIN IMAGING SERVICES.—

(1) PROGRAM ESTABLISHED.—

(A) IN GENERAL.—The Secretary shall establish a program to promote the use of appropriate use criteria (as defined in subparagraph (B)) for applicable imaging services (as defined in subparagraph (C)) furnished in an applicable setting (as defined in subparagraph (D)) by ordering professionals and furnishing professionals (as defined in subparagraphs (E) and (F), respectively).

(B) APPROPRIATE USE CRITERIA DEFINED.—In this subsection, the term "appropriate use criteria" means criteria, only developed or endorsed by national professional medical specialty societies or other provider-led entities, to assist ordering professionals and furnishing professionals in making the most appropriate treatment decision for a specific clinical condition for an individual. To the extent feasible, such criteria shall be evidence-based.

(C) APPLICABLE IMAGING SERVICE DEFINED.—In this subsection, the term "applicable imaging service" means an advanced diagnostic imaging service (as defined in subsection (e)(1)(B)) for which the Secretary determines—

(i) one or more applicable appropriate use criteria specified under paragraph (2) apply;

(ii) there are one or more qualified clinical decision support mechanisms listed under paragraph (3)(C); and

(iii) one or more of such mechanisms is available free of charge.

(D) APPLICABLE SETTING DEFINED.—In this subsection, the term "applicable setting" means a physician's office, a hospital outpatient department (including an emergency department), an ambulatory surgical center, and any other provider-led outpatient setting determined appropriate by the Secretary.

(E) ORDERING PROFESSIONAL DEFINED.—In this subsection, the term "ordering professional" means a physician (as defined in section 1861(r)) or a practitioner described in section 1842(b)(18)(C) who orders an applicable imaging service.

(F) FURNISHING PROFESSIONAL DEFINED.—In this subsection, the term "furnishing professional" means a physician (as defined in section 1861(r)) or a practitioner described in section 1842(b)(18)(C) who furnishes an applicable imaging service.

(2) ESTABLISHMENT OF APPLICABLE APPROPRIATE USE CRITERIA.—

(A) IN GENERAL.—Not later than November 15, 2015, the Secretary shall through rulemaking, and in consultation with physicians, practitioners, and other stakeholders, specify applicable appropriate use criteria for applicable imaging services only from among appropriate use criteria developed or endorsed by national professional medical specialty societies or other provider-led entities.

(B) CONSIDERATIONS.—In specifying applicable appropriate use criteria under subparagraph (A), the Secretary shall take into account whether the criteria—

(i) have stakeholder consensus;

(ii) are scientifically valid and evidence based; and

(iii) are based on studies that are published and reviewable by stakeholders.

(C) REVISIONS.—The Secretary shall review, on an annual basis, the specified applicable appropriate use criteria to determine if there is a need to update or revise (as appropriate) such specification of applicable appropriate use criteria and make such updates or revisions through rulemaking.

(D) TREATMENT OF MULTIPLE APPLICABLE APPROPRIATE USE CRITERIA.—In the case where the Secretary determines that more than one appropriate use criterion applies with respect to an applicable imaging service, the Secretary shall apply one or more applicable appropriate use criteria under this paragraph for the service.

(3) MECHANISMS FOR CONSULTATION WITH APPLICABLE APPROPRIATE USE CRITERIA.—

(A) IDENTIFICATION OF MECHANISMS TO CONSULT WITH APPLICABLE APPROPRIATE USE CRITERIA.—

(i) IN GENERAL.—The Secretary shall specify qualified clinical decision support mechanisms that could be used by ordering professionals to consult with applicable appropriate use criteria for applicable imaging services.

(ii) CONSULTATION.—The Secretary shall consult with physicians, practitioners, health care technology experts, and other stakeholders in specifying mechanisms under this paragraph.

(iii) INCLUSION OF CERTAIN MECHANISMS.—Mechanisms specified under this paragraph may include any or all of the following that meet the requirements described in subparagraph (B)(ii):

(I) Use of clinical decision support modules in certified EHR technology (as defined in section 1848(o)(4)).

(II) Use of private sector clinical decision support mechanisms that are independent from certified EHR technology, which may include use of clinical decision support mechanisms available from medical specialty organizations.

(III) Use of a clinical decision support mechanism established by the Secretary.

(B) QUALIFIED CLINICAL DECISION SUPPORT MECHANISMS.—

(i) IN GENERAL.—For purposes of this subsection, a qualified clinical decision support mechanism is a mechanism that the Secretary determines meets the requirements described in clause (ii).

(ii) REQUIREMENTS.—The requirements described in this clause are the following:

(I) The mechanism makes available to the ordering professional applicable appropriate use criteria specified under paragraph (2) and the supporting documentation for the applicable imaging service ordered.

(II) In the case where there is more than one applicable appropriate use criterion specified under such paragraph for an applicable imaging service, the mechanism indicates the criteria that it uses for the service.

(III) The mechanism determines the extent to which an applicable imaging service ordered is consistent with the applicable appropriate use criteria so specified.

(IV) The mechanism generates and provides to the ordering professional a certification or documentation that documents that the qualified clinical decision support mechanism was consulted by the ordering professional.

(V) The mechanism is updated on a timely basis to reflect revisions to the specification of applicable appropriate use criteria under such paragraph.

(VI) The mechanism meets privacy and security standards under applicable provisions of law.

(VII) The mechanism performs such other functions as specified by the Secretary, which may include a requirement to provide aggregate feedback to the ordering professional.

(C) LIST OF MECHANISMS FOR CONSULTATION WITH APPLICABLE APPROPRIATE USE CRITERIA.—

(i) INITIAL LIST.—Not later than April 1, 2016, the Secretary shall publish a list of mechanisms specified under this paragraph.

(ii) PERIODIC UPDATING OF LIST.—The Secretary shall identify on an annual basis the list of qualified clinical decision support mechanisms specified under this paragraph.

(4) CONSULTATION WITH APPLICABLE APPROPRIATE USE CRITERIA.—

(A) CONSULTATION BY ORDERING PROFESSIONAL.—Beginning with January 1, 2017, subject to subparagraph (C), with respect to an applicable imaging service ordered by an ordering professional that would be furnished in an applicable setting and paid for under an applicable payment system (as defined in subparagraph (D)), an ordering professional shall—

(i) consult with a qualified decision support mechanism listed under paragraph (3)(C); and

(ii) provide to the furnishing professional the information described in clauses (i) through (iii) of subparagraph (B).

(B) REPORTING BY FURNISHING PROFESSIONAL.—Beginning with January 1, 2017, subject to subparagraph (C), with respect to an applicable imaging service furnished in an applicable setting and paid for under an applicable payment system (as defined in subparagraph (D)), payment for such service may only be made if the claim for the service includes the following:

(i) Information about which qualified clinical decision support mechanism was consulted by the ordering professional for the service.

(ii) Information regarding—

(I) whether the service ordered would adhere to the applicable appropriate use criteria specified under paragraph (2);

(II) whether the service ordered would not adhere to such criteria; or

(III) whether such criteria was not applicable to the service ordered.

(iii) The national provider identifier of the ordering professional (if different from the furnishing professional).

(C) EXCEPTIONS.—The provisions of subparagraphs (A) and (B) and paragraph (6)(A) shall not apply to the following:

(i) EMERGENCY SERVICES.—An applicable imaging service ordered for an individual with an emergency medical condition (as defined in section 1867(e)(1)).

(ii) INPATIENT SERVICES.—An applicable imaging service ordered for an inpatient and for which payment is made under part A.

(iii) SIGNIFICANT HARDSHIP.—An applicable imaging service ordered by an ordering professional who the Secretary may, on a case-by-case basis, exempt from the application of such provisions if the Secretary determines, subject to annual renewal, that consultation with applicable appropriate use criteria would result in a significant hardship, such as in the case of a professional who practices in a rural area without sufficient Internet access.

(D) APPLICABLE PAYMENT SYSTEM DEFINED.—In this subsection, the term "applicable payment system" means the following:

(i) The physician fee schedule established under section 1848(b).

(ii) The prospective payment system for hospital outpatient department services under section 1833(t).

(iii) The ambulatory surgical center payment systems under section 1833(i).

(5) IDENTIFICATION OF OUTLIER ORDERING PROFESSIONALS.—

(A) IN GENERAL.—With respect to applicable imaging services furnished beginning with 2017, the Secretary shall determine, on an annual basis, no more than five percent of the total number of ordering professionals who are outlier ordering professionals.

(B) OUTLIER ORDERING PROFESSIONALS.—The determination of an outlier ordering professional shall—

(i) be based on low adherence to applicable appropriate use criteria specified under paragraph (2), which may be based on comparison to other ordering professionals; and

(ii) include data for ordering professionals for whom prior authorization under paragraph (6)(A) applies.

(C) USE OF TWO YEARS OF DATA.—The Secretary shall use two years of data to identify outlier ordering professionals under this paragraph.

(D) PROCESS.—The Secretary shall establish a process for determining when an outlier ordering professional is no longer an outlier ordering professional.

(E) CONSULTATION WITH STAKEHOLDERS.—The Secretary shall consult with physicians, practitioners and other stakeholders in developing methods to identify outlier ordering professionals under this paragraph.

(6) PRIOR AUTHORIZATION FOR ORDERING PROFESSIONALS WHO ARE OUTLIERS.—

(A) IN GENERAL.—Beginning January 1, 2020, subject to paragraph (4)(C), with respect to services furnished during a year, the Secretary shall, for a period determined appropriate by the Secretary, apply prior authorization for applicable imaging services that are ordered by an outlier ordering professional identified under paragraph (5).

(B) APPROPRIATE USE CRITERIA IN PRIOR AUTHORIZATION.—In applying prior authorization under subparagraph (A), the Secretary shall utilize only the applicable appropriate use criteria specified under this subsection.

(C) FUNDING.—For purposes of carrying out this paragraph, the Secretary shall provide for the transfer, from the Federal Supplementary Medical Insurance Trust Fund under section 1841, of $5,000,000 to the Centers for Medicare & Medicaid Services Program Management Account for each of fiscal years 2019 through 2021. Amounts transferred under the preceding sentence shall remain available until expended.

(7) CONSTRUCTION.—Nothing in this subsection shall be construed as granting the Secretary the authority to develop or initiate the development of clinical practice guidelines or appropriate use criteria.

(r) PAYMENT FOR RENAL DIALYSIS SERVICES FOR INDIVIDUALS WITH ACUTE KIDNEY INJURY.—

(1) PAYMENT RATE.—In the case of renal dialysis services (as defined in subparagraph (B) of section 1881(b)(14)) furnished under this part by a renal dialysis facility or provider of services paid under such section during a year (beginning with 2017) to an individual with acute kidney injury (as defined in paragraph (2)), the amount of payment under this part for such services shall be the base rate for renal dialysis services determined for such year under such section, as adjusted by any applicable geographic adjustment factor applied under subparagraph (D)(iv)(II) of such section and may be adjusted by the Secretary (on a budget neutral basis for payments under this paragraph) by any other adjustment factor under subparagraph (D) of such section.

(2) INDIVIDUAL WITH ACUTE KIDNEY INJURY DEFINED.—In this subsection, the term "individual with acute kidney injury" means an individual who has acute loss of renal function and does not receive renal dialysis services for which payment is made under section 1881(b)(14).

(s) PAYMENT FOR APPLICABLE DISPOSABLE DEVICES.—

(1) SEPARATE PAYMENT.—The Secretary shall make a payment (separate from the payments otherwise made under section 1895) in the amount established under paragraph (3) to a home health agency for an applicable disposable device (as defined in paragraph (2)) when furnished on or after January 1, 2017, to an individual who receives home health services for which payment is made under section 1895(b).

(2) APPLICABLE DISPOSABLE DEVICE.—In this subsection, the term applicable disposable device means a disposable device that, as determined by the Secretary, is—

(A) a disposable negative pressure wound therapy device that is an integrated system comprised of a non-manual vacuum pump, a receptacle for collecting exudate, and dressings for the purposes of wound therapy; and

(B) a substitute for, and used in lieu of, a negative pressure wound therapy durable medical equipment item that is an integrated system of a negative pressure vacuum pump, a separate exudate collection canister, and dressings that would otherwise be covered for individuals for such wound therapy.

(3) PAYMENT AMOUNT.—The separate payment amount established under this paragraph for an applicable disposable device for a year shall be equal to the amount of the payment that would be made under section 1833(t) (relating to payment for covered OPD services) for the year for the Level I Healthcare Common Procedure Coding System (HCPCS) code for which the description for a professional service includes the furnishing of such device.

(t) SITE-OF-SERVICE PRICE TRANSPARENCY.—

(1) IN GENERAL.—In order to facilitate price transparency with respect to items and services for which payment may be made either to a hospital outpatient department or to an ambulatory surgical center under this title, the Secretary shall, for 2018 and each year thereafter, make available to the public via a searchable Internet website, with respect to an appropriate number of such items and services—

(A) the estimated payment amount for the item or service under the outpatient department fee schedule under subsection (t) of section 1833 and the ambulatory surgical center payment system under subsection (i) of such section; and

(B) the estimated amount of beneficiary liability applicable to the item or service.

(2) CALCULATION OF ESTIMATED BENEFICIARY LIABILITY.—For purposes of paragraph (1)(B), the estimated amount of beneficiary liability, with respect to an item or service, is the amount for such item or service for which an individual who does not have coverage under a Medicare supplemental policy certified under section 1882 or any other supplemental insurance coverage is responsible.

(3) IMPLEMENTATION.—In carrying out this subsection, the Secretary—

(A) shall include in the notice described in section 1804(a) a notification of the availability of the estimated amounts made available under paragraph (1); and

(B) may utilize mechanisms in existence on the date of enactment of this subsection, such as the portion of the Internet website of the Centers for Medicare & Medicaid Services on which information comparing physician performance is posted (commonly referred to as the Physician Compare Internet website), to make available such estimated amounts under such paragraph.

(4) FUNDING.—For purposes of implementing this subsection, the Secretary shall provide for the transfer, from the Federal Supplementary Medical Insurance Trust Fund under section 1841 to the Centers for Medicare & Medicaid Services Program Management Account, of $6,000,000 for fiscal year 2017, to remain available until expended.

(u) PAYMENT AND RELATED REQUIREMENTS FOR HOME INFUSION THERAPY.—

(1) PAYMENT.—

(A) SINGLE PAYMENT.—

(i) IN GENERAL.—Subject to clause (iii) and subparagraphs (B) and (C), the Secretary shall implement a payment system under which a single payment is made under this title to a qualified home infusion therapy supplier for items and services described in subparagraphs (A) and (B) of section 1861(iii)(2)) furnished by a qualified home infusion therapy supplier (as defined in section 1861(iii)(3)(D)) in coordination with the furnishing of home infusion drugs (as defined in section 1861(iii)(3)(C)) under this part.

(ii) UNIT OF SINGLE PAYMENT.—A unit of single payment under the payment system implemented under this subparagraph is for each infusion drug administration calendar day in the individual's home. The Secretary shall, as appropriate, establish single payment amounts for types of infusion therapy, including to take into account variation in utilization of nursing services by therapy type.

(iii) LIMITATION.—The single payment amount determined under this subparagraph after application of subparagraph (B) and paragraph (3) shall not exceed the amount determined under the fee schedule under section 1848 for infusion therapy services furnished in a calendar day if furnished in a physician office setting, except such single payment shall not reflect more than 5 hours of infusion for a particular therapy in a calendar day.

(B) REQUIRED ADJUSTMENTS.—The Secretary shall adjust the single payment amount determined under subparagraph (A) for home infusion therapy services under section 1861(iii)(1) to reflect other factors such as—

(i) a geographic wage index and other costs that may vary by region; and

(ii) patient acuity and complexity of drug administration.

(C) DISCRETIONARY ADJUSTMENTS.—

(i) IN GENERAL.—Subject to clause (ii), the Secretary may adjust the single payment amount determined

under subparagraph (A) (after application of subparagraph (B)) to reflect outlier situations and other factors as the Secretary determines appropriate.

(ii) REQUIREMENT OF BUDGET NEUTRALITY.—Any adjustment under this subparagraph shall be made in a budget neutral manner.

(2) CONSIDERATIONS.—In developing the payment system under this subsection, the Secretary may consider the costs of furnishing infusion therapy in the home, consult with home infusion therapy suppliers, consider payment amounts for similar items and services under this part and part A, and consider payment amounts established by Medicare Advantage plans under part C and in the private insurance market for home infusion therapy (including average per treatment day payment amounts by type of home infusion therapy).

(3) ANNUAL UPDATES.—

(A) IN GENERAL.—Subject to subparagraph (B), the Secretary shall update the single payment amount under this subsection from year to year beginning in 2022 by increasing the single payment amount from the prior year by the percentage increase in the Consumer Price Index for all urban consumers (United States city average) for the 12-month period ending with June of the preceding year.

(B) ADJUSTMENT.—For each year, the Secretary shall reduce the percentage increase described in subparagraph (A) by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II). The application of the preceding sentence may result in a percentage being less than 0.0 for a year, and may result in payment being less than such payment rates for the preceding year.

(4) AUTHORITY TO APPLY PRIOR AUTHORIZATION.—The Secretary may, as determined appropriate by the Secretary, apply prior authorization for home infusion therapy services under section 1861(iii)(1).

(5) ACCREDITATION OF QUALIFIED HOME INFUSION THERAPY SUPPLIERS.—

(A) FACTORS FOR DESIGNATION OF ACCREDITATION ORGANIZATIONS.—The Secretary shall consider the following factors in designating accreditation organizations under subparagraph (B) and in reviewing and modifying the list of accreditation organizations designated pursuant to subparagraph (C):

(i) The ability of the organization to conduct timely reviews of accreditation applications.

(ii) The ability of the organization to take into account the capacities of suppliers located in a rural area (as defined in section 1886(d)(2)(D)).

(iii) Whether the organization has established reasonable fees to be charged to suppliers applying for accreditation.

(iv) Such other factors as the Secretary determines appropriate.

(B) DESIGNATION.—Not later than January 1, 2021, the Secretary shall designate organizations to accredit suppliers furnishing home infusion therapy. The list of accred-

itation organizations so designated may be modified pursuant to subparagraph (C).

(C) REVIEW AND MODIFICATION OF LIST OF ACCREDITATION ORGANIZATIONS.—

(i) IN GENERAL.—The Secretary shall review the list of accreditation organizations designated under subparagraph (B) taking into account the factors under subparagraph (A). Taking into account the results of such review, the Secretary may, by regulation, modify the list of accreditation organizations designated under subparagraph (B).

(ii) SPECIAL RULE FOR ACCREDITATIONS DONE PRIOR TO REMOVAL FROM LIST OF DESIGNATED ACCREDITATION ORGANIZATIONS.—In the case where the Secretary removes an organization from the list of accreditation organizations designated under subparagraph (B), any supplier that is accredited by the organization during the period beginning on the date on which the organization is designated as an accreditation organization under subparagraph (B) and ending on the date on which the organization is removed from such list shall be considered to have been accredited by an organization designated by the Secretary under subparagraph (B) for the remaining period such accreditation is in effect.

(D) RULE FOR ACCREDITATIONS MADE PRIOR TO DESIGNATION.—In the case of a supplier that is accredited before January 1, 2021, by an accreditation organization designated by the Secretary under subparagraph (B) as of January 1, 2019, such supplier shall be considered to have been accredited by an organization designated by the Secretary under such paragraph as of January 1, 2023, for the remaining period such accreditation is in effect.

(6) NOTIFICATION OF INFUSION THERAPY OPTIONS AVAILABLE PRIOR TO FURNISHING HOME INFUSION THERAPY.—Prior to the furnishing of home infusion therapy to an individual, the physician who establishes the plan described in section 1861(iii)(1) for the individual shall provide notification (in a form, manner, and frequency determined appropriate by the Secretary) of the options available (such as home, physician's office, hospital outpatient department) for the furnishing of infusion therapy under this part.

(7) HOME INFUSION THERAPY SERVICES TEMPORARY TRANSITIONAL PAYMENT.—

(A) TEMPORARY TRANSITIONAL PAYMENT.—

(i) IN GENERAL.—The Secretary shall, in accordance with the payment methodology described in subparagraph (B) and subject to the provisions of this paragraph, provide a home infusion therapy services temporary transitional payment under this part to an eligible home infusion supplier (as defined in subparagraph (F)) for items and services described in subparagraphs (A) and (B) of section 1861(iii)(2)) furnished during the period specified in clause (ii) by such sup-

plier in coordination with the furnishing of transitional home infusion drugs (as defined in clause (iii)).

(ii) PERIOD SPECIFIED.—For purposes of clause (i), the period specified in this clause is the period beginning on January 1, 2019, and ending on the day before the date of the implementation of the payment system under paragraph (1)(A).

(iii) TRANSITIONAL HOME INFUSION DRUG DEFINED.—For purposes of this paragraph, the term "transitional home infusion drug" has the meaning given to the term "home infusion drug" under section 1861(iii)(3)(C)), except that clause (ii) of such section shall not apply if a drug described in such clause is identified in clauses (i), (ii), (iii) or (iv) of subparagraph (C) as of the date of the enactment of this paragraph.

(B) PAYMENT METHODOLOGY.—For purposes of this paragraph, the Secretary shall establish a payment methodology, with respect to items and services described in subparagraph (A)(i). Under such payment methodology the Secretary shall—

(i) create the three payment categories described in clauses (i), (ii), and (iii) of subparagraph (C);

(ii) assign drugs to such categories, in accordance with such clauses;

(iii) assign appropriate Healthcare Common Procedure Coding System (HCPCS) codes to each payment category; and

(iv) establish a single payment amount for each such payment category, in accordance with subparagraph (D), for each infusion drug administration calendar day in the individual's home for drugs assigned to such category.

(C) PAYMENT CATEGORIES.—

(i) PAYMENT CATEGORY 1.—The Secretary shall create a payment category 1 and assign to such category drugs which are covered under the Local Coverage Determination on External Infusion Pumps (LCD number L33794) and billed with the following HCPCS codes (as identified as of January 1, 2018, and as subsequently modified by the Secretary): J0133, J0285, J0287, J0288, J0289, J0895, J1170, J1250, J1265, J1325, J1455, J1457, J1570, J2175, J2260, J2270, J2274, J2278, J3010, or J3285.

(ii) PAYMENT CATEGORY 2.—The Secretary shall create a payment category 2 and assign to such category drugs which are covered under such local coverage determination and billed with the following HCPCS codes (as identified as of January 1, 2018, and as subsequently modified by the Secretary): J1555 JB, J1559 JB, J1561 JB, J1562 JB, J1569 JB, or J1575 JB.

(iii) PAYMENT CATEGORY 3.—The Secretary shall create a payment category 3 and assign to such category drugs which are covered under such local coverage determination and billed with the following HCPCS

codes (as identified as of January 1, 2018, and as subsequently modified by the Secretary): J9000, J9039, J9040, J9065, J9100, J9190, J9200, J9360, or J9370.

(iv) INFUSION DRUGS NOT OTHERWISE INCLUDED.—With respect to drugs that are not included in payment category 1, 2, or 3 under clause (i), (ii), or (iii), respectively, the Secretary shall assign to the most appropriate of such categories, as determined by the Secretary, drugs which are—

(I) covered under such local coverage determination and billed under HCPCS codes J7799 or J7999 (as identified as of July 1, 2017, and as subsequently modified by the Secretary); or

(II) billed under any code that is implemented after the date of the enactment of this paragraph and included in such local coverage determination or included in subregulatory guidance as a home infusion drug described in subparagraph (A)(i).

(D) PAYMENT AMOUNTS.—

(i) IN GENERAL.—Under the payment methodology, the Secretary shall pay eligible home infusion suppliers, with respect to items and services described in subparagraph (A)(i) furnished during the period described in subparagraph (A)(ii) by such supplier to an individual, at amounts equal to the amounts determined under the physician fee schedule established under section 1848 for services furnished during the year for codes and units of such codes described in clauses (ii), (iii), and (iv) with respect to drugs included in the payment category under subparagraph (C) specified in the respective clause, determined without application of the geographic adjustment under subsection (e) of such section.

(ii) PAYMENT AMOUNT FOR CATEGORY 1.—For purposes of clause (i), the codes and units described in this clause, with respect to drugs included in payment category 1 described in subparagraph (C)(i), are one unit of HCPCS code 96365 plus three units of HCPCS code 96366 (as identified as of January 1, 2018, and as subsequently modified by the Secretary).

(iii) PAYMENT AMOUNT FOR CATEGORY 2.—For purposes of clause (i), the codes and units described in this clause, with respect to drugs included in payment category 2 described in subparagraph (C)(i), are one unit of HCPCS code 96369 plus three units of HCPCS code 96370 (as identified as of January 1, 2018, and as subsequently modified by the Secretary).

(iv) PAYMENT AMOUNT FOR CATEGORY 3.—For purposes of clause (i), the codes and units described in this clause, with respect to drugs included in payment category 3 described in subparagraph (C)(i), are one unit of HCPCS code 96413 plus three units of HCPCS code 96415 (as identified as of January 1, 2018, and as subsequently modified by the Secretary).

(E) CLARIFICATIONS.—

(i) INFUSION DRUG ADMINISTRATION DAY.—For purposes of this subsection, with respect to the furnishing of transitional home infusion drugs or home infusion drugs to an individual by an eligible home infusion supplier or a qualified home infusion therapy supplier, a reference to payment to such supplier for an infusion drug administration calendar day in the individual's home shall refer to payment only for the date on which professional services (as described in section 1861(iii)(2)(A)) were furnished to administer such drugs to such individual. For purposes of the previous sentence, an infusion drug administration calendar day shall include all such drugs administered to such individual on such day.

(ii) TREATMENT OF MULTIPLE DRUGS ADMINISTERED ON SAME INFUSION DRUG ADMINISTRATION DAY.—In the case that an eligible home infusion supplier, with respect to an infusion drug administration calendar day in an individual's home, furnishes to such individual transitional home infusion drugs which are not all assigned to the same payment category under subparagraph (C), payment to such supplier for such infusion drug administration calendar day in the individual's home shall be a single payment equal to the amount of payment under this paragraph for the drug, among all such drugs so furnished to such individual during such calendar day, for which the highest payment would be made under this paragraph.

(F) ELIGIBLE HOME INFUSION SUPPLIERS.—In this paragraph, the term "eligible home infusion supplier" means a supplier that is enrolled under this part as a pharmacy that provides external infusion pumps and external infusion pump supplies and that maintains all pharmacy licensure requirements in the State in which the applicable infusion drugs are administered.

(G) IMPLEMENTATION.—Notwithstanding any other provision of law, the Secretary may implement this paragraph by program instruction or otherwise.

(v) PAYMENT FOR OUTPATIENT PHYSICAL THERAPY SERVICES AND OUTPATIENT OCCUPATIONAL THERAPY SERVICES FURNISHED BY A THERAPY ASSISTANT.—

(1) IN GENERAL.—In the case of an outpatient physical therapy service or outpatient occupational therapy service furnished on or after January 1, 2022, for which payment is made under section 1848 or subsection (k), that is furnished in whole or in part by a therapy assistant (as defined by the Secretary), the amount of payment for such service shall be an amount equal to 85 percent of the amount of payment otherwise applicable for the service under this part. Nothing in the preceding sentence shall be construed to change applicable requirements with respect to such services.

(2) USE OF MODIFIER.—

(A) ESTABLISHMENT.—Not later than January 1, 2019, the Secretary shall establish a modifier to indicate (in a form and manner specified by the Secretary), in the case

of an outpatient physical therapy service or outpatient occupational therapy service furnished in whole or in part by a therapy assistant (as so defined), that the service was furnished by a therapy assistant.

(B) REQUIRED USE.—Each request for payment, or bill submitted, for an outpatient physical therapy service or outpatient occupational therapy service furnished in whole or in part by a therapy assistant (as so defined) on or after January 1, 2020, shall include the modifier established under subparagraph (A) for each such service.

(3) IMPLEMENTATION.—The Secretary shall implement this subsection through notice and comment rulemaking.

(w) OPIOID USE DISORDER TREATMENT SERVICES.—

(1) IN GENERAL.—The Secretary shall pay to an opioid treatment program (as defined in paragraph (2) of section 1861(jjj)) an amount that is equal to 100 percent of a bundled payment under this part for opioid use disorder treatment services (as defined in paragraph (1) of such section) that are furnished by such program to an individual during an episode of care (as defined by the Secretary) beginning on or after January 1, 2020. The Secretary shall ensure, as determined appropriate by the Secretary, that no duplicative payments are made under this part or part D for items and services furnished by an opioid treatment program.

(2) CONSIDERATIONS.—The Secretary may implement this subsection through one or more bundles based on the type of medication provided (such as buprenorphine, methadone, naltrexone, or a new innovative drug), the frequency of services, the scope of services furnished, characteristics of the individuals furnished such services, or other factors as the Secretary determine appropriate. In developing such bundles, the Secretary may consider payment rates paid to opioid treatment programs for comparable services under State plans under title XIX or under the TRICARE program under chapter 55 of title 10 of the United States Code.

(3) ANNUAL UPDATES.—The Secretary shall provide an update each year to the bundled payment amounts under this subsection.

(x) PAYMENT RULES RELATING TO RURAL EMERGENCY HOSPITALS.—

(1) PAYMENT FOR RURAL EMERGENCY HOSPITAL SERVICES.—In the case of rural emergency hospital services (as defined in section 1861(kkk)(1)), furnished by a rural emergency hospital (as defined in section 1861(kkk)(2)) on or after January 1, 2023, the amount of payment for such services shall be equal to the amount of payment that would otherwise apply under section 1833(t) for covered OPD services (as defined in section 1833(t)(1)(B) (other than clause (ii) of such section)), increased by 5 percent to reflect the higher costs incurred by such hospitals, and shall include the application of any copayment amount determined under section 1833(t)(8) as if such increase had not occurred.

(2) ADDITIONAL FACILITY PAYMENT.—

(A) IN GENERAL.—The Secretary shall make monthly payments to a rural emergency hospital in an amount that

is equal to 1/12 of the annual additional facility payment specified in subparagraph (B).

(B) ANNUAL ADDITIONAL FACILITY PAYMENT AMOUNT.—The annual additional facility payment amount specified in this subparagraph is—

(i) for 2023, a Medicare subsidy amount determined under subparagraph (C); and

(ii) for 2024 and each subsequent year, the amount determined under this subparagraph for the preceding year, increased by the hospital market basket percentage increase.

(C) DETERMINATION OF MEDICARE SUBSIDY AMOUNT.—For purposes of subparagraph (B)(i), the Medicare subsidy amount determined under this subparagraph is an amount equal to—

(i) the excess (if any) of—

(I) the total amount that the Secretary determines was paid under this title to all critical access hospitals in 2019; over

(II) the estimated total amount that the Secretary determines would have been paid under this title to such hospitals in 2019 if payment were made for inpatient hospital, outpatient hospital, and skilled nursing facility services under the applicable prospective payment systems for such services during such year; divided by

(ii) the total number of such hospitals in 2019.

(D) REPORTING ON USE OF THE ADDITIONAL FACILITY PAYMENT.—A rural emergency hospital receiving the additional facility payment under this paragraph shall maintain detailed information as specified by the Secretary as to how the facility has used the additional facility payments. Such information shall be made available to the Secretary upon request.

(3) PAYMENT FOR AMBULANCE SERVICES.—For provisions relating to payment for ambulance services furnished by an entity owned and operated by a rural emergency hospital, see section 1834(l).

(4) PAYMENT FOR POST-HOSPITAL EXTENDED CARE SERVICES.—For provisions relating to payment for post-hospital extended care services furnished by a rural emergency hospital that has a unit that is a distinct part licensed as a skilled nursing facility, see section 1888(e).

(5) SOURCE OF PAYMENTS.—

(A) IN GENERAL.—Except as provided in subparagraph (B), payments under this subsection shall be made from the Federal Supplementary Medical Insurance Trust Fund under section 1841.

(B) ADDITIONAL FACILITY PAYMENT AND POST-HOSPITAL EXTENDED CARE SERVICES.—Payments under paragraph (2) shall be made from the Federal Hospital Insurance Trust Fund under section 1817.

(y) PAYMENT FOR CERTAIN SERVICES FURNISHED BY RURAL HEALTH CLINICS TO HOSPICE PATIENTS.—

(1) ATTENDING PHYSICIAN SERVICES FOR HOSPICE PATIENTS.—In the case of services described in section 1812(d)(2)(A)(ii) furnished on or after January 1, 2022, by an attending physician (as defined in section 1861(dd)(3)(B), other than a physician or practitioner who is employed by a hospice program) who is employed by or working under contract with a rural health clinic, a rural health clinic shall be paid for such services under the methodology for all-inclusive rates (established by the Secretary) under section 1833(a)(3), subject to the limits described in section 1833(f).

(2) MENTAL HEALTH VISITS FURNISHED VIA TELECOMMUNICATIONS TECHNOLOGY.—In the case of mental health visits furnished via interactive, real-time, audio and video telecommunications technology or audio-only interactions, the in-person mental health visit requirements established under section 405.2463(b)(3) of title 42 of the Code of Federal Regulations (or a successor regulation) shall not apply prior to the day that is the 152nd day after the end of the emergency period described in section 1135(g)(1)(B)).

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PART E—MISCELLANEOUS PROVISIONS

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SEC. 1866F. OPIOID USE DISORDER TREATMENT DEMONSTRATION PROGRAM.

(a) IMPLEMENTATION OF 4-YEAR DEMONSTRATION PROGRAM.—

(1) IN GENERAL.—Not later than January 1, 2021, the Secretary shall implement a 4-year demonstration program under this title (in this section referred to as the "Program") to increase access of applicable beneficiaries to opioid use disorder treatment services, improve physical and mental health outcomes for such beneficiaries, and to the extent possible, reduce expenditures under this title. Under the Program, the Secretary shall make payments under subsection (e) to participants (as defined in subsection (c)(1)(A)) for furnishing opioid use disorder treatment services delivered through opioid use disorder care teams, or arranging for such services to be furnished, to applicable beneficiaries participating in the Program.

(2) OPIOID USE DISORDER TREATMENT SERVICES.—For purposes of this section, the term "opioid use disorder treatment services"—

(A) means, with respect to an applicable beneficiary, services that are furnished for the treatment of opioid use disorders and that utilize drugs approved under section 505 of the Federal Food, Drug, and Cosmetic Act for the treatment of opioid use disorders in an outpatient setting; and

(B) includes—

(i) medication-assisted treatment;

(ii) treatment planning;

(iii) psychiatric, psychological, or counseling services (or any combination of such services), as appropriate;

(iv) social support services, as appropriate; and

(v) care management and care coordination services, including coordination with other providers of services and suppliers not on an opioid use disorder care team.

(b) PROGRAM DESIGN.—

(1) IN GENERAL.—The Secretary shall design the Program in such a manner to allow for the evaluation of the extent to which the Program accomplishes the following purposes:

(A) Reduces hospitalizations and emergency department visits.

(B) Increases use of medication-assisted treatment for opioid use disorders.

(C) Improves health outcomes of individuals with opioid use disorders, including by reducing the incidence of infectious diseases (such as hepatitis C and HIV).

(D) Does not increase the total spending on items and services under this title.

(E) Reduces deaths from opioid overdose.

(F) Reduces the utilization of inpatient residential treatment.

(2) CONSULTATION.—In designing the Program, including the criteria under subsection (e)(2)(A), the Secretary shall, not later than 3 months after the date of the enactment of this section, consult with specialists in the field of addiction, clinicians in the primary care community, and beneficiary groups.

(c) PARTICIPANTS; OPIOID USE DISORDER CARE TEAMS.—

(1) PARTICIPANTS.—

(A) DEFINITION.—In this section, the term "participant" means an entity or individual—

(i) that is otherwise enrolled under this title and that is—

(I) a physician (as defined in section 1861(r)(1));

(II) a group practice comprised of at least one physician described in subclause (I);

(III) a hospital outpatient department;

(IV) a federally qualified health center (as defined in section 1861(aa)(4));

(V) a rural health clinic (as defined in section 1861(aa)(2));

(VI) a community mental health center (as defined in section 1861(ff)(3)(B));

(VII) a clinic certified as a certified community behavioral health clinic pursuant to section 223 of the Protecting Access to Medicare Act of 2014; or

(VIII) any other individual or entity specified by the Secretary;

(ii) that applied for and was selected to participate in the Program pursuant to an application and selection process established by the Secretary; and

(iii) that establishes an opioid use disorder care team (as defined in paragraph (2)) through employing or contracting with health care practitioners described in paragraph (2)(A), and uses such team to furnish or arrange for opioid use disorder treatment services in the outpatient setting under the Program.

(B) PREFERENCE.—In selecting participants for the Program, the Secretary shall give preference to individuals and entities that are located in areas with a prevalence of opioid use disorders that is higher than the national average prevalence.

(2) OPIOID USE DISORDER CARE TEAMS.—

(A) IN GENERAL.—For purposes of this section, the term "opioid use disorder care team" means a team of health care practitioners established by a participant described in paragraph (1)(A) that—

(i) shall include—

(I) at least one physician (as defined in section 1861(r)(1)) furnishing primary care services or addiction treatment services to an applicable beneficiary; and

(II) at least one eligible practitioner (as defined in paragraph (3)), who may be a physician who meets the criterion in subclause (I); and

(ii) may include other practitioners licensed under State law to furnish psychiatric, psychological, counseling, and social services to applicable beneficiaries.

(B) REQUIREMENTS FOR RECEIPT OF PAYMENT UNDER PROGRAM.—In order to receive payments under subsection (e), each participant in the Program shall—

(i) furnish opioid use disorder treatment services through opioid use disorder care teams to applicable beneficiaries who agree to receive the services;

(ii) meet minimum criteria, as established by the Secretary; and

(iii) submit to the Secretary, in such form, manner, and frequency as specified by the Secretary, with respect to each applicable beneficiary for whom opioid use disorder treatment services are furnished by the opioid use disorder care team, data and such other information as the Secretary determines appropriate to—

(I) monitor and evaluate the Program;

(II) determine if minimum criteria are met under clause (ii); and

(III) determine the incentive payment under subsection (e).

(3) ELIGIBLE PRACTITIONER DEFINED.—For purposes of this section, the term "eligible practitioner" means a physician or other health care practitioner, such as a nurse practitioner, that—

(A) is enrolled under section 1866(j)(1); *and*

(B) is authorized to prescribe or dispense narcotic drugs to individuals for maintenance treatment or detoxification treatment**[**; and**]**.

[(C) has in effect a waiver in accordance with section 303(g) of the Controlled Substances Act for such purpose and is otherwise in compliance with regulations promulgated by the Substance Abuse and Mental Health Services Administration to carry out such section.**]**

(d) PARTICIPATION OF APPLICABLE BENEFICIARIES.—

(1) APPLICABLE BENEFICIARY DEFINED.—In this section, the term "applicable beneficiary" means an individual who—

(A) is entitled to, or enrolled for, benefits under part A and enrolled for benefits under part B;

(B) is not enrolled in a Medicare Advantage plan under part C;

(C) has a current diagnosis for an opioid use disorder; and

(D) meets such other criteria as the Secretary determines appropriate.

Such term shall include an individual who is dually eligible for benefits under this title and title XIX if such individual satisfies the criteria described in subparagraphs (A) through (D).

(2) VOLUNTARY BENEFICIARY PARTICIPATION; LIMITATION ON NUMBER OF BENEFICIARIES.—An applicable beneficiary may participate in the Program on a voluntary basis and may terminate participation in the Program at any time. Not more than 20,000 applicable beneficiaries may participate in the Program at any time.

(3) SERVICES.—In order to participate in the Program, an applicable beneficiary shall agree to receive opioid use disorder treatment services from a participant. Participation under the Program shall not affect coverage of or payment for any other item or service under this title for the applicable beneficiary.

(4) BENEFICIARY ACCESS TO SERVICES.—Nothing in this section shall be construed as encouraging providers to limit applicable beneficiary access to services covered under this title, and applicable beneficiaries shall not be required to relinquish access to any benefit under this title as a condition of receiving services from a participant in the Program.

(e) PAYMENTS.—

(1) PER APPLICABLE BENEFICIARY PER MONTH CARE MANAGEMENT FEE.—

(A) IN GENERAL.—The Secretary shall establish a schedule of per applicable beneficiary per month care management fees. Such a per applicable beneficiary per month care management fee shall be paid to a participant in addition to any other amount otherwise payable under this title to the health care practitioners in the participant's opioid use disorder care team or, if applicable, to the participant. A participant may use such per applicable beneficiary per month care management fee to deliver additional services to applicable beneficiaries, including services not otherwise eligible for payment under this title.

(B) PAYMENT AMOUNTS.—In carrying out subparagraph (A), the Secretary may—

(i) consider payments otherwise payable under this title for opioid use disorder treatment services and the needs of applicable beneficiaries;

(ii) pay a higher per applicable beneficiary per month care management fee for an applicable beneficiary who receives more intensive treatment services from a participant and for whom those services are appropriate based on clinical guidelines for opioid use disorder care;

(iii) pay a higher per applicable beneficiary per month care management fee for the month in which the applicable beneficiary begins treatment with a participant than in subsequent months, to reflect the greater time and costs required for the planning and initiation of treatment, as compared to maintenance of treatment; and

(iv) take into account whether a participant's opioid use disorder care team refers applicable beneficiaries to other suppliers or providers for any opioid use disorder treatment services.

(C) NO DUPLICATE PAYMENT.—The Secretary shall make payments under this paragraph to only one participant for services furnished to an applicable beneficiary during a calendar month.

(2) INCENTIVE PAYMENTS.—

(A) IN GENERAL.—Under the Program, the Secretary shall establish a performance-based incentive payment, which shall be paid (using a methodology established and at a time determined appropriate by the Secretary) to participants based on the performance of participants with respect to criteria, as determined appropriate by the Secretary, in accordance with subparagraph (B).

(B) CRITERIA.—

(i) IN GENERAL.—Criteria described in subparagraph (A) may include consideration of the following:

(I) Patient engagement and retention in treatment.

(II) Evidence-based medication-assisted treatment.

(III) Other criteria established by the Secretary.

(ii) REQUIRED CONSULTATION AND CONSIDERATION.—In determining criteria described in subparagraph (A), the Secretary shall—

(I) consult with stakeholders, including clinicians in the primary care community and in the field of addiction medicine; and

(II) consider existing clinical guidelines for the treatment of opioid use disorders.

(C) NO DUPLICATE PAYMENT.—The Secretary shall ensure that no duplicate payments under this paragraph are made with respect to an applicable beneficiary.

(f) MULTIPAYER STRATEGY.—In carrying out the Program, the Secretary shall encourage other payers to provide similar payments and to use similar criteria as applied under the Program under subsection (e)(2)(C). The Secretary may enter into a memorandum of understanding with other payers to align the methodology for payment provided by such a payer related to opioid use disorder treatment services with such methodology for payment under the Program.

(g) EVALUATION.—

(1) IN GENERAL.—The Secretary shall conduct an intermediate and final evaluation of the program. Each such evaluation shall determine the extent to which each of the pur-

poses described in subsection (b) have been accomplished under the Program.

(2) REPORTS.—The Secretary shall submit to Congress—

(A) a report with respect to the intermediate evaluation under paragraph (1) not later than 3 years after the date of the implementation of the Program; and

(B) a report with respect to the final evaluation under paragraph (1) not later than 6 years after such date.

(h) FUNDING.—

(1) ADMINISTRATIVE FUNDING.—For the purposes of implementing, administering, and carrying out the Program (other than for purposes described in paragraph (2)), $5,000,000 shall be available from the Federal Supplementary Medical Insurance Trust Fund under section 1841.

(2) CARE MANAGEMENT FEES AND INCENTIVES.—For the purposes of making payments under subsection (e), $10,000,000 shall be available from the Federal Supplementary Medical Insurance Trust Fund under section 1841 for each of fiscal years 2021 through 2024.

(3) AVAILABILITY.—Amounts transferred under this subsection for a fiscal year shall be available until expended.

(i) WAIVERS.—The Secretary may waive any provision of this title as may be necessary to carry out the Program under this section.

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TITLE XIX—GRANTS TO STATES FOR MEDICAL ASSISTANCE PROGRAMS

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PAYMENT TO STATES

SEC. 1903. (a) From the sums appropriated therefor, the Secretary (except as otherwise provided in this section) shall pay to each State which has a plan approved under this title, for each quarter, beginning with the quarter commencing January 1, 1966—

(1) an amount equal to the Federal medical assistance percentage (as defined in section 1905(b), subject to subsections (g) and (j) of this section and subsection 1923(f)) of the total amount expended during such quarter as medical assistance under the State plan; plus

(2)(A) an amount equal to 75 per centum of so much of the sums expended during such quarter (as found necessary by the Secretary for the proper and efficient administration of the State plan) as are attributable to compensation or training of skilled professional medical personnel, and staff directly supporting such personnel, of the State agency or any other public agency; plus

(B) notwithstanding paragraph (1) or subparagraph (A), with respect to amounts expended for nursing aide training and competency evaluation programs, and competency evaluation programs, described in section 1919(e)(1) (including the costs for nurse aides to complete such competency evaluation programs), regardless of whether the programs are provided in or outside nursing facilities or of the skill of the personnel involved in such programs, an amount equal to 50 percent (or,

for calendar quarters beginning on or after July 1, 1988, and before October 1, 1990, the lesser of 90 percent or the Federal medical assistance percentage plus 25 percentage points) of so much of the sums expended during such quarter (as found necessary by the Secretary for the proper and efficient administration of the State plan) as are attributable to such programs; plus

(C) an amount equal to 75 percent of so much of the sums expended during such quarter (as found necessary by the Secretary for the proper and efficient administration of the State plan) as are attributable to preadmission screening and resident review activities conducted by the State under section 1919(e)(7); plus

(D) for each calendar quarter during—

(i) fiscal year 1991, an amount equal to 90 percent,

(ii) fiscal year 1992, an amount equal to 85 percent,

(iii) fiscal year 1993, an amount equal to 80 percent, and

(iv) fiscal year 1994 and thereafter, an amount equal to 75 percent,

of so much of the sums expended during such quarter (as found necessary by the Secretary for the proper and efficient administration of the State plan) as are attributable to State activities under section 1919(g); plus

(E) an amount equal to 75 percent of so much of the sums expended during such quarter (as found necessary by the Secretary for the proper and efficient administration of the State plan) as are attributable to translation or interpretation services in connection with the enrollment of, retention of, and use of services under this title by, children of families for whom English is not the primary language; plus

(3) an amount equal to—

(A)(i) 90 per centum of so much of the sums expended during such quarter as are attributable to the design, development, or installation of such mechanized claims processing and information retrieval systems as the Secretary determines are likely to provide more efficient, economical, and effective administration of the plan and to be compatible with the claims processing and information retrieval systems utilized in the administration of title XVIII, including the State's share of the cost of installing such a system to be used jointly in the administration of such State's plan and the plan of any other State approved under this title,

(ii) 90 per centum of so much of the sums expended during any such quarter in the fiscal year ending June 30, 1972, or the fiscal year ending June 30, 1973, as are attributable to the design, development, or installation of cost determination systems for State-owned general hospitals (except that the total amount paid to all States under this clause for either such fiscal year shall not exceed $150,000), and

(iii) an amount equal to the Federal medical assistance percentage (as defined in section 1905(b)) of so much of the sums expended during such quarter (as found necessary by the Secretary for the proper and efficient administration of

the State plan) as are attributable to such developments or modifications of systems of the type described in clause (i) as are necessary for the efficient collection and reporting on child health measures; and

(B) 75 per centum of so much of the sums expended during such quarter as are attributable to the operation of systems (whether such systems are operated directly by the State or by another person under a contract with the State) of the type described in subparagraph (A)(i) (whether or not designed, developed, or installed with assistance under such subparagraph) which are approved by the Secretary and which include provision for prompt written notice to each individual who is furnished services covered by the plan, or to each individual in a sample group of individuals who are furnished such services, of the specific services (other than confidential services) so covered, the name of the person or persons furnishing the services, the date or dates on which the services were furnished, and the amount of the payment or payments made under the plan on account of the services; and

(C)(i) 75 per centum of the sums expended with respect to costs incurred during such quarter (as found necessary by the Secretary for the proper and efficient administration of the State plan) as are attributable to the performance of medical and utilization review by a utilization and quality control peer review organization or by an entity which meets the requirements of section 1152, as determined by the Secretary, under a contract entered into under section 1902(d); and

(ii) 75 percent of the sums expended with respect to costs incurred during such quarter (as found necessary by the Secretary for the proper and efficient administration of the State plan) as are attributable to the performance of independent external reviews conducted under section 1932(c)(2); and

(D) 75 percent of so much of the sums expended by the State plan during a quarter in 1991, 1992, or 1993, as the Secretary determines is attributable to the statewide adoption of a drug use review program which conforms to the requirements of section 1927(g);

(E) 50 percent of the sums expended with respect to costs incurred during such quarter as are attributable to providing—

(i) services to identify and educate individuals who are likely to be eligible for medical assistance under this title and who have Sickle Cell Disease or who are carriers of the sickle cell gene, including education regarding how to identify such individuals; or

(ii) education regarding the risks of stroke and other complications, as well as the prevention of stroke and other complications, in individuals who are likely to be eligible for medical assistance under this title and who have Sickle Cell Disease; and

(F)(i) 100 percent of so much of the sums expended during such quarter as are attributable to payments to Med-

icaid providers described in subsection (t)(1) to encourage the adoption and use of certified EHR technology; and

(ii) 90 percent of so much of the sums expended during such quarter as are attributable to payments for reasonable administrative expenses related to the administration of payments described in clause (i) if the State meets the condition described in subsection (t)(9); plus

(H)(i) 90 percent of the sums expended during the quarter as are attributable to the design, development, or installation of such mechanized verification and information retrieval systems as the Secretary determines are necessary to implement section 1902(ee) (including a system described in paragraph (2)(B) thereof), and

(ii) 75 percent of the sums expended during the quarter as are attributable to the operation of systems to which clause (i) applies, plus

(4) an amount equal to 100 percent of the sums expended during the quarter which are attributable to the costs of the implementation and operation of the immigration status verification system described in section 1137(d); plus

(5) an amount equal to 90 per centum of the sums expended during such quarter which are attributable to the offering, arranging, and furnishing (directly or on a contract basis) of family planning services and supplies;

(6) subject to subsection (b)(3), an amount equal to—

(A) 90 per centum of the sums expended during such a quarter within the twelve-quarter period beginning with the first quarter in which a payment is made to the State pursuant to this paragraph, and

(B) 75 per centum of the sums expended during each succeeding calendar quarter,

with respect to costs incurred during such quarter (as found necessary by the Secretary for the elimination of fraud in the provision and administration of medical assistance provided under the State plan) which are attributable to the establishment and operation of (including the training of personnel employed by) a State medicaid fraud control unit (described in subsection (q)); plus

(7) subject to section 1919(g)(3)(B), an amount equal to 50 per centum of the remainder of the amounts expended during such quarter as found necessary by the Secretary for the proper and efficient administration of the State plan.

(b)(1) Notwithstanding the preceding provisions of this section, the amount determined under subsection (a)(1) for any State for any quarter beginning after December 31, 1969, shall not take into account any amounts expended as medical assistance with respect to individuals aged 65 or over and disabled individuals entitled to hospital insurance benefits under title XVIII which would not have been so expended if the individuals involved had been enrolled in the insurance program established by part B of title XVIII, other than amounts expended under provisions of the plan of such State required by section 1902(a)(34).

(2) For limitation on Federal participation for capital expenditures which are out of conformity with a comprehensive plan of a State or areawide planning agency, see section 1122.

(3) The amount of funds which the Secretary is otherwise obligated to pay a State during a quarter under subsection (a)(6) may not exceed the higher of—

(A) $125,000, or

(B) one-quarter of 1 per centum of the sums expended by the Federal, State, and local governments during the previous quarter in carrying out the State's plan under this title.

(4) Amounts expended by a State for the use of an enrollment broker in marketing medicaid managed care organizations and other managed care entities to eligible individuals under this title shall be considered, for purposes of subsection (a)(7), to be necessary for the proper and efficient administration of the State plan but only if the following conditions are met with respect to the broker:

(A) The broker is independent of any such entity and of any health care providers (whether or not any such provider participates in the State plan under this title) that provide coverage of services in the same State in which the broker is conducting enrollment activities.

(B) No person who is an owner, employee, consultant, or has a contract with the broker either has any direct or indirect financial interest with such an entity or health care provider or has been excluded from participation in the program under this title or title XVIII or debarred by any Federal agency, or subject to a civil money penalty under this Act.

(5) Notwithstanding the preceding provisions of this section, the amount determined under subsection (a)(1) for any State shall be decreased in a quarter by the amount of any health care related taxes (described in section 1902(w)(3)(A)) that are imposed on a hospital described in subsection (w)(3)(F) in that quarter.

(c) Nothing in this title shall be construed as prohibiting or restricting, or authorizing the Secretary to prohibit or restrict, payment under subsection (a) for medical assistance for covered services furnished to a child with a disability because such services are included in the child's individualized education program established pursuant to part B of the Individuals with Disabilities Education Act or furnished to an infant or toddler with a disability because such services are included in the child's individualized family service plan adopted pursuant to part C of such Act.

(d)(1) Prior to the beginning of each quarter, the Secretary shall estimate the amount to which a State will be entitled under subsections (a) and (b) for such quarter, such estimates to be based on (A) a report filed by the State containing its estimate of the total sum to be expended in such quarter in accordance with the provisions of such subsections, and stating the amount appropriated or made available by the State and its political subdivisions for such expenditures in such quarter, and if such amount is less than the State's proportionate share of the total sum of such estimated expenditures, the source or sources from which the difference is expected to be derived, and (B) such other investigation as the Secretary may find necessary.

(2)(A) The Secretary shall then pay to the State, in such installments as he may determine, the amount so estimated, reduced or increased to the extent of any overpayment or underpayment which the Secretary determines was made under this section to such

State for any prior quarter and with respect to which adjustment has not already been made under this subsection.

(B) Expenditures for which payments were made to the State under subsection (a) shall be treated as an overpayment to the extent that the State or local agency administering such plan has been reimbursed for such expenditures by a third party pursuant to the provisions of its plan in compliance with section 1902(a)(25).

(C) For purposes of this subsection, when an overpayment is discovered, which was made by a State to a person or other entity, the State shall have a period of 1 year in which to recover or attempt to recover such overpayment before adjustment is made in the Federal payment to such State on account of such overpayment. Except as otherwise provided in subparagraph (D), the adjustment in the Federal payment shall be made at the end of the 1-year period, whether or not recovery was made.

(D)(i) In any case where the State is unable to recover a debt which represents an overpayment (or any portion thereof) made to a person or other entity on account of such debt having been discharged in bankruptcy or otherwise being uncollectable, no adjustment shall be made in the Federal payment to such State on account of such overpayment (or portion thereof).

(ii) In any case where the State is unable to recover a debt which represents an overpayment (or any portion thereof) made to a person or other entity due to fraud within 1 year of discovery because there is not a final determination of the amount of the overpayment under an administrative or judicial process (as applicable), including as a result of a judgment being under appeal, no adjustment shall be made in the Federal payment to such State on account of such overpayment (or portion thereof) before the date that is 30 days after the date on which a final judgment (including, if applicable, a final determination on an appeal) is made.

(3)(A) The pro rata share to which the United States is equitably entitled, as determined by the Secretary, of the net amount recovered during any quarter by the State or any political subdivision thereof with respect to medical assistance furnished under the State plan shall be considered an overpayment to be adjusted under this subsection.

(B)(i) Subparagraph (A) and paragraph (2)(B) shall not apply to any amount recovered or paid to a State as part of the comprehensive settlement of November 1998 between manufacturers of tobacco products, as defined in section 5702(d) of the Internal Revenue Code of 1986, and State Attorneys General, or as part of any individual State settlement or judgment reached in litigation initiated or pursued by a State against one or more such manufacturers.

(ii) Except as provided in subsection (i)(19), a State may use amounts recovered or paid to the State as part of a comprehensive or individual settlement, or a judgment, described in clause (i) for any expenditures determined appropriate by the State.

(4) Upon the making of any estimate by the Secretary under this subsection, any appropriations available for payments under this section shall be deemed obligated.

(5) In any case in which the Secretary estimates that there has been an overpayment under this section to a State on the basis of a claim by such State that has been disallowed by the Secretary

under section 1116(d), and such State disputes such disallowance, the amount of the Federal payment in controversy shall, at the option of the State, be retained by such State or recovered by the Secretary pending a final determination with respect to such payment amount. If such final determination is to the effect that any amount was properly disallowed, and the State chose to retain payment of the amount in controversy, the Secretary shall offset, from any subsequent payments made to such State under this title, an amount equal to the proper amount of the disallowance plus interest on such amount disallowed for the period beginning on the date such amount was disallowed and ending on the date of such final determination at a rate (determined by the Secretary) based on the average of the bond equivalent of the weekly 90-day treasury bill auction rates during such period.

(6)(A) Each State (as defined in subsection (w)(7)(D)) shall include, in the first report submitted under paragraph (1) after the end of each fiscal year, information related to—

(i) provider-related donations made to the State or units of local government during such fiscal year, and

(ii) health care related taxes collected by the State or such units during such fiscal year.

(B) Each State shall include, in the first report submitted under paragraph (1) after the end of each fiscal year, information related to the total amount of payment adjustments made, and the amount of payment adjustments made to individual providers (by provider), under section 1923(c) during such fiscal year.

(e) A State plan approved under this title may include, as a cost with respect to hospital services under the plan under this title, periodic expenditures made to reflect transitional allowances established with respect to a hospital closure or conversion under section 1884.

(f)(1)(A) Except as provided in paragraph (4), payment under the preceding provisions of this section shall not be made with respect to any amount expended as medical assistance in a calendar quarter, in any State, for any member of a family the annual income of which exceeds the applicable income limitation determined under this paragraph.

(B)(i) Except as provided in clause (ii) of this subparagraph, the applicable income limitation with respect to any family is the amount determined, in accordance with standards prescribed by the Secretary, to be equivalent to 133⅓ percent of the highest amount which would ordinarily be paid to a family of the same size without any income or resources, in the form of money payments, under the plan of the State approved under part A of title IV of this Act.

(ii) If the Secretary finds that the operation of a uniform maximum limits payments to families of more than one size, he may adjust the amount otherwise determined under clause (i) to take account of families of different sizes.

(C) The total amount of any applicable income limitation determined under subparagraph (B) shall, if it is not a multiple of $100 or such other amount as the Secretary may prescribe, be rounded to the next higher multiple of $100 or such other amount, as the case may be.

(2)(A) In computing a family's income for purposes of paragraph (1), there shall be excluded any costs (whether in the form of insurance premiums or otherwise and regardless of whether such costs are reimbursed under another public program of the State or political subdivision thereof) incurred by such family for medical care or for any other type of remedial care recognized under State law or, (B) notwithstanding section 1916 at State option, an amount paid by such family, at the family's option, to the State, provided that the amount, when combined with costs incurred in prior months, is sufficient when excluded from the family's income to reduce such family's income below the applicable income limitation described in paragraph (1). The amount of State expenditures for which medical assistance is available under subsection (a)(1) will be reduced by amounts paid to the State pursuant to this subparagraph.

(3) For purposes of paragraph (1)(B), in the case of a family consisting of only one individual, the "highest amount which would ordinarily be paid" to such family under the State's plan approved under part A of title IV of this Act shall be the amount determined by the State agency (on the basis of reasonable relationship to the amounts payable under such plan to families consisting of two or more persons) to be the amount of the aid which would ordinarily be payable under such plan to a family (without any income or resources) consisting of one person if such plan provided for aid to such a family.

(4) The limitations on payment imposed by the preceding provisions of this subsection shall not apply with respect to any amount expended by a State as medical assistance for any individual described in section 1902(a)(10)(A)(i)(III), 1902(a)(10)(A)(i)(IV), 1902(a)(10)(A)(i)(V), 1902(a)(10)(A)(i)(VI), 1902(a)(10)(A)(i)(VII), 1902(a)(10)(A)(i)(VIII),1902(a)(10)(A)(i)(IX), 1902(a)(10)(A)(ii)(IX), 1902(a)(10)(A)(ii)(X), 1902(a)(10)(A)(ii)(XIII), 1902(a)(10)(A)(ii)(XIV), or 1902(a)(10)(A)(ii)(XV), 1902(a)(10)(A)(ii)(XVI), 1902(a)(10)(A)(ii)(XVII), 1902(a)(10)(A)(ii)(XVIII), 1902(a)(10)(A)(ii)(XIX), 1902(a)(10)(A)(ii)(XX), 1902(a)(10)(A)(ii)(XXI), 1902(a)(10)(A)(ii)(XXII), 1905(p)(1) or for any individual—

(A) who is receiving aid or assistance under any plan of the State approved under title I, X, XIV or XVI, or part A of title IV, or with respect to whom supplemental security income benefits are being paid under title XVI, or

(B) who is not receiving such aid or assistance, and with respect to whom such benefits are not being paid, but (i) is eligible to receive such aid or assistance, or to have such benefits paid with respect to him, or (ii) would be eligible to receive such aid or assistance, or to have such benefits paid with respect to him if he were not in a medical institution, or

(C) with respect to whom there is being paid, or who is eligible, or would be eligible if he were not in a medical institution, to have paid with respect to him, a State supplementary payment and is eligible for medical assistance equal in amount, duration, and scope to the medical assistance made available to individuals described in section 1902(a)(10)(A), or who is a PACE program eligible individual enrolled in a PACE program under section 1934, but only if the income of such individual

(as determined under section 1612, but without regard to subsection (b) thereof) does not exceed 300 percent of the supplemental security income benefit rate established by section 1611(b)(1),

at the time of the provision of the medical assistance giving rise to such expenditure.

(g)(1) Subject to paragraph (3), with respect to amounts paid for the following services furnished under the State plan after June 30, 1973 (other than services furnished pursuant to a contract with a health maintenance organization as defined in section 1876 or which is a qualified health maintenance organization (as defined in section 1310(d) of the Public Health Service Act)), the Federal medical assistance percentage shall be decreased as follows: After an individual has received inpatient hospital services or services in an intermediate care facility for the mentally retarded for 60 days or inpatient mental hospital services for 90 days (whether or not such days are consecutive), during any fiscal year, the Federal medical assistance percentage with respect to amounts paid for any such care furnished thereafter to such individual shall be decreased by a per centum thereof (determined under paragraph (5)) unless the State agency responsible for the administration of the plan makes a showing satisfactory to the Secretary that, with respect to each calendar quarter for which the State submits a request for payment at the full Federal medical assistance percentage for amounts paid for inpatient hospital services or services in an intermediate care facility for the mentally retarded furnished beyond 60 days (or inpatient mental hospital services furnished beyond 90 days), such State has an effective program of medical review of the care of patients in mental hospitals and intermediate care facilities for the mentally retarded pursuant to paragraphs (26) and (31) of section 1902(a) whereby the professional management of each case is reviewed and evaluated at least annually by independent professional review teams. In determining the number of days on which an individual has received services described in this subsection, there shall not be counted any days with respect to which such individual is entitled to have payments made (in whole or in part) on his behalf under section 1812.

(2) The Secretary shall, as part of his validation procedures under this subsection, conduct timely sample onsite surveys of private and public institutions in which recipients of medical assistance may receive care and services under a State plan approved under this title, and his findings with respect to such surveys (as well as the showings of the State agency required under this subsection) shall be made available for public inspection.

(3)(A) No reduction in the Federal medical assistance percentage of a State otherwise required to be imposed under this subsection shall take effect—

(i) if such reduction is due to the State's unsatisfactory or invalid showing made with respect to a calendar quarter beginning before January 1, 1977;

(ii) before January 1, 1978;

(iii) unless a notice of such reduction has been provided to the State at least 30 days before the date such reduction takes effect; or

(iv) due to the State's unsatisfactory or invalid showing made with respect to a calendar quarter beginning after September 30, 1977, unless notice of such reduction has been provided to the State no later than the first day of the fourth calendar quarter following the calendar quarter with respect to which such showing was made.

(B) The Secretary shall waive application of any reduction in the Federal medical assistance percentage of a State otherwise required to be imposed under paragraph (1) because a showing by the State, made under such paragraph with respect to a calendar quarter ending after January 1, 1977, and before January 1, 1978, is determined to be either unsatisfactory under such paragraph or invalid under paragraph (2), if the Secretary determines that the State's showing made under paragraph (1) with respect to any calendar quarter ending on or before December 31, 1978, is satisfactory under such paragraph and is valid under paragraph (2).

(4)(A) The Secretary may not find the showing of a State, with respect to a calendar quarter under paragraph (1), to be satisfactory if the showing is submitted to the Secretary later than the 30th day after the last day of the calendar quarter, unless the State demonstrates to the satisfaction of the Secretary good cause for not meeting such deadline.

(B) The Secretary shall find a showing of a State, with respect to a calendar quarter under paragraph (1), to be satisfactory under such paragraph with respect to the requirement that the State conduct annual onsite inspections in mental hospitals and intermediate care facilities for the mentally retarded under paragraphs (26) and (31) of section 1902(a), if the showing demonstrates that the State has conducted such an onsite inspection during the 12-month period ending on the last date of the calendar quarter—

(i) in each of not less than 98 per centum of the number of such hospitals and facilities requiring such inspection, and

(ii) in every such hospital or facility which has 200 or more beds,

and that, with respect to such hospitals and facilities not inspected within such period, the State has exercised good faith and due diligence in attempting to conduct such inspection, or if the State demonstrates to the satisfaction of the Secretary that it would have made such a showing but for failings of a technical nature only.

(5) In the case of a State's unsatisfactory or invalid showing made with respect to a type of facility or institutional services in a calendar quarter, the per centum amount of the reduction of the State's Federal medical assistance percentage for that type of services under paragraph (1) is equal to 33⅓ per centum multiplied by a fraction, the denominator of which is equal to the total number of patients receiving that type of services in that quarter under the State plan in facilities or institutions for which a showing was required to be made under this subsection, and the numerator of which is equal to the number of such patients receiving such type of services in that quarter in those facilities or institutions for which a satisfactory and valid showing was not made for that calendar quarter.

(6)(A) Recertifications required under section 1902(a)(44) shall be conducted at least every 60 days in the case of inpatient hospital services.

(B) Such recertifications in the case of services in an intermediate care facility for the mentally retarded shall be conducted at least—

(i) 60 days after the date of the initial certification,

(ii) 180 days after the date of the initial certification,

(iii) 12 months after the date of the initial certification,

(iv) 18 months after the date of the initial certification,

(v) 24 months after the date of the initial certification, and

(vi) every 12 months thereafter.

(C) For purposes of determining compliance with the schedule established by this paragraph, a recertification shall be considered to have been done on a timely basis if it was performed not later than 10 days after the date the recertification was otherwise required and the State establishes good cause why the physician or other person making such recertification did not meet such schedule.

(i) Payment under the preceding provisions of this section shall not be made—

(1) for organ transplant procedures unless the State plan provides for written standards respecting the coverage of such procedures and unless such standards provide that—

(A) similarly situated individuals are treated alike; and

(B) any restriction, on the facilities or practitioners which may provide such procedures, is consistent with the accessibility of high quality care to individuals eligible for the procedures under the State plan; or

(2) with respect to any amount expended for an item or service (other than an emergency item or service, not including items or services furnished in an emergency room of a hospital) furnished—

(A) under the plan by any individual or entity during any period when the individual or entity is excluded from participation under title V, XVIII, or XX or under this title pursuant to section 1128, 1128A, 1156, or 1842(j)(2);

(B) at the medical direction or on the prescription of a physician, during the period when such physician is excluded from participation under title V, XVIII, or XX or under this title pursuant to section 1128, 1128A, 1156, or 1842(j)(2) and when the person furnishing such item or service knew or had reason to know of the exclusion (after a reasonable time period after reasonable notice has been furnished to the person);

(C) by any individual or entity to whom the State has failed to suspend payments under the plan during any period when there is pending an investigation of a credible allegation of fraud against the individual or entity, as determined by the State in accordance with regulations promulgated by the Secretary for purposes of section 1862(o) and this subparagraph, unless the State determines in accordance with such regulations there is good cause not to suspend such payments;

(D) beginning on July 1, 2018, under the plan by any provider of services or person whose participation in the State plan is terminated (as described in section 1902(kk)(8)) after the date that is 60 days after the date

on which such termination is included in the database or other system under section 1902(ll); or

(E) with respect to any amount expended for such an item or service furnished during calendar quarters beginning on or after October 1, 2017, subject to section 1902(kk)(4)(A)(ii)(II), within a geographic area that is subject to a moratorium imposed under section 1866(j)(7) by a provider or supplier that meets the requirements specified in subparagraph (C)(iii) of such section, during the period of such moratorium; or

(3) with respect to any amount expended for inpatient hospital services furnished under the plan (other than amounts attributable to the special situation of a hospital which serves a disproportionate number of low income patients with special needs) to the extent that such amount exceeds the hospital's customary charges with respect to such services or (if such services are furnished under the plan by a public institution free of charge or at nominal charges to the public) exceeds an amount determined on the basis of those items (specified in regulations prescribed by the Secretary) included in the determination of such payment which the Secretary finds will provide fair compensation to such institution for such services; or

(4) with respect to any amount expended for care or services furnished under the plan by a hospital unless such hospital has in effect a utilization review plan which meets the requirements imposed by section 1861(k) for purposes of title XVIII; and if such hospital has in effect such a utilization review plan for purposes of title XVIII, such plan shall serve as the plan required by this subsection (with the same standards and procedures and the same review committee or group) as a condition of payment under this title; the Secretary is authorized to waive the requirements of this paragraph if the State agency demonstrates to his satisfaction that it has in operation utilization review procedures which are superior in their effectiveness to the procedures required under section 1861(k); or

(5) with respect to any amount expended for any drug product for which payment may not be made under part B of title XVIII because of section 1862(c); or

(6) with respect to any amount expended for inpatient hospital tests (other than in emergency situations) not specifically ordered by the attending physician or other responsible practitioner; or

(7) with respect to any amount expended for clinical diagnostic laboratory tests performed by a physician, independent laboratory, or hospital, to the extent such amount exceeds the amount that would be recognized under section 1833(h) for such tests performed for an individual enrolled under part B of title XVIII; or

(8) with respect to any amount expended for medical assistance (A) for nursing facility services to reimburse (or otherwise compensate) a nursing facility for payment of a civil money penalty imposed under section 1919(h) or (B) for home and community care to reimburse (or otherwise compensate) a provider of such care for payment of a civil money penalty imposed under this title or title XI or for legal expenses in de-

fense of an exclusion or civil money penalty under this title or title XI if there is no reasonable legal ground for the provider's case; or

(9) with respect to any amount expended for non-emergency transportation authorized under section 1902(a)(4), unless the State plan provides for the methods and procedures required under section 1902(a)(30)(A); or

(10)(A) with respect to covered outpatient drugs unless there is a rebate agreement in effect under section 1927 with respect to such drugs or unless section 1927(a)(3) applies,

(B) with respect to any amount expended for an innovator multiple source drug (as defined in section 1927(k)) dispensed on or after July 1, 1991, if, under applicable State law, a less expensive multiple source drug could have been dispensed, but only to the extent that such amount exceeds the upper payment limit for such multiple source drug;

(C) with respect to covered outpatient drugs described in section 1927(a)(7), unless information respecting utilization data and coding on such drugs that is required to be submitted under such section is submitted in accordance with such section;

(D) with respect to any amount expended for reimbursement to a pharmacy under this title for the ingredient cost of a covered outpatient drug for which the pharmacy has already received payment under this title (other than with respect to a reasonable restocking fee for such drug); and

(E) with respect to any amount expended for a covered outpatient drug for which a suspension under section 1927(c)(4)(B)(ii)(II) is in effect; or

(11) with respect to any amount expended for physicians' services furnished on or after the first day of the first quarter beginning more than 60 days after the date of establishment of the physician identifier system under section 1902(x), unless the claim for the services includes the unique physician identifier provided under such system; or

(12) with respect to any amounts expended for—

(A) a vacuum erection system that is not medically necessary; or

(B) the insertion, repair, or removal and replacement of a penile prosthetic implant (unless such insertion, repair, or removal and replacement is medically necessary); or

(13) with respect to any amount expended to reimburse (or otherwise compensate) a nursing facility for payment of legal expenses associated with any action initiated by the facility that is dismissed on the basis that no reasonable legal ground existed for the institution of such action; or

(14) with respect to any amount expended on administrative costs to carry out the program under section 1928; or

(15) with respect to any amount expended for a single-antigen vaccine and its administration in any case in which the administration of a combined-antigen vaccine was medically appropriate (as determined by the Secretary); or

(16) with respect to any amount expended for which funds may not be used under the Assisted Suicide Funding Restriction Act of 1997; or

(17) with respect to any amount expended for roads, bridges, stadiums, or any other item or service not covered under a State plan under this title; or

(18) with respect to any amount expended for home health care services provided by an agency or organization unless the agency or organization provides the State agency on a continuing basis a surety bond in a form specified by the Secretary under paragraph (7) of section 1861(o) and in an amount that is not less than $50,000 or such comparable surety bond as the Secretary may permit under the last sentence of such section; or

(19) with respect to any amount expended on administrative costs to initiate or pursue litigation described in subsection (d)(3)(B);

(20) with respect to amounts expended for medical assistance provided to an individual described in subclause (XV) or (XVI) of section 1902(a)(10)(A)(ii) for a fiscal year unless the State demonstrates to the satisfaction of the Secretary that the level of State funds expended for such fiscal year for programs to enable working individuals with disabilities to work (other than for such medical assistance) is not less than the level expended for such programs during the most recent State fiscal year ending before the date of the enactment of this paragraph;

(21) with respect to amounts expended for covered outpatient drugs described in section 1927(d)(2)(C) (relating to drugs when used for cosmetic purposes or hair growth), except where medically necessary, and section 1927(d)(2)(K) (relating to drugs when used for treatment of sexual or erectile dysfunction);

(22) with respect to amounts expended for medical assistance for an individual who declares under section 1137(d)(1)(A) to be a citizen or national of the United States for purposes of establishing eligibility for benefits under this title, unless the requirement of section 1902(a)(46)(B) is met;

(23) with respect to amounts expended for medical assistance for covered outpatient drugs (as defined in section 1927(k)(2)) for which the prescription was executed in written (and nonelectronic) form unless the prescription was executed on a tamper-resistant pad;

(24) if a State is required to implement an asset verification program under section 1940 and fails to implement such program in accordance with such section, with respect to amounts expended by such State for medical assistance for individuals subject to asset verification under such section, unless—

(A) the State demonstrates to the Secretary's satisfaction that the State made a good faith effort to comply;

(B) not later than 60 days after the date of a finding that the State is in noncompliance, the State submits to the Secretary (and the Secretary approves) a corrective action plan to remedy such noncompliance; and

(C) not later than 12 months after the date of such submission (and approval), the State fulfills the terms of such corrective action plan;

(25) with respect to any amounts expended for medical assistance for individuals for whom the State does not report en-

rollee encounter data (as defined by the Secretary) to the Medicaid Statistical Information System (MSIS) in a timely manner (as determined by the Secretary);

(26) with respect to any amounts expended for medical assistance for individuals described in subclause (VIII) of subsection (a)(10)(A)(i) other than medical assistance provided through benchmark coverage described in section 1937(b)(1) or benchmark equivalent coverage described in section 1937(b)(2); or

(27) with respect to any amounts expended by the State on the basis of a fee schedule for items described in section 1861(n) and furnished on or after January 1, 2018, as determined in the aggregate with respect to each class of such items as defined by the Secretary, in excess of the aggregate amount, if any, that would be paid for such items within such class on a fee-for-service basis under the program under part B of title XVIII, including, as applicable, under a competitive acquisition program under section 1847 in an area of the State.

Nothing in paragraph (1) shall be construed as permitting a State to provide services under its plan under this title that are not reasonable in amount, duration, and scope to achieve their purpose. Paragraphs (1), (2), (16), (17), and (18) shall apply with respect to items or services furnished and amounts expended by or through a managed care entity (as defined in section 1932(a)(1)(B)) in the same manner as such paragraphs apply to items or services furnished and amounts expended directly by the State.

(j) Notwithstanding the preceding provisions of this section, the amount determined under subsection (a)(1) for any State for any quarter shall be adjusted in accordance with section 1914.

(k) The Secretary is authorized to provide at the request of any State (and without cost to such State) such technical and actuarial assistance as may be necessary to assist such State to contract with any medicaid managed care organization which meets the requirements of subsection (m) of this section for the purpose of providing medical care and services to individuals who are entitled to medical assistance under this title.

(l)(1) Subject to paragraphs (3) and (4), with respect to any amount expended for personal care services or home health care services requiring an in-home visit by a provider that are provided under a State plan under this title (or under a waiver of the plan) and furnished in a calendar quarter beginning on or after January 1, 2020 (or, in the case of home health care services, on or after January 1, 2023), unless a State requires the use of an electronic visit verification system for such services furnished in such quarter under the plan or such waiver, the Federal medical assistance percentage shall be reduced—

(A) in the case of personal care services—

(i) for calendar quarters in 2020, by .25 percentage points;

(ii) for calendar quarters in 2021, by .5 percentage points;

(iii) for calendar quarters in 2022, by .75 percentage points; and

(iv) for calendar quarters in 2023 and each year thereafter, by 1 percentage point; and

(B) in the case of home health care services—

(i) for calendar quarters in 2023 and 2024, by .25 percentage points;

(ii) for calendar quarters in 2025, by .5 percentage points;

(iii) for calendar quarters in 2026, by .75 percentage points; and

(iv) for calendar quarters in 2027 and each year thereafter, by 1 percentage point.

(2) Subject to paragraphs (3) and (4), in implementing the requirement for the use of an electronic visit verification system under paragraph (1), a State shall—

(A) consult with agencies and entities that provide personal care services, home health care services, or both under the State plan (or under a waiver of the plan) to ensure that such system—

(i) is minimally burdensome;

(ii) takes into account existing best practices and electronic visit verification systems in use in the State; and

(iii) is conducted in accordance with the requirements of HIPAA privacy and security law (as defined in section 3009 of the Public Health Service Act);

(B) take into account a stakeholder process that includes input from beneficiaries, family caregivers, individuals who furnish personal care services or home health care services, and other stakeholders, as determined by the State in accordance with guidance from the Secretary; and

(C) ensure that individuals who furnish personal care services, home health care services, or both under the State plan (or under a waiver of the plan) are provided the opportunity for training on the use of such system.

(3) Paragraphs (1) and (2) shall not apply in the case of a State that, as of the date of the enactment of this subsection, requires the use of any system for the electronic verification of visits conducted as part of both personal care services and home health care services, so long as the State continues to require the use of such system with respect to the electronic verification of such visits.

(4)(A) In the case of a State described in subparagraph (B), the reduction under paragraph (1) shall not apply—

(i) in the case of personal care services, for calendar quarters in 2020; and

(ii) in the case of home health care services, for calendar quarters in 2023.

(B) For purposes of subparagraph (A), a State described in this subparagraph is a State that demonstrates to the Secretary that the State—

(i) has made a good faith effort to comply with the requirements of paragraphs (1) and (2) (including by taking steps to adopt the technology used for an electronic visit verification system); and

(ii) in implementing such a system, has encountered unavoidable system delays.

(5) In this subsection:

(A) The term "electronic visit verification system" means, with respect to personal care services or home health care

services, a system under which visits conducted as part of such services are electronically verified with respect to—

(i) the type of service performed;

(ii) the individual receiving the service;

(iii) the date of the service;

(iv) the location of service delivery;

(v) the individual providing the service; and

(vi) the time the service begins and ends.

(B) The term "home health care services" means services described in section 1905(a)(7) provided under a State plan under this title (or under a waiver of the plan).

(C) The term "personal care services" means personal care services provided under a State plan under this title (or under a waiver of the plan), including services provided under section 1905(a)(24), 1915(c), 1915(i), 1915(j), or 1915(k) or under a wavier under section 1115.

(6)(A) In the case in which a State requires personal care service and home health care service providers to utilize an electronic visit verification system operated by the State or a contractor on behalf of the State, the Secretary shall pay to the State, for each quarter, an amount equal to 90 per centum of so much of the sums expended during such quarter as are attributable to the design, development, or installation of such system, and 75 per centum of so much of the sums for the operation and maintenance of such system.

(B) Subparagraph (A) shall not apply in the case in which a State requires personal care service and home health care service providers to utilize an electronic visit verification system that is not operated by the State or a contractor on behalf of the State.

(m)(1)(A) The term "medicaid managed care organization" means a health maintenance organization, an eligible organization with a contract under section 1876 or a Medicare+Choice organization with a contract under part C of title XVIII, a provider sponsored organization, or any other public or private organization, which meets the requirement of section 1902(w) and—

(i) makes services it provides to individuals eligible for benefits under this title accessible to such individuals, within the area served by the organization, to the same extent as such services are made accessible to individuals (eligible for medical assistance under the State plan) not enrolled with the organization, and

(ii) has made adequate provision against the risk of insolvency, which provision is satisfactory to the State, meets the requirements of subparagraph (C)(i) (if applicable), and which assures that individuals eligible for benefits under this title are in no case held liable for debts of the organization in case of the organization's insolvency.

An organization that is a qualified health maintenance organization (as defined in section 1310(d) of the Public Health Service Act) is deemed to meet the requirements of clauses (i) and (ii).

(B) The duties and functions of the Secretary, insofar as they involve making determinations as to whether an organization is a medicaid managed care organization within the meaning of subparagraph (A), shall be integrated with the administration of section 1312 (a) and (b) of the Public Health Service Act.

(C)(i) Subject to clause (ii), a provision meets the requirements of this subparagraph for an organization if the organization meets solvency standards established by the State for private health maintenance organizations or is licensed or certified by the State as a risk-bearing entity.

(ii) Clause (i) shall not apply to an organization if—

(I) the organization is not responsible for the provision (directly or through arrangements with providers of services) of inpatient hospital services and physicians' services;

(II) the organization is a public entity;

(III) the solvency of the organization is guaranteed by the State; or

(IV) the organization is (or is controlled by) one or more Federally-qualified health centers and meets solvency standards established by the State for such an organization.

For purposes of subclause (IV), the term "control" means the possession, whether direct or indirect, of the power to direct or cause the direction of the management and policies of the organization through membership, board representation, or an ownership interest equal to or greater than 50.1 percent.

(2)(A) Except as provided in subparagraphs (B), (C), and (G), no payment shall be made under this title to a State with respect to expenditures incurred by it for payment (determined under a prepaid capitation basis or under any other risk basis) for services provided by any entity (including a health insuring organization) which is responsible for the provision (directly or through arrangements with providers of services) of inpatient hospital services and any other service described in paragraph (2), (3), (4), (5), or (7) of section 1905(a) or for the provision of any three or more of the services described in such paragraphs unless—

(i) the Secretary has determined that the entity is a medicaid managed care organization organization as defined in paragraph (1);

(iii) such services are provided for the benefit of individuals eligible for benefits under this title in accordance with a contract between the State and the entity under which prepaid payments to the entity are made on an actuarially sound basis and under which the Secretary must provide prior approval for contracts providing for expenditures in excess of $1,000,000 for 1998 and, for a subsequent year, the amount established under this clause for the previous year increased by the percentage increase in the consumer price index for all urban consumers over the previous year;

(iv) such contract provides that the Secretary and the State (or any person or organization designated by either) shall have the right to audit and inspect any books and records of the entity (and of any subcontractor) that pertain (I) to the ability of the entity to bear the risk of potential financial losses, or (II) to services performed or determinations of amounts payable under the contract;

(v) such contract provides that in the entity's enrollment, reenrollment, or disenrollment of individuals who are eligible for benefits under this title and eligible to enroll, reenroll, or disenroll with the entity pursuant to the contract, the entity

will not discriminate among such individuals on the basis of their health status or requirements for health care services;

(vi) such contract (I) permits individuals who have elected under the plan to enroll with the entity for provision of such benefits to terminate such enrollment in accordance with section 1932(a)(4), and (II) provides for notification in accordance with such section of each such individual, at the time of the individual's enrollment, of such right to terminate such enrollment;

(vii) such contract provides that, in the case of medically necessary services which were provided (I) to an individual enrolled with the entity under the contract and entitled to benefits with respect to such services under the State's plan and (II) other than through the organization because the services were immediately required due to an unforeseen illness, injury, or condition, either the entity or the State provides for reimbursement with respect to those services,

(viii) such contract provides for disclosure of information in accordance with section 1124 and paragraph (4) of this subsection;

(ix) such contract provides, in the case of an entity that has entered into a contract for the provision of services with a Federally-qualified health center or a rural health clinic, that the entity shall provide payment that is not less than the level and amount of payment which the entity would make for the services if the services were furnished by a provider which is not a Federally-qualified health center or a rural health clinic;

(x) any physician incentive plan that it operates meets the requirements described in section 1876(i)(8);

(xi) such contract provides for maintenance of sufficient patient encounter data to identify the physician who delivers services to patients and for the provision of such data to the State at a frequency and level of detail to be specified by the Secretary;

(xii) such contract, and the entity complies with the applicable requirements of section 1932; and

(xiii) such contract provides that (I) covered outpatient drugs dispensed to individuals eligible for medical assistance who are enrolled with the entity shall be subject to the same rebate required by the agreement entered into under section 1927 as the State is subject to and that the State shall collect such rebates from manufacturers, (II) capitation rates paid to the entity shall be based on actual cost experience related to rebates and subject to the Federal regulations requiring actuarially sound rates, and (III) the entity shall report to the State, on such timely and periodic basis as specified by the Secretary in order to include in the information submitted by the State to a manufacturer and the Secretary under section 1927(b)(2)(A), information on the total number of units of each dosage form and strength and package size by National Drug Code of each covered outpatient drug dispensed to individuals eligible for medical assistance who are enrolled with the entity and for which the entity is responsible for coverage of such drug under this subsection (other than cov-

ered outpatient drugs that under subsection (j)(1) of section 1927 are not subject to the requirements of that section) and such other data as the Secretary determines necessary to carry out this subsection.

(B) Subparagraph (A) except with respect to clause (ix) of subparagraph (A), does not apply with respect to payments under this title to a State with respect to expenditures incurred by it for payment for services provided by an entity which—

(i)(I) received a grant of at least $100,000 in the fiscal year ending June 30, 1976, under section 329(d)(1)(A) or 330(d)(1) of the Public Health Service Act, and for the period beginning July 1, 1976, and ending on the expiration of the period for which payments are to be made under this title has been the recipient of a grant under either such section; and

(II) provides to its enrollees, on a prepaid capitation risk basis or on any other risk basis, all of the services and benefits described in paragraphs (1), (2), (3), (4)(C), and (5) of section 1905(a) and, to the extent required by section 1902(a)(10)(D) to be provided under a State plan for medical assistance, the services and benefits described in paragraph (7) of section 1905(a); or

(ii) is a nonprofit primary health care entity located in a rural area (as defined by the Appalachian Regional Commission)—

(I) which received in the fiscal year ending June 30, 1976, at least $100,000 (by grant, subgrant, or subcontract) under the Appalachian Regional Development Act of 1965, and

(II) for the period beginning July 1, 1976, and ending on the expiration of the period for which payments are to be made under this title either has been the recipient of a grant, subgrant, or subcontract under such Act or has provided services under a contract (initially entered into during a year in which the entity was the recipient of such a grant, subgrant, or subcontract) with a State agency under this title on a prepaid capitation risk basis or on any other risk basis; or

(iii) which has contracted with the single State agency for the provision of services (but not including inpatient hospital services) to persons eligible under this title on a prepaid risk basis prior to 1970.

(G) In the case of an entity which is receiving (and has received during the previous two years) a grant of at least $100,000 under section 329(d)(1)(A) or 330(d)(1) of the Public Health Service Act or is receiving (and has received during the previous two years) at least $100,000 (by grant, subgrant, or subcontract) under the Appalachian Regional Development Act of 1965, clause (i) of subparagraph (A) shall not apply.

(H) In the case of an individual who—

(i) in a month is eligible for benefits under this title and enrolled with a medicaid managed care organization with a contract under this paragraph or with a primary care case manager with a contract described in section 1905(t)(3),

(ii) in the next month (or in the next 2 months) is not eligible for such benefits, but

(iii) in the succeeding month is again eligible for such benefits,

the State plan, subject to subparagraph (A)(vi), may enroll the individual for that succeeding month with the organization described in clause (i) if the organization continues to have a contract under this paragraph with the State or with the manager described in such clause if the manager continues to have a contract described in section 1905(t)(3) with the State.

(3) No payment shall be made under this title to a State with respect to expenditures incurred by the State for payment for services provided by a managed care entity (as defined under section 1932(a)(1)) under the State plan under this title (or under a waiver of the plan) unless the State—

(A) beginning on July 1, 2018, has a contract with such entity that complies with the requirement specified in section 1932(d)(5); and

(B) beginning on January 1, 2018, complies with the requirement specified in section 1932(d)(6)(A).

(4)(A) Each medicaid managed care organization which is not a qualified health maintenance organization (as defined in section 1310(d) of the Public Health Service Act) must report to the State and, upon request, to the Secretary, the Inspector General of the Department of Health and Human Services, and the Comptroller General a description of transactions between the organization and a party in interest (as defined in section 1318(b) of such Act), including the following transactions:

(i) Any sale or exchange, or leasing of any property between the organization and such a party.

(ii) Any furnishing for consideration of goods, services (including management services), or facilities between the organization and such a party, but not including salaries paid to employees for services provided in the normal course of their employment.

(iii) Any lending of money or other extension of credit between the organization and such a party.

The State or Secretary may require that information reported respecting an organization which controls, or is controlled by, or is under common control with, another entity be in the form of a consolidated financial statement for the organization and such entity.

(B) Each organization shall make the information reported pursuant to subparagraph (A) available to its enrollees upon reasonable request.

(5)(A) If the Secretary determines that an entity with a contract under this subsection—

(i) fails substantially to provide medically necessary items and services that are required (under law or under the contract) to be provided to an individual covered under the contract, if the failure has adversely affected (or has substantial likelihood of adversely affecting) the individual;

(ii) imposes premiums on individuals enrolled under this subsection in excess of the premiums permitted under this title;

(iii) acts to discriminate among individuals in violation of the provision of paragraph (2)(A)(v), including expulsion or refusal to re-enroll an individual or engaging in any practice that

would reasonably be expected to have the effect of denying or discouraging enrollment (except as permitted by this subsection) by eligible individuals with the organization whose medical condition or history indicates a need for substantial future medical services;

(iv) misrepresents or falsifies information that is furnished—

(I) to the Secretary or the State under this subsection, or

(II) to an individual or to any other entity under this subsection, or

(v) fails to comply with the requirements of section 1876(i)(8),

the Secretary may provide, in addition to any other remedies available under law, for any of the remedies described in subparagraph (B).

(B) The remedies described in this subparagraph are—

(i) civil money penalties of not more than $25,000 for each determination under subparagraph (A), or, with respect to a determination under clause (iii) or (iv)(I) of such subparagraph, of not more than $100,000 for each such determination, plus, with respect to a determination under subparagraph (A)(ii), double the excess amount charged in violation of such subparagraph (and the excess amount charged shall be deducted from the penalty and returned to the individual concerned), and plus, with respect to a determination under subparagraph (A)(iii), $15,000 for each individual not enrolled as a result of a practice described in such subparagraph, or

(ii) denial of payment to the State for medical assistance furnished under the contract under this subsection for individuals enrolled after the date the Secretary notifies the organization of a determination under subparagraph (A) and until the Secretary is satisfied that the basis for such determination has been corrected and is not likely to recur.

The provisions of section 1128A (other than subsections (a) and (b)) shall apply to a civil money penalty under clause (i) in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

(6)(A) For purposes of this subsection and section 1902(e)(2)(A), in the case of the State of New Jersey, the term "contract" shall be deemed to include an undertaking by the State agency, in the State plan under this title, to operate a program meeting all requirements of this subsection.

(B) The undertaking described in subparagraph (A) must provide—

(i) for the establishment of a separate entity responsible for the operation of a program meeting the requirements of this subsection, which entity may be a subdivision of the State agency administering the State plan under this title;

(ii) for separate accounting for the funds used to operate such program; and

(iii) for setting the capitation rates and any other payment rates for services provided in accordance with this subsection using a methodology satisfactory to the Secretary designed to ensure that total Federal matching payments under this title for such services will be lower than the matching payments

that would be made for the same services, if provided under the State plan on a fee for service basis to an actuarially equivalent population.

(C) The undertaking described in subparagraph (A) shall be subject to approval (and annual re-approval) by the Secretary in the same manner as a contract under this subsection.

(D) The undertaking described in subparagraph (A) shall not be eligible for a waiver under section 1915(b).

(7) Payment shall be made under this title to a State for expenditures for capitation payments described in section 438.6(e) of title 42, Code of Federal Regulations (or any successor regulation).

(8)(A) The State agency administering the State plan under this title may have reasonable access, as determined by the State, to 1 or more prescription drug monitoring program databases administered or accessed by the State to the extent the State agency is permitted to access such databases under State law.

(B) Such State agency may facilitate reasonable access, as determined by the State, to 1 or more prescription drug monitoring program databases administered or accessed by the State, to same extent that the State agency is permitted under State law to access such databases, for—

(i) any provider enrolled under the State plan to provide services to Medicaid beneficiaries; and

(ii) any managed care entity (as defined under section 1932(a)(1)(B)) that has a contract with the State under this subsection or under section 1905(t)(3).

(C) Such State agency may share information in such databases, to the same extent that the State agency is permitted under State law to share information in such databases, with—

(i) any provider enrolled under the State plan to provide services to Medicaid beneficiaries; and

(ii) any managed care entity (as defined under section 1932(a)(1)(B)) that has a contract with the State under this subsection or under section 1905(t)(3).

(9)(A) With respect to expenditures described in subparagraph (B) that are incurred by a State for any fiscal year after fiscal year 2020 (and before fiscal year 2024), in determining the pro rata share to which the United States is equitably entitled under subsection (d)(3), the Secretary shall substitute the Federal medical assistance percentage that applies for such fiscal year to the State under section 1905(b) (without regard to any adjustments to such percentage applicable under such section or any other provision of law) for the percentage that applies to such expenditures under section 1905(y).

(B) Expenditures described in this subparagraph, with respect to a fiscal year to which subparagraph (A) applies, are expenditures incurred by a State for payment for medical assistance provided to individuals described in subclause (VIII) of section 1902(a)(10)(A)(i) by a managed care entity, or other specified entity (as defined in subparagraph (D)(iii)), that are treated as remittances because the State—

(i) has satisfied the requirement of section 438.8 of title 42, Code of Federal Regulations (or any successor regulation), by electing—

(I) in the case of a State described in subparagraph (C), to apply a minimum medical loss ratio (as defined in subparagraph (D)(ii)) that is at least 85 percent but not greater than the minimum medical loss ratio (as so defined) that such State applied as of May 31, 2018; or

(II) in the case of a State not described in subparagraph (C), to apply a minimum medical loss ratio that is equal to 85 percent; and

(ii) recovered all or a portion of the expenditures as a result of the entity's failure to meet such ratio.

(C) For purposes of subparagraph (B), a State described in this subparagraph is a State that as of May 31, 2018, applied a minimum medical loss ratio (as calculated under subsection (d) of section 438.8 of title 42, Code of Federal Regulations (as in effect on June 1, 2018)) for payment for services provided by entities described in such subparagraph under the State plan under this title (or a waiver of the plan) that is equal to or greater than 85 percent.

(D) For purposes of this paragraph:

(i) The term "managed care entity" means a medicaid managed care organization described in section 1932(a)(1)(B)(i).

(ii) The term "minimum medical loss ratio" means, with respect to a State, a minimum medical loss ratio (as calculated under subsection (d) of section 438.8 of title 42, Code of Federal Regulations (as in effect on June 1, 2018)) for payment for services provided by entities described in subparagraph (B) under the State plan under this title (or a waiver of the plan).

(iii) The term "other specified entity" means—

(I) a prepaid inpatient health plan, as defined in section 438.2 of title 42, Code of Federal Regulations (or any successor regulation); and

(II) a prepaid ambulatory health plan, as defined in such section (or any successor regulation).

(o) Notwithstanding the preceding provisions of this section, no payment shall be made to a State under the preceding provisions of this section for expenditures for medical assistance provided for an individual under its State plan approved under this title to the extent that a private insurer (as defined by the Secretary by regulation and including a group health plan (as defined in section 607(1) of the Employee Retirement Income Security Act of 1974), a service benefit plan, and a health maintenance organization) would have been obligated to provide such assistance but for a provision of its insurance contract which has the effect of limiting or excluding such obligation because the individual is eligible for or is provided medical assistance under the plan.

(p)(1) When a political subdivision of a State makes, for the State of which it is a political subdivision, or one State makes, for another State, the enforcement and collection of rights of support or payment assigned under section 1912, pursuant to a cooperative arrangement under such section (either within or outside of such State), there shall be paid to such political subdivision or such other State from amounts which would otherwise represent the Federal share of payments for medical assistance provided to the eligible individuals on whose behalf such enforcement and collection was made, an amount equal to 15 percent of any amount collected which is attributable to such rights of support or payment.

(2) Where more than one jurisdiction is involved in such enforcement or collection, the amount of the incentive payment determined under paragraph (1) shall be allocated among the jurisdictions in a manner to be prescribed by the Secretary.

(q) For the purposes of this section, the term "State medicaid fraud control unit" means a single identifiable entity of the State government which the Secretary certifies (and annually recertifies) as meeting the following requirements:

(1) The entity (A) is a unit of the office of the State Attorney General or of another department of State government which possesses statewide authority to prosecute individuals for criminal violations, (B) is in a State the constitution of which does not provide for the criminal prosecution of individuals by a statewide authority and has formal procedures, approved by the Secretary, that (i) assure its referral of suspected criminal violations relating to the program under this title to the appropriate authority or authorities in the State for prosecution and (ii) assure its assistance of, and coordination with, such authority or authorities in such prosecutions, or (C) has a formal working relationship with the office of the State Attorney General and has formal procedures (including procedures for its referral of suspected criminal violations to such office) which are approved by the Secretary and which provide effective coordination of activities between the entity and such office with respect to the detection, investigation, and prosecution of suspected criminal violations relating to the program under this title.

(2) The entity is separate and distinct from the single State agency that administers or supervises the administration of the State plan under this title.

(3) The entity's function is conducting a statewide program for the investigation and prosecution of violations of all applicable State laws regarding any and all aspects of fraud in connection with (A) any aspect of the provision of medical assistance and the activities of providers of such assistance under the State plan under this title; and (B) upon the approval of the Inspector General of the relevant Federal agency, any aspect of the provision of health care services and activities of providers of such services under any Federal health care program (as defined in section 1128B(f)(1)), if the suspected fraud or violation of law in such case or investigation is primarily related to the State plan under this title.

(4)(A) The entity has—

(i) procedures for reviewing complaints of abuse or neglect of patients in health care facilities which receive payments under the State plan under this title;

(ii) at the option of the entity, procedures for reviewing complaints of abuse or neglect of patients residing in board and care facilities and of patients (who are receiving medical assistance under the State plan under this title (or waiver of such plan)) in a noninstitutional or other setting; and

(iii) procedures for acting upon such complaints under the criminal laws of the State or for referring such complaints to other State agencies for action.

(B) For purposes of this paragraph, the term "board and care facility" means a residential setting which receives payment (regardless of whether such payment is made under the State plan under this title) from or on behalf of two or more unrelated adults who reside in such facility, and for whom one or both of the following is provided:

(i) Nursing care services provided by, or under the supervision of, a registered nurse, licensed practical nurse, or licensed nursing assistant.

(ii) A substantial amount of personal care services that assist residents with the activities of daily living, including personal hygiene, dressing, bathing, eating, toileting, ambulation, transfer, positioning, self-medication, body care, travel to medical services, essential shopping, meal preparation, laundry, and housework.

(5) The entity provides for the collection, or referral for collection to a single State agency, of overpayments that are made under the State plan or under any Federal health care program (as so defined) to health care facilities and that are discovered by the entity in carrying out its activities. All funds collected in accordance with this paragraph shall be credited exclusively to, and available for expenditure under, the Federal health care program (including the State plan under this title) that was subject to the activity that was the basis for the collection.

(6) The entity employs such auditors, attorneys, investigators, and other necessary personnel and is organized in such a manner as is necessary to promote the effective and efficient conduct of the entity's activities.

(7) The entity submits to the Secretary an application and annual reports containing such information as the Secretary determines, by regulation, to be necessary to determine whether the entity meets the other requirements of this subsection.

(r)(1) In order to receive payments under subsection (a) for use of automated data systems in administration of the State plan under this title, a State must, in addition to meeting the requirements of paragraph (3), have in operation mechanized claims processing and information retrieval systems that meet the requirements of this subsection and that the Secretary has found—

(A) are adequate to provide efficient, economical, and effective administration of such State plan;

(B) are compatible with the claims processing and information retrieval systems used in the administration of title XVIII, and for this purpose—

(i) have a uniform identification coding system for providers, other payees, and beneficiaries under this title or title XVIII;

(ii) provide liaison between States and carriers and intermediaries with agreements under title XVIII to facilitate timely exchange of appropriate data;

(iii) provide for exchange of data between the States and the Secretary with respect to persons sanctioned under this title or title XVIII; and

(iv) effective for claims filed on or after October 1, 2010, incorporate compatible methodologies of the National Cor-

rect Coding Initiative administered by the Secretary (or any successor initiative to promote correct coding and to control improper coding leading to inappropriate payment) and such other methodologies of that Initiative (or such other national correct coding methodologies) as the Secretary identifies in accordance with paragraph (4);

(C) are capable of providing accurate and timely data;

(D) are complying with the applicable provisions of part C of title XI;

(E) are designed to receive provider claims in standard formats to the extent specified by the Secretary; and

(F) effective for claims filed on or after January 1, 1999, provide for electronic transmission of claims data in the format specified by the Secretary and consistent with the Medicaid Statistical Information System (MSIS) (including detailed individual enrollee encounter data and other information that the Secretary may find necessary and including, for data submitted to the Secretary on or after January 1, 2010, data elements from the automated data system that the Secretary determines to be necessary for program integrity, program oversight, and administration, at such frequency as the Secretary shall determine).

(2) In order to meet the requirements of this paragraph, mechanized claims processing and information retrieval systems must meet the following requirements:

(A) The systems must be capable of developing provider, physician, and patient profiles which are sufficient to provide specific information as to the use of covered types of services and items, including prescribed drugs.

(B) The State must provide that information on probable fraud or abuse which is obtained from, or developed by, the systems, is made available to the State's medicaid fraud control unit (if any) certified under subsection (q) of this section.

(C) The systems must meet all performance standards and other requirements for initial approval developed by the Secretary.

(3) In order to meet the requirements of this paragraph, a State must have in operation an eligibility determination system which provides for data matching through the Public Assistance Reporting Information System (PARIS) facilitated by the Secretary (or any successor system), including matching with medical assistance programs operated by other States.

(4) For purposes of paragraph (1)(B)(iv), the Secretary shall do the following:

(A) Not later than September 1, 2010:

(i) Identify those methodologies of the National Correct Coding Initiative administered by the Secretary (or any successor initiative to promote correct coding and to control improper coding leading to inappropriate payment) which are compatible to claims filed under this title.

(ii) Identify those methodologies of such Initiative (or such other national correct coding methodologies) that should be incorporated into claims filed under this title with respect to items or services for which States provide medical assistance under this title and no national correct

coding methodologies have been established under such Initiative with respect to title XVIII.

(iii) Notify States of—

(I) the methodologies identified under subparagraphs (A) and (B) (and of any other national correct coding methodologies identified under subparagraph (B)); and

(II) how States are to incorporate such methodologies into claims filed under this title.

(B) Not later than March 1, 2011, submit a report to Congress that includes the notice to States under clause (iii) of subparagraph (A) and an analysis supporting the identification of the methodologies made under clauses (i) and (ii) of subparagraph (A).

(s) Notwithstanding the preceding provisions of this section, no payment shall be made to a State under this section for expenditures for medical assistance under the State plan consisting of a designated health service (as defined in subsection (h)(6) of section 1877) furnished to an individual on the basis of a referral that would result in the denial of payment for the service under title XVIII if such title provided for coverage of such service to the same extent and under the same terms and conditions as under the State plan, and subsections (f) and (g)(5) of such section shall apply to a provider of such a designated health service for which payment may be made under this title in the same manner as such subsections apply to a provider of such a service for which payment may be made under such title.

(t)(1) For purposes of subsection (a)(3)(F), the payments described in this paragraph to encourage the adoption and use of certified EHR technology are payments made by the State in accordance with this subsection —

(A) to Medicaid providers described in paragraph (2)(A) not in excess of 85 percent of net average allowable costs (as defined in paragraph (3)(E)) for certified EHR technology (and support services including maintenance and training that is for, or is necessary for the adoption and operation of, such technology) with respect to such providers; and

(B) to Medicaid providers described in paragraph (2)(B) not in excess of the maximum amount permitted under paragraph (5) for the provider involved.

(2) In this subsection and subsection (a)(3)(F), the term "Medicaid provider" means—

(A) an eligible professional (as defined in paragraph (3)(B))—

(i) who is not hospital-based and has at least 30 percent of the professional's patient volume (as estimated in accordance with a methodology established by the Secretary) attributable to individuals who are receiving medical assistance under this title;

(ii) who is not described in clause (i), who is a pediatrician, who is not hospital-based, and who has at least 20 percent of the professional's patient volume (as estimated in accordance with a methodology established by the Secretary) attributable to individuals who are receiving medical assistance under this title; and

(iii) who practices predominantly in a Federally qualified health center or rural health clinic and has at least 30 percent of the professional's patient volume (as estimated in accordance with a methodology established by the Secretary) attributable to needy individuals (as defined in paragraph (3)(F)); and

(B)(i) a children's hospital, or

(ii) an acute-care hospital that is not described in clause (i) and that has at least 10 percent of the hospital's patient volume (as estimated in accordance with a methodology established by the Secretary) attributable to individuals who are receiving medical assistance under this title.

An eligible professional shall not qualify as a Medicaid provider under this subsection unless any right to payment under sections 1848(o) and 1853(l) with respect to the eligible professional has been waived in a manner specified by the Secretary. For purposes of calculating patient volume under subparagraph (A)(iii), insofar as it is related to uncompensated care, the Secretary may require the adjustment of such uncompensated care data so that it would be an appropriate proxy for charity care, including a downward adjustment to eliminate bad debt data from uncompensated care. In applying subparagraphs (A) and (B)(ii), the methodology established by the Secretary for patient volume shall include individuals enrolled in a Medicaid managed care plan (under section 1903(m) or section 1932).

(3) In this subsection and subsection (a)(3)(F):

(A) The term "certified EHR technology" means a qualified electronic health record (as defined in 3000(13) of the Public Health Service Act) that is certified pursuant to section 3001(c)(5) of such Act as meeting standards adopted under section 3004 of such Act that are applicable to the type of record involved (as determined by the Secretary, such as an ambulatory electronic health record for office-based physicians or an inpatient hospital electronic health record for hospitals).

(B) The term "eligible professional" means a—

(i) physician;

(ii) dentist;

(iii) certified nurse mid-wife;

(iv) nurse practitioner; and

(v) physician assistant insofar as the assistant is practicing in a rural health clinic that is led by a physician assistant or is practicing in a Federally qualified health center that is so led.

(C) The term "average allowable costs" means, with respect to certified EHR technology of Medicaid providers described in paragraph (2)(A) for—

(i) the first year of payment with respect to such a provider, the average costs for the purchase and initial implementation or upgrade of such technology (and support services including training that is for, or is necessary for the adoption and initial operation of, such technology) for such providers, as determined by the Secretary based upon studies conducted under paragraph (4)(C); and

(ii) a subsequent year of payment with respect to such a provider, the average costs not described in clause (i) re-

lating to the operation, maintenance, and use of such technology for such providers, as determined by the Secretary based upon studies conducted under paragraph (4)(C).

(D) The term "hospital-based" means, with respect to an eligible professional, a professional (such as a pathologist, anesthesiologist, or emergency physician) who furnishes substantially all of the individual's professional services in a hospital inpatient or emergency room setting and through the use of the facilities and equipment, including qualified electronic health records, of the hospital. The determination of whether an eligible professional is a hospital-based eligible professional shall be made on the basis of the site of service (as defined by the Secretary) and without regard to any employment or billing arrangement between the eligible professional and any other provider.

(E) The term "net average allowable costs" means, with respect to a Medicaid provider described in paragraph (2)(A), average allowable costs reduced by the average payment the Secretary estimates will be made to such Medicaid providers (determined on a percentage or other basis for such classes or types of providers as the Secretary may specify) from other sources (other than under this subsection, or by the Federal government or a State or local government) that is directly attributable to payment for certified EHR technology or support services described in subparagraph (C).

(F) The term "needy individual" means, with respect to a Medicaid provider, an individual—

(i) who is receiving assistance under this title;

(ii) who is receiving assistance under title XXI;

(iii) who is furnished uncompensated care by the provider; or

(iv) for whom charges are reduced by the provider on a sliding scale basis based on an individual's ability to pay.

(4)(A) With respect to a Medicaid provider described in paragraph (2)(A), subject to subparagraph (B), in no case shall—

(i) the net average allowable costs under this subsection for the first year of payment (which may not be later than 2016), which is intended to cover the costs described in paragraph (3)(C)(i), exceed $25,000 (or such lesser amount as the Secretary determines based on studies conducted under subparagraph (C));

(ii) the net average allowable costs under this subsection for a subsequent year of payment, which is intended to cover costs described in paragraph (3)(C)(ii), exceed $10,000; and

(iii) payments be made for costs described in clause (ii) after 2021 or over a period of longer than 5 years.

(B) In the case of Medicaid provider described in paragraph (2)(A)(ii), the dollar amounts specified in subparagraph (A) shall be ⅔ of the dollar amounts otherwise specified.

(C) For the purposes of determining average allowable costs under this subsection, the Secretary shall study the average costs to Medicaid providers described in paragraph (2)(A) of purchase and initial implementation and upgrade of certified EHR technology described in paragraph (3)(C)(i) and the average costs to

such providers of operations, maintenance, and use of such technology described in paragraph (3)(C)(ii). In determining such costs for such providers, the Secretary may utilize studies of such amounts submitted by States.

(5)(A) In no case shall the payments described in paragraph (1)(B) with respect to a Medicaid provider described in paragraph (2)(B) exceed—

(i) in the aggregate the product of—

(I) the overall hospital EHR amount for the provider computed under subparagraph (B); and

(II) the Medicaid share for such provider computed under subparagraph (C);

(ii) in any year 50 percent of the product described in clause (i); and

(iii) in any 2-year period 90 percent of such product.

(B) For purposes of this paragraph, the overall hospital EHR amount, with respect to a Medicaid provider, is the sum of the applicable amounts specified in section 1886(n)(2)(A) for such provider for the first 4 payment years (as estimated by the Secretary) determined as if the Medicare share specified in clause (ii) of such section were 1. The Secretary shall establish, in consultation with the State, the overall hospital EHR amount for each such Medicaid provider eligible for payments under paragraph (1)(B). For purposes of this subparagraph in computing the amounts under section 1886(n)(2)(C) for payment years after the first payment year, the Secretary shall assume that in subsequent payment years discharges increase at the average annual rate of growth of the most recent 3 years for which discharge data are available per year.

(C) The Medicaid share computed under this subparagraph, for a Medicaid provider for a period specified by the Secretary, shall be calculated in the same manner as the Medicare share under section 1886(n)(2)(D) for such a hospital and period, except that there shall be substituted for the numerator under clause (i) of such section the amount that is equal to the number of inpatient-bed-days (as established by the Secretary) which are attributable to individuals who are receiving medical assistance under this title and who are not described in section 1886(n)(2)(D)(i). In computing inpatient-bed-days under the previous sentence, the Secretary shall take into account inpatient-bed-days attributable to inpatient-bed-days that are paid for individuals enrolled in a Medicaid managed care plan (under section 1903(m) or section 1932).

(D) In no case may the payments described in paragraph (1)(B) with respect to a Medicaid provider described in paragraph (2)(B) be paid—

(i) for any year beginning after 2016 unless the provider has been provided payment under paragraph (1)(B) for the previous year; and

(ii) over a period of more than 6 years of payment.

(6) Payments described in paragraph (1) are not in accordance with this subsection unless the following requirements are met:

(A)(i) The State provides assurances satisfactory to the Secretary that amounts received under subsection (a)(3)(F) with respect to payments to a Medicaid provider are paid, subject to clause (ii), directly to such provider (or to an employer or facil-

ity to which such provider has assigned payments) without any deduction or rebate.

(ii) Amounts described in clause (i) may also be paid to an entity promoting the adoption of certified EHR technology, as designated by the State, if participation in such a payment arrangement is voluntary for the eligible professional involved and if such entity does not retain more than 5 percent of such payments for costs not related to certified EHR technology (and support services including maintenance and training) that is for, or is necessary for the operation of, such technology.

(B) A Medicaid provider described in paragraph (2)(A) is responsible for payment of the remaining 15 percent of the net average allowable cost and shall be determined to have met such responsibility to the extent that the payment to the Medicaid provider is not in excess of 85 percent of the net average allowable cost.

(C)(i) Subject to clause (ii), with respect to payments to a Medicaid provider—

(I) for the first year of payment to the Medicaid provider under this subsection, the Medicaid provider demonstrates that it is engaged in efforts to adopt, implement, or upgrade certified EHR technology; and

(II) for a year of payment, other than the first year of payment to the Medicaid provider under this subsection, the Medicaid provider demonstrates meaningful use of certified EHR technology through a means that is approved by the State and acceptable to the Secretary, and that may be based upon the methodologies applied under section 1848(o) or 1886(n).

(ii) In the case of a Medicaid provider who has completed adopting, implementing, or upgrading such technology prior to the first year of payment to the Medicaid provider under this subsection, clause (i)(I) shall not apply and clause (i)(II) shall apply to each year of payment to the Medicaid provider under this subsection, including the first year of payment.

(D) To the extent specified by the Secretary, the certified EHR technology is compatible with State or Federal administrative management systems.

For purposes of subparagraph (B), a Medicaid provider described in paragraph (2)(A) may accept payments for the costs described in such subparagraph from a State or local government. For purposes of subparagraph (C), in establishing the means described in such subparagraph, which may include clinical quality reporting to the State, the State shall ensure that populations with unique needs, such as children, are appropriately addressed.

(7) With respect to Medicaid providers described in paragraph (2)(A), the Secretary shall ensure coordination of payment with respect to such providers under sections 1848(o) and 1853(l) and under this subsection to assure no duplication of funding. Such coordination shall include, to the extent practicable, a data matching process between State Medicaid agencies and the Centers for Medicare & Medicaid Services using national provider identifiers. For such purposes, the Secretary may require the submission of such data relating to payments to such Medicaid providers as the Secretary may specify.

(8) In carrying out paragraph (6)(C), the State and Secretary shall seek, to the maximum extent practicable, to avoid duplicative requirements from Federal and State governments to demonstrate meaningful use of certified EHR technology under this title and title XVIII. In doing so, the Secretary may deem satisfaction of requirements for such meaningful use for a payment year under title XVIII to be sufficient to qualify as meaningful use under this subsection. The Secretary may also specify the reporting periods under this subsection in order to carry out this paragraph.

(9) In order to be provided Federal financial participation under subsection (a)(3)(F)(ii), a State must demonstrate to the satisfaction of the Secretary, that the State—

(A) is using the funds provided for the purposes of administering payments under this subsection, including tracking of meaningful use by Medicaid providers;

(B) is conducting adequate oversight of the program under this subsection, including routine tracking of meaningful use attestations and reporting mechanisms; and

(C) is pursuing initiatives to encourage the adoption of certified EHR technology to promote health care quality and the exchange of health care information under this title, subject to applicable laws and regulations governing such exchange.

(10) The Secretary shall periodically submit reports to the Committee on Energy and Commerce of the House of Representatives and the Committee on Finance of the Senate on status, progress, and oversight of payments described in paragraph (1), including steps taken to carry out paragraph (7). Such reports shall also describe the extent of adoption of certified EHR technology among Medicaid providers resulting from the provisions of this subsection and any improvements in health outcomes, clinical quality, or efficiency resulting from such adoption.

(u)(1)(A) Notwithstanding subsection (a)(1), if the ratio of a State's erroneous excess payments for medical assistance (as defined in subparagraph (D)) to its total expenditures for medical assistance under the State plan approved under this title exceeds 0.03, for the period consisting of the third and fourth quarters of fiscal year 1983, or for any full fiscal year thereafter, then the Secretary shall make no payment for such period or fiscal year with respect to so much of such erroneous excess payments as exceeds such allowable error rate of 0.03.

(B) The Secretary may waive, in certain limited cases, all or part of the reduction required under subparagraph (A) with respect to any State if such State is unable to reach the allowable error rate for a period or fiscal year despite a good faith effort by such State.

(C) In estimating the amount to be paid to a State under subsection (d), the Secretary shall take into consideration the limitation on Federal financial participation imposed by subparagraph (A) and shall reduce the estimate he makes under subsection (d)(1), for purposes of payment to the State under subsection (d)(3), in light of any expected erroneous excess payments for medical assistance (estimated in accordance with such criteria, including sampling procedures, as he may prescribe and subject to subsequent adjustment, if necessary, under subsection (d)(2)).

(D)(i) For purposes of this subsection, the term "erroneous excess payments for medical assistance" means the total of—

(I) payments under the State plan with respect to ineligible individuals and families, and

(II) overpayments on behalf of eligible individuals and families by reason of error in determining the amount of expenditures for medical care required of an individual or family as a condition of eligibility.

(ii) In determining the amount of erroneous excess payments for medical assistance to an ineligible individual or family under clause (i)(I), if such ineligibility is the result of an error in determining the amount of the resources of such individual or family, the amount of the erroneous excess payment shall be the smaller of (I) the amount of the payment with respect to such individual or family, or (II) the difference between the actual amount of such resources and the allowable resource level established under the State plan.

(iii) In determining the amount of erroneous excess payments for medical assistance to an individual or family under clause (i)(II), the amount of the erroneous excess payment shall be the smaller of (I) the amount of the payment on behalf of the individual or family, or (II) the difference between the actual amount incurred for medical care by the individual or family and the amount which should have been incurred in order to establish eligibility for medical assistance.

(iv) In determining the amount of erroneous excess payments, there shall not be included any error resulting from a failure of an individual to cooperate or give correct information with respect to third-party liability as required under section 1912(a)(1)(C) or 402(a)(26)(C) or with respect to payments made in violation of section 1906.

(v) In determining the amount of erroneous excess payments, there shall not be included any erroneous payments made for ambulatory prenatal care provided during a presumptive eligibility period (as defined in section 1920(b)(1)), for items and services described in subsection (a) of section 1920A provided to a child during a presumptive eligibility period under such section, for medical assistance provided to an individual described in subsection (a) of section 1920B during a presumptive eligibility period under such section, or for medical assistance provided to an individual during a presumptive eligibility period resulting from a determination of presumptive eligibility made by a hospital that elects under section 1902(a)(47)(B) to be a qualified entity for such purpose.

(E) For purposes of subparagraph (D), there shall be excluded, in determining both erroneous excess payments for medical assistance and total expenditures for medical assistance—

(i) payments with respect to any individual whose eligibility therefor was determined exclusively by the Secretary under an agreement pursuant to section 1634 and such other classes of individuals as the Secretary may by regulation prescribe whose eligibility was determined in part under such an agreement; and

(ii) payments made as the result of a technical error.

(2) The State agency administering the plan approved under this title shall, at such times and in such form as the Secretary may specify, provide information on the rates of erroneous excess payments made (or expected, with respect to future periods specified

by the Secretary) in connection with its administration of such plan, together with any other data he requests that are reasonably necessary for him to carry out the provisions of this subsection.

(3)(A) If a State fails to cooperate with the Secretary in providing information necessary to carry out this subsection, the Secretary, directly or through contractual or such other arrangements as he may find appropriate, shall establish the error rates for that State on the basis of the best data reasonably available to him and in accordance with such techniques for sampling and estimating as he finds appropriate.

(B) In any case in which it is necessary for the Secretary to exercise his authority under subparagraph (A) to determine a State's error rates for a fiscal year, the amount that would otherwise be payable to such State under this title for quarters in such year shall be reduced by the costs incurred by the Secretary in making (directly or otherwise) such determination.

(4) This subsection shall not apply with respect to Puerto Rico, Guam, the Virgin Islands, the Northern Mariana Islands, or American Samoa.

(v)(1) Notwithstanding the preceding provisions of this section, except as provided in paragraphs (2) and (4), no payment may be made to a State under this section for medical assistance furnished to an alien who is not lawfully admitted for permanent residence or otherwise permanently residing in the United States under color of law.

(2) Payment shall be made under this section for care and services that are furnished to an alien described in paragraph (1) only if—

(A) such care and services are necessary for the treatment of an emergency medical condition of the alien,

(B) such alien otherwise meets the eligibility requirements for medical assistance under the State plan approved under this title (other than the requirement of the receipt of aid or assistance under title IV, supplemental security income benefits under title XVI, or a State supplementary payment), and

(C) such care and services are not related to an organ transplant procedure.

(3) For purposes of this subsection, the term "emergency medical condition" means a medical condition (including emergency labor and delivery) manifesting itself by acute symptoms of sufficient severity (including severe pain) such that the absence of immediate medical attention could reasonably be expected to result in—

(A) placing the patient's health in serious jeopardy,

(B) serious impairment to bodily functions, or

(C) serious dysfunction of any bodily organ or part.

(4)(A) A State may elect (in a plan amendment under this title) to provide medical assistance under this title, notwithstanding sections 401(a), 402(b), 403, and 421 of the Personal Responsibility and Work Opportunity Reconciliation Act of 1996, to children and pregnant women who are lawfully residing in the United States (including battered individuals described in section 431(c) of such Act) and who are otherwise eligible for such assistance, within either or both of the following eligibility categories:

(i) PREGNANT WOMEN.—Women during pregnancy (and during the 60-day period beginning on the last day of the pregnancy).

(ii) CHILDREN.—Individuals under 21 years of age, including optional targeted low-income children described in section 1905(u)(2)(B).

(B) In the case of a State that has elected to provide medical assistance to a category of aliens under subparagraph (A), no debt shall accrue under an affidavit of support against any sponsor of such an alien on the basis of provision of assistance to such category and the cost of such assistance shall not be considered as an unreimbursed cost.

(C) As part of the State's ongoing eligibility redetermination requirements and procedures for an individual provided medical assistance as a result of an election by the State under subparagraph (A), a State shall verify that the individual continues to lawfully reside in the United States using the documentation presented to the State by the individual on initial enrollment. If the State cannot successfully verify that the individual is lawfully residing in the United States in this manner, it shall require that the individual provide the State with further documentation or other evidence to verify that the individual is lawfully residing in the United States.

(w)(1)(A) Notwithstanding the previous provisions of this section, for purposes of determining the amount to be paid to a State (as defined in paragraph (7)(D)) under subsection (a)(1) for quarters in any fiscal year, the total amount expended during such fiscal year as medical assistance under the State plan (as determined without regard to this subsection) shall be reduced by the sum of any revenues received by the State (or by a unit of local government in the State) during the fiscal year—

(i) from provider-related donations (as defined in paragraph (2)(A)), other than—

(I) bona fide provider-related donations (as defined in paragraph (2)(B)), and

(II) donations described in paragraph (2)(C);

(ii) from health care related taxes (as defined in paragraph (3)(A)), other than broad-based health care related taxes (as defined in paragraph (3)(B));

(iii) from a broad-based health care related tax, if there is in effect a hold harmless provision (described in paragraph (4)) with respect to the tax; or

(iv) only with respect to State fiscal years (or portions thereof) occurring on or after January 1, 1992, and before October 1, 1995, from broad-based health care related taxes to the extent the amount of such taxes collected exceeds the limit established under paragraph (5).

(B) Notwithstanding the previous provisions of this section, for purposes of determining the amount to be paid to a State under subsection (a)(7) for all quarters in a Federal fiscal year (beginning with fiscal year 1993), the total amount expended during the fiscal year for administrative expenditures under the State plan (as determined without regard to this subsection) shall be reduced by the sum of any revenues received by the State (or by a unit of local government in the State) during such quarters from donations de-

scribed in paragraph (2)(C), to the extent the amount of such donations exceeds 10 percent of the amounts expended under the State plan under this title during the fiscal year for purposes described in paragraphs (2), (3), (4), (6), and (7) of subsection (a).

(C)(i) Except as otherwise provided in clause (ii), subparagraph (A)(i) shall apply to donations received on or after January 1, 1992.

(ii) Subject to the limits described in clause (iii) and subparagraph (E), subparagraph (A)(i) shall not apply to donations received before the effective date specified in subparagraph (F) if such donations are received under programs in effect or as described in State plan amendments or related documents submitted to the Secretary by September 30, 1991, and applicable to State fiscal year 1992, as demonstrated by State plan amendments, written agreements, State budget documentation, or other documentary evidence in existence on that date.

(iii) In applying clause (ii) in the case of donations received in State fiscal year 1993, the maximum amount of such donations to which such clause may be applied may not exceed the total amount of such donations received in the corresponding period in State fiscal year 1992 (or not later than 5 days after the last day of the corresponding period).

(D)(i) Except as otherwise provided in clause (ii), subparagraphs (A)(ii) and (A)(iii) shall apply to taxes received on or after January 1, 1992.

(ii) Subparagraphs (A)(ii) and (A)(iii) shall not apply to impermissible taxes (as defined in clause (iii)) received before the effective date specified in subparagraph (F) to the extent the taxes (including the tax rate or base) were in effect, or the legislation or regulations imposing such taxes were enacted or adopted, as of November 22, 1991.

(iii) In this subparagraph and subparagraph (E), the term "impermissible tax" means a health care related tax for which a reduction may be made under clause (ii) or (iii) of subparagraph (A).

(E)(i) In no case may the total amount of donations and taxes permitted under the exception provided in subparagraphs (C)(ii) and (D)(ii) for the portion of State fiscal year 1992 occurring during calendar year 1992 exceed the limit under paragraph (5) minus the total amount of broad-based health care related taxes received in the portion of that fiscal year.

(ii) In no case may the total amount of donations and taxes permitted under the exception provided in subparagraphs (C)(ii) and (D)(ii) for State fiscal year 1993 exceed the limit under paragraph (5) minus the total amount of broad-based health care related taxes received in that fiscal year.

(F) In this paragraph in the case of a State—

(i) except as provided in clause (iii), with a State fiscal year beginning on or before July 1, the effective date is October 1, 1992,

(ii) except as provided in clause (iii), with a State fiscal year that begins after July 1, the effective date is January 1, 1993, or

(iii) with a State legislature which is not scheduled to have a regular legislative session in 1992, with a State legislature which is not scheduled to have a regular legislative session in

1993, or with a provider-specific tax enacted on November 4, 1991, the effective date is July 1, 1993.

(2)(A) In this subsection (except as provided in paragraph (6)), the term "provider-related donation" means any donation or other voluntary payment (whether in cash or in kind) made (directly or indirectly) to a State or unit of local government by—

(i) a health care provider (as defined in paragraph (7)(B)),

(ii) an entity related to a health care provider (as defined in paragraph (7)(C)), or

(iii) an entity providing goods or services under the State plan for which payment is made to the State under paragraph (2), (3), (4), (6), or (7) of subsection (a).

(B) For purposes of paragraph (1)(A)(i)(I), the term "bona fide provider-related donation" means a provider-related donation that has no direct or indirect relationship (as determined by the Secretary) to payments made under this title to that provider, to providers furnishing the same class of items and services as that provider, or to any related entity, as established by the State to the satisfaction of the Secretary. The Secretary may by regulation specify types of provider-related donations described in the previous sentence that will be considered to be bona fide provider-related donations.

(C) For purposes of paragraph (1)(A)(i)(II), donations described in this subparagraph are funds expended by a hospital, clinic, or similar entity for the direct cost (including costs of training and of preparing and distributing outreach materials) of State or local agency personnel who are stationed at the hospital, clinic, or entity to determine the eligibility of individuals for medical assistance under this title and to provide outreach services to eligible or potentially eligible individuals.

(3)(A) In this subsection (except as provided in paragraph (6)), the term "health care related tax" means a tax (as defined in paragraph (7)(F)) that—

(i) is related to health care items or services, or to the provision of, the authority to provide, or payment for, such items or services, or

(ii) is not limited to such items or services but provides for treatment of individuals or entities that are providing or paying for such items or services that is different from the treatment provided to other individuals or entities.

In applying clause (i), a tax is considered to relate to health care items or services if at least 85 percent of the burden of such tax falls on health care providers.

(B) In this subsection, the term "broad-based health care related tax" means a health care related tax which is imposed with respect to a class of health care items or services (as described in paragraph (7)(A)) or with respect to providers of such items or services and which, except as provided in subparagraphs (D), (E), and (F)—

(i) is imposed at least with respect to all items or services in the class furnished by all non-Federal, nonpublic providers in the State (or, in the case of a tax imposed by a unit of local government, the area over which the unit has jurisdiction) or is imposed with respect to all non-Federal, nonpublic providers in the class; and

(ii) is imposed uniformly (in accordance with subparagraph (C)).

(C)(i) Subject to clause (ii), for purposes of subparagraph (B)(ii), a tax is considered to be imposed uniformly if—

(I) in the case of a tax consisting of a licensing fee or similar tax on a class of health care items or services (or providers of such items or services), the amount of the tax imposed is the same for every provider providing items or services within the class;

(II) in the case of a tax consisting of a licensing fee or similar tax imposed on a class of health care items or services (or providers of such services) on the basis of the number of beds (licensed or otherwise) of the provider, the amount of the tax is the same for each bed of each provider of such items or services in the class;

(III) in the case of a tax based on revenues or receipts with respect to a class of items or services (or providers of items or services) the tax is imposed at a uniform rate for all items and services (or providers of such items of services) in the class on all the gross revenues or receipts, or net operating revenues, relating to the provision of all such items or services (or all such providers) in the State (or, in the case of a tax imposed by a unit of local government within the State, in the area over which the unit has jurisdiction); or

(IV) in the case of any other tax, the State establishes to the satisfaction of the Secretary that the tax is imposed uniformly.

(ii) Subject to subparagraphs (D) and (E), a tax imposed with respect to a class of health care items and services is not considered to be imposed uniformly if the tax provides for any credits, exclusions, or deductions which have as their purpose or effect the return to providers of all or a portion of the tax paid in a manner that is inconsistent with subclauses (I) and (II) of subparagraph (E)(ii) or provides for a hold harmless provision described in paragraph (4).

(D) A tax imposed with respect to a class of health care items and services is considered to be imposed uniformly—

(i) notwithstanding that the tax is not imposed with respect to items or services (or the providers thereof) for which payment is made under a State plan under this title or title XVIII, or

(ii) in the case of a tax described in subparagraph (C)(i)(III), notwithstanding that the tax provides for exclusion (in whole or in part) of revenues or receipts from a State plan under this title or title XVIII.

(E)(i) A State may submit an application to the Secretary requesting that the Secretary treat a tax as a broad-based health care related tax, notwithstanding that the tax does not apply to all health care items or services in class (or all providers of such items and services), provides for a credit, deduction, or exclusion, is not applied uniformly, or otherwise does not meet the requirements of subparagraph (B) or (C). Permissible waivers may include exemptions for rural or sole-community providers.

(ii) The Secretary shall approve such an application if the State establishes to the satisfaction of the Secretary that—

(I) the net impact of the tax and associated expenditures under this title as proposed by the State is generally redistributive in nature, and

(II) the amount of the tax is not directly correlated to payments under this title for items or services with respect to which the tax is imposed.

The Secretary shall by regulation specify types of credits, exclusions, and deductions that will be considered to meet the requirements of this subparagraph.

(F) In no case shall a tax not qualify as a broad-based health care related tax under this paragraph because it does not apply to a hospital that is described in section 501(c)(3) of the Internal Revenue Code of 1986 and exempt from taxation under section 501(a) of such Code and that does not accept payment under the State plan under this title or under title XVIII.

(4) For purposes of paragraph (1)(A)(iii), there is in effect a hold harmless provision with respect to a broad-based health care related tax imposed with respect to a class of items or services if the Secretary determines that any of the following applies:

(A) The State or other unit of government imposing the tax provides (directly or indirectly) for a payment (other than under this title) to taxpayers and the amount of such payment is positively correlated either to the amount of such tax or to the difference between the amount of the tax and the amount of payment under the State plan.

(B) All or any portion of the payment made under this title to the taxpayer varies based only upon the amount of the total tax paid.

(C)(i) The State or other unit of government imposing the tax provides (directly or indirectly) for any payment, offset, or waiver that guarantees to hold taxpayers harmless for any portion of the costs of the tax.

(ii) For purposes of clause (i), a determination of the existence of an indirect guarantee shall be made under paragraph (3)(i) of section 433.68(f) of title 42, Code of Federal Regulations, as in effect on November 1, 2006, except that for portions of fiscal years beginning on or after January 1, 2008, and before October 1, 2011, "5.5 percent" shall be substituted for "6 percent" each place it appears.

The provisions of this paragraph shall not prevent use of the tax to reimburse health care providers in a class for expenditures under this title nor preclude States from relying on such reimbursement to justify or explain the tax in the legislative process.

(5)(A) For purposes of this subsection, the limit under this subparagraph with respect to a State is an amount equal to 25 percent (or, if greater, the State base percentage, as defined in subparagraph (B)) of the non-Federal share of the total amount expended under the State plan during a State fiscal year (or portion thereof), as it would be determined pursuant to paragraph (1)(A) without regard to paragraph (1)(A)(iv).

(B)(i) In subparagraph (A), the term "State base percentage" means, with respect to a State, an amount (expressed as a percentage) equal to—

(I) the total of the amount of health care related taxes (whether or not broad-based) and the amount of provider-re-

lated donations (whether or not bona fide) projected to be collected (in accordance with clause (ii)) during State fiscal year 1992, divided by

(II) the non-Federal share of the total amount estimated to be expended under the State plan during such State fiscal year.

(ii) For purposes of clause (i)(I), in the case of a tax that is not in effect throughout State fiscal year 1992 or the rate (or base) of which is increased during such fiscal year, the Secretary shall project the amount to be collected during such fiscal year as if the tax (or increase) were in effect during the entire State fiscal year.

(C)(i) The total amount of health care related taxes under subparagraph (B)(i)(I) shall be determined by the Secretary based on only those taxes (including the tax rate or base) which were in effect, or for which legislation or regulations imposing such taxes were enacted or adopted, as of November 22, 1991.

(ii) The amount of provider-related donations under subparagraph (B)(i)(I) shall be determined by the Secretary based on programs in effect on September 30, 1991, and applicable to State fiscal year 1992, as demonstrated by State plan amendments, written agreements, State budget documentation, or other documentary evidence in existence on that date.

(iii) The amount of expenditures described in subparagraph (B)(i)(II) shall be determined by the Secretary based on the best data available as of the date of the enactment of this subsection.

(6)(A) Notwithstanding the provisions of this subsection, the Secretary may not restrict States' use of funds where such funds are derived from State or local taxes (or funds appropriated to State university teaching hospitals) transferred from or certified by units of government within a State as the non-Federal share of expenditures under this title, regardless of whether the unit of government is also a health care provider, except as provided in section 1902(a)(2), unless the transferred funds are derived by the unit of government from donations or taxes that would not otherwise be recognized as the non-Federal share under this section.

(B) For purposes of this subsection, funds the use of which the Secretary may not restrict under subparagraph (A) shall not be considered to be a provider-related donation or a health care related tax.

(7) For purposes of this subsection:

(A) Each of the following shall be considered a separate class of health care items and services:

(i) Inpatient hospital services.

(ii) Outpatient hospital services.

(iii) Nursing facility services (other than services of intermediate care facilities for the mentally retarded).

(iv) Services of intermediate care facilities for the mentally retarded.

(v) Physicians' services.

(vi) Home health care services.

(vii) Outpatient prescription drugs.

(viii) Services of managed care organizations (including health maintenance organizations, preferred provider organizations, and such other similar organizations as the Secretary may specify by regulation).

(ix) Such other classification of health care items and services consistent with this subparagraph as the Secretary may establish by regulation.

(B) The term "health care provider" means an individual or person that receives payments for the provision of health care items or services.

(C) An entity is considered to be "related" to a health care provider if the entity—

(i) is an organization, association, corporation or partnership formed by or on behalf of health care providers;

(ii) is a person with an ownership or control interest (as defined in section 1124(a)(3)) in the provider;

(iii) is the employee, spouse, parent, child, or sibling of the provider (or of a person described in clause (ii)); or

(iv) has a similar, close relationship (as defined in regulations) to the provider.

(D) The term "State" means only the 50 States and the District of Columbia but does not include any State whose entire program under this title is operated under a waiver granted under section 1115.

(E) The "State fiscal year" means, with respect to a specified year, a State fiscal year ending in that specified year.

(F) The term "tax" includes any licensing fee, assessment, or other mandatory payment, but does not include payment of a criminal or civil fine or penalty (other than a fine or penalty imposed in lieu of or instead of a fee, assessment, or other mandatory payment).

(G) The term "unit of local government" means, with respect to a State, a city, county, special purpose district, or other governmental unit in the State.

(x)(1) For purposes of section 1902(a)(46)(B)(i), the requirement of this subsection is, with respect to an individual declaring to be a citizen or national of the United States, that, subject to paragraph (2), there is presented satisfactory documentary evidence of citizenship or nationality (as defined in paragraph (3)) of the individual.

(2) The requirement of paragraph (1) shall not apply to an individual declaring to be a citizen or national of the United States who is eligible for medical assistance under this title—

(A) and is entitled to or enrolled for benefits under any part of title XVIII;

(B) and is receiving—

(i) disability insurance benefits under section 223 or monthly insurance benefits under section 202 based on such individual's disability (as defined in section 223(d)); or

(ii) supplemental security income benefits under title XVI;

(C) and with respect to whom—

(i) child welfare services are made available under part B of title IV on the basis of being a child in foster care; or

(ii) adoption or foster care assistance is made available under part E of title IV;

(D) pursuant to the application of section 1902(e)(4) (and, in the case of an individual who is eligible for medical assistance on such basis, the individual shall be deemed to have provided satisfactory documentary evidence of citizenship or nationality and shall not be required to provide further documentary evidence on any date that occurs during or after the period in which the individual is eligible for medical assistance on such basis); or

(E) on such basis as the Secretary may specify under which satisfactory documentary evidence of citizenship or nationality has been previously presented.

(3)(A) For purposes of this subsection, the term "satisfactory documentary evidence of citizenship or nationality" means—

(i) any document described in subparagraph (B); or

(ii) a document described in subparagraph (C) and a document described in subparagraph (D).

(B) The following are documents described in this subparagraph:

(i) A United States passport.

(ii) Form N–550 or N–570 (Certificate of Naturalization).

(iii) Form N–560 or N–561 (Certificate of United States Citizenship).

(iv) A valid State-issued driver's license or other identity document described in section 274A(b)(1)(D) of the Immigration and Nationality Act, but only if the State issuing the license or such document requires proof of United States citizenship before issuance of such license or document or obtains a social security number from the applicant and verifies before certification that such number is valid and assigned to the applicant who is a citizen.

(v)(I) Except as provided in subclause (II), a document issued by a federally recognized Indian tribe evidencing membership or enrollment in, or affiliation with, such tribe (such as a tribal enrollment card or certificate of degree of Indian blood).

(II) With respect to those federally recognized Indian tribes located within States having an international border whose membership includes individuals who are not citizens of the United States, the Secretary shall, after consulting with such tribes, issue regulations authorizing the presentation of such other forms of documentation (including tribal documentation, if appropriate) that the Secretary determines to be satisfactory documentary evidence of citizenship or nationality for purposes of satisfying the requirement of this subsection.

(vi) Such other document as the Secretary may specify, by regulation, that provides proof of United States citizenship or nationality and that provides a reliable means of documentation of personal identity.

(C) The following are documents described in this subparagraph:

(i) A certificate of birth in the United States.

(ii) Form FS–545 or Form DS–1350 (Certification of Birth Abroad).

(iii) Form I–197 (United States Citizen Identification Card).

(iv) Form FS–240 (Report of Birth Abroad of a Citizen of the United States).

(v) Such other document (not described in subparagraph (B)(iv)) as the Secretary may specify that provides proof of United States citizenship or nationality.

(D) The following are documents described in this subparagraph:

(i) Any identity document described in section 274A(b)(1)(D) of the Immigration and Nationality Act.

(ii) Any other documentation of personal identity of such other type as the Secretary finds, by regulation, provides a reliable means of identification.

(E) A reference in this paragraph to a form includes a reference to any successor form.

(4) In the case of an individual declaring to be a citizen or national of the United States with respect to whom a State requires the presentation of satisfactory documentary evidence of citizenship or nationality under section 1902(a)(46)(B)(i), the individual shall be provided at least the reasonable opportunity to present satisfactory documentary evidence of citizenship or nationality under this subsection as is provided under clauses (i) and (ii) of section 1137(d)(4)(A) to an individual for the submittal to the State of evidence indicating a satisfactory immigration status.

(5) Nothing in subparagraph (A) or (B) of section 1902(a)(46), the preceding paragraphs of this subsection, or the Deficit Reduction Act of 2005, including section 6036 of such Act, shall be construed as changing the requirement of section 1902(e)(4) that a child born in the United States to an alien mother for whom medical assistance for the delivery of such child is available as treatment of an emergency medical condition pursuant to subsection (v) shall be deemed eligible for medical assistance during the first year of such child's life.

(y) PAYMENTS FOR ESTABLISHMENT OF ALTERNATE NON-EMERGENCY SERVICES PROVIDERS.—

(1) PAYMENTS.—In addition to the payments otherwise provided under subsection (a), subject to paragraph (2), the Secretary shall provide for payments to States under such subsection for the establishment of alternate non-emergency service providers (as defined in section 1916A(e)(5)(B)), or networks of such providers.

(2) LIMITATION.—The total amount of payments under this subsection shall not exceed $50,000,000 during the 4-year period beginning with 2006. This subsection constitutes budget authority in advance of appropriations Acts and represents the obligation of the Secretary to provide for the payment of amounts provided under this subsection.

(3) PREFERENCE.—In providing for payments to States under this subsection, the Secretary shall provide preference to States that establish, or provide for, alternate non-emergency services providers or networks of such providers that—

(A) serve rural or underserved areas where beneficiaries under this title may not have regular access to providers of primary care services; or

(B) are in partnership with local community hospitals.

(4) FORM AND MANNER OF PAYMENT.—Payment to a State under this subsection shall be made only upon the filing of such application in such form and in such manner as the Secretary shall specify. Payment to a State under this subsection

shall be made in the same manner as other payments under section 1903(a).

(z) MEDICAID TRANSFORMATION PAYMENTS.—

(1) IN GENERAL.—In addition to the payments provided under subsection (a), subject to paragraph (4), the Secretary shall provide for payments to States for the adoption of innovative methods to improve the effectiveness and efficiency in providing medical assistance under this title.

(2) PERMISSIBLE USES OF FUNDS.—The following are examples of innovative methods for which funds provided under this subsection may be used:

(A) Methods for reducing patient error rates through the implementation and use of electronic health records, electronic clinical decision support tools, or e-prescribing programs.

(B) Methods for improving rates of collection from estates of amounts owed under this title.

(C) Methods for reducing waste, fraud, and abuse under the program under this title, such as reducing improper payment rates as measured by annual payment error rate measurement (PERM) project rates.

(D) Implementation of a medication risk management program as part of a drug use review program under section 1927(g).

(E) Methods in reducing, in clinically appropriate ways, expenditures under this title for covered outpatient drugs, particularly in the categories of greatest drug utilization, by increasing the utilization of generic drugs through the use of education programs and other incentives to promote greater use of generic drugs.

(F) Methods for improving access to primary and specialty physician care for the uninsured using integrated university-based hospital and clinic systems.

(3) APPLICATION; TERMS AND CONDITIONS.—

(A) IN GENERAL.—No payments shall be made to a State under this subsection unless the State applies to the Secretary for such payments in a form, manner, and time specified by the Secretary.

(B) TERMS AND CONDITIONS.—Such payments are made under such terms and conditions consistent with this subsection as the Secretary prescribes.

(C) ANNUAL REPORT.—Payment to a State under this subsection is conditioned on the State submitting to the Secretary an annual report on the programs supported by such payment. Such report shall include information on—

(i) the specific uses of such payment;

(ii) an assessment of quality improvements and clinical outcomes under such programs; and

(iii) estimates of cost savings resulting from such programs.

(4) FUNDING.—

(A) LIMITATION ON FUNDS.—The total amount of payments under this subsection shall be equal to, and shall not exceed—

(i) $75,000,000 for fiscal year 2007; and

(ii) $75,000,000 for fiscal year 2008.

This subsection constitutes budget authority in advance of appropriations Acts and represents the obligation of the Secretary to provide for the payment of amounts provided under this subsection.

(B) ALLOCATION OF FUNDS.—The Secretary shall specify a method for allocating the funds made available under this subsection among States. Such method shall provide preference for States that design programs that target health providers that treat significant numbers of Medicaid beneficiaries. Such method shall provide that not less than 25 percent of such funds shall be allocated among States the population of which (as determined according to data collected by the United States Census Bureau) as of July 1, 2004, was more than 105 percent of the population of the respective State (as so determined) as of April 1, 2000.

(C) FORM AND MANNER OF PAYMENT.—Payment to a State under this subsection shall be made in the same manner as other payments under section 1903(a). There is no requirement for State matching funds to receive payments under this subsection.

(5) MEDICATION RISK MANAGEMENT PROGRAM.—

(A) IN GENERAL.—For purposes of this subsection, the term "medication risk management program" means a program for targeted beneficiaries that ensures that covered outpatient drugs are appropriately used to optimize therapeutic outcomes through improved medication use and to reduce the risk of adverse events.

(B) ELEMENTS.—Such program may include the following elements:

(i) The use of established principles and standards for drug utilization review and best practices to analyze prescription drug claims of targeted beneficiaries and identify outlier physicians.

(ii) On an ongoing basis provide outlier physicians—

(I) a comprehensive pharmacy claims history for each targeted beneficiary under their care;

(II) information regarding the frequency and cost of relapses and hospitalizations of targeted beneficiaries under the physician's care; and

(III) applicable best practice guidelines and empirical references.

(iii) Monitor outlier physician's prescribing, such as failure to refill, dosage strengths, and provide incentives and information to encourage the adoption of best clinical practices.

(C) TARGETED BENEFICIARIES.—For purposes of this paragraph, the term "targeted beneficiaries" means Medicaid eligible beneficiaries who are identified as having high prescription drug costs and medical costs, such as individuals with behavioral disorders or multiple chronic diseases who are taking multiple medications.

(aa) DEMONSTRATION PROJECT TO INCREASE SUBSTANCE USE PROVIDER CAPACITY.—

(1) IN GENERAL.—Not later than the date that is 180 days after the date of the enactment of this subsection, the Secretary shall, in consultation, as appropriate, with the Director of the Agency for Healthcare Research and Quality and the Assistant Secretary for Mental Health and Substance Use, conduct a 54-month demonstration project for the purpose described in paragraph (2) under which the Secretary shall—

(A) for the first 18-month period of such project, award planning grants described in paragraph (3); and

(B) for the remaining 36-month period of such project, provide to each State selected under paragraph (4) payments in accordance with paragraph (5).

(2) PURPOSE.—The purpose described in this paragraph is for each State selected under paragraph (4) to increase the treatment capacity of providers participating under the State plan (or a waiver of such plan) to provide substance use disorder treatment or recovery services under such plan (or waiver) through the following activities:

(A) For the purpose described in paragraph (3)(C)(i), activities that support an ongoing assessment of the behavioral health treatment needs of the State, taking into account the matters described in subclauses (I) through (IV) of such paragraph.

(B) Activities that, taking into account the results of the assessment described in subparagraph (A), support the recruitment, training, and provision of technical assistance for providers participating under the State plan (or a waiver of such plan) that offer substance use disorder treatment or recovery services.

(C) Improved reimbursement for and expansion of, through the provision of education, training, and technical assistance, the number or treatment capacity of providers participating under the State plan (or waiver) that—

(i) are authorized to dispense drugs approved by the Food and Drug Administration for individuals with a substance use disorder who need withdrawal management or maintenance treatment for such disorder; *and*

[(ii) have in effect a registration or waiver under section 303(g) of the Controlled Substances Act for purposes of dispensing narcotic drugs to individuals for maintenance treatment or detoxification treatment and are in compliance with any regulation promulgated by the Assistant Secretary for Mental Health and Substance Use for purposes of carrying out the requirements of such section 303(g); and**]**

[(iii)**]** *(ii)* are qualified under applicable State law to provide substance use disorder treatment or recovery services.

(D) Improved reimbursement for and expansion of, through the provision of education, training, and technical assistance, the number or treatment capacity of providers participating under the State plan (or waiver) that have the qualifications to address the treatment or recovery needs of—

(i) individuals enrolled under the State plan (or a waiver of such plan) who have neonatal abstinence syndrome, in accordance with guidelines issued by the American Academy of Pediatrics and American College of Obstetricians and Gynecologists relating to maternal care and infant care with respect to neonatal abstinence syndrome;

(ii) pregnant women, postpartum women, and infants, particularly the concurrent treatment, as appropriate, and comprehensive case management of pregnant women, post–partum women and infants, enrolled under the State plan (or a waiver of such plan);

(iii) adolescents and young adults between the ages of 12 and 21 enrolled under the State plan (or a waiver of such plan); or

(iv) American Indian and Alaska Native individuals enrolled under the State plan (or a waiver of such plan).

(3) PLANNING GRANTS.—

(A) IN GENERAL.—The Secretary shall, with respect to the first 18-month period of the demonstration project conducted under paragraph (1), award planning grants to at least 10 States selected in accordance with subparagraph (B) for purposes of preparing an application described in paragraph (4)(C) and carrying out the activities described in subparagraph (C).

(B) SELECTION.—In selecting States for purposes of this paragraph, the Secretary shall—

(i) select States that have a State plan (or waiver of the State plan) approved under this title;

(ii) select States in a manner that ensures geographic diversity; and

(iii) give preference to States with a prevalence of substance use disorders (in particular opioid use disorders) that is comparable to or higher than the national average prevalence, as measured by aggregate per capita drug overdoses, or any other measure that the Secretary deems appropriate.

(C) ACTIVITIES DESCRIBED.—Activities described in this subparagraph are, with respect to a State, each of the following:

(i) Activities that support the development of an initial assessment of the behavioral health treatment needs of the State to determine the extent to which providers are needed (including the types of such providers and geographic area of need) to improve the network of providers that treat substance use disorders under the State plan (or waiver), including the following:

(I) An estimate of the number of individuals enrolled under the State plan (or a waiver of such plan) who have a substance use disorder.

(II) Information on the capacity of providers to provide substance use disorder treatment or recovery services to individuals enrolled under the

State plan (or waiver), including information on providers who provide such services and their participation under the State plan (or waiver).

(III) Information on the gap in substance use disorder treatment or recovery services under the State plan (or waiver) based on the information described in subclauses (I) and (II).

(IV) Projections regarding the extent to which the State participating under the demonstration project would increase the number of providers offering substance use disorder treatment or recovery services under the State plan (or waiver) during the period of the demonstration project.

(ii) Activities that, taking into account the results of the assessment described in clause (i), support the development of State infrastructure to, with respect to the provision of substance use disorder treatment or recovery services under the State plan (or a waiver of such plan), recruit prospective providers and provide training and technical assistance to such providers.

(D) FUNDING.—For purposes of subparagraph (A), there is appropriated, out of any funds in the Treasury not otherwise appropriated, $50,000,000, to remain available until expended.

(4) POST-PLANNING STATES.—

(A) IN GENERAL.—The Secretary shall, with respect to the remaining 36-month period of the demonstration project conducted under paragraph (1), select not more than 5 States in accordance with subparagraph (B) for purposes of carrying out the activities described in paragraph (2) and receiving payments in accordance with paragraph (5).

(B) SELECTION.—In selecting States for purposes of this paragraph, the Secretary shall—

(i) select States that received a planning grant under paragraph (3);

(ii) select States that submit to the Secretary an application in accordance with the requirements in subparagraph (C), taking into consideration the quality of each such application;

(iii) select States in a manner that ensures geographic diversity; and

(iv) give preference to States with a prevalence of substance use disorders (in particular opioid use disorders) that is comparable to or higher than the national average prevalence, as measured by aggregate per capita drug overdoses, or any other measure that the Secretary deems appropriate.

(C) APPLICATIONS.—

(i) IN GENERAL.—A State seeking to be selected for purposes of this paragraph shall submit to the Secretary, at such time and in such form and manner as the Secretary requires, an application that includes such information, provisions, and assurances, as the Secretary may require, in addition to the following:

(I) A proposed process for carrying out the ongoing assessment described in paragraph (2)(A), taking into account the results of the initial assessment described in paragraph (3)(C)(i).

(II) A review of reimbursement methodologies and other policies related to substance use disorder treatment or recovery services under the State plan (or waiver) that may create barriers to increasing the number of providers delivering such services.

(III) The development of a plan, taking into account activities carried out under paragraph (3)(C)(ii), that will result in long-term and sustainable provider networks under the State plan (or waiver) that will offer a continuum of care for substance use disorders. Such plan shall include the following:

(aa) Specific activities to increase the number of providers (including providers that specialize in providing substance use disorder treatment or recovery services, hospitals, health care systems, Federally qualified health centers, and, as applicable, certified community behavioral health clinics) that offer substance use disorder treatment, recovery, or support services, including short-term detoxification services, outpatient substance use disorder services, and evidence-based peer recovery services.

(bb) Strategies that will incentivize providers described in subparagraphs (C) and (D) of paragraph (2) to obtain the necessary training, education, and support to deliver substance use disorder treatment or recovery services in the State.

(cc) Milestones and timeliness for implementing activities set forth in the plan.

(dd) Specific measurable targets for increasing the substance use disorder treatment and recovery provider network under the State plan (or a waiver of such plan).

(IV) A proposed process for reporting the information required under paragraph (6)(A), including information to assess the effectiveness of the efforts of the State to expand the capacity of providers to deliver substance use disorder treatment or recovery services during the period of the demonstration project under this subsection.

(V) The expected financial impact of the demonstration project under this subsection on the State.

(VI) A description of all funding sources available to the State to provide substance use disorder treatment or recovery services in the State.

(VII) A preliminary plan for how the State will sustain any increase in the capacity of providers to deliver substance use disorder treatment or recovery services resulting from the demonstration project under this subsection after the termination of such demonstration project.

(VIII) A description of how the State will coordinate the goals of the demonstration project with any waiver granted (or submitted by the State and pending) pursuant to section 1115 for the delivery of substance use services under the State plan, as applicable.

(ii) CONSULTATION.—In completing an application under clause (i), a State shall consult with relevant stakeholders, including Medicaid managed care plans, health care providers, and Medicaid beneficiary advocates, and include in such application a description of such consultation.

(5) PAYMENT.—

(A) IN GENERAL.—For each quarter occurring during the period for which the demonstration project is conducted (after the first 18 months of such period), the Secretary shall pay under this subsection, subject to subparagraph (C), to each State selected under paragraph (4) an amount equal to 80 percent of so much of the qualified sums expended during such quarter.

(B) QUALIFIED SUMS DEFINED.—For purposes of subparagraph (A), the term "qualified sums" means, with respect to a State and a quarter, the amount equal to the amount (if any) by which the sums expended by the State during such quarter attributable to substance use disorder treatment or recovery services furnished by providers participating under the State plan (or a waiver of such plan) exceeds 1/4 of such sums expended by the State during fiscal year 2018 attributable to substance use disorder treatment or recovery services.

(C) NON-DUPLICATION OF PAYMENT.—In the case that payment is made under subparagraph (A) with respect to expenditures for substance use disorder treatment or recovery services furnished by providers participating under the State plan (or a waiver of such plan), payment may not also be made under subsection (a) with respect to expenditures for the same services so furnished.

(6) REPORTS.—

(A) STATE REPORTS.—A State receiving payments under paragraph (5) shall, for the period of the demonstration project under this subsection, submit to the Secretary a quarterly report, with respect to expenditures for substance use disorder treatment or recovery services for which payment is made to the State under this subsection, on the following:

(i) The specific activities with respect to which payment under this subsection was provided.

(ii) The number of providers that delivered substance use disorder treatment or recovery services in

the State under the demonstration project compared to the estimated number of providers that would have otherwise delivered such services in the absence of such demonstration project.

(iii) The number of individuals enrolled under the State plan (or a waiver of such plan) who received substance use disorder treatment or recovery services under the demonstration project compared to the estimated number of such individuals who would have otherwise received such services in the absence of such demonstration project.

(iv) Other matters as determined by the Secretary.

(B) CMS REPORTS.—

(i) INITIAL REPORT.—Not later than October 1, 2020, the Administrator of the Centers for Medicare & Medicaid Services shall, in consultation with the Director of the Agency for Healthcare Research and Quality and the Assistant Secretary for Mental Health and Substance Use, submit to Congress an initial report on—

(I) the States awarded planning grants under paragraph (3);

(II) the criteria used in such selection; and

(III) the activities carried out by such States under such planning grants.

(ii) INTERIM REPORT.—Not later than October 1, 2022, the Administrator of the Centers for Medicare & Medicaid Services shall, in consultation with the Director of the Agency for Healthcare Research and Quality and the Assistant Secretary for Mental Health and Substance Use, submit to Congress an interim report—

(I) on activities carried out under the demonstration project under this subsection;

(II) on the extent to which States selected under paragraph (4) have achieved the stated goals submitted in their applications under subparagraph (C) of such paragraph;

(III) with a description of the strengths and limitations of such demonstration project; and

(IV) with a plan for the sustainability of such project.

(iii) FINAL REPORT.—Not later than October 1, 2024, the Administrator of the Centers for Medicare & Medicaid Services shall, in consultation with the Director of the Agency for Healthcare Research and Quality and the Assistant Secretary for Mental Health and Substance Use, submit to Congress a final report—

(I) providing updates on the matters reported in the interim report under clause (ii);

(II) including a description of any changes made with respect to the demonstration project under this subsection after the submission of such interim report; and

(III) evaluating such demonstration project.

(C) AHRQ REPORT.—Not later than 3 years after the date of the enactment of this subsection, the Director of the Agency for Healthcare Research and Quality, in consultation with the Administrator of the Centers for Medicare & Medicaid Services, shall submit to Congress a summary on the experiences of States awarded planning grants under paragraph (3) and States selected under paragraph (4).

(7) DATA SHARING AND BEST PRACTICES.—During the period of the demonstration project under this subsection, the Secretary shall, in collaboration with States selected under paragraph (4), facilitate data sharing and the development of best practices between such States and States that were not so selected.

(8) CMS FUNDING.—There is appropriated, out of any funds in the Treasury not otherwise appropriated, $5,000,000 to the Centers for Medicare & Medicaid Services for purposes of implementing this subsection. Such amount shall remain available until expended.

(bb) SUPPLEMENTAL PAYMENT REPORTING REQUIREMENTS.—

(1) COLLECTION AND AVAILABILITY OF SUPPLEMENTAL PAYMENT DATA.—

(A) IN GENERAL.—Not later than October 1, 2021, the Secretary shall establish a system for each State to submit reports, as determined appropriate by the Secretary, on supplemental payments data, as a requirement for a State plan or State plan amendment that would provide for a supplemental payment.

(B) REQUIREMENTS.—Each report submitted by a State in accordance with the requirement established under subparagraph (A) shall include the following:

(i) An explanation of how supplemental payments made under the State plan or a State plan amendment will result in payments that are consistent with section 1902(a)(30)(A), including standards with respect to efficiency, economy, quality of care, and access, along with the stated purpose and intended effects of the supplemental payment.

(ii) The criteria used to determine which providers are eligible to receive the supplemental payment.

(iii) A comprehensive description of the methodology used to calculate the amount of, and distribute, the supplemental payment to each eligible provider, including—

(I) data on the amount of the supplemental payment made to each eligible provider, if known, or, if the total amount is distributed using a formula based on data from 1 or more fiscal years, data on the total amount of the supplemental payments for the fiscal year or years available to all providers eligible to receive a supplemental payment;

(II) if applicable, the specific criteria with respect to Medicaid service, utilization, or cost data to be used as the basis for calculations regarding

the amount or distribution of the supplemental payment; and

(III) the timing of the supplemental payment made to each eligible provider.

(iv) An assurance that the total Medicaid payments made to an inpatient hospital provider, including the supplemental payment, will not exceed upper payment limits.

(v) If not already submitted, an upper payment limit demonstration under section 447.272 of title 42, Code of Federal Regulations (as such section is in effect as of the date of enactment of this subsection).

(C) PUBLIC AVAILABILITY.—The Secretary shall make all reports and related data submitted under this paragraph publicly available on the website of the Centers for Medicare & Medicaid Services on a timely basis.

(2) SUPPLEMENTAL PAYMENT DEFINED.—

(A) IN GENERAL.—Subject to subparagraph (B), in this subsection, the term "supplemental payment" means a payment to a provider that is in addition to any base payment made to the provider under the State plan under this title or under demonstration authority.

(B) DSH PAYMENTS EXCLUDED.—Such term does not include a disproportionate share hospital payment made under section 1923.

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JERROLD NADLER, New York
CHAIRMAN

JIM JORDAN, Ohio
RANKING MEMBER

ONE HUNDRED SEVENTEENTH CONGRESS

Congress of the United States
House of Representatives
COMMITTEE ON THE JUDICIARY
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WASHINGTON, DC 20515-6216
(202) 225-3951
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June 13, 2022

The Honorable Frank Pallone, Jr.
Chairman
Committee on Energy and Commerce
U.S. House of Representatives
2125 Rayburn House Office Building
Washington, DC 20515

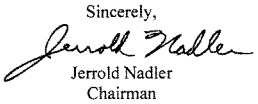
Dear Chairman Pallone:

This letter is to advise you that the Committee on the Judiciary has now had an opportunity to review the provisions in H.R. 7666, the "Restoring Hope for Mental Health and Well-Being Act of 2022," that fall within our Rule X jurisdiction. I appreciate your consulting with us on those provisions. The Judiciary Committee has no objection to your including them in the bill for consideration on the House floor, and to expedite that consideration is willing to forgo action on H.R. 7666, with the understanding that we do not thereby waive any future jurisdictional claim over those provisions or their subject matters.

In the event a House-Senate conference on this or similar legislation is convened, the Judiciary Committee reserves the right to request an appropriate number of conferees to address any concerns with these or similar provisions that may arise in conference.

Please place this letter into the *Congressional Record* during consideration of the measure on the House floor. Thank you for the cooperative spirit in which you have worked regarding this matter and others between our committees.

Sincerely,



Jerrold Nadler
Chairman

cc: The Honorable Jim Jordan, Ranking Member, Committee on the Judiciary
The Honorable Jason Smith, Parliamentarian
The Honorable Cathy McMorris Rodgers, Ranking Member, Committee on Energy and Commerce

FRANK PALLONE, JR., NEW JERSEY
CHAIRMAN

CATHY McMORRIS RODGERS, WASHINGTON
RANKING MEMBER

ONE HUNDRED SEVENTEENTH CONGRESS

Congress of the United States
House of Representatives

COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6115

Majority (202) 225-2927
Minority (202) 225-3641

June 13, 2022

The Honorable Jerrold Nadler
Chairman
Committee on Judiciary
2138 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Nadler:

Thank you for consulting with the Committee on Energy and Commerce and agreeing to be discharged from further consideration of H.R. 7666, the "Restoring Hope for Mental Health and Well-Being Act of 2022," so that the bill may proceed expeditiously to the House floor.

I agree that your forgoing further action on this measure does not in any way diminish or alter the jurisdiction of your committee or prejudice its jurisdictional prerogatives on this measure or similar legislation in the future. I would support your effort to seek appointment of an appropriate number of conferees from your committee to any House-Senate conference on this legislation.

I will ensure our letters on H.R. 7666 are included in the report for this bill and entered into the *Congressional Record* during floor consideration of the bill. I appreciate your cooperation regarding this legislation and look forward to continuing to work together as this measure moves through the legislative process.

Sincerely,

Frank Pallone, Jr.

Frank Pallone, Jr.
Chairman

cc: The Honorable Cathy McMorris Rodgers, Ranking Member. Committee on Energy and Commerce
The Honorable Jim Jordan, Ranking Member, Committee on Judiciary
The Honorable Jason Smith, Parliamentarian