115TH CONGRESS
2D SESSION

S. 2700

To provide emergency assistance to States, territories, Tribal nations, and local areas affected by the opioid epidemic and to make financial assistance available to States, territories, Tribal nations, local areas, and public or private nonprofit entities to provide for the development, organization, coordination, and operation of more effective and cost efficient systems for the delivery of essential services to individuals with substance use disorder and their families.

IN THE SENATE OF THE UNITED STATES

APRIL 18, 2018

Ms. WARREN introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To provide emergency assistance to States, territories, Tribal nations, and local areas affected by the opioid epidemic and to make financial assistance available to States, territories, Tribal nations, local areas, and public or private nonprofit entities to provide for the development, organization, coordination, and operation of more effective and cost efficient systems for the delivery of essential services to individuals with substance use disorder and their families.

1 Be it enacted by the Senate and House of Representa-
2 tives of the United States of America in Congress assembled,
SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) Short Title.—This Act may be cited as the “Comprehensive Addiction Resources Emergency Act of 2018”.

(b) Table of Contents.—The table of contents of this Act is as follows:

Sec. 1. Short title; table of contents.
Sec. 2. Purpose.
Sec. 3. Amendment to the Public Health Service Act.

“Title XXXIV—Substance Use and Opioid Health Resources

Subtitle A—Substance Use and Opioid Emergency Relief Grant Program

“Sec. 3401. Establishment of program of grants.
“Sec. 3402. Planning council.
“Sec. 3403. Amount of grant and use of amounts.
“Sec. 3404. Application.
“Sec. 3405. Technical assistance.
“Sec. 3406. Authorization of appropriations.

Subtitle B—State and Tribal Substance Use Disorder Prevention and Intervention Grant Program

“Sec. 3411. Establishment of program of grants.
“Sec. 3412. Amount of grant and use of amounts.
“Sec. 3413. Application and limitation.
“Sec. 3414. Technical assistance.
“Sec. 3415. Authorization of appropriations.

Subtitle C—Other Grant Program

“Sec. 3421. Establishment of grant program.
“Sec. 3422. Use of amounts.
“Sec. 3423. Technical assistance.
“Sec. 3424. Planning and development grants.
“Sec. 3425. Authorization of appropriations.

Subtitle D—Miscellaneous Provisions

“Sec. 3431. Special projects of national significance.
“Sec. 3432. Education and training centers.
“Sec. 3433. Other provisions.
“Sec. 3434. Standards for substance use disorder treatment and recovery facilities.
“Sec. 3435. Naloxone distribution program.
“Sec. 3436. Additional funding for the National Institutes of Health.
“Sec. 3437. Additional funding for improved data collection and prevention of infectious disease transmission.
SEC. 2. PURPOSE.

It is the purpose of this Act to provide emergency assistance to States, territories, Tribal nations, and local areas that are disproportionately affected by the opioid epidemic and to make financial assistance available to States, territories, Tribal nations, local areas, and other public or private nonprofit entities to provide for the development, organization, coordination, and operation of more effective and cost efficient systems for the delivery of essential services to individuals and families with substance use disorder.

SEC. 3. AMENDMENT TO THE PUBLIC HEALTH SERVICE ACT.

The Public Health Service Act (42 U.S.C. 201 et seq.) is amended by adding at the end the following:

“TITLE XXXIV—SUBSTANCE USE AND OPIOID HEALTH RESOURCES

“Subtitle A—Substance Use and Opioid Emergency Relief Grant Program

“SEC. 3401. ESTABLISHMENT OF PROGRAM OF GRANTS.

“(a) IN GENERAL.—The Secretary, in coordination with the Director of the Office of National Drug Control
Policy, shall award grants to eligible localities for the purpose of addressing substance use within such localities.

“(b) Eligibility.—

“(1) In general.—To be eligible to receive a grant under subsection (a) a locality shall—

“(A) be—

“(i) a county that can demonstrate that the rate of drug overdose deaths per 100,000 individuals residing in the county during the most recent 3-year period for which such data are available was not less than the rate of such deaths for the county that ranked at the 67th percentile of all counties, as determined by the Secretary;

“(ii) a county that can demonstrate that the number of drug overdose deaths during the most recent 3-year period for which such data are available was not less than the number of such deaths for the county that ranked at the 90th percentile of all counties, as determined by the Secretary; or

“(iii) a city that is located within a county described in clause (i) or (ii), that
meets the requirements of paragraph (3); and

“(B) submit to the Secretary an application in accordance with section 3404.

“(2) MULTIPLE CONTIGUOUS COUNTIES.—In the case of an eligible county that is contiguous to one or more other eligible counties within the same State, the group of counties shall—

“(A) be considered as a single eligible county for purposes of a grant under this section;

“(B) submit a single application under section 3404;

“(C) form a joint planning council (for the purposes of section 3402); and

“(D) establish, through intergovernmental agreements, an administrative mechanism to allocate funds and substance use disorder treatment services under the grant based on—

“(i) the number and rate of drug overdose deaths and nonfatal drug overdoses in each of the counties that compose the eligible county;

“(ii) the severity of need for services in each such county; and
“(iii) the health and support personnel needs of each such county.

“(3) CITIES AND COUNTIES WITHIN MULTIPLE CONTIGUOUS COUNTIES.—

“(A) IN GENERAL.—A city that is within an eligible county described in paragraph (1), or a group of counties that is within a group of counties determined to be an eligible county under paragraph (2), shall be eligible to receive a grant under section 3401 if such city or county or group of counties meets the requirements of subparagraph (B).

“(B) REQUIREMENTS.—A city or county meets the requirements of this subparagraph if such city or county—

“(i) except as provided in subparagraph (C), has a population of not less than 50,000 residents;

“(ii) meets the requirements of paragraph (1)(A);

“(iii) submits an application under section 3404;

“(iv) establishes a planning council (for purposes of section 3402); and
“(v) establishes an administrative mechanism to allocate funds and services under the grant based on—

“(I) the number and rate of drug overdose deaths and nonfatal drug overdoses in the city or county;

“(II) the severity of need for substance use disorder treatment services in the city or county; and

“(III) the health and support personnel needs of the city or county.

“(C) POPULATION EXCEPTION.—A city or county or group of counties that does not meet the requirements of subparagraph (B)(i) may apply to the Secretary for a waiver of such requirement. Such application shall demonstrate—

“(i) that the needs of the population to be served are distinct or that addressing substance use in the service area would be best served by the formation of an independent council; and

“(ii) that the city or county or group of counties has the capacity to administer the funding received under this subtitle.
“(D) Minimum Funding.—A city or county that meets the requirement of this paragraph and receives a grant under section 3401 shall be entitled to an amount of funding under the grant in an amount that is not less than the amount determined under section 3403(a) with respect to such city or county.

“(4) Independent City.—Independent cities that are not located within the territory of a county shall be treated as eligible counties for purposes of this subtitle.

“(5) Political Subdivisions.—With respect to States that do not have a local county system of governance, the Secretary shall determine the local political subdivisions within such States that are eligible to receive a grant under section 3401 and such subdivisions shall be treated as eligible counties for purposes of this subtitle.

“(6) Determinations where there is a lack of data.—The Secretary shall establish eligibility and allocation criteria related to the prevalence of drug overdose deaths, the mortality rate from drug overdoses, and that provides an equivalent measure of need for funding for cities and counties.
for which the data described in paragraph (1)(A) or
(2)(D)(i) is not available.

“(7) STUDY.—Not later than 3 years after the
date of enactment of this title, the Comptroller Gen-
eral shall conduct a study to determine whether the
data utilized for purposes of paragraph (1)(A) pro-
vides the most precise measure of local area need re-
lated to substance use and addiction prevalence and
whether additional data would provide more precise
measures of substance use and addiction prevalence
in local areas. Such study shall identify barriers to
collecting or analyzing such data, and make rec-
ommendations for revising the indicators used under
such paragraph to determine eligibility in order to
direct funds to the local areas in most need of fund-
ing to provide assistance related to substance use
and addiction.

“(8) REFERENCE.—For purposes of this sub-
title, the term ‘eligible local area’ includes—

“(A) a city or county described in para-
graph (1);

“(B) multiple contiguous counties de-
scribed in paragraph (2);

“(C) an independent locality described in
paragraph (3);
“(D) an independent city described in paragraph (4); and

“(E) a political subdivision described in paragraph (5).

“(c) ADMINISTRATION.—

“(1) IN GENERAL.—Assistance made available under a grant awarded under this section shall be directed to the chief elected official of the eligible local area who shall administer the grant funds.

“(2) MULTIPLE CONTIGUOUS COUNTIES.—

“(A) IN GENERAL.—Except as provided in subparagraph (B), in the case of an eligible county described in subsection (b)(2), assistance made available under a grant awarded under this section shall be directed to the chief elected official of the particular county designated in the application submitted for the grant under section 3404. Such chief elected official shall be the administrator of the grant.

“(B) STATE ADMINISTRATION.—Notwithstanding subparagraph (A), the eligible county described in subsection (b)(2) may elect to designate the chief elected State official of the State in which the eligible county is located as the administrator of the grant funds.
“(a) Establishment.—To be eligible to receive a grant under section 3401, the chief elected official of the eligible local area shall establish or designate a substance use disorder treatment and services planning council that shall, to the maximum extent practicable—

“(1) be representative of the demographics of the population of individuals with substance use disorder in the area; and

“(2) include representatives of—

“(A) health care providers, including federally qualified health centers, rural health clinics, Indian health programs as defined in section 4 of the Indian Health Care Improvement Act, urban Indian organizations as defined in section 4 of the Indian Health Care Improvement Act, Native Hawaiian organizations as defined in section 12 of the Native Hawaiian Health Care Act of 1988, and facilities operated by the Department of Veterans Affairs;

“(B) community-based health, harm reduction, or addiction service organizations, including, where applicable, representatives of Drug Free Communities Coalition grantees;
“(C) social service providers, including providers of housing and homelessness services and recovery residence providers;

“(D) mental health care providers;

“(E) local public health agencies;

“(F) law enforcement officials, including officials from High Intensity Drug Trafficking Area program, where applicable;

“(G) affected communities, including individuals with substance use disorder or a history of substance use disorder, including individuals in recovery from substance use disorders;

“(H) State governments, including the State Medicaid agency and the Single State Agency for Substance Abuse Services;

“(I) local governments;

“(J) non-elected community leaders;

“(K) substance use disorder treatment providers;

“(L) Indian tribes and tribal organizations as defined in section 4 of the Indian Self-Determination and Education Assistance Act;

“(M) urban Indians as defined in section 4 of the Indian Health Care Improvement Act;
“(N) historically underserved groups and subpopulations;
“(O) individuals who were formerly incarcerated;
“(P) organizations serving individuals who are currently or were formerly incarcerated;
“(Q) representatives of Federal agencies;
“(R) representatives of organizations that provide services to youth at risk of substance use;
“(S) representatives of medical examiners or coroners;
“(T) representatives of labor unions and the workplace community; and
“(U) representatives of local fire departments and emergency medical services.

“(b) Method of Providing for Council.—
“(1) In general.—In providing for a council for purposes of subsection (a), the chief elected official of the eligible local area may establish the council directly or designate an existing entity to serve as the council, subject to paragraph (2).
“(2) Consideration regarding designation of council.—In making a determination of whether to establish or designate a council under para-
graph (1), the chief elected official shall give priority to the designation of an existing entity that has demonstrated experience in the provision of health and support services to individuals with substance use disorder within the eligible local area, that has a structure that recognizes the Federal trust responsibility when spending Federal health care dollars, and that has demonstrated a commitment to respecting the obligation of government agencies using Federal dollars to consult with Indian tribes and confer with Urban Indian health programs.

“(3) JOINT COUNCIL.—The Secretary shall establish a process to permit an eligible local area that is not contiguous with any other eligible local area to form a joint planning council with such other eligible local area or areas, as long as such areas are located in geographical proximity to each other, as determined by the Secretary, and submit a joint application under section 3404.

“(4) JOINT COUNCIL ACROSS STATE LINES.—Eligible local areas may form a joint planning council with other eligible local areas across State lines if such areas are located in geographical proximity to each other, as determined by the Secretary, submit a joint application under section 3404, and es-
establish intergovernmental agreements to allow the
administration of the grant across State lines.

“(c) Membership.—Members of the planning coun-
cil established or designated under subsection (a) shall—

“(1) be nominated and selected through an
open process;

“(2) elect from among their membership a chair
and vice chair;

“(3) include at least one representative from
Indian tribes located within any eligible local area
that receives funding under the grant program es-
tablished in section 3401; and

“(4) serve no more than 3 consecutive years on
the planning council.

“(d) Membership Terms.—Members of the plan-
ing council established or designated under subsection
(a) may serve additional terms if nominated and selected
through the process established in subsection (c)(1).

“(e) Duties.—The planning council established or
designated under subsection (a) shall—

“(1) establish priorities for the allocation of
grant funds within the eligible local area that em-
phasize reducing drug overdose and substance use
disorder through evidence-based interventions in
both community and criminal justice settings and
that are based on—

“(A) the use by the grantee of substance
use disorder treatment and intervention strate-
gies that comply with best practices identified
by the Secretary;

“(B) the demonstrated or probable cost-effec-
tiveness of proposed substance use disorder
treatment services;

“(C) the health priorities of the commu-
nities within the eligible local area that are af-
fected by substance use;

“(D) the priorities and needs of individuals
with substance use disorder; and

“(E) the availability of other governmental
and nongovernmental services;

“(2) ensure the use of grant funds are con-
sistent with any existing State or local plan regard-
ing the provision of substance use disorder treat-
ment services to individuals with substance use dis-
order;

“(3) in the absence of a State or local plan,
work with local public health agencies to develop a
comprehensive plan for the organization and delivery
of substance use disorder treatment services;
“(4) regularly assess the efficiency of the administrative mechanism in rapidly allocating funds to support evidence-based substance use disorder treatment services in the areas of greatest need within the eligible local area;

“(5) work with local public health agencies to determine the size and demographics of the population of individuals with substance use disorders and the types of substance use that are most prevalent in the eligible local area;

“(6) work with local public health agencies to determine the needs of such population, including the need for substance use disorder treatment services;

“(7) work with local public agencies to determine the disparities in access to services among affected subpopulations and historically underserved communities, including infrastructure and capacity shortcomings of providers that contribute to these disparities;

“(8) work with local public agencies to establish methods for obtaining input on community needs and priorities, including by partnering with organizations that serve targeted communities experiencing high opioid related health disparities to gather data
using culturally attuned data collection methodologies;

“(9) coordinate with Federal grantees that provide substance use disorder treatment services within the eligible local area; and

“(10) annually assess the effectiveness of the substance use disorder treatment services being supported by the grant received by the eligible local area, including—

“(A) reductions in the rates of overdose and death from substance use disorders;

“(B) rates of discontinuation from substance use disorder treatment services;

“(C) long-term outcomes among individuals receiving treatment for substance use disorders; and

“(D) the availability of substance use disorder treatment services needed by individuals with substance use disorders over their lifetimes.

“(f) CONFLICTS OF INTEREST.—

“(1) IN GENERAL.—The planning council under subsection (a) may not be directly involved in the administration of a grant under section 3401.
“(2) **REQUIRED AGREEMENTS.**—An individual may serve on the planning council under subsection (a) only if the individual agrees that if the individual has a financial interest in an entity, if the individual is an employee of a public or private entity, or if the individual is a member of a public or private organization, and such entity or organization is seeking amounts from a grant under section 3401, the individual will not, with respect to the purpose for which the entity seeks such amounts, participate (directly or in an advisory capacity) in the process of selecting entities to receive such amounts for such purpose.

“(g) **GRIEVANCE PROCEDURES.**—A planning council under subsection (a) shall develop procedures for addressing grievances with respect to funding under this subtitle, including procedures for submitting grievances that cannot be resolved to binding arbitration. Such procedures shall be described in the by-laws of the planning council.

“(h) **PUBLIC DELIBERATIONS.**—With respect to a planning council under subsection (a), in accordance with criteria established by the Secretary, the following applies:

“(1) The meetings of the council shall be open to the public and shall be held only after adequate notice to the public.
“(2) The records, reports, transcripts, minutes, agenda, or other documents which were made available to or prepared for or by the council shall be available for public inspection and copying at a single location.

“(3) Detailed minutes of each meeting of the council shall be kept. The accuracy of all minutes shall be certified to by the chair of the council.

“(4) This subparagraph does not apply to any disclosure of information of a personal nature that would constitute a clearly unwarranted invasion of personal privacy, including any disclosure of medical information or personnel matters.

“SEC. 3403. AMOUNT OF GRANT AND USE OF AMOUNTS.

“(a) Amount of Grant.—

“(1) Grants based on relative need of area.—

“(A) In general.—In carrying out this subtitle, the Secretary shall make a grant for each eligible local area for which an application under section 3404 has been approved. Each such grant shall be made in an amount determined in accordance with paragraph (3).

“(B) Expedited distribution.—Not later than 90 days after an appropriation be-
comes available to carry out this subtitle for a fiscal year, the Secretary shall disburse 53 percent of the amount made available under section 3406 for carrying out this subtitle for such fiscal year through grants to eligible local areas under section 3401, in accordance with subparagraphs (C) and (D).

“(C) AMOUNT.—

“(i) IN GENERAL.—Subject to the extent of amounts made available in appropriations Acts, a grant made for purposes of this subparagraph to an eligible local area shall be made in an amount equal to the product of—

“(I) an amount equal to the amount available for distribution under subparagraph (B) for the fiscal year involved; and

“(II) the percentage constituted by the ratio of the distribution factor for the eligible local area to the sum of the respective distribution factors for all eligible local areas;

which product shall then, as applicable, be increased under subparagraph (D).
“(ii) Distribution factor.—For purposes of clause (i)(II), the term ‘distribution factor’ means—

“(I) an amount equal to—

“(aa) the estimated number of drug overdose deaths in the eligible local area, as determined under clause (iii); or

“(bb) the estimated number of non-fatal drug overdoses in the eligible local area, as determined under clause (iv);

as determined by the Secretary based on which distribution factor (item (aa) or (bb)) will result in the eligible local area receiving the greatest amount of funds; or

“(II) in the case of an eligible local area for which the data described in subclause (I) is not available, an amount determined by the Secretary—

“(aa) based on other data the Secretary determines appropriate; and
“(bb) that is related to the prevalence of non-fatal drug overdoses, drug overdose deaths, and the mortality rate from drug overdoses and provides an equivalent measure of need for funding.

“(iii) Number of drug overdose deaths.—The number of drug overdose deaths determined under this clause for an eligible county for a fiscal year for purposes of clause (ii) is the number of drug overdose deaths during the most recent 3-year period for which such data are available.

“(iv) Number of non-fatal drug overdoses.—The number of non-fatal drug overdose deaths determined under this clause for an eligible county for a fiscal year for purposes of clause (ii) may be determined by using data including emergency department syndromic data, visits, or other emergency medical services for drug-related causes during the most recent
3-year period for which such data are available.

“(v) STUDY.—Not later than 3 years after the date of enactment of this title, the Comptroller General shall conduct a study to determine whether the data utilized for purposes of clause (ii) provide the most precise measure of local area need related to substance use and addiction prevalence in local areas and whether additional data would provide more precise measures of substance use and addiction prevalence in local areas. Such study shall identify barriers to collecting or analyzing such data, and make recommendations for revising the distribution factors used under such clause to determine funding levels in order to direct funds to the local areas in most need of funding to provide substance use disorder treatment services.

“(vi) REDUCTIONS IN AMOUNTS.—If a local area that is an eligible local area for a year loses such eligibility in a subsequent year based on the failure to meet the re-
requirements of section 3401(b)(1)(A), such area will remain eligible to receive—

“(I) for such subsequent year, an amount equal to 80 percent of the amount received under the grant in the previous year; and

“(II) for the second such subsequent year, an amount equal to 50 percent of the amount received in the such previous year.

“(2) SUPPLEMENTAL GRANTS.—

“(A) IN GENERAL.—The Secretary shall disburse the remainder of amounts not disbursed under paragraph (1) for such fiscal year for the purpose of making grants to cities and counties whose application under section 3404—

“(i) contains a report concerning the dissemination of emergency relief funds under paragraph (1) and the plan for utilization of such funds, if applicable;

“(ii) demonstrates the need in such local area, on an objective and quantified basis, for supplemental financial assistance to combat substance use disorder;
“(iii) demonstrates the existing commitment of local resources of the area, both financial and in-kind, to combating substance use disorder;

“(iv) demonstrates the ability of the area to utilize such supplemental financial resources in a manner that is immediately responsive and cost effective;

“(v) demonstrates that resources will be allocated in accordance with the local demographic incidence of substance use disorders and drug overdose mortality;

“(vi) demonstrates the inclusiveness of affected communities and individuals with substance use disorders, including those communities and individuals that are disproportionately affected or historically underserved;

“(vii) demonstrates the manner in which the proposed services are consistent with the local needs assessment and the statewide coordinated statement of need required in section 3413(e);
“(viii) demonstrates success in identifying individuals with substance use disorders; and

“(ix) demonstrates that support for substance use disorder treatment services is organized to maximize the value to the population to be served with an appropriate mix of substance use disorder treatment services and attention to transition in care.

“(B) AMOUNT.—

“(i) IN GENERAL.—The amount of each grant made for purposes of this paragraph shall be determined by the Secretary. In making such determination, the Secretary shall consider—

“(I) the rate of drug overdose deaths per 100,000 population in the eligible local area; and

“(II) the increasing need for substance use disorder treatment services, including relative rates of increase in the number of drug overdoses or drug overdose deaths, recent increases in drug overdoses or
drug overdose deaths since data was
provided under section 3401(b), if ap-
plicable.

“(ii) **DEMONSTRATED NEED.**—The
factors considered by the Secretary in de-
determining whether a local area has a dem-
onstrated need for purposes of clause
(i)(II) may include any or all of the fol-
lowing:

“(I) The unmet need for sub-
stance use disorder treatment serv-
ices, including factors identified in
subparagraph (B)(i)(II).

“(II) Relative rates of increase in
the number of drug overdoses or drug
overdose deaths.

“(III) The relative rates of in-
crease in the number of drug
overdoses or drug overdose deaths
within new or emerging subpopula-
tions.

“(IV) The current prevalence of
substance use disorders.

“(V) Relevant factors related to
the cost and complexity of delivering
substance use disorder treatment services to individuals in the eligible local area.

“(VI) The impact of co-morbid factors, including co-occurring conditions, determined relevant by the Secretary.

“(VII) The prevalence of homelessness among individuals with substance use disorders.

“(VIII) The relevant factors that limit access to health care, including geographic variation, adequacy of health insurance coverage, and language barriers.

“(IX) The impact of a decline in the amount received pursuant to paragraph (1) on substance use disorder treatment services available to all individuals with substance use disorders identified and eligible under this subtitle.

“(X) The increasing incidence in conditions related to substance use, including hepatitis C, human immuno-
deficiency virus, hepatitis B and other infections associated with injection drug use.

“(C) APPLICATION OF PROVISIONS.—A local area that receives a grant under this paragraph—

“(i) shall use amounts received in accordance with subsection (b);

“(ii) shall not have to meet the eligible criteria in section 3401(b); and

“(iii) shall not have to establish a planning council under section 3402.

“(3) AMOUNT OF GRANT TO TRIBAL GOVERNMENTS.—

“(A) INDIAN TRIBES.—In this section, the term ‘Indian tribe’ has the meaning given such term in section 4 of the Indian Self-Determination and Education Assistance Act.

“(B) FORMULA GRANTS.—The Secretary, acting through the Indian Health Service, shall use 10 percent of the amount available under section 3406 for each fiscal year to provide formula grants to Indian tribes disproportionately affected by substance use, in an amount determined pursuant to a formula and eligibility cri-
teria developed by the Secretary in consultation with Indian tribes, for the purposes of addressing substance use.

“(C) USE OF AMOUNTS.—Notwithstanding any requirements in this section, an Indian tribe may use amounts provided under grants awarded under this paragraph for the uses identified in subsection (b) and any other activities determined appropriate by the Secretary, in consultation with Indian tribes.

“(b) USE OF AMOUNTS.—

“(1) REQUIREMENTS.—The Secretary may not make a grant under section 3401 to an eligible local area unless the chief elected official of the area agrees that—

“(A) the allocation of funds and services within the area under the grant will be made in accordance with the priorities established by the substance use disorder treatment services planning council; and

“(B) funds provided under this grant will be expended for—

“(i) prevention services described in paragraph (3);
“(ii) core medical services described in paragraph (4);

“(iii) recovery and support services described in paragraph (5);

“(iv) early intervention and engagement services described in paragraph (6);

“(v) harm reduction services described in paragraph (7);

“(vi) financial assistance with health insurance described in paragraph (8); and

“(vii) administrative expenses described in paragraph (10).

“(2) DIRECT FINANCIAL ASSISTANCE.—

“(A) IN GENERAL.—An eligible local area shall use amounts received under a grant under section 3401 to provide direct financial assistance to eligible entities for the purpose of providing prevention services, core medical services, recovery and support services, harm reduction services, and early intervention and engagement services.

“(B) APPROPRIATE ENTITIES.—Direct financial assistance may be provided under subparagraph (A) to public or nonprofit private entities, or private for-profit entities if such enti-
ties are the only available provider of quality
substance use disorder treatment services in the
area.

“(3) PREVENTION SERVICES.—

“(A) In general.—For purposes of this
subsection, the term ‘prevention services’ means
services, programs, or multi-sector strategies to
prevent substance use disorder (such as evi-
dence-based education campaigns, community-
based prevention programs, opioid diversion,
collection and disposal or unused opioids, and
services to at-risk populations).

“(B) Limit.—An eligible local area may
use not to exceed 20 percent of the amount of
the grant under section 3401 for prevention
services. An eligible local area may apply to the
Secretary for a waiver of this subparagraph.

“(4) CORE MEDICAL SERVICES.—For purposes
of this subsection, the term ‘core medical services’
means the following evidence-based services provided
to individuals with substance use disorder or at risk
for developing substance use disorder:

“(A) Substance use disorder treatments,
including clinical stabilization services, with-
drawal management and detoxification, inten-
sive inpatient treatment, intensive outpatient treatment, all forms of Federally-approved medication-assisted treatment, outpatient treatment, and residential recovery treatment.

“(B) Outpatient and ambulatory health services, including those administered by Federally qualified health centers and rural health clinics.

“(C) Hospice services.

“(D) Mental health services.

“(E) Naloxone procurement, distribution, and training.

“(F) Pharmaceutical assistance and diagnostic testing related to the management of substance-use disorders a co-morbid conditions.

“(G) Home and community based health services.

“(H) Comprehensive Case Management, including substance use disorder treatment adherence services.

“(I) Health insurance enrollment and cost-sharing assistance in accordance with paragraph (8).

“(5) Recovery and Support Services.—For purposes of paragraph (1)(B)(ii), the term ‘recovery
and support services’ means services, subject to the approval of the Secretary, that are provided to individuals with substance use disorder, including residential recovery treatment and housing, including for individuals receiving medication-assisted treatment, long term recovery services, 24/7 hotline crisis center support, medical transportation services, respite care for persons caring for individuals with substance use disorder, child care and family services while an individual is receiving inpatient treatment services or at the time of outpatient services, outreach services, peer recovery services, nutrition services, and referrals for job training and career services, housing, legal services, and child care and family services.

“(6) E ARLY INTERVENTION AND ENGAGEMENT SERVICES.—For purposes of this section, the term ‘early intervention and engagement services’ means services to provide rapid access to substance use disorder treatment, counseling provided to individuals who have misused substances, who have experienced an overdose, or are at risk of developing substance use disorder, and the provision of referrals to facilitate the access of such individuals to core medical services or recovery and support services. The enti-
ties through which such services may be provided include emergency rooms, fire departments and emergency medical services, detention facilities, homeless shelters, law enforcement agencies, health care points of entry specified by eligible local areas, Federally qualified health centers, and rural health clinics.

“(7) HARM REDUCTION SERVICES.—For purposes of this section, the term ‘harm reduction services’ means evidence-based services provided to individuals engaging in substance use that reduce the risk of infectious disease transmission, overdose, or death, including by increasing access to health care.

“(8) AFFORDABLE HEALTH INSURANCE COVERAGE.—An eligible local area may use amounts provided under a grant awarded under section 3401 to establish a program of financial assistance to assist eligible individuals with substance use disorder in—

“(A) enrolling in health insurance coverage; or

“(B) affording health care services, including assistance paying cost-sharing amounts, including premiums.
“(9) Requirement of status as Medicaid provider.—

“(A) Provision of service.—Subject to paragraph (2), the Secretary may not make a grant under section 3401 for the provision of substance use disorder treatment services under this section in an eligible local area unless, in the case of any such service that is available pursuant to the State plan approved under title XIX of the Social Security Act for the State—

“(i) the political subdivision involved will provide the service directly, and the political subdivision has entered into a participation agreement under the State plan and is qualified to receive payments under such plan; or

“(ii) the eligible local area involved will enter into an agreement with a public or nonprofit private entity under which the entity will provide the service, and the entity has entered into such a participation agreement and is qualified to receive such payments.

“(B) Waiver.—
“(i) IN GENERAL.—In the case of an entity making an agreement pursuant to subparagraph (A)(ii) regarding the provision of substance use disorder treatment services, the requirement established in such subparagraph shall be waived by the substance use planning council for the area involved if the entity does not, in providing health care services, impose a charge or accept reimbursement available from any third-party payor, including reimbursement under any insurance policy or under any Federal or State health benefits program.

“(ii) DETERMINATION.—A determination by the substance use planning council of whether an entity referred to in clause (i) meets the criteria for a waiver under such clause shall be made without regard to whether the entity accepts voluntary donations for the purpose of providing services to the public.

“(10) ADMINISTRATION AND PLANNING.—An eligible local area shall not use in excess of 10 percent of amounts received under a grant under section 3401 for administration, accounting, reporting,
and program oversight functions, including the development of systems to improve data collection and data sharing.

“(11) **INCARCERATED INDIVIDUALS.**—Amounts received under a grant under section 3401 may be used to provide substance use disorder treatment services to currently incarcerated individuals.

**SEC. 3404. APPLICATION.**

“(a) **IN GENERAL.**—To be eligible to receive a grant under section 3401, an eligible local area shall prepare and submit to the Secretary an application in such form, and containing such information, as the Secretary shall require, including—

“(1) a complete accounting of the disbursement of any prior grants received under this subtitle by the applicant and the results achieved through such disbursements;

“(2) a demonstration of the extent of local need for the funds under the grant and a plan for proposed substance use disorder treatment services that is consistent with local needs, including a comprehensive plan for the use of the grant funds developed by the planning council established under section 3402, except that the planning council require-
ment shall not apply with respect to areas receiving supplemental grant funds under section 3403(a)(2);

“(3) a demonstration that the area will use funds in a manner that provides substance use dis-
order treatment services compliant with the evi-
dence-based standards developed in accordance with section 3434, including all forms of Federally-ap-
proved medication-assisted treatments;

“(4) information on the number of individuals likely to be served by the funds sought, including de-

demographic data on the populations to be served;

“(5) key outcomes that will be measured by all entities that receive assistance, as well as an expla-
nation of how the outcomes will be measured;

“(6) a demonstration that resources provided under the grant will be allocated in accordance with the local demographic incidence of substance use, in-
cluding allocations for services for children, youths, and women;

“(7) a demonstration that funds received from a grant under this subtitle in any prior year were ex-
pended in accordance with the priorities established by the planning council;

“(8) a demonstration that at least one rep-
resentative from Indian tribes located within any eli-
gible local area are included in the membership of a planning council;

“(9) a demonstration that the confidentiality of individuals receiving substance use disorder treatment services will be maintained in a manner not inconsistent with applicable law; and

“(10) an explanation of how income, asset, and medical expense criteria will be established and applied to those who qualify for assistance under the program under this subtitle.

“(b) ASSURANCES.—To be eligible to receive a grant under section 3401, the application submitted by the eligible local area shall include assurances adequate to ensure—

“(1) that funds received under the grant will be utilized to supplement not supplant other State or local funds made available in the year for which the grant is awarded to provide substance use disorder treatment services;

“(2) that the political subdivisions within the eligible local area will maintain the level of expenditures by such political subdivisions for substance use-related services at a level that is equal to the level of such expenditures by such political subdivisions for the preceding fiscal year;
“(3) that political subdivisions within the eligible local area will not use funds received under a grant awarded under section 3401 in maintaining the level of substance use disorder treatment services as required in paragraph (2);

“(4) that substance use disorder treatment services provided with assistance made available under the grant will be provided without regard—

“(A) to the ability of the individual to pay for such services; and

“(B) to the current or past health condition of the individual to be served;

“(5) that substance use disorder treatment services will be provided in a setting that is accessible to low-income individuals with substance use disorder, and to individuals with substance use disorder residing in rural areas;

“(6) that a program of outreach will be provided to low-income individuals with substance use disorder to inform such individuals of substance use disorder treatment services, and to individuals with substance use disorder residing in rural areas; and

“(7) that funds received under a grant awarded under this subtitle will not be utilized to make payments for any item or service to the extent that pay-
ment has been made, or can reasonably be expected to be made, with respect to that item or service under any State compensation program, under an insurance policy, or under any Federal or State health benefits program (except for a program administered by, or providing the services of, the Indian Health Service).

“(c) Requirements Regarding Imposition of Charges for Services.—

“(1) In general.—The Secretary may not make a grant under section 3401 to an eligible local area unless the eligible local area provides assurances that in the provision of substance use disorder treatment services with assistance provided under the grant—

“(A) in the case of individuals with an income less than or equal to 138 percent of the official poverty level, the provider will not impose charges on any such individual for the services provided under the grant;

“(B) in the case of individuals with an income greater than 138 percent of the official poverty level, the provider will impose a charge on each such individual according to a schedule of charges made available to the public;
“(C) in the case of individuals with an income greater than 138 percent of the official poverty level but not exceeding 200 percent of such poverty level, the provider will not, for an calendar year, impose charges in an amount exceeding 5 percent of the annual gross income of the individual;

“(D) in the case of individuals with an income greater than 200 percent of the official poverty level but not exceeding 300 percent of such poverty level, the provider will not, for any calendar year, impose charges in an amount exceeding 7 percent of the annual gross income of the individual involved;

“(E) in the case of individuals with an income greater than 300 percent of the official poverty level, the provider will not, for any calendar year, impose charges in an amount exceeding 15 percent of the annual gross income of the individual involved; and

“(F) in the case of eligible American Indian and Alaska Native individuals as defined by section 447.50 of title 42, Code of Federal Regulations (as in effect on July 1, 2010), the provider will not impose any charges for sub-
stance use disorder treatment services, including any charges or cost-sharing prohibited by section 1402(d) of the Patient Protection and Affordable Care Act.

“(2) CHARGES.—With respect to compliance with the assurances made under paragraph (1), an eligible local area may, in the case of individuals subject to a charge—

“(A) assess the amount of the charge in the discretion of the area, including imposing only a nominal charge for the provision of substance use disorder treatment services, subject to the provisions of the paragraph regarding public schedules and regarding limitations on the maximum amount of charges; and

“(B) take into consideration the total medical expenses of individuals in assessing the amount of the charge, subject to such provisions.

“(3) AGGREGATE CHARGES.—The Secretary may not make a grant under section 3401 to an eligible local area unless the area agrees that the limitations on charges for substance use disorder treatment services under this subsection applies to the annual aggregate of charges imposed for such serv-
ices, however the charges are characterized, includes
enrollment fees, premiums, deductibles, cost sharing,
copayments, co-insurance costs, or any other
charges.

“(d) INDIAN TRIBES.—Any application requirements
for grants distributed in accordance with section
3403(a)(3) shall be developed by the Secretary in con-
sultation with Indian tribes.

“SEC. 3405. TECHNICAL ASSISTANCE.

“The Secretary shall, beginning on the date of enact-
ment of this title, provide technical assistance, including
assistance from other grantees, contractors or subcontrac-
tors under this title to assist newly eligible local areas in
the establishment of planning councils and, to assist enti-
ties in complying with the requirements of this subtitle
in order to make such areas eligible to receive a grant
under this subtitle. The Secretary may make planning
grants available to eligible local areas, in an amount not
to exceed $75,000 for any area, that is projected to be
eligible for funding under section 3401 in the following
fiscal year. Such grant amounts shall be deducted from
the first year formula award to eligible local areas accept-
ing such grants.
“SEC. 3406. AUTHORIZATION OF APPROPRIATIONS.

There is authorized to be appropriated to carry out this subtitle—

“(1) $2,700,000,000 for fiscal year 2019;
“(2) $2,700,000,000 for fiscal year 2020;
“(3) $2,700,000,000 for fiscal year 2021;
“(4) $2,700,000,000 for fiscal year 2022;
“(5) $2,700,000,000 for fiscal year 2023;
“(6) $2,700,000,000 for fiscal year 2024;
“(7) $2,700,000,000 for fiscal year 2025;
“(8) $2,700,000,000 for fiscal year 2026;
“(9) $2,700,000,000 for fiscal year 2027; and
“(10) $2,700,000,000 for fiscal year 2028.

“Subtitle B—State and Tribal Substance Use Disorder Prevention and Intervention Grant Program

“SEC. 3411. ESTABLISHMENT OF PROGRAM OF GRANTS.

The Secretary, acting in coordination with the Director of the Office of National Drug Control Policy, shall award grants to States, territories, and tribal governments for the purpose of addressing substance use within such States.

“SEC. 3412. AMOUNT OF GRANT AND USE OF AMOUNTS.

“(a) Amount of Grant to States and Territories.—
“(1) In general.—

“(A) Expedited distribution.—Not later than 90 days after an appropriation becomes available, the Secretary shall disburse 50 percent of the amount made available under section 3415 for carrying out this subtitle for such fiscal year through grants to States under section 3411, in accordance with subparagraphs (B) and (C).

“(B) Minimum allotment.—Subject to the amount made available under section 3415, the amount of a grant under section 3411 for—

“(i) each of the 50 States, the District of Columbia, and Puerto Rico for a fiscal year shall be the greater of—

“(I) $2,000,000; or

“(II) an amount determined under the subparagraph (C); and

“(ii) each territory other than Puerto Rico for a fiscal year shall be the greater of—

“(I) $500,000; or

“(II) an amount determined under the subparagraph (C).

“(C) Determination.—
“(i) FORMULA.—For purposes of sub-
paragraph (B), the amount referred to in
this subparagraph for a State (including a
territory) for a fiscal year is—

“(I) an amount equal to the
amount made available under section
3415 for the fiscal year involved for
grants pursuant to subparagraph (B);
and

“(II) the percentage constituted
by the sum of—

“(aa) the product of 0.85
and the ratio of the State dis-
tribution factor for the State or
territory to the sum of the re-
spective distribution factors for
all States; and

“(bb) the product of 0.15
and the ratio of the non-local dis-
tribution factor for the State or
territory (as determined under
clause (iv)) to the sum of the re-
spective non-local distribution
factors for all States or terri-
tories.
“(ii) State distribution factor.—

For purposes of clause (i)(II)(aa), the term ‘State distribution factor’ means an amount equal to—

“(I) the estimated number of drug overdose deaths in the State, as determined under clause (iii); or

“(II) the number of non-fatal drug overdoses in the State, as determined under clause (iv);

as determined by the Secretary based on which distribution factor (subclause (I) or (II)) will result in the State receiving the greatest amount of funds.

“(iii) Number of drug overdoses.—For purposes of clause (ii), the number of drug overdose deaths determined under this clause for a State for a fiscal year is the number of drug overdose deaths during the most recent 3-year period for which such data are available.

“(iv) Number of non-fatal drug overdoses.—For purposes of clause (ii), the number of non-fatal drug overdose deaths determined under this clause for
State for a fiscal year for purposes of clause (ii) may be determined by using data including emergency department syndromic data, visits, or other emergency medical services for drug-related causes during the most recent 3-year period for which such data are available.

“(v) NON-LOCAL DISTRIBUTION FACTORS.—For purposes of clause (i)(II)(bb), the term ‘non-local distribution factor’ means an amount equal to the sum of—

“(I) the number of drug overdoses deaths in the State involved, as determined under clause (iii), or

the number of non-fatal drug overdoses in the State, based on the criteria used by the State under clause (ii); less

“(II) the total number of drug overdose deaths or non-fatal drug overdoses that are within areas in such State or territory that are eligible counties under section 3401.

“(vi) STUDY.—Not later than 3 years after the date of enactment of this title,
the Comptroller General shall conduct a study to determine whether the data utilized for purposes of clause (ii) provides the most precise measure of State need related to substance use and addiction prevalence and whether additional data would provide more precise measures the levels of substance use and addiction prevalent in States. Such study shall identify barriers to collecting or analyzing such data, and make recommendations for revising the distribution factors used under such clause to determine funding levels in order to direct funds to the States in most need of funding to provide substance use disorder treatment services.

“(2) SUPPLEMENTAL GRANTS.—

“(A) IN GENERAL.—Subject to subparagraph (C), the Secretary shall disburse the remainder of amounts not disbursed under paragraph (1) for such fiscal year for the purpose of making grants to States whose application—

“(i) contains a report concerning the dissemination of emergency relief funds
under paragraph (1) and the plan for utilization of such funds;

“(ii) demonstrates the need in such State, on an objective and quantified basis, for supplemental financial assistance to combat substance use disorder;

“(iii) demonstrates the existing commitment of local resources of the State, both financial and in-kind, to combating substance use disorder;

“(iv) demonstrates the ability of the State to utilize such supplemental financial resources in a manner that is immediately responsive and cost effective;

“(v) demonstrates that resources will be allocated in accordance with the local demographic incidence of substances use disorders and drug overdose mortality;

“(vi) demonstrates the inclusiveness of affected communities and individuals with substance use disorders, including those communities and individuals that are disproportionately affected or historically underserved;
“(vii) demonstrates the manner in which the proposed services are consistent with the local needs assessment and the statewide coordinated statement of need required under section 3413(e);

“(viii) demonstrates success in identifying individuals with substance use disorders; and

“(ix) demonstrates that support for substance use disorder treatment services is organized to maximize the value to the population to be served with an appropriate mix of substance use disorder treatment services and attention to transition in care.

“(B) AMOUNT.—

“(i) IN GENERAL.—The amount of each grant made for purposes of this paragraph shall be determined by the Secretary. In making such determination, the Secretary shall consider:

“(I) the rate of drug overdose deaths per 100,000 population in the State; and
“(II) the increasing need for substance use disorder treatment services, including relative rates of increase in the number of drug overdoses or drug overdose deaths, or recent increases in drug overdoses or drug overdose deaths since the data was reported under section 3413.

“(ii) DEMONSTRATED NEED.—The factors considered by the Secretary in determining whether a State has a demonstrated need for purposes of subparagraph (A)(ii) may include any or all of the following:

“(I) The unmet need for such services, including the factors identified in clause (i)(II).

“(II) Relative rates of increase in the number of drug overdoses or drug overdose deaths.

“(III) The relative rates of increase in the number of drug deaths within new or emerging subpopulations.
“(IV) The current prevalence of substance use disorders.

“(V) Relevant factors related to the cost and complexity of delivering substance use disorder treatment services to individuals in the State.

“(VI) The impact of co-morbid factors, including co-occurring conditions, determined relevant by the Secretary.

“(VII) The prevalence of homelessness among individuals with substance use disorder.

“(VIII) The relevant factors that limit access to health care, including geographic variation, adequacy of health insurance coverage, and language barriers.

“(IX) The impact of a decline in the amount received pursuant to paragraph (1) on substance use disorder treatment services available to all individuals with substance use disorders identified and eligible under this subtitle.
“(X) The increasing incidence in conditions related to substance use, including hepatitis C, human immunodeficiency virus, hepatitis B and other infections associated with injection drug use.

“(C) MODEL STANDARDS.—

“(i) PREFERENCE.—In determining whether a State will receive funds under this paragraph, except as provided in clause (ii), the Secretary shall give preference to States that have adopted the model standards developed in accordance with section 3434.

“(ii) REQUIREMENT.—Effective beginning in fiscal year 2025, the Secretary shall not award a grant under this paragraph to a State unless that State has adopted the model standards developed in accordance with section 3434.

“(3) AMOUNT OF GRANT TO TRIBAL GOVERNMENTS.—

“(A) INDIAN TRIBES.—In this section, the term ‘Indian tribe’ has the meaning given such
term in section 4 of the Indian Self-Determination and Education Assistance Act.

“(B) FORMULA GRANTS.—The Secretary, acting through the Indian Health Service, shall use 10 percent of the amount available under section 3415 for each fiscal year to provide formula grants to Indian tribes in an amount determined pursuant to a formula and eligibility criteria developed by the Secretary in consultation with Indian tribes, for the purposes of addressing substance use.

“(C) USE OF AMOUNTS.—Notwithstanding any requirements in this section, an Indian tribe may use amounts provided under grants awarded under this paragraph for the uses identified in subsection (b) and any other activities determined appropriate by the Secretary, in consultation with Indian tribes.

“(b) USE OF AMOUNTS.—

“(1) IN GENERAL.—A State may use amounts provided under grants awarded under section 3411 for—

“(A) prevention services described in paragraph (2);
“(B) core medical services described in paragraph (3);
“(C) recovery and support services described in paragraph (4);
“(D) early intervention and engagement services described in paragraph (5);
“(E) harm reduction services described in paragraph (6); and
“(F) administrative expenses described in paragraph (8).

“(2) PREVENTION SERVICES.—
“(A) IN GENERAL.—For purposes of this subsection, the term ‘prevention services’ means services, programs, or multi-sector strategies to prevent substance use disorder (including evidence-based education campaigns, community-based prevention programs, opioid diversion, collection and disposal of unused opioids, and services to at-risk populations).

“(B) LIMIT.—A State may use not to exceed 20 percent of the amount of the grant under section 3411 for prevention services. A State may apply to the Secretary for a waiver of this subparagraph.
“(3) Core medical services.—For purposes of this subsection, the term ‘core medical services’ means the following evidence-based services when provided to individuals with substance use disorder or at risk for developing substance use disorder:

“(A) Substance use disorder treatments, including clinical stabilization services, withdrawal management and detoxification, intensive inpatient treatment, intensive outpatient treatment, all forms of Federally-approved medication-assisted treatment, outpatient treatment, and residential recovery treatment.

“(B) Outpatient and ambulatory health services, including those administered by Federally qualified health centers and rural health clinics.

“(C) Hospice services.

“(D) Mental health services.

“(E) Naloxone procurement, distribution, and training.

“(F) Pharmaceutical assistance related to the management of substance-use disorders and co-morbid conditions.

“(G) Home and community based health services.
“(H) Comprehensive Case Management and care coordination, including treatment adherence services.

“(I) Health insurance enrollment and cost-sharing assistance in accordance with subsection (e).

“(4) RECOVERY AND SUPPORT SERVICES.—For purposes of paragraph (1)(C), the term ‘recovery and support services’ means services, subject to the approval of the Secretary, that are provided to individuals with substance use disorder, including residential recovery treatment and housing, including for individuals receiving medication-assisted treatment, long term recovery services, 24/7 hotline crisis center services, medical transportation services, respite care for persons caring for individuals with substance use disorder, child care and family services while an individual is receiving inpatient treatment services or at the time of outpatient services, outreach services, peer recovery services, nutrition services, and referrals for job training and career services, housing, legal services, and child care and family services.

“(5) EARLY INTERVENTION AND ENGAGEMENT SERVICES.—For purposes of this subsection, the
term ‘early intervention and engagement services’ means services to provide rapid access to substance use disorder treatment services, counseling provided to individuals who have misused substances, who have experienced an overdose, or are at risk of developing substance use disorder, and the provision of referrals to facilitate the access of such individuals to core medical services or recovery and support services. The entities through which such services may be provided include emergency rooms, fire departments and emergency medical services, detention facilities, homeless shelters, law enforcement agencies, health care points of entry specified by eligible areas, Federally qualified health centers, and rural health clinics.

“(6) HARM REDUCTION SERVICES.—For purposes of this subsection, the term ‘harm reduction services’ means evidence-based services provided to individuals engaging in substance use disorder that reduce the risk of infectious disease transmission, overdose, or death, including by increasing access to health care.

“(7) AFFORDABLE HEALTH INSURANCE COVERAGE.—A State may use amounts provided under a grant awarded under section 3411 to establish a
program of financial assistance to assist eligible individuals with substance use disorder in—

“(A) enrolling in health insurance coverage; or

“(B) affording health care services, including assistance paying cost-sharing amounts, including premiums.

“(8) ADMINISTRATION AND PLANNING.—A State shall not use in excess of 10 percent of amounts received under a grant under section 3411 for administration, accounting, reporting, and program oversight functions, including the development of systems to improve data collection and data sharing.

“(9) INCARCERATED INDIVIDUALS.—Amounts received under a grant under section 3411 may be used to provide substance use disorder treatment services to currently incarcerated individuals.

“SEC. 3413. APPLICATION AND LIMITATION.

“(a) APPLICATION.—To be eligible to receive a grant under section 3411, a State shall prepare and submit to the Secretary an application in such form, and containing such information, as the Secretary shall require, including—
“(1) a complete accounting of the disbursement of any prior grants received under this subtitle by the applicant and the results achieved by these expenditures;

“(2) a comprehensive plan for the use of the grant, including a demonstration of the extent of local need for the funds sought and a plan for proposed substance use disorder treatment services that is consistent with local needs;

“(3) a demonstration that the State will use funds in a manner that provides substance use disorder treatment services compliant with the evidence-based standards developed in accordance with section 3434, including all Federally-approved medication-assisted treatments;

“(4) information on the number of individuals likely to be served by the funds sought, including demographic data on the populations to be served;

“(5) an identification of key outcomes that will be measured by all entities that receive assistance, as well as an explanation of how the outcomes will be measured;

“(6) a demonstration that resources provided under the grant will be allocated in accordance with the local demographic incidence of substance use, in-
cluding allocations for services for children, youths, and women;

“(7) a demonstration that funds received from a grant under this subtitle in any prior year were expended in accordance with State priorities;

“(8) a demonstration that the confidentiality of individuals receiving substance use disorder treatment services will be maintained in a manner not inconsistent with applicable law; and

“(9) an explanation of how income, asset, and medical expense criteria will be established and applied to those who qualify for assistance under the program.

“(b) ASSURANCES.—To be eligible to receive a grant under section 3401, the application submitted by an eligible State shall include assurances adequate to ensure—

“(1) that funds received under the grant will be utilized to supplement not supplant other State or local funds made available in the year for which the grant is awarded to provide substance use disorder treatment services to individuals with substance use disorder;

“(2) that the political subdivisions within the State will maintain the level of expenditures by such political subdivisions for substance use disorder
treatment services at a level that is equal to the level
of such expenditures by such political subdivisions
for the preceding fiscal year;

“(3) that political subdivisions within the State
will not use funds received under a grant awarded
under section 3411 in maintaining the level of sub-
stance use disorder treatment services as required in
paragraph (2);

“(4) that substance use disorder treatment
services provided with assistance made available
under the grant will be provided without regard—

“(A) to the ability of the individual to pay
for such services; and

“(B) to the current or past health condi-
tion of the individual to be served;

“(5) that substance use disorder treatment
services will be provided in a setting that is acces-
sible to low-income individuals with substance use
disorders and to individuals with substance use dis-
orders residing in rural areas;

“(6) that a program of outreach will be pro-
vided to low-income individuals with substance use
disorders to inform such individuals of substance use
disorder treatment services and to individuals with
substance use disorders residing in rural areas;
“(7) that Indian tribes are included in planning for the use of grant funds and that the Federal trust responsibility is upheld at all levels of program administration; and

“(8) that funds received under a grant awarded under this section will not be utilized to make payments for any item or service to the extent that payment has been made, or can reasonably be expected to be made, with respect to that item or service under a State compensation program, under an insurance policy, or under any Federal or State health benefits program (except for a program administered by or providing the services of the Indian Health Service).

“(c) MEDICAID IMD WAIVER APPLICATION REQUIREMENT.—A State shall not be eligible to receive a grant under this subtitle for a fiscal year unless the State—

“(1) has in effect for the year a waiver under section 1115 of the Social Security Act (42 U.S.C. 1315) to provide medical assistance under the State plan under title XIX of such Act to individuals who—

“(A) have not attained age 65 (or, if the State provides the medical assistance described
in section 1905(a)(16) of such Act, have attained age 21 but have not attained age 65);

“(B) are patients in an institution for mental diseases; and

“(C) are eligible for medical assistance under the State plan; or

“(2) has submitted an application for the year for such a waiver.

“(d) Requirements Regarding Imposition of Charges for Services.—

“(1) In general.—The Secretary may not make a grant under section 3411 to a State unless the State provides assurances that in the provision of services with assistance provided under the grant—

“(A) in the case of individuals with an income less than or equal to 138 percent of the official poverty level, the provider will not impose charges on any such individual for the services provided under the grant;

“(B) in the case of individuals with an income greater than 138 percent of the official poverty level, the provider will impose a charge on each such individual according to a schedule of charges made available to the public;
“(C) in the case of individuals with an income greater than 138 percent of the official poverty level but not exceeding 200 percent of such poverty level, the provider will not, for an calendar year, impose charges in an amount exceeding 5 percent of the annual gross income of the individual;

“(D) in the case of individuals with an income greater than 200 percent of the official poverty level but not exceeding 300 percent of such poverty level, the provider will not, for any calendar year, impose charges in an amount exceeding 7 percent of the annual gross income of the individual involved;

“(E) in the case of individuals with an income greater than 300 percent of the official poverty level, the provider will not, for any calendar year, impose charges in an amount exceeding 15 percent of the annual gross income of the individual involved; and

“(F) in the case of eligible American Indian and Alaska Native individuals as defined by section 447.50 of title 42, Code of Federal Regulations (as in effect on July 1, 2010), the provider will not impose any charges for sub-
stance use disorder treatment services, including any charges or cost-sharing prohibited by section 1402(d) of the Patient Protection and Affordable Care Act.

“(2) CHARGES.—With respect to compliance with the assurances made under paragraph (1), a State may, in the case of individuals subject to a charge—

“(A) assess the amount of the charge in the discretion of the State, including imposing only a nominal charge for the provision of services, subject to the provisions of the paragraph regarding public schedules and regarding limitations on the maximum amount of charges; and

“(B) take into consideration the total medical expenses of individuals in assessing the amount of the charge, subject to such provisions.

“(3) AGGREGATE CHARGES.—The Secretary may not make a grant under section 3411 to a State unless the State agrees that the limitations on charges for substance use disorder treatment services under this subsection applies to the annual aggregate of charges imposed for such services, how-
ever the charges are characterized, includes enrollment fees, premiums, deductibles, cost sharing, co-
payments, co-insurance costs, or any other charges.

“(e) **STATEWIDE COORDINATED STATEMENT OF NEED.**—A State shall not be eligible to receive a grant under this subtitle for a fiscal year unless the State develops and publishes a statewide coordinated statement of need, including a demonstration of the extent of State need for assistance in addressing addiction and substance use disorder in the State and identifying priorities for the delivery of essential services to individuals with substance use disorder and their families.

“(f) **INDIAN TRIBES.**—Any application requirements applying to grants distributed in accordance with section 3412(c) shall be developed by the Secretary in consultation with Indian tribes.

**SEC. 3414. TECHNICAL ASSISTANCE.**

“The Secretary shall provide technical assistance in administering and coordinating the activities authorized under section 3412, including technical assistance for the development of State applications for supplementary grants authorized in section 3212(a)(2).

**SEC. 3415. AUTHORIZATION OF APPROPRIATIONS.**

“There is authorized to be appropriated to carry out this subtitle—
“(1) $4,000,000,000 for fiscal year 2019;
“(2) $4,000,000,000 for fiscal year 2020;
“(3) $4,000,000,000 for fiscal year 2021;
“(4) $4,000,000,000 for fiscal year 2022;
“(5) $4,000,000,000 for fiscal year 2023;
“(6) $4,000,000,000 for fiscal year 2024;
“(7) $4,000,000,000 for fiscal year 2025;
“(8) $4,000,000,000 for fiscal year 2026;
“(9) $4,000,000,000 for fiscal year 2027; and
“(10) $4,000,000,000 for fiscal year 2028.

“Subtitle C—Other Grant Program

“SEC. 3421. ESTABLISHMENT OF GRANT PROGRAM.

“(a) IN GENERAL.—The Secretary shall award grants to public, nonprofit, and Native entities for the purpose of funding core medical services, recovery and support services, harm reduction services, administrative expenses, and early intervention and engagement services in accordance with this section.

“(b) ELIGIBILITY.—

“(1) ENTITIES.—Public, nonprofit, or Native entities eligible to receive a grant under subsection (a) may include—

“(A) federally qualified health centers under section 1905(l)(2)(B) of the Social Security Act;
“(B) family planning clinics;

“(C) rural health clinics;

“(D) Native entities, including Indian health programs as defined in section 4 of the Indian Health Care Improvement Act, urban Indian organizations as defined in section 4 of the Indian Health Care Improvement Act, and Native Hawaiian organizations as defined in section 12 of the Native Hawaiian Health Care Act of 1988;

“(E) community-based organizations, clinics, hospitals, and other health facilities that provide substance use disorder treatment services;

“(F) other nonprofit entities that provide substance use disorder treatment services; and

“(G) faith based organizations that provide substance use disorder treatment services.

“(2) Underserved Populations.—Entities described in paragraph (1) shall serve underserved populations which may include minority populations and Indian populations, ex-offenders, individuals with comorbidities including HIV/AIDS, hepatitis B or C, mental illness, or other behavioral health dis-
orders, low-income populations, inner city populations, and rural populations.

“(3) APPLICATION.—To be eligible to receive a grant under this section, a public or nonprofit entity described in this subsection shall prepare and submit to the Secretary an application in such form, and containing such information, as the Secretary shall require, including—

“(A) a complete accounting of the disbursement of any prior grants received under this subtitle by the applicant and the results achieved by these expenditures;

“(B) a comprehensive plan for the use of the grant, including a demonstration of the extent of local need for the funds sought and a plan for proposed substance use disorder treatment services that is consistent with local needs;

“(C) a demonstration that the grantee will use funds in a manner that provides substance use disorder treatment services compliant with the evidence-based standards developed in accordance with section 3434, including all Federally-approved medication-assisted treatments;
“(D) information on the number of individuals likely to be served by the funds sought, including demographic data on the populations to be served;

“(E) an identification of key outcomes that will be measured by all entities that receive assistance, as well as an explanation of how the outcomes will be measured;

“(F) a demonstration that resources provided under the grant will be allocated in accordance with the local demographic incidence of substance use, including allocations for services for children, youths, and women;

“(G) a demonstration that the confidentiality of individuals receiving substance use disorder treatment services will be maintained in a manner not inconsistent with applicable law; and

“(H) an explanation of how income, asset, and medical expense criteria will be established and applied to those who qualify for assistance under the program.

“(e) Requirement of Status as Medicaid Provider.—
“(1) Provision of Service.—Subject to paragraph (2), the Secretary may not make a grant under this section for the provision of substance use disorder treatment services under this section in a State unless, in the case of any such service that is available pursuant to the State plan approved under title XIX of the Social Security Act for the State—

“(A) the political subdivision involved will provide the substance use disorder treatment service directly, and the political subdivision has entered into a participation agreement under the State plan and is qualified to receive payments under such plan; or

“(B) the political subdivision involved will enter into an agreement with a public or nonprofit private entity under which the entity will provide the substance use disorder treatment service, and the entity has entered into such a participation agreement and is qualified to receive such payments.

“(2) Waiver.—

“(A) In General.—In the case of an entity making an agreement pursuant to paragraph (1)(B) regarding the provision of substance use disorder treatment services, the requirement es-
established in such paragraph shall be waived by the State if the entity does not, in providing such services, impose a charge or accept reimbursement available from any third-party payor, including reimbursement under any insurance policy or under any Federal or State health benefits program.

“(B) Determination.—A determination by the State of whether an entity referred to in subparagraph (A) meets the criteria for a waiver under such subparagraph shall be made without regard to whether the entity accepts voluntary donations for the purpose of providing services to the public.

“(d) Amount of Grant to Native Entities.—

“(1) Indian tribes.—In this section, the term ‘Indian tribe’ has the meaning given such term in section 4 of the Indian Self-Determination and Education Assistance Act.

“(2) Formula grants.—The Secretary, acting through the Indian Health Service, shall use 10 percent of the amount available under section 3425 for each fiscal year to provide grants to Native entities in an amount determined pursuant to criteria devel-
oped by the Secretary in consultation with Indian tribes, for the purposes of addressing substance use.

“(3) USE OF AMOUNTS.—Notwithstanding any requirements in this section, Native entities may use amounts provided under grants awarded under this section for the uses identified in section 3422 and any other activities determined appropriate by the Secretary, in consultation with Indian tribes.

“SEC. 3422. USE OF AMOUNTS.

“(a) USE OF FUNDS.—An entity shall use amounts received under a grant under section 3421 to provide direct financial assistance to eligible entities for the purpose of delivering or enhancing—

“(1) prevention services described in subsection (b);

“(2) core medical services described in subsection (c);

“(3) recovery and support services described in subsection (d);

“(4) early intervention and engagement services described in subsection (e);

“(5) harm reduction services described in subsection (f); and

“(6) administrative expenses described in subsection (g).
“(b) PREVENTION SERVICES.—For purposes of this subsection, the term ‘prevention services’ means services, programs, or multi-sector strategies to prevent substance use disorder, including evidence-based education campaigns, community-based prevention programs, opioid diversion, collection and disposal of unused opioids, and services to at-risk populations.

“(c) CORE MEDICAL SERVICES.—For purposes of this section, the term ‘core medical services’ means the following services when provided to individuals with substance use disorder or at risk for developing substance use disorder:

“(1) Substance use disorder treatments, including clinical stabilization services, withdrawal management and detoxification, intensive inpatient treatment, intensive outpatient treatment, all forms of Federally-approved medication-assisted treatment, and residential recovery treatment.

“(2) Outpatient and ambulatory health services, including those administered by federally qualified health centers and rural health clinics.

“(3) Hospice services.

“(4) Mental health services.

“(5) Naloxone procurement, distribution, and training.
“(6) Pharmaceutical assistance and diagnostic testing related to the management of substance-use disorder and co-morbid conditions.

“(7) Home and community based health services.

“(8) Comprehensive Case Management and care coordination, including treatment adherence services.

“(9) Health insurance enrollment and cost-sharing assistance in accordance with section 3412.

“(d) RECOVERY AND SUPPORT SERVICES.—For purposes of subsection (a)(3), the term ‘recovery and support services’ means services, subject to the approval of the Secretary, that are provided to individuals with substance use disorder, including residential recovery treatment and housing, including for individuals receiving medication-assisted treatment, long term recovery services, 24/7 hotline services, medical transportation services, respite care for persons caring for individuals with substance use disorder, child care and family services while an individual is receiving inpatient treatment services or at the time of outpatient services, outreach services, peer recovery services, nutrition services, and referrals for job training and career services, housing, legal services, and child care and family services.
“(e) EARLY INTERVENTION AND ENGAGEMENT SERVICES.—For purposes of this section, the term ‘early intervention and engagement services’ means services to provide rapid access to substance use disorder treatment services, counseling provided to individuals who have misused substances, who have experienced an overdose, or are at risk of developing substance use disorder and the provision of referrals to facilitate the access of such individuals to core medical services or recovery and support services. The entities through which such services may be provided include emergency rooms, fire departments and emergency medical services, detention facilities, homeless shelters, law enforcement agencies, health care points of entry specified by eligible areas, Federally qualified health centers, and rural health clinics.

“(f) HARM REDUCTION SERVICES.—For purposes of this subsection, the term ‘harm reduction services’ means evidence-based services provided to individuals engaging in substance use that reduce the risk of infectious disease transmission, overdose, or death, including by increasing access to health care.

“(g) ADMINISTRATION AND PLANNING.—An entity shall not use in excess of 10 percent of amounts received under a grant under section 3421 for administration, accounting, reporting, and program oversight functions, in-
including for the purposes of developing systems to improve data collection and data sharing.

"SEC. 3423. TECHNICAL ASSISTANCE.

"The Secretary may, directly or through grants or contracts, provide technical assistance to nonprofit private entities and Native entities regarding the process of submitting to the Secretary applications for grants under section 3421, and may provide technical assistance with respect to the planning, development, and operation of any program or service carried out pursuant to such section.

"SEC. 3424. PLANNING AND DEVELOPMENT GRANTS.

"(a) IN GENERAL.—The Secretary may provide planning grants to public, nonprofit private, and Native entities for purposes of assisting such entities in expanding their capacity to provide substance use disorder treatment services in low-income communities and affected sub-populations that are underserviced with respect to such services.

"(b) AMOUNT.—A grant under this section may be made in an amount not to exceed $150,000.

"SEC. 3425. AUTHORIZATION OF APPROPRIATIONS.

"There is authorized to be appropriated to carry out this subtitle—

"(1) $500,000,000 for fiscal year 2019;

"(2) $500,000,000 for fiscal year 2020;
“(3) $500,000,000 for fiscal year 2021;
“(4) $500,000,000 for fiscal year 2022;
“(5) $500,000,000 for fiscal year 2023;
“(6) $500,000,000 for fiscal year 2024;
“(7) $500,000,000 for fiscal year 2025;
“(8) $500,000,000 for fiscal year 2026;
“(9) $500,000,000 for fiscal year 2027; and
“(10) $500,000,000 for fiscal year 2028.

“Subtitle D—Miscellaneous
Provisions

“SEC. 3431. SPECIAL PROJECTS OF NATIONAL SIGNIFICANCE.

“(a) IN GENERAL.—The Secretary, acting in consultation with the Director of the Office of National Drug Control Policy, shall award grants to entities to administer special projects of national significance to support the development of innovative and original models for the delivery of substance use disorder treatment services.

“(b) GRANTS.—The Secretary shall award grants under a project under subsection (a) to entities eligible for grants under subtitiles A, B, and C based on newly emerging needs of individuals receiving assistance under this title.

“(c) REPLICATION.—The Secretary shall make information concerning successful models or programs devel-
op ed under this section available to grantees under this
title for the purpose of coordination, replication, and inte-
gration. To facilitate efforts under this subsection, the
Secretary may provide for peer-based technical assistance
for grantees funded under this section.

“(d) GRANTS TO TRIBAL GOVERNMENTS.—

“(1) INDIAN TRIBES.—In this section, the term
‘Indian tribe’ has the meaning given such term in
section 4 of the Indian Self-Determination and Edu-
cation Assistance Act.

“(2) USE OF FUNDS.—The Secretary, acting
through the Indian Health Service, shall use 10 per-
cent of the amount available under this section for
each fiscal year to provide grants to Indian tribes
for the purposes of supporting the development of
innovative and original models for the delivery of
substance use disorder treatment and services, in-
cluding the development of culturally-informed care
models.

“(e) AUTHORIZATION OF APPROPRIATIONS.—There
is authorized to be appropriated to carry out this section—

“(1) $500,000,000 for fiscal year 2019;
“(2) $500,000,000 for fiscal year 2020;
“(3) $500,000,000 for fiscal year 2021;
“(4) $500,000,000 for fiscal year 2022;
“(5) $500,000,000 for fiscal year 2023;
“(6) $500,000,000 for fiscal year 2024;
“(7) $500,000,000 for fiscal year 2025;
“(8) $500,000,000 for fiscal year 2026;
“(9) $500,000,000 for fiscal year 2027; and
“(10) $500,000,000 for fiscal year 2028.

“SEC. 3432. EDUCATION AND TRAINING CENTERS.

“(a) IN GENERAL.—The Secretary may make grants and enter into contracts to assist public and nonprofit private entities, and schools, and academic health centers in meeting the cost of projects—

“(1) to train health personnel, including practitioners in programs under this title and other community providers, including counselors, case managers, social workers, peer recovery coaches, and harm reduction workers, in the diagnosis, treatment, and prevention of substance use disorders, including measures for the prevention and treatment of co-occurring infectious diseases and other conditions, and including (as applicable to the type of health professional involved), care for women, pregnant women, and children;

“(2) to train the faculty of schools of medicine, nursing, public health, osteopathic medicine, dentistry, allied health, and mental health practice to
teach health professions students to screen for and
provide for the needs of individuals with substance
use disorders or at risk of substance use; and

“(3) to develop and disseminate curricula and
resource materials relating to evidence-based prac-
tices for the screening, prevention, and treatment of
substance use disorders, including information about
prescribing best practices, alternative pain therapies,
and Federally-approved medication-assisted treat-
ment options.

“(b) PREFERENCE IN MAKING GRANTS.—In making
grants under subsection (a), the Secretary shall give pref-
ference to qualified projects that will—

“(1) train, or result in the training of, health
professionals, including counselors, case managers,
social workers, peer recovery coaches, and harm re-
duction workers, who will provide substance use dis-
order treatments for underserved groups, including
minority individuals and Indians with substance use
disorder and other individuals who are at a high risk
of substance use;

“(2) train, or result in the training of, minority
health professionals and minority allied health pro-
fessionals, including counselors, case managers, so-
cial workers, peer recovery coaches, and harm reduc-
tion workers, to provide substance use disorder treatment for individuals with such disease;

“(3) train or result in the training of individuals, including counselors, case managers, social workers, peer recovery coaches, and harm reduction workers, who will provide substance use disorder treatment in rural or other areas that are underserved by current treatment structures; and

“(4) train or result in the training of health professionals and allied health professionals, including counselors, case managers, social workers, peer recovery coaches, and harm reduction workers, to provide treatment for infectious diseases and mental health conditions co-occurring with substance use disorder.

“(c) NATIVE EDUCATION AND TRAINING CENTERS.—The Secretary shall use 10 percent of the amount available under subsection (d) for each fiscal year to provide grants authorized under this subtitle to—

“(1) tribal colleges and universities;

“(2) Indian Health Service grant funded institutions; and

“(3) Native partner institutions, including institutions of higher education with medical training programs that partner with one or more Indian
tribes, tribal organizations, Native Hawaiian organizations, or tribal colleges and universities to train Native health professionals that will provide substance use disorder treatment services in Native communities.

“(d) Authorization of Appropriations.—There is authorized to be appropriated to carry out this section—

“(1) $400,000,000 for fiscal year 2019;
“(2) $400,000,000 for fiscal year 2020;
“(3) $400,000,000 for fiscal year 2021;
“(4) $400,000,000 for fiscal year 2022;
“(5) $400,000,000 for fiscal year 2023;
“(6) $400,000,000 for fiscal year 2024;
“(7) $400,000,000 for fiscal year 2025;
“(8) $400,000,000 for fiscal year 2026;
“(9) $400,000,000 for fiscal year 2027; and
“(10) $400,000,000 for fiscal year 2028.

“SEC. 3433. OTHER PROVISIONS.

“(a) Medication-Assisted Treatment.—The Secretary may not make a grant under this title unless the applicant for the grant agrees to require all entities offering substance use disorder treatment services under the grant to offer all Federally-approved forms of medication-assisted substance use treatment for the substance use disorders for which the applicant offers treatment.
“(b) Waiver.—The Secretary may grant a waiver with respect to any requirement of this title if the grant applicant involved—

“(1) submits to the Secretary a justification containing such information as the Secretary shall require; and

“(2) agrees to require all entities offering substance use disorder treatment services under the grant—

“(A) to offer at least two Federally-approved forms of medication-assisted treatment on site;

“(B) provide counseling to patients on the benefits and risks of all forms of Federally-approved medication-assisted treatments; and

“(C) maintain an affiliation with a provider that can prescribe or otherwise dispense all other forms of Federally-approved medication-assisted treatment.

“(c) GAO Study.—Not later than 1 year after the date of enactment of this title, the Comptroller General of the United States shall submit to Congress a comprehensive report describing any relationship between substance use rates, pain management practices of the Indian Health Service, and patient request denials through the
purchased/referred care program of the Indian Health Service.

“SEC. 3434. STANDARDS FOR SUBSTANCE USE DISORDER TREATMENT AND RECOVERY FACILITIES.

“(a) In General.—Not later than 3 years after the date of enactment of this title, the Secretary, in consultation with the American Society of Addiction Medicine, shall promulgate model standards for the regulation of substance use disorder treatment services.

“(b) Contents.—The model standards promulgated under subsection (a) shall—

“(1) identify the types of providers intended to be covered without regard to whether such providers participate in any Federal health care program (as defined in section 1128B(f) of the Social Security Act (42 U.S.C. 1320a–7b(f))) and shall not include a private practitioner who is already licensed by a State medical licensing board and whose practice is limited to outpatient care;

“(2) require that all substance use disorder treatment services be licensed by the respective States for the levels of care which they provide;

“(3) identify the professional credentials needed by each type of substance use disorder treatment professional;
“(4) require that patients have access to licensed substance use disorder treatment services, including health care providers and physicians, for inpatient and outpatient care;

“(5) identify and develop strategies for States to ensure that all substance use disorder patients receive a medical assessment, including for co-occurring mental health issues and infectious diseases;

“(6) require States to implement a process to ensure that residential treatment provider qualifications are verified by the single State agency serving as the primary regulator in the State for substance use disorder treatment services (as required in paragraph (13)) or by an independent third party with the necessary competencies to use evidence-based patient placement assessment tools and nationally-recognized program standards, as applicable;

“(7) ensure that patients receiving substance use disorder treatment have access directly, by referral, or in such other manner as determined by the Secretary, to all Federally-approved medication-assisted treatments for substance use disorder;

“(8) develop standards for data reporting and require compilation of Statewide reports;
“(9) develop standards for licensed providers to ensure all patients receive an outpatient treatment and discharge plan;

“(10) develop standards for the certification of recovery residences that have an ongoing economic relationship with any commercial substance use disorder treatment service, including any relationship with any such service that includes receiving or making referrals for substance use disorder treatment, including—

“(A) application, inspection, and renewal procedures for recovery residences;

“(B) fire, safety, and health standards;

“(C) standards for equipping residences with naloxone and training residence owners, operators, and employees in the administration of naloxone;

“(D) standards for recovery residence owners and operators; and

“(E) standards to identify, disqualify from grant funding, and refer to the appropriate regulatory authority any entity engaged in the soliciting or receiving of a commission, benefit, bonus, rebate, kickback, or bribe, directly or indirectly, in cash or in kind, or engaging in any
split-fee arrangement, aimed at inducing the referral of a patient to or from a substance use disorder treatment service;

“(11) establish a toll-free telephone number to handle complaints about recovery residences;

“(12) establish and maintain on a publicly accessible internet website a list of all recovery residences in the State that have a certification in effect in accordance with this section;

“(13) require the designation of a single State agency to serve as the primary regulator in the State for substance use disorder treatment services;

“(14) require a single State agency to implement a process to ensure that treatment provider assessments for all substance use disorder treatment services, including levels of care and length-of-stay recommendations, are verified by an independent third party that has the necessary competencies to use evidence-based patient placement assessment tools and nationally-recognized program standards, as applicable; and

“(15) consider existing barriers to substance use disorder treatment and service access, including capacity and infrastructure needs, as well as access to culturally attuned services.
“(c) ANNUAL ASSESSMENT.—Beginning with respect to fiscal year 2021, the Secretary shall make a determination with respect to each State on whether the State has adopted the model standards promulgated in accordance with this section.

“(d) QUALITY MEASURES.—The Secretary shall engage a nonprofit, non-partisan standards development and quality measurement organization to convene government regulators, State representatives, consumer representatives, substance use disorder treatment providers, recovery residence owners and operators, and purchasers of substance use disorder treatments exercising leadership in quality-based purchasing to develop and annually revise a set of health care quality measures for substance use disorder treatment providers and owners and operators of recovery residences.

“SEC. 3435. NALOXONE DISTRIBUTION PROGRAM.

“(a) ESTABLISHMENT OF PROGRAM.—

“(1) IN GENERAL.—The Secretary shall provide for the purchase and delivery of Federally-approved opioid overdose reversal drug products on behalf of each State (or Indian tribe as defined in section 4 of the Indian Health Care Improvement Act) that receives a grant under subtitle B. This paragraph constitutes budget authority in advance of appro-
pensions Acts, and represents the obligation of the
Federal Government to provide for the purchase and
delivery to States of the opioid overdose reversal
drug products in accordance with this paragraph.

“(2) Special rules where opioid overdose
reversal drug products are unavailable.—To
the extent that a sufficient quantity of opioid over-
dose reversal drug products are not available for
purchase or delivery under paragraph (1), the Sec-
retary shall provide for the purchase and delivery of
the available opioid overdose reversal drug products
in accordance with priorities established by the Sec-
retary, with priority given to States with at least one
local area eligible for funding under section 3401(a).

“(b) Negotiation of Contracts With Manufac-
turers.—

“(1) In general.—For the purpose of car-
rying out this section, the Secretary shall negotiate
and enter into contracts with manufacturers of
opioid overdose reversal drug products consistent
with the requirements of this subsection and, to the
maximum extent practicable, consolidate such con-
tracting with any other contracting activities con-
ducted by the Secretary to purchase opioid overdose
reversal drug products. The Secretary may enter
into such contracts under which the Federal Government is obligated to make outlays, the budget authority for which is not provided for in advance in appropriations Acts, for the purchase and delivery of opioid overdose reversal drug products under subsection (a).

“(2) AUTHORITY TO DECLINE CONTRACTS.—
The Secretary may decline to enter into contracts under this subsection and may modify or extend such contracts.

“(3) CONTRACT PRICE.—

“(A) IN GENERAL.—The Secretary, in negotiating the prices at which opioid overdose reversal drug products will be purchased and delivered from a manufacturer under this subsection, shall take into account quantities of opioid overdose reversal drug products to be purchased by States under the option under paragraph (4)(B).

“(B) NEGOTIATION OF DISCOUNTED PRICE FOR OPIOID OVERDOSE REVERSAL DRUG PRODUCTS.—With respect to contracts entered into for the purchase of opioid overdose reversal drug products on behalf of States under this subsection, the price for the purchase of such
drug product shall be a discounted price negotiated by the Secretary.

“(4) PRODUCT DOSAGE.—All opioid overdose reversal products purchased under this section shall contain—

“(A) for each dose, the maximum amount of active pharmaceutical ingredient that acts as an opioid receptor antagonist as recommended by the Food and Drug Administration as an initial dose when administered by one of the approved, labeled routes of administration in adults; and

“(B) a minimum of two doses packaged together.

“(5) QUANTITIES AND TERMS OF DELIVERY.—Under contracts under this subsection—

“(A) the Secretary shall provide, consistent with paragraph (6), for the purchase and delivery on behalf of States and Indian tribes of quantities of opioid overdose reversal drug products; and

“(B) each State and Indian tribe, at the option of the State or tribe, shall be permitted to obtain additional quantities of opioid overdose reversal drug products (subject to amounts
specified to the Secretary by the State or tribe in advance of negotiations) through purchasing the opioid overdose reversal drug products from the manufacturers at the applicable price negotiated by the Secretary consistent with paragraph (3), if the State or tribe provides to the Secretary such information (at a time and manner specified by the Secretary, including in advance of negotiations under paragraph (1)) as the Secretary determines to be necessary, to provide for quantities of opioid overdose reversal drug products for the State or tribe to purchase pursuant to this subsection and to determine annually the percentage of the opioid overdose reversal drug market that is purchased pursuant to this section and this subparagraph.

The Secretary shall enter into the initial negotiations not later than 180 days after the date of the enactment of this title.

“(6) CHARGES FOR SHIPPING AND HANDLING.—The Secretary may enter into a contract referred to in paragraph (1) only if the manufacturer involved agrees to submit to the Secretary such reports as the Secretary determines to be appropriate to assure compliance with the contract and
if, with respect to a State program under this section that does not provide for the direct delivery of qualified opioid overdose reversal drug products, the manufacturer involved agrees that the manufacturer will provide for the delivery of the opioid overdose reversal drug products on behalf of the State in accordance with such program and will not impose any charges for the costs of such delivery (except to the extent such costs are provided for in the price established under paragraph (3)).

“(7) MULTIPLE SUPPLIERS.—In the case of the opioid overdose reversal drug product involved, the Secretary may, as appropriate, enter into a contract referred to in paragraph (1) with each manufacturer of the opioid overdose reversal drug product that meets the terms and conditions of the Secretary for an award of such a contract (including terms and conditions regarding safety and quality). With respect to multiple contracts entered into pursuant to this paragraph, the Secretary may have in effect different prices under each of such contracts and, with respect to a purchase by States pursuant to paragraph (4)(B), each eligible State may choose which of such contracts will be applicable to the purchase.
“(c) Use of Opioid Overdose Reversal Drug Product List.—Beginning not later than one year after the first contract has been entered into under this section, the Secretary shall use, for the purpose of the purchase, delivery, and administration of opioid overdose reversal drug products under this section, the list established (and periodically reviewed and, as appropriate, revised) by an advisory committee, established by the Secretary and located within the Centers for Disease Control and Prevention, which considers the cost effectiveness of each opioid overdose reversal drug product.

“(d) State Distribution of Opioid Overdose Reversal Drug Products.—States shall distribute opioid overdose reversal drug products received under this section to the following:

“(1) First Responders, including—

“(A) all State, county, and local law enforcement departments;

“(B) all Tribal police departments;

“(C) all local fire departments, including career fire departments, combination fire departments, and volunteer fire departments; and

“(D) all local emergency medical services organizations, including volunteer emergency medical services organizations.
“(2) Public entities with authority to administer local public health services, including all local health departments, for the purposes of making opioid overdose reversal drug products available to—

“(A) public and nonprofit entities, including—

“(i) community-based organizations that provide substance use disorder treatments or harm reduction services;

“(ii) nonprofit entities that provide substance use disorder treatments or harm reduction services; and

“(iii) faith based organizations that provide substance use disorder treatments or harm reduction services; and

“(B) the general public.

“(e) STATE REQUIREMENTS.—To be eligible to receive opioid overdose reversal drugs under this section, each State shall—

“(1) establish a program for distributing opioid overdose reversal drug products to first responders and entities with authority to administer local public health services, including local health departments;

“(2) beginning in the second year of the program, demonstrate a distribution rate of a minimum
of 90 percent of the opioid overdose reversal drug
products received under this program; and

“(3) certify to the Secretary that the State has
in place measures that enhance access to opioid
overdose reversal drug products, such as laws that
provide civil or disciplinary immunity for medical
personnel who prescribe an opioid overdose reversal
drug product, Good Samaritan Laws, Third Party
Prescription Laws, Collaborative Practice Agree-
ments, and Standing Orders.

“(f) INDIAN TRIBE REQUIREMENTS.—The Indian
Health Service, in consultation with Indian tribes, shall
determine any requirements that shall apply to Indian
tribes receiving opioid overdose reversal drug products
made available under this section.

“(g) DEFINITIONS.—For purposes of this section:

“(1) CAREER FIRE DEPARTMENT.—The term
‘career fire department’ means a fire department
that has an all-paid force of firefighting personnel
other than paid-on-call firefighters.

“(2) COLLABORATIVE PRACTICE AGREEMENT.—
The term ‘Collaborative Practice Agreement’ means
an agreement under which a pharmacist operates
under authority delegated by another licensed practi-
tioner with prescribing authority.
“(3) COMBINATION FIRE DEPARTMENT.—The term ‘combination fire department’ means a fire department that has paid firefighting personnel and volunteer firefighting personnel.

“(4) EMERGENCY MEDICAL SERVICE.—The term ‘emergency medical service’ means resources used by a public or private nonprofit licensed entity to deliver medical care outside of a medical facility under emergency conditions that occur as a result of the condition of the patient and includes services delivered (either on a compensated or volunteer basis) by an emergency medical services provider or other provider that is licensed or certified by the State involved as an emergency medical technician, a paramedic, or an equivalent professional (as determined by the State).

“(5) GOOD SAMARITAN LAW.—The term ‘Good Samaritan Law’ means a law that provides criminal immunity for a person who administers an opioid overdose reversal drug product, a person who, in good faith, seeks medical assistance for someone experiencing a drug-related overdose, or a person who experiences a drug-related overdose and is in need of medical assistance and, in good faith, seeks such
medical assistance, or is the subject of such a good faith request for medical assistance.

“(6) INDIANS.—The terms ‘Indian’, ‘Indian tribe’, ‘tribal organization’, and ‘Urban Indian Health Program’ have the meanings given such terms in section 4 of the Indian Health Care Improvement Act.

“(7) MANUFACTURER.—The term ‘manufacturer’ means any corporation, organization, or institution, whether public or private (including Federal, State, and local departments, agencies, and instrumentalities), which manufactures, imports, processes, or distributes under its label any opioid overdose reversal drug product. The term ‘manufacture’ means to manufacture, import, process, or distribute an opioid overdose reversal drug.

“(8) OPIOID OVERDOSE REVERSAL DRUG PRODUCT.—The term ‘opioid overdose reversal drug product’ means a finished dosage form that has been approved by the Food and Drug Administration and that contains an active pharmaceutical ingredient that acts as an opioid receptor antagonist. The term ‘opioid overdose reversal drug product’ includes a combination product, as defined in section 3.2(e) of title 21, Code of Federal Regulations.
“(9) STANDING ORDER.—The term ‘standing order’ means a non-patient-specific order covering administration of medication by others to a patient who may be unknown to the prescriber at the time of the order.

“(10) THIRD PARTY PRESCRIPTION.—The term ‘third party prescription’ means an order written for medication dispensed to one person with the intention that it will be administered to another person.

“(11) VOLUNTEER FIRE DEPARTMENT.—The term ‘volunteer fire department’ means a fire department that has an all-volunteer force of firefighting personnel.

“(h) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section—

“(1) $500,000,000 for fiscal year 2019;
“(2) $500,000,000 for fiscal year 2020;
“(3) $500,000,000 for fiscal year 2021;
“(4) $500,000,000 for fiscal year 2022;
“(5) $500,000,000 for fiscal year 2023;
“(6) $500,000,000 for fiscal year 2024;
“(7) $500,000,000 for fiscal year 2025;
“(8) $500,000,000 for fiscal year 2026;
“(9) $500,000,000 for fiscal year 2027; and
“(10) $500,000,000 for fiscal year 2028.

SEC. 3436. ADDITIONAL FUNDING FOR THE NATIONAL INSTITUTES OF HEALTH.

“There is authorized to be appropriated to the National Institute of Health for the purpose of conducting research on addiction and pain related to substance misuse, including research to develop overdose reversal drug products, non-addictive drug products for treating pain, and drug products used to treat substance use disorder—

“(1) $1,000,000,000 for fiscal year 2019;
“(2) $1,000,000,000 for fiscal year 2020;
“(3) $1,000,000,000 for fiscal year 2021;
“(4) $1,000,000,000 for fiscal year 2022;
“(5) $1,000,000,000 for fiscal year 2023;
“(6) $1,000,000,000 for fiscal year 2024;
“(7) $1,000,000,000 for fiscal year 2025;
“(8) $1,000,000,000 for fiscal year 2026;
“(9) $1,000,000,000 for fiscal year 2027; and
“(10) $1,000,000,000 for fiscal year 2028.

SEC. 3437. ADDITIONAL FUNDING FOR IMPROVED DATA COLLECTION AND PREVENTION OF INFECTIOUS DISEASE TRANSMISSION.

“(a) Data Collection.—The Centers for Disease Control and Prevention shall use a portion of the funding appropriated under this section to ensure that all States
participate in the Enhanced State Opioid Overdose Surveillance program and to provide technical assistance to medical examiners and coroners to facilitate improved data collection on fatal overdoses through such program.

“(b) CENTERS FOR DISEASE CONTROL AND PREVENTION.—The Centers for Disease Control and Prevention shall use amounts appropriated under this section for the purpose of improving data on drug overdose deaths and non-fatal drug overdoses, surveillance related to addiction and substance use disorder, and the prevention of transmission of infectious diseases related to substance use.

“(c) TRIBAL EPIDEMIOLOGY CENTERS.—There shall be made available to the Indian Health Service for the purpose of funding efforts by tribal epidemiology centers to improve data on drug overdose deaths and non-fatal drug overdoses and surveillance related to addiction and substance use disorder, not less than 1.5 percent of the total amount appropriated under this section for each fiscal year.

“(d) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section—

“(1) $400,000,000 for fiscal year 2019;

“(2) $400,000,000 for fiscal year 2020;

“(3) $400,000,000 for fiscal year 2021;

“(4) $400,000,000 for fiscal year 2022;
“(5) $400,000,000 for fiscal year 2023;
“(6) $400,000,000 for fiscal year 2024;
“(7) $400,000,000 for fiscal year 2025;
“(8) $400,000,000 for fiscal year 2026;
“(9) $400,000,000 for fiscal year 2027; and
“(10) $400,000,000 for fiscal year 2028.

“SEC. 3438. DEFINITIONS.

“In this title:

“(1) PLANNING COUNCIL.—The term ‘planning council’ means the substance use planning council established under section 3402.

“(2) RECOVERY RESIDENCE.—The term ‘recovery residence’ means a residential dwelling unit, or other form of group housing, that is offered or advertised through any means, including oral, written, electronic, or printed means, by any individual or entity as a residence that provides an evidence-based, peer-supported living environment for individuals undergoing any type of substance use disorder treatment or who have received any type of substance use disorder treatment in the past 3 years, including medication-assisted treatment.

“(3) STATE.—
“(A) IN GENERAL.—The term ‘State’ means each of the 50 States, the District of Columbia, and each of the territories.

“(B) TERRITORIES.—The term ‘territory’ means each of American Samoa, Guam, the Commonwealth of Puerto Rico, the Commonwealth of the Northern Mariana Islands, the Virgin Islands, the Republic of the Marshall Islands, the Federated States of Micronesia, and Palau.

“(4) SUBSTANCE USE DISORDER TREATMENT.—

“(A) IN GENERAL.—The term ‘substance use disorder treatment’ means an evidence-based, professionally directed, deliberate, and planned regimen including evaluation, observation, medical monitoring, and rehabilitative services and interventions such as pharmacotherapy, behavioral therapy, and individual and group counseling, on an inpatient or outpatient basis, to help patients with substance use disorder reach recovery.

“(B) TYPES OF TREATMENT.—Substance use disorder treatments shall include the following:
“(i) Clinical stabilization services, which are evidence-based services provided in secure, acute care facilities (which may be referred to as ‘addictions receiving facilities’) that, at a minimum—

“(I) provide detoxification and stabilization services;

“(II) are operated 24 hours per day, 7 days per week; and

“(III) that serve individuals found to be substance use impaired. These can also be referred to as ‘Addictions receiving facilities’.

“(ii) Withdrawal management and detoxification, which is a service that is provided on an inpatient or an outpatient basis to assist individuals manage the process of withdrawing from the physiological and psychological effects of substance use disorder.

“(iii) Intensive inpatient treatment, which is a service that provides a planned regimen of evidence-based evaluation, observation, medical monitoring, and evidence-based rehabilitative services and
interventions such as pharmacotherapy, behavioral therapy, and counseling, 24 hours per day, 7 days per week, in a highly structured, residential environment.

“(iv) Intensive outpatient treatment, which is a service that provides a planned regimen of evidence-based evaluation, observation, medical monitoring, and evidence-based rehabilitative services and interventions such as pharmacotherapy, behavioral therapy, and counseling, in a structured, nonresidential environment at a higher level of intensity and duration than outpatient treatment.

“(v) Medication-assisted treatment, which is a service that uses Federally-approved medication as authorized by Federal and State law, in combination with evidence-based medical, rehabilitative, and counseling services, in the treatment of individuals who suffer from substance use disorder.

“(vi) Outpatient treatment, which is a service that provides a planned regimen of evidence-based evaluation, observation,
medical monitoring, and evidence-based rehabilitative services and interventions such as pharmacotherapy, behavioral therapy, and counseling in a structured, nonresidential environment by appointment during scheduled operating hours.

“(vii) Residential recovery treatment, which is a service that provides a planned regimen of evidence-based evaluation, observation, medical monitoring, and evidence-based rehabilitative services and interventions such as pharmacotherapy, behavioral therapy, and counseling provided in a structured, live-in environment within a nonhospital setting on a 24-hours-per-day, 7-days-per-week basis.

“(C) LIMITATION.—Substance use disorder treatment providers shall not include—

“(i) prevention only providers; and

“(ii) a private practitioner who is licensed by a State medical licensing board and whose practice is limited to outpatient care.

“(5) SUBSTANCE USE DISORDER TREATMENT SERVICES.—The term ‘substance use disorder treat-
ment services’ means any prevention services, core medical services, recovery and support services, early intervention and engagement services, and harm reduction services authorized under this title.”.

SEC. 4. AMENDMENTS TO THE CONTROLLED SUBSTANCES ACT.

(a) CERTIFICATIONS.—Part C of the Controlled Substances Act (21 U.S.C. 821 et seq.) is amended by adding at the end the following:

“CERTIFICATIONS RELATING TO DIVERSION CONTROLS AND MISBRANDING

“Sec. 312. (a) Definitions.—In this section—

“(1) the term ‘covered dispenser’—

“(A) means a dispenser—

“(i) that is required to register under section 302(a)(2); and

“(ii) dispenses a controlled substance in schedule II; and

“(B) does not include a dispenser that is—

“(i) registered to dispense opioid agonist treatment medication under section 303(g)(1); and

“(ii) operating in that capacity;

“(2) the term ‘covered distributor’ means a di-

 distrubutor—
“(A) that is required to register under section 302(a)(1); and

“(B) distributes a controlled substance in schedule II;

“(3) the term ‘covered manufacturer’ means a manufacturer—

“(A) that is required to register under section 302(a)(1); and

“(B) manufactures a controlled substance in schedule II;

“(4) the term ‘covered officer’, with respect to a covered person means—

“(A) in the case of a covered person that is not an individual—

“(i) the chief executive officer of the covered person;

“(ii) the president of the covered person;

“(iii) the chief medical officer of the covered person; and

“(iv) the chief counsel of the covered person; and

“(B) in the case of a covered person that is an individual, that individual; and
“(5) the term ‘covered person’ means a covered dispenser, a covered distributor, or a covered manufacturer.

“(b) CERTIFICATIONS RELATING TO DIVERSION CONTROLS.—Not later than 180 days after the date of enactment of this section, and each year thereafter, each covered officer of a covered person shall submit to the Attorney General, for each controlled substance in schedule II dispensed, distributed, or manufactured by the covered person, a certification—

“(1) signed by the covered officer; and

“(2) certifying that—

“(A) the covered person maintains effective controls against diversion of the controlled substance into channels other than legitimate medical, scientific, research, or industrial channels;

“(B) all information contained in any record, inventory, or report required to be kept or submitted to the Attorney General by the covered person under section 307, or under any regulation issued under that section, is accurate; and

“(C) the covered person is in compliance with all applicable requirements under Federal
law relating to reporting suspicious orders for
controlled substances.

“(c) Certifications Relating to Misbranding.—Not later than 180 days after the date of enactment of this section, and each year thereafter, each covered officer of a covered manufacturer shall submit to the Attorney General, for each controlled substance in schedule II manufactured by the covered manufacturer, a certification—

“(1) signed by the covered officer; and

“(2) certifying that the controlled substance is not misbranded, as described in section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352).”.

(b) Offenses.—Part D of title II of the Controlled Substances Act (21 U.S.C. 841 et seq.) is amended by adding at the end the following:

“CERTIFICATIONS BY COVERED OFFICERS

“Sec. 424. (a) Definitions.—In this section, the terms ‘covered dispenser’, ‘covered distributor’, ‘covered manufacturer’, ‘covered officer’, and ‘covered person’ have the meanings given those terms in section 312.

“(b) Offenses.—

“(1) Failure to submit certifications.—

“(A) Certifications relating to diversion controls.—It shall be unlawful for a
covered officer of a covered person to fail to submit a certification required under section 312(b), without regard to the state of mind of the covered officer.

“(B) CERTIFICATIONS RELATING TO MISBRANDING.—It shall be unlawful for a covered officer of a covered manufacturer to fail to submit a certification required under section 312(c), without regard to the state of mind of the covered officer.

“(2) SUBMISSION OF FALSE CERTIFICATIONS.—

“(A) FALSE CERTIFICATIONS RELATING TO DIVERSION CONTROLS.—It shall be unlawful for a covered officer of a covered person to submit a certification required under section 312(b), without regard to the state of mind of the covered officer, that contains a materially false statement or representation relating to the information required to be certified under that section for the year for which the certification is submitted.

“(B) FALSE CERTIFICATIONS RELATING TO MISBRANDING.—It shall be unlawful for a covered officer of a covered manufacturer to submit a certification required under section
312(c), without regard to the state of mind of
the covered officer, that contains a materially
false statement or representation relating to the
misbranding of a controlled substance with re-
spect to the year for which the certification is
submitted.

“(c) Penalties.—

“(1) Civil Penalties.—Except as provided in
paragraph (2), a covered officer who violates sub-
section (b) shall be subject to a civil penalty of not
more than $25,000.

“(2) Criminal Penalties.—A covered officer
who knowingly violates subsection (b)(2) shall be
subject to criminal penalties under section 403(d).

“(d) Comprehensive Addiction Resources
Fund.—

“(1) Establishment.—There is established in
the Treasury a fund to be known as the ‘Com-
prehensive Addiction Resources Fund’.

“(2) Transfer of Amounts.—There shall be
transferred to the Comprehensive Addiction Re-
sources Fund 100 percent of—

“(A) any civil penalty paid to the United
States under this section; and
“(B) any fine paid to the United States under section 403(d) for a knowing violation of subsection (b)(2) of this section.

“(3) **Availability and Use of Funds.**—

Amounts transferred to the Comprehensive Addiction Fund under paragraph (2) shall—

“(A) remain available until expended; and

“(B) be made available to supplement amounts appropriated to carry out title XXXIV of the Public Health Service Act.”.

**Criminal Penalties.**—Section 403 of the Controlled Substances Act (21 U.S.C. 843) is amended—

(1) in subsection (d)(1)—

(A) by inserting “or knowingly violates section 424(b)(2)” after “any person who violates this section”; and

(B) by striking “violation of this section” and inserting “such a violation”; and

(2) in subsection (f)—

(A) in paragraph (1), by striking “or 416” and inserting “or section 416, or knowing violations of section 424(b)(2)”; and

(B) in paragraph (3), by inserting “or knowing violations of section 424(b)(2)” before the period at the end.
(d) TECHNICAL AND CONFORMING AMENDMENTS.—

The table of contents for the Comprehensive Drug Abuse Prevention and Control Act of 1970 (Public Law 91–513; 84 Stat. 1236) is amended—

(1) by inserting after the item relating to section 311 the following:

“Sec. 312. Certifications relating to diversion controls and misbranding.”;

and

(2) by inserting after the item relating to section 423 the following:

“Sec. 424. Certifications by covered officers.”.

(e) EFFECTIVE DATE.—The amendments made by subsections (b) and (e) of this section shall take effect on the date that is 180 days after the date of enactment of this Act.