In the House of Representatives, U. S.,

May 13, 2016.

Resolved, That the bill from the Senate (S. 524) entitled ''An Act to authorize the Attorney General to award grants to address the national epidemics of prescription opioid abuse and heroin use.'', do pass with the following

AMENDMENTS:

Strike out all after the enacting clause and insert:

SECTION 1. TABLE OF CONTENTS.

The table of contents for this Act is as follows:

TITLE I—PAIN MANAGEMENT BEST PRACTICES INTER-AGENCY TASK FORCE

SEC. 101. DEVELOPMENT OF BEST PRACTICES FOR THE USE OF PRESCRIPTION OPIOIDS.

(a) DEFINITIONS.—In this section—

(1) the term "Secretary" means the Secretary of Health and Human Services; and

(2) the term "task force" means the Pain Management Best Practices Inter-Agency Task Force convened under subsection (b).

(b) INTER-AGENCY TASK FORCE.—Not later than December 14, 2018, the Secretary, in cooperation with the Secretary of Veterans Affairs, the Secretary of Defense, and the Administrator of the Drug Enforcement Administration, shall convene a Pain Management Best Practices Inter-Agency Task Force to review, modify, and update, as appropriate, best practices for pain management (including chronic and acute pain) and prescribing pain medication.

(c) MEMBERSHIP.—The task force shall be comprised of—

(1) representatives of—

(A) the Department of Health and Human Services;

(B) the Department of Veterans Affairs;

(C) the Food and Drug Administration;

(D) the Department of Defense;

(E) the Drug Enforcement Administration;

(F) the Centers for Disease Control and Prevention;

(G) the Health Resources and Services Administration;

(H) the Indian Health Service;

(I) the National Academy of Medicine;

(J) the National Institutes of Health;

(K) the Office of National Drug Control Policy;

(L) the Substance Abuse and Mental Health Services Administration; and

(M) the Office of Women's Health;

(2) State medical boards;

(3) subject to subsection (e), physicians, dentists, and nonphysician prescribers;

(4) hospitals;

(5) subject to subsection (e), pharmacists and pharmacies;

(6) first responders;

(7) experts in the fields of pain research and addiction research;

(8) experts in the fields of adolescent and young adult addiction research;

(9) representatives of—

(A) pain management professional organizations;

(B) the mental health treatment community;

(C) the addiction treatment and recovery community;

(D) pain advocacy groups;

(E) veteran service organizations; and

(F) groups with expertise on overdose reversal;

(10) a person in recovery from addiction to medication for chronic pain;

(11) a person in recovery from addiction to medication for chronic pain, whose addiction began in adolescence or young adulthood;

(12) a person with chronic pain;

(13) an expert on active duty military, armed forces personnel, and veteran health and prescription opioid addiction;

(14) an expert in the field of minority health; and

(15) other stakeholders, as the Secretary determines appropriate.

(d) CONDITION ON PARTICIPATION ON TASK FORCE.—An individual representing a profession or entity described in paragraph (3) or (5) of subsection (c) may not serve as a member of the task force unless such individual—

(1) is currently licensed in a State in which such individual is practicing (as defined by such State) such profession (or, in the case of an individual representing an entity, a State in which the entity is engaged in business); and

(2) is currently practicing (as defined by such State) such profession (or, in the case of an individual representing an entity, the entity is in operation).

(e) DUTIES.—The task force shall—

(1) not later than 180 days after the date on which the task force is convened under subsection (b), review, modify, and update, as appropriate, best practices for pain management (including chronic and acute pain) and prescribing pain medication, taking into consideration—

(A) existing pain management research;

(B) research on trends in areas and communities in which the prescription opioid abuse rate and fatality rate exceed the national average prescription opioid abuse rate and fatality rate;

(C) recommendations from relevant conferences and existing relevant evidence-based guidelines;

(D) ongoing efforts at the State and local levels and by medical professional organizations to develop improved pain management strategies, including consideration of differences within and between classes of opioids, the availability of opioids with abuse deterrent technology, and pharmacological, nonpharmacological, medical device alternatives to opioids to reduce opioid monotherapy in appropriate cases and the coordination of information collected from State prescription drug monitoring programs for the purpose of preventing the diversion of pain medication;

(E) ongoing efforts at the Federal, State, and local levels to examine the potential benefits of electronic prescribing of opioids, including any public comments collected in the course of those efforts;

(F) the management of high-risk populations, other than populations who suffer pain, who—

(i) may use or be prescribed benzodiazepines, alcohol, and diverted opioids; or

(ii) receive opioids in the course of medical care;

(G) the distinct needs of adolescents and young adults with respect to pain management, pain medication, substance use disorder, and medication-assisted treatment;

(H) the 2016 Guideline for Prescribing Opioids for Chronic Pain issued by the Centers for Disease Control and Prevention;

(I) the practice of co-prescribing naloxone for both pain patients receiving chronic opioid therapy and patients being treated for opioid use disorders;

(J) research that has been, or is being, conducted or supported by the Federal Government on prevention of, treatment for, and recovery from substance use by and substance use disorders among adolescents and young adults relative to any unique circumstances (including so-

cial and biological circumstances) of adolescents and young adults that may make adolescent-specific and young adult-specific treatment protocols necessary, including any effects that substance use and substance use disorders may have on brain development and the implications for treatment and recovery;

(K) Federal non-research programs and activities that address prevention of, treatment for, and recovery from substance use by and substance use disorders among adolescents and young adults, including an assessment of the effectiveness of such programs and activities in—

(i) preventing substance use by and substance use disorders among adolescents and young adults;

(ii) treating such adolescents and young adults in a way that accounts for any unique circumstances faced by adolescents and young adults; and

(iii) supporting long-term recovery among adolescents and young adults; and

(L) gaps that have been identified by Federal officials and experts in Federal efforts relating to prevention of, treatment for, and recovery

from substance use by and substance use disorders among adolescents and young adults, including gaps in research, data collection, and measures to evaluate the effectiveness of Federal efforts, and the reasons for such gaps;

(2) solicit and take into consideration public comment on the practices developed under paragraph (1), amending such best practices if appropriate;

(3) develop a strategy for disseminating information about the best practices developed under paragraphs (1) and (2) to prescribers, pharmacists, State medical boards, educational institutions that educate prescribers and pharmacists, and other parties, as the Secretary determines appropriate;

(4) review, modify, and update best practices for pain management and prescribing pain medication, specifically as it pertains to physician education and consumer education; and

(5) examine and identify—

(A) the extent of the need for the development of new pharmacological, nonpharmacological, and medical device alternatives to opioids;

(B) the current status of research efforts to develop such alternatives; and

(C) the pharmacological, nonpharmacological, and medical device alternatives to opioids that are currently available that could be better utilized.

(f) CONSIDERATION OF STUDY RESULTS.—In reviewing, modifying, and updating, best practices for pain management and prescribing pain medication, the task force shall take into consideration existing private sector, State, and local government efforts related to pain management and prescribing pain medication.

(g) LIMITATION.—The task force shall not have rulemaking authority.

(h) REPORT.—Not later than 270 days after the date on which the task force is convened under subsection (b), the task force shall submit to Congress a report that includes—

(1) the strategy for disseminating best practices for pain management (including chronic and acute pain) and prescribing pain medication, as developed under subsection (e);

(2) the results of a feasibility study on linking the best practices described in paragraph (1) to receiving and renewing registrations under section 303(f) of the Controlled Substances Act (21 U.S.C. 823(f));

(3) recommendations for effectively applying the best practices described in paragraph (1) to improve prescribing practices at medical facilities, including medical facilities of the Veterans Health Administration and Indian Health Service;

(4) the modified and updated best practices described in subsection (e)(4); and

(5) the results of the examination and identification conducted pursuant to subsection (e)(4), and recommendations regarding—

(A) the development of new pharmacological, nonpharmacological, and medical device alternatives to opioids; and

(B) the improved utilization of pharmacological, nonpharmacological, and medical device alternatives to opioids that are currently available.

TITLE II—COMPREHENSIVE OPIOID ABUSE REDUCTION ACT

SEC. 201. SHORT TITLE.

This title may be cited as the "Comprehensive Opioid Abuse Reduction Act of 2016".

SEC. 202. COMPREHENSIVE OPIOID ABUSE GRANT PROGRAM.

(a) IN GENERAL.—Title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3711 et seq.) is amended by adding at the end the following:

"PART LL—COMPREHENSIVE OPIOID ABUSE GRANT PROGRAM

"SEC. 3021. DESCRIPTION.

"(a) GRANTS AUTHORIZED.—From amounts made available to carry out this part, the Attorney General may make grants to States, units of local government, and Indian tribes, for use by the State, unit of local government, or Indian tribe to provide services primarily relating to opioid abuse, including for any one or more of the following:

"(1) Developing, implementing, or expanding a treatment alternative to incarceration program, which may include—

"(A) pre-booking or post-booking components, which may include the activities described in part DD or HH of this title;

"(B) training for criminal justice agency personnel on substance use disorders and co-occurring mental illness and substance use disorders;

"(C) a mental health court, including the activities described in part V of this title;

"(D) a drug court, including the activities described in part EE of this title;

"(E) a veterans treatment court program, including the activities described in subsection (i) of section 2991 of this title;

"(F) a focus on parents whose incarceration could result in their children entering the child welfare system; and

"(G) a community-based substance use diversion program sponsored by a law enforcement agency.

"(2) In the case of a State, facilitating or enhancing planning and collaboration between State criminal justice agencies and State substance abuse systems in order to more efficiently and effectively carry out programs described in paragraph (1) that address problems related to opioid abuse.

"(3) Providing training and resources for first responders on carrying and administering an opioid overdose reversal drug or device approved by the Food and Drug Administration, and purchasing such a drug or device for first responders who have received such training to carry and administer.

"(4) Investigative purposes to locate or investigate illicit activities related to the unlawful distribution of opioids.

"(5) Developing, implementing, or expanding a medication-assisted treatment program used or operated by a criminal justice agency, which may include training criminal justice agency personnel on medication-assisted treatment, and carrying out the activities described in part S of this title.

"(6) In the case of a State, developing, implementing, or expanding a prescription drug monitoring program to collect and analyze data related to the prescribing of schedules II, III, and IV controlled substances through a centralized database administered by an authorized State agency, which includes tracking the dispensation of such substances, and providing for interoperability and data sharing with other States.

"(7) Developing, implementing, or expanding a program to prevent and address opioid abuse by juveniles.

"(8) Developing, implementing, or expanding an integrated and comprehensive opioid abuse response program, including prevention and recovery programs.

"(9) Developing, implementing, or expanding a program (which may include demonstration projects) to utilize technology that provides a secure container for prescription drugs that would prevent individuals, particularly adolescents, from gaining access to opioid medications that are lawfully prescribed for other individuals.

"(10) Developing, implementing, or expanding a program to prevent and address opioid abuse by veterans.

"(11) Developing, implementing, or expanding a prescription drug take-back program.

"(b) CONTRACTS AND SUBAWARDS.—A State, unit of local government, or Indian tribe may, in using a grant under this subpart for purposes authorized by subsection (a), use all or a portion of that grant to contract with or make one or more subawards to one or more—

"(1) local or regional organizations that are private and nonprofit, including faith-based organizations;

"(2) units of local government; or

"(3) tribal organizations.

"(c) PROGRAM ASSESSMENT COMPONENT; WAIVER.—

"(1) PROGRAM ASSESSMENT COMPONENT.—Each program funded under this subpart shall contain a

program assessment component, developed pursuant to guidelines established by the Attorney General, in coordination with the National Institute of Justice.

"(2) WAIVER.—The Attorney General may waive the requirement of paragraph (1) with respect to a program if, in the opinion of the Attorney General, the program is not of sufficient size to justify a full program assessment.

"(d) ADMINISTRATIVE COSTS.—Not more than 10 percent of a grant made under this subpart may be used for costs incurred to administer such grant.

"(e) PERIOD.—The period of a grant made under this part may not be longer than 4 years, except that renewals and extensions beyond that period may be granted at the discretion of the Attorney General.

"SEC. 3022. APPLICATIONS.

"To request a grant under this part, the chief executive officer of a State, unit of local government, or Indian tribe shall submit an application to the Attorney General at such time and in such form as the Attorney General may require. Such application shall include the following:

"(1) A certification that Federal funds made available under this subpart will not be used to supplant State, local, or tribal funds, but will be used to increase the amounts of such funds that would, in the

absence of Federal funds, be made available for the activities described in section 3021(a).

"(2) An assurance that, for each fiscal year covered by an application, the applicant shall maintain and report such data, records, and information (programmatic and financial) as the Attorney General may reasonably require.

"(3) A certification, made in a form acceptable to the Attorney General and executed by the chief executive officer of the applicant (or by another officer of the applicant, if qualified under regulations promulgated by the Attorney General), that—

"(A) the programs to be funded by the grant meet all the requirements of this part;

"(B) all the information contained in the application is correct;

"(C) there has been appropriate coordination with affected agencies; and

"(D) the applicant will comply with all provisions of this part and all other applicable Federal laws.

"(4) An assurance that the applicant will work with the Drug Enforcement Administration to develop an integrated and comprehensive strategy to address opioid abuse.

"SEC. 3023. REVIEW OF APPLICATIONS.

"The Attorney General shall not finally disapprove any application (or any amendment to that application) submitted under this part without first affording the applicant reasonable notice of any deficiencies in the application and opportunity for correction and reconsideration.

"SEC. 3024. EQUITABLE DISTRIBUTION OF FUNDS.

"In awarding grants under this part, the Attorney General shall ensure equitable distribution of funds based on the following:

"(1) The geographic distribution of grants under this part, taking into consideration the needs of underserved populations, including rural and tribal communities.

"(2) The needs of communities to address the problems related to opioid abuse, taking into consideration the prevalence of opioid abuse and overdose-related death in a community.

"SEC. 3025. DEFINITIONS.

"In this part:

"(1) The term 'first responder' includes a firefighter, law enforcement officer, paramedic, emergency medical technician, or other individual (including an employee of a legally organized and recognized volunteer organization, whether compensated or not), who, in the course of professional duties, responds to fire,

medical, hazardous material, or other similar emergencies.

"(2) The term 'medication-assisted treatment' means the use of medications approved by the Food and Drug Administration for the treatment of opioid abuse.

"(3) The term 'opioid' means any drug, including heroin, having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having such addiction-forming or addiction-sustaining liability.

"(4) The term 'schedule II, III, or IV controlled substance' means a controlled substance that is listed on schedule II, schedule III, or schedule IV of section 202(c) of the Controlled Substances Act (21 U.S.C. 812(c)).

"(5) The terms 'drug' and 'device' have the meanings given those terms in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

"(6) The term 'criminal justice agency' means a State, local, or tribal—

"(A) court;

"(B) prison;

"(C) jail;

"(D) law enforcement agency; or

"(E) other agency that performs the administration of criminal justice, including prosecution, pretrial services, and community supervision.

"(7) The term 'tribal organization' has the meaning given that term in section 4 of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 450b).".

(b) AUTHORIZATION OF APPROPRIATIONS.—Section 1001(a) of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3793(a)) is amended by inserting after paragraph (26) the following:

"(27) There are authorized to be appropriated to carry out part LL $103,000,000 for each of fiscal years 2017 through 2021.".

SEC. 203. AUDIT AND ACCOUNTABILITY OF GRANTEES.

(a) DEFINITIONS.—In this section—

(1) the term "covered grant program" means a grant program operated by the Department of Justice;

(2) the term "covered grantee" means a recipient of a grant from a covered grant program;

(3) the term "nonprofit", when used with respect to an organization, means an organization that is described in section 501(c)(3) of the Internal Revenue

Code of 1986, and is exempt from taxation under section 501(a) of such Code; and

(4) the term "unresolved audit finding" means an audit report finding in a final audit report of the Inspector General of the Department of Justice that a covered grantee has used grant funds awarded to that grantee under a covered grant program for an unauthorized expenditure or otherwise unallowable cost that is not closed or resolved during a 12-month period prior to the date on which the final audit report is issued.

(b) AUDIT REQUIREMENT.—Beginning in fiscal year 2016, and annually thereafter, the Inspector General of the Department of Justice shall conduct audits of covered grantees to prevent waste, fraud, and abuse of funds awarded under covered grant programs. The Inspector General shall determine the appropriate number of covered grantees to be audited each year.

(c) MANDATORY EXCLUSION.—A grantee that is found to have an unresolved audit finding under an audit conducted under subsection (b) may not receive grant funds under a covered grant program in the fiscal year following the fiscal year to which the finding relates.

(d) REIMBURSEMENT.—If a covered grantee is awarded funds under the covered grant program from which it

received a grant award during the 1-fiscal-year period during which the covered grantee is ineligible for an allocation of grant funds under subsection (c), the Attorney General shall—

(1) deposit into the General Fund of the Treasury an amount that is equal to the amount of the grant funds that were improperly awarded to the covered grantee; and

(2) seek to recoup the costs of the repayment to the Fund from the covered grantee that was improperly awarded the grant funds.

(e) PRIORITY OF GRANT AWARDS.—The Attorney General, in awarding grants under a covered grant program shall give priority to eligible entities that during the 2-year period preceding the application for a grant have not been found to have an unresolved audit finding.

(f) NONPROFIT REQUIREMENTS.—

(1) PROHIBITION.—A nonprofit organization that holds money in offshore accounts for the purpose of avoiding the tax described in section 511(a) of the Internal Revenue Code of 1986, shall not be eligible to receive, directly or indirectly, any funds from a covered grant program.

(2) DISCLOSURE.—Each nonprofit organization that is a covered grantee shall disclose in its applica-

tion for such a grant, as a condition of receipt of such a grant, the compensation of its officers, directors, and trustees. Such disclosure shall include a description of the criteria relied on to determine such compensation.

SEC. 204. VETERANS TREATMENT COURTS.

Section 2991 of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3797aa) is amended—

(1) by redesignating subsection (i) as subsection (j); and

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

"(i) ASSISTING VETERANS.—

"(1) DEFINITIONS.—In this subsection:

"(A) PEER TO PEER SERVICES OR PROGRAMS.—The term 'peer to peer services or programs' means services or programs that connect qualified veterans with other veterans for the purpose of providing support and mentorship to assist qualified veterans in obtaining treatment, recovery, stabilization, or rehabilitation.

"(B) QUALIFIED VETERAN.—The term 'qualified veteran' means a preliminarily qualified offender who—

"(i) served on active duty in any branch of the Armed Forces, including the National Guard or Reserves; and

"(ii) was discharged or released from such service under conditions other than dishonorable.

"(C) VETERANS TREATMENT COURT PROGRAM.—The term 'veterans treatment court program' means a court program involving collaboration among criminal justice, veterans, and mental health and substance abuse agencies that provides qualified veterans with—

"(i) intensive judicial supervision and case management, which may include random and frequent drug testing where appropriate;

"(ii) a full continuum of treatment services, including mental health services, substance abuse services, medical services, and services to address trauma;

"(iii) alternatives to incarceration; or

"(iv) other appropriate services, including housing, transportation, mentoring, employment, job training, education, or as-

sistance in applying for and obtaining available benefits.

"(2) VETERANS ASSISTANCE PROGRAM.—

"(A) IN GENERAL.—The Attorney General, in consultation with the Secretary of Veterans Affairs, may award grants under this subsection to applicants to establish or expand—

"(i) veterans treatment court programs;

"(ii) peer to peer services or programs for qualified veterans;

"(iii) practices that identify and provide treatment, rehabilitation, legal, transitional, and other appropriate services to qualified veterans who have been incarcerated; or

"(iv) training programs to teach criminal justice, law enforcement, corrections, mental health, and substance abuse personnel how to identify and appropriately respond to incidents involving qualified veterans.

"(B) PRIORITY.—In awarding grants under this subsection, the Attorney General shall give priority to applications that—

"(i) demonstrate collaboration between and joint investments by criminal justice, mental health, substance abuse, and veterans service agencies;

"(ii) promote effective strategies to identify and reduce the risk of harm to qualified veterans and public safety; and

"(iii) propose interventions with empirical support to improve outcomes for qualified veterans.".

SEC. 205. EMERGENCY FEDERAL LAW ENFORCEMENT ASSISTANCE.

Section 609Y(a) of the Justice Assistance Act of 1984 (42 U.S.C. 10513(a)) is amended by striking "September 30, 1984" and inserting "September 30, 2021".

SEC. 206. INCLUSION OF SERVICES FOR PREGNANT WOMEN UNDER FAMILY-BASED SUBSTANCE ABUSE GRANTS.

Part DD of title I of the Omnibus Crime Control and Safe Streets Act (42 U.S.C. 3797s et seq.) is amended—

(1) in section 2921(2), by inserting before the period at the end "or pregnant women"; and

(2) in section 2927—

(A) in paragraph (1)(A), by inserting "pregnant or" before "a parent"; and

(B) in paragraph (3), by inserting "or pregnant women" after "incarcerated parents".

SEC. 207. GAO STUDY AND REPORT ON DEPARTMENT OF JUSTICE PROGRAMS AND RESEARCH RELATIVE TO SUBSTANCE USE AND SUBSTANCE USE DISORDERS AMONG ADOLESCENTS AND YOUNG ADULTS.

(a) STUDY.—The Comptroller General of the United States shall conduct a study on how the Department of Justice, through grant programs, is addressing prevention of, treatment for, and recovery from substance use by and substance use disorders among adolescents and young adults. Such study shall include an analysis of each of the following:

(1) The research that has been, and is being, conducted or supported pursuant to grant programs operated by the Department of Justice on prevention of, treatment for, and recovery from substance use by and substance use disorders among adolescents and young adults, including an assessment of—

(A) such research relative to any unique circumstances (including social and biological circumstances) of adolescents and young adults that may make adolescent-specific and young adult-specific treatment protocols necessary, in-

cluding any effects that substance use and substance use disorders may have on brain development and the implications for treatment and recovery; and

(B) areas of such research in which greater investment or focus is necessary relative to other areas of such research.

(2) Department of Justice non-research programs and activities that address prevention of, treatment for, and recovery from substance use by and substance use disorders among adolescents and young adults, including an assessment of the effectiveness of such programs and activities in preventing substance use by and substance use disorders among adolescents and young adults, treating such adolescents and young adults in a way that accounts for any unique circumstances faced by adolescents and young adults, and supports long term recovery among adolescents and young adults.

(3) Gaps that have been identified by officials of the Department of Justice or experts in the efforts supported by grant programs operated by the Department of Justice relating to prevention of, treatment for, and recovery from substance use by and substance use disorders among adolescents and young adults, in-

cluding gaps in research, data collection, and measures to evaluate the effectiveness of such efforts, and the reasons for such gaps.

(b) REPORT.—Not later than 2 years after the date of enactment of this Act, the Comptroller General shall submit to the appropriate committees of the Congress a report containing the results of the study conducted under subsection (a), including—

(1) a summary of the findings of the study; and

(2) recommendations based on the results of the study, including recommendations for such areas of research and legislative and administrative action as the Comptroller General determines appropriate.

TITLE III—JASON SIMCAKOSKI PROMISE ACT

SEC. 301. SHORT TITLE.

This title may be cited as the "Promoting Responsible Opioid Management and Incorporating Scientific Expertise Act" or the "Jason Simcakoski PROMISE Act".

SEC. 302. IMPROVEMENT OF OPIOID SAFETY MEASURES BY DEPARTMENT OF VETERANS AFFAIRS.

(a) EXPANSION OF OPIOID SAFETY INITIATIVE.—

(1) INCLUSION OF ALL MEDICAL FACILITIES.—Not later than 180 days after the date of the enactment of this Act, the Secretary of Veterans Affairs

shall expand the Opioid Safety Initiative of the Department of Veterans Affairs to include all medical facilities of the Department.

(2) GUIDANCE.—The Secretary shall establish guidance that each health care provider of the Department of Veterans Affairs, before initiating opioid therapy to treat a patient as part of the comprehensive assessment conducted by the health care provider, use the Opioid Therapy Risk Report tool of the Department of Veterans Affairs (or any subsequent tool), which shall include information from the prescription drug monitoring program of each participating State as applicable, that includes the most recent information to date relating to the patient that accessed such program to assess the risk for adverse outcomes of opioid therapy for the patient, including the concurrent use of controlled substances such as benzodiazepines, as part of the comprehensive assessment conducted by the health care provider.

(3) ENHANCED STANDARDS.—The Secretary shall establish enhanced standards with respect to the use of routine and random urine drug tests for all patients before and during opioid therapy to help prevent substance abuse, dependence, and diversion, including—

(A) that such tests occur not less frequently than once each year; and

(B) that health care providers appropriately order, interpret and respond to the results from such tests to tailor pain therapy, safeguards, and risk management strategies to each patient.

(b) PAIN MANAGEMENT EDUCATION AND TRAINING.—

(1) IN GENERAL.—In carrying out the Opioid Safety Initiative of the Department, the Secretary shall require all employees of the Department responsible for prescribing opioids to receive education and training described in paragraph (2).

(2) EDUCATION AND TRAINING.—Education and training described in this paragraph is education and training on pain management and safe opioid prescribing practices for purposes of safely and effectively managing patients with chronic pain, including education and training on the following:

(A) The implementation of and full compliance with the VA/DOD Clinical Practice Guideline for Management of Opioid Therapy for Chronic Pain, including any update to such guideline.

(B) The use of evidence-based pain management therapies, including cognitive-behavioral

therapy, non-opioid alternatives, and non-drug methods and procedures to managing pain and related health conditions including medical devices approved or cleared by the Food and Drug Administration for the treatment of patients with chronic pain and complementary alternative medicines.

(C) Screening and identification of patients with substance use disorder, including drug-seeking behavior, before prescribing opioids, assessment of risk potential for patients developing an addiction, and referral of patients to appropriate addiction treatment professionals if addiction is identified or strongly suspected.

(D) Communication with patients on the potential harm associated with the use of opioids and other controlled substances, including the need to safely store and dispose of supplies relating to the use of opioids and other controlled substances.

(E) Such other education and training as the Secretary considers appropriate to ensure that veterans receive safe and high-quality pain management care from the Department.

(3) USE OF EXISTING PROGRAM.—In providing education and training described in paragraph (2), the Secretary shall use the Interdisciplinary Chronic Pain Management Training Team Program of the Department (or success program).

(c) PAIN MANAGEMENT TEAMS.—

(1) IN GENERAL.—In carrying out the Opioid Safety Initiative of the Department, the director of each medical facility of the Department shall identify and designate a pain management team of health care professionals, which may include board certified pain medicine specialists, responsible for coordinating and overseeing pain management therapy at such facility for patients experiencing acute and chronic pain that is non-cancer related.

(2) ESTABLISHMENT OF PROTOCOLS.—

(A) IN GENERAL.—In consultation with the Directors of each Veterans Integrated Service Network, the Secretary shall establish standard protocols for the designation of pain management teams at each medical facility within the Department.

(B) CONSULTATION ON PRESCRIPTION OF OPIOIDS.—Each protocol established under subparagraph (A) shall ensure that any health care

provider without expertise in prescribing analgesics or who has not completed the education and training under subsection (b), including a mental health care provider, does not prescribe opioids to a patient unless that health care provider—

(i) consults with a health care provider with pain management expertise or who is on the pain management team of the medical facility; and

(ii) refers the patient to the pain management team for any subsequent prescriptions and related therapy.

(3) REPORT.—

(A) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, the director of each medical facility of the Department shall submit to the Under Secretary for Health and the director of the Veterans Integrated Service Network in which the medical facility is located a report identifying the health care professionals that have been designated as members of the pain management team at the medical facility pursuant to paragraph (1).

(B) ELEMENTS.—Each report submitted under subparagraph (A) with respect to a medical facility of the Department shall include—

(i) a certification as to whether all members of the pain management team at the medical facility have completed the education and training required under subsection (b);

(ii) a plan for the management and referral of patients to such pain management team if health care providers without expertise in prescribing analgesics prescribe opioid medications to treat acute and chronic pain that is non-cancer related; and

(iii) a certification as to whether the medical facility—

(I) fully complies with the stepped-care model of pain management and other pain management policies contained in Directive 2009–053 of the Veterans Health Administration, or successor directive; or

(II) does not fully comply with such stepped-care model of pain management and other pain management

policies but is carrying out a corrective plan of action to ensure such full compliance.

(d) TRACKING AND MONITORING OF OPIOID USE.—

(1) PRESCRIPTION DRUG MONITORING PROGRAMS OF STATES.—In carrying out the Opioid Safety Initiative and the Opioid Therapy Risk Report tool of the Department, the Secretary shall—

(A) ensure access by health care providers of the Department to information on controlled substances, including opioids and benzodiazepines, prescribed to veterans who receive care outside the Department through the prescription drug monitoring program of each State with such a program, including by seeking to enter into memoranda of understanding with States to allow shared access of such information between States and the Department;

(B) include such information in the Opioid Therapy Risk Report; and

(C) require health care providers of the Department to submit to the prescription drug monitoring program of each State information on prescriptions of controlled substances received

by veterans in that State under the laws administered by the Secretary.

(2) REPORT ON TRACKING OF DATA ON OPIOID USE.—Not later than 18 months after the date of the enactment of this Act, the Secretary shall submit to the Committee on Veterans' Affairs of the Senate and the Committee on Veterans' Affairs of the House of Representatives a report on the feasibility and advisability of improving the Opioid Therapy Risk Report tool of the Department to allow for more advanced real-time tracking of and access to data on—

(A) the key clinical indicators with respect to the totality of opioid use by veterans;

(B) concurrent prescribing by health care providers of the Department of opioids in different health care settings, including data on concurrent prescribing of opioids to treat mental health disorders other than opioid use disorder; and

(C) mail-order prescriptions of opioid prescribed to veterans under the laws administered by the Secretary.

(e) AVAILABILITY OF OPIOID RECEPTOR ANTAGONISTS.—

(1) INCREASED AVAILABILITY AND USE.—

(A) IN GENERAL.—The Secretary shall maximize the availability of opioid receptor antagonists approved by the Food and Drug Administration, including naloxone, to veterans.

(B) AVAILABILITY, TRAINING, AND DISTRIBUTING.—In carrying out subparagraph (A), not later than 90 days after the date of the enactment of this Act, the Secretary shall—

(i) equip each pharmacy of the Department with opioid receptor antagonists approved by the Food and Drug Administration to be dispensed to outpatients as needed; and

(ii) expand the Overdose Education and Naloxone Distribution program of the Department to ensure that all veterans in receipt of health care under laws administered by the Secretary who are at risk of opioid overdose may access such opioid receptor antagonists and training on the proper administration of such opioid receptor antagonists.

(C) VETERANS WHO ARE AT RISK.—For purposes of subparagraph (B), veterans who are at risk of opioid overdose include—

(i) veterans receiving long-term opioid therapy;

(ii) veterans receiving opioid therapy who have a history of substance use disorder or prior instances of overdose; and

(iii) veterans who are at risk as determined by a health care provider who is treating the veteran.

(2) REPORT.—Not later than 120 days after the date of the enactment of this Act, the Secretary shall submit to the Committee on Veterans' Affairs of the Senate and the Committee on Veterans' Affairs of the House of Representatives a report on carrying out paragraph (1), including an assessment of any remaining steps to be carried out by the Secretary to carry out such paragraph.

(f) INCLUSION OF CERTAIN INFORMATION AND CAPABILITIES IN OPIOID THERAPY RISK REPORT TOOL OF THE DEPARTMENT.—

(1) INFORMATION.—The Secretary shall include in the Opioid Therapy Risk Report tool of the Department—

(A) information on the most recent time the tool was accessed by a health care provider of the Department with respect to each veteran; and

(B) information on the results of the most recent urine drug test for each veteran.

(2) CAPABILITIES.—The Secretary shall include in the Opioid Therapy Risk Report tool the ability of the health care providers of the Department to determine whether a health care provider of the Department prescribed opioids to a veteran without checking the information in the tool with respect to the veteran.

(g) NOTIFICATIONS OF RISK IN COMPUTERIZED HEALTH RECORD.—The Secretary shall modify the computerized patient record system of the Department to ensure that any health care provider that accesses the record of a veteran, regardless of the reason the veteran seeks care from the health care provider, will be immediately notified whether the veteran—

(1) is receiving opioid therapy and has a history of substance use disorder or prior instances of overdose;

(2) has a history of opioid abuse; or

(3) is at risk of becoming an opioid abuser as determined by a health care provider who is treating the veteran.

(h) DEFINITIONS.—In this section:

(1) The term "controlled substance" has the meaning given that term in section 102 of the Controlled Substances Act (21 U.S.C. 802).

(2) The term "State" means each of the several States, territories, and possessions of the United States, the District of Columbia, and the Commonwealth of Puerto Rico.

SEC. 303. STRENGTHENING OF JOINT WORKING GROUP ON PAIN MANAGEMENT OF THE DEPARTMENT OF VETERANS AFFAIRS AND THE DEPARTMENT OF DEFENSE.

(a) IN GENERAL.—Not later than 90 days after the date of enactment of this Act, the Secretary of Veterans Affairs and the Secretary of Defense shall ensure that the Pain Management Working Group of the Health Executive Committee of the Department of Veterans Affairs–Department of Defense Joint Executive Committee (Pain Management Working Group) established under section 320 of title 38, United States Code, includes a focus on the following:

(1) The opioid prescribing practices of health care providers of each Department.

(2) The ability of each Department to manage acute and chronic pain among individuals receiving health care from the Department, including training

health care providers with respect to pain management.

(3) The use by each Department of complementary and integrative health and complementary alternative medicines in treating such individuals.

(4) The concurrent use by health care providers of each Department of opioids and prescription drugs to treat mental health disorders, including benzodiazepines.

(5) The practice by health care providers of each Department of prescribing opioids to treat mental health disorders.

(6) The coordination in coverage of and consistent access to medications prescribed for patients transitioning from receiving health care from the Department of Defense to receiving health care from the Department of Veterans Affairs.

(7) The ability of each Department to identify and treat substance use disorders among individuals receiving health care from that Department.

(b) COORDINATION AND CONSULTATION.—The Secretary of Veterans Affairs and the Secretary of Defense shall ensure that the working group described in subsection (a)—

(1) coordinates the activities of the working group with other relevant working groups established under section 320 of title 38, United States Code;

(2) consults with other relevant Federal agencies with respect to the activities of the working group; and

(3) consults with the Department of Veterans Affairs and the Department of Defense with respect to, reviews, and comments on the VA/DOD Clinical Practice Guideline for Management of Opioid Therapy for Chronic Pain, or any successor guideline, before any update to the guideline is released.

(c) CLINICAL PRACTICE GUIDELINES.—

(1) IN GENERAL.—Not later than 180 days after the date of the enactment of this Act, the Secretary of Veterans Affairs and the Secretary of Defense shall issue an update to the VA/DOD Clinical Practice Guideline for Management of Opioid Therapy for Chronic Pain.

(2) MATTERS INCLUDED.—In conducting the update under subsection (a), the Pain Management Working Group, in coordination with the Clinical Practice Guideline VA/DOD Management of Opioid Therapy for Chronic Pain Working Group, shall ex-

amine whether the Clinical Practical Guideline should include the following:

(A) Enhanced guidance with respect to—

(i) the coadministration of an opioid and other drugs, including benzodiazepines, that may result in life-limiting drug interactions;

(ii) the treatment of patients with current acute psychiatric instability or substance use disorder or patients at risk of suicide; and

(iii) the use of opioid therapy to treat mental health disorders other than opioid use disorder.

(B) Enhanced guidance with respect to the treatment of patients with behaviors or comorbidities, such as post-traumatic stress disorder or other psychiatric disorders, or a history of substance abuse or addiction, that requires a consultation or comanagement of opioid therapy with one or more specialists in pain management, mental health, or addictions.

(C) Enhanced guidance with respect to health care providers—

(i) conducting an effective assessment for patients beginning or continuing opioid therapy, including understanding and setting realistic goals with respect to achieving and maintaining an expected level of pain relief, improved function, or a clinically appropriate combination of both; and

(ii) effectively assessing whether opioid therapy is achieving or maintaining the established treatment goals of the patient or whether the patient and health care provider should discuss adjusting, augmenting, or discontinuing the opioid therapy.

(D) Guidelines to govern the methodologies used by health care providers of the Department of Veterans Affairs and the Department of Defense to taper opioid therapy when adjusting or discontinuing the use of opioid therapy.

(E) Guidelines with respect to appropriate case management for patients receiving opioid therapy who transition between inpatient and outpatient health care settings, which may include the use of care transition plans.

(F) Guidelines with respect to appropriate case management for patients receiving opioid

therapy who transition from receiving care during active duty to post-military health care networks.

(G) Guidelines with respect to providing options, before initiating opioid therapy, for pain management therapies without the use of opioids and options to augment opioid therapy with other clinical and complementary and integrative health services to minimize opioid dependence.

(H) Guidelines with respect to the provision of evidence-based non-opioid treatments within the Department of Veterans Affairs and the Department of Defense, including medical devices and other therapies approved or cleared by the Food and Drug Administration for the treatment of chronic pain as an alternative to or to augment opioid therapy.

SEC. 304. REVIEW, INVESTIGATION, AND REPORT ON USE OF OPIOIDS IN TREATMENT BY DEPARTMENT OF VETERANS AFFAIRS.

(a) COMPTROLLER GENERAL REPORT.—

(1) IN GENERAL.—Not later than 2 years after the date of the enactment of this Act, the Comptroller General of the United States shall submit to the Com-

mittee on Veterans' Affairs of the Senate and the Committee on Veterans' Affairs of the House of Representatives a report on the Opioid Safety Initiative of the Department of Veterans Affairs and the opioid prescribing practices of health care providers of the Department.

(2) ELEMENTS.—The report submitted under paragraph (1) shall include the following:

(A) Recommendations on such improvements to the Opioid Safety Initiative of the Department as the Comptroller General considers appropriate.

(B) Information with respect to—

(i) deaths resulting from sentinel events involving veterans prescribed opioids by a health care provider of the Department;

(ii) overall prescription rates and prescriptions indications of opioids to treat non-cancer, non-palliative, and non-hospice care patients;

(iii) the prescription rates and prescriptions indications of benzodiazepines and opioids concomitantly by health care providers of the Department;

(iv) the practice by health care providers of the Department of prescribing opioids to treat patients without any pain, including to treat patients with mental health disorders other than opioid use disorder; and

(v) the effectiveness of opioid therapy for patients receiving such therapy, including the effectiveness of long-term opioid therapy.

(C) An evaluation of processes of the Department in place to oversee opioid use among veterans, including procedures to identify and remedy potential over-prescribing of opioids by health care providers of the Department.

(D) An assessment of the implementation by the Secretary of the VA/DOD Clinical Practice Guideline for Management of Opioid Therapy for Chronic Pain.

(b) QUARTERLY PROGRESS REPORT ON IMPLEMENTATION OF COMPTROLLER GENERAL RECOMMENDATIONS.—Not later than 2 years after the date of the enactment of this Act, and not later than 30 days after the end of each quarter thereafter, the Secretary of Veterans Affairs shall submit to the Committee on Veterans' Affairs of the Senate

and the Committee on Veterans' Affairs of the House of Representatives a progress report detailing the actions by the Secretary during the period covered by the report to address any outstanding findings and recommendations by the Comptroller General of the United States under subsection (a) with respect to the Veterans Health Administration.

(c) ANNUAL REVIEW OF PRESCRIPTION RATES.—Not later than 1 year after the date of the enactment of this Act, and not less frequently than annually for the following 5 years, the Secretary shall submit to the Committee on Veterans' Affairs of the Senate and the Committee on Veterans' Affairs of the House of Representatives a report, with respect to each medical facility of the Department of Veterans Affairs, to collect and review information on opioids prescribed by health care providers at the facility to treat non-cancer, non-palliative, and non-hospice care patients that contains, for the 1-year period preceding the submission of the report, the following:

(1) The number of patients and the percentage of the patient population of the Department who were prescribed benzodiazepines and opioids concurrently by a health care provider of the Department.

(2) The number of patients and the percentage of the patient population of the Department without any pain who were prescribed opioids by a health care

provider of the Department, including those who were prescribed benzodiazepines and opioids concurrently.

(3) The number of non-cancer, non-palliative, and non-hospice care patients and the percentage of such patients who were treated with opioids by a health care provider of the Department on an inpatient-basis and who also received prescription opioids by mail from the Department while being treated on an inpatient-basis.

(4) The number of non-cancer, non-palliative, and non-hospice care patients and the percentage of such patients who were prescribed opioids concurrently by a health care provider of the Department and a health care provider that is not health care provider of the Department.

(5) With respect to each medical facility of the Department, information on opioids prescribed by health care providers at the facility to treat non-cancer, non-palliative, and non-hospice care patients, including information on—

(A) the prescription rate at which each health care provider at the facility prescribed benzodiazepines and opioids concurrently to such patients and the aggregate such prescription rate for all health care providers at the facility;

(B) the prescription rate at which each health care provider at the facility prescribed benzodiazepines or opioids to such patients to treat conditions for which benzodiazepines or opioids are not approved treatment and the aggregate such prescription rate for all health care providers at the facility;

(C) the prescription rate at which each health care provider at the facility prescribed or dispensed mail-order prescriptions of opioids to such patients while such patients were being treated with opioids on an inpatient-basis and the aggregate of such prescription rate for all health care providers at the facility; and

(D) the prescription rate at which each health care provider at the facility prescribed opioids to such patients who were also concurrently prescribed opioids by a health care provider that is not a health care provider of the Department and the aggregate of such prescription rates for all health care providers at the facility.

(6) With respect to each medical facility of the Department, the number of times a pharmacist at the facility overrode a critical drug interaction warning

with respect to an interaction between opioids and another medication before dispensing such medication to a veteran.

(d) INVESTIGATION OF PRESCRIPTION RATES.—If the Secretary determines that a prescription rate with respect to a health care provider or medical facility of the Department conflicts with or is otherwise inconsistent with the standards of appropriate and safe care, the Secretary shall—

(1) immediately notify the Committee on Veterans' Affairs of the Senate and the Committee on Veterans' Affairs of the House of Representatives of such determination, including information relating to such determination, prescription rate, and health care provider or medical facility, as the case may be; and

(2) through the Office of the Medical Inspector of the Veterans Health Administration, conduct a full investigation of the health care provider or medical facility, as the case may be.

(e) PRESCRIPTION RATE DEFINED.—In this section, the term "prescription rate" means, with respect to a health care provider or medical facility of the Department, each of the following:

(1) The number of patients treated with opioids by the health care provider or at the medical facility,

as the case may be, divided by the total number of pharmacy users of that health care provider or medical facility.

(2) The average number of morphine equivalents per day prescribed by the health care provider or at the medical facility, as the case may be, to patients being treated with opioids.

(3) Of the patients being treated with opioids by the health care provider or at the medical facility, as the case may be, the average number of prescriptions of opioids per patient.

SEC. 305. MANDATORY DISCLOSURE OF CERTAIN VETERAN INFORMATION TO STATE CONTROLLED SUBSTANCE MONITORING PROGRAMS.

Section 5701(l) of title 38, United States Code, is amended by striking ''may'' and inserting ''shall''.

SEC. 306. MODIFICATION TO LIMITATION ON AWARDS AND BONUSES.

Section 705 of the Veterans Access, Choice, and Accountability Act of 2014 (Public Law 113–146; 38 U.S.C. 703 note) is amended to read as follows:

"SEC. 705. LIMITATION ON AWARDS AND BONUSES PAID TO EMPLOYEES OF DEPARTMENT OF VETERANS AFFAIRS.

"The Secretary of Veterans Affairs shall ensure that the aggregate amount of awards and bonuses paid by the Secretary in a fiscal year under chapter 45 or 53 of title 5, United States Code, or any other awards or bonuses authorized under such title or title 38, United States Code, does not exceed the following amounts:

"(1) With respect to each of fiscal years 2017 through 2021, $230,000,000.

"(2) With respect to each of fiscal years 2022 through 2024, $360,000,000.".

TITLE IV—KINGPIN DESIGNATION IMPROVEMENT ACT

SEC. 401. SHORT TITLE.

This title may be cited as the "Kingpin Designation Improvement Act of 2016".

SEC. 402. PROTECTION OF CLASSIFIED INFORMATION IN FEDERAL COURT CHALLENGES RELATING TO DESIGNATIONS UNDER THE NARCOTICS KINGPIN DESIGNATION ACT.

Section 804 of the Foreign Narcotics Kingpin Designation Act (21 U.S.C. 1903) is amended by adding at the end the following:

"(i) PROTECTION OF CLASSIFIED INFORMATION IN FEDERAL COURT CHALLENGES RELATING TO DESIGNATIONS.—In any judicial review of a determination made under this section, if the determination was based on classified information (as defined in section 1(a) of the Classified Information Procedures Act) such information may be submitted to the reviewing court ex parte and in camera. This subsection does not confer or imply any right to judicial review.".

TITLE V—GOOD SAMARITAN ASSESSMENT ACT

SEC. 501. SHORT TITLE.

This title may be cited as the "Good Samaritan Assessment Act of 2016".

SEC. 502. FINDING.

The Congress finds that the executive branch, including the Office of National Drug Control Policy, has a policy focus on preventing and addressing prescription drug misuse and heroin use, and has worked with States and municipalities to enact Good Samaritan laws that would protect caregivers, law enforcement personnel, and first responders who administer opioid overdose reversal drugs or devices.

SEC. 503. GAO STUDY ON GOOD SAMARITAN LAWS PERTAINING TO TREATMENT OF OPIOID OVERDOSES.

The Comptroller General of the United States shall submit to the Committee on the Judiciary of the House of Representatives, the Committee on Oversight and Government Reform of the House of Representatives, the Committee on the Judiciary of the Senate, and the Committee on Homeland Security and Governmental Affairs of the Senate a report on—

(1) the extent to which the Director of National Drug Control Policy has reviewed Good Samaritan laws, and any findings from such a review, including findings related to the potential effects of such laws, if available;

(2) efforts by the Director to encourage the enactment of Good Samaritan laws; and

(3) a compilation of Good Samaritan laws in effect in the States, the territories, and the District of Columbia.

SEC. 504. DEFINITIONS.

In this title—

(1) the term "Good Samaritan law" means a law of a State or unit of local government that exempts from criminal or civil liability any individual who administers an opioid overdose reversal drug or

device, or who contacts emergency services providers in response to an overdose; and

(2) the term ''opioid'' means any drug, including heroin, having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having such addiction-forming or addiction-sustaining liability.

TITLE VI—OPEN ACT

SEC. 601. SHORT TITLE.

This title may be cited as the ''Opioid Program Evaluation Act'' or the ''OPEN Act''.

SEC. 602. EVALUATION OF PERFORMANCE OF DEPARTMENT OF JUSTICE PROGRAM.

(a) EVALUATION OF JUSTICE DEPARTMENT COMPREHENSIVE OPIOID ABUSE GRANT PROGRAM.—Not later than 5 years after the date of enactment of this Act, the Attorney General shall complete an evaluation of the effectiveness of the Comprehensive Opioid Abuse Grant Program under part LL of the Omnibus Crime Control and Safe Streets Act of 1968 administered by the Department of Justice based upon the information reported under subsection (d) of this section.

(b) INTERIM EVALUATION.—Not later than 3 years after the date of enactment of this Act, the Attorney General shall complete an interim evaluation assessing the nature

and extent of the incidence of opioid abuse and illegal opioid distribution in the United States.

(c) METRICS AND OUTCOMES FOR EVALUATION.—Not later than 180 days after the date of enactment of this Act, the Attorney General shall identify outcomes that are to be achieved by activities funded by the Comprehensive Opioid Grant Abuse Program and the metrics by which the achievement of such outcomes shall be determined.

(d) METRICS DATA COLLECTION.—The Attorney General shall require grantees under the Comprehensive Opioid Abuse Grant Program (and those receiving subawards under section 3021(b) of part LL of the Omnibus Crime Control and Safe Streets Act of 1968) to collect and annually report to the Department of Justice data based upon the metrics identified under subsection (c).

(e) PUBLICATION OF DATA AND FINDINGS.—

(1) PUBLICATION OF OUTCOMES AND METRICS.—The Attorney General shall, not later than 30 days after completion of the requirement under subsection (c), publish the outcomes and metrics identified under that subsection.

(2) PUBLICATION OF EVALUATION.—In the case of the interim evaluation under subsection (b), and the final evaluation under subsection (a), the National Academy of Sciences shall, not later than 90

days after such an evaluation is completed, publish the results of such evaluation and issue a report on such evaluation to the Committee on the Judiciary of the House of Representatives and the Committee on the Judiciary of the Senate. Such report shall also be published along with the data used to make such evaluation.

(f) ARRANGEMENT WITH THE NATIONAL ACADEMY OF SCIENCES.—For purposes of subsections (a), (b), and (c), the Attorney General shall enter into an arrangement with the National Academy of Sciences.

SEC. 603. EVALUATION OF PERFORMANCE OF DEPARTMENT OF HEALTH AND HUMAN SERVICES PROGRAM.

(a) EVALUATION OF DEPARTMENT OF HEALTH AND HUMAN SERVICES PROGRAMS.—Not later than 5 years after the date of enactment of this Act, except as otherwise provided in this section, the Secretary of Health and Human Services shall complete an evaluation of any program administered by the Secretary that provides grants for the primary purpose of providing assistance in addressing problems pertaining to opioid abuse based upon the information reported under subsection (d) of this section.

(b) INTERIM EVALUATION.—Not later than 3 years after the date of enactment of this Act, the Secretary shall

complete an interim evaluation assessing the nature and extent of the incidence of opioid abuse and illegal opioid distribution in the United States.

(c) METRICS AND OUTCOMES FOR EVALUATION.—Not later than 180 days after the date of enactment of this Act, the Secretary shall identify outcomes that are to be achieved by activities funded by the programs described in subsection (a) and the metrics by which the achievement of such outcomes shall be determined.

(d) METRICS DATA COLLECTION.—The Secretary shall require grantees under the programs described in subsection (a) to collect and annually report to the Department of Health and Human Services data based upon the metrics identified under subsection (c).

(e) PUBLICATION OF DATA AND FINDINGS.—

(1) PUBLICATION OF OUTCOMES AND METRICS.—The Secretary shall, not later than 30 days after completion of the requirement under subsection (c), publish the outcomes and metrics identified under that subsection.

(2) PUBLICATION OF EVALUATION.—In the case of the interim evaluation under subsection (b), and each final evaluation under subsection (a), the National Academy of Sciences shall, not later than 90 days after such an evaluation is completed, publish

the results of such evaluation and issue a report on such evaluation to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate. Such report shall also be published along with the data used to make such evaluation.

(f) ARRANGEMENT WITH THE NATIONAL ACADEMY OF SCIENCES.—For purposes of subsections (a), (b), and (c), the Secretary shall—

(1) enter into an arrangement with the National Academy of Sciences; or

(2) enter into a contract or cooperative agreement with an entity that is not an agency of the Federal Government.

(g) EXCEPTION.—If a program described under subsection (a) is subject to an evaluation substantially similar to the evaluation under subsection (a) pursuant to another provision of law, the Secretary may opt not to conduct an evaluation under subsection (a) of such program.

SEC. 604. DEFINITION.

In this title, the term "opioid" has the meaning given the term "opiate" in section 102 of the Controlled Substances Act (21 U.S.C. 802).

SEC. 605. NO ADDITIONAL FUNDS AUTHORIZED.

No additional funds are authorized to be appropriated to carry out this Act.

SEC. 606. MATTERS REGARDING CERTAIN FEDERAL LAW ENFORCEMENT ASSISTANCE.

Section 609Y of the Justice Assistance Act of 1984 (42 U.S.C. 10513) is amended—

(1) in subsection (a), by striking "There is" and inserting "Except as provided in subsection (c), there is"; and

(2) by adding at the end the following:

"(c) For fiscal year 2022, there is authorized to be appropriated $16,000,000, to provide under this chapter Federal law enforcement assistance in the form of funds.".

TITLE VII—INFANT PLAN OF SAFE CARE IMPROVEMENT ACT

SEC. 701. SHORT TITLE.

This title may be cited as the "Infant Plan of Safe Care Improvement Act".

SEC. 702. BEST PRACTICES FOR DEVELOPMENT OF PLANS OF SAFE CARE.

Section 103(b) of the Child Abuse Prevention and Treatment Act (42 U.S.C. 5104(b)) is amended—

(1) by redesignating paragraphs (5) through (8) as paragraphs (6) through (9), respectively; and

(2) by inserting after paragraph (4), the following:

"(5) maintain and disseminate information about the requirements of section 106(b)(2)(B)(iii) and best practices relating to the development of plans of safe care as described in such section for infants born and identified as being affected by illegal substance abuse or withdrawal symptoms, or a Fetal Alcohol Spectrum Disorder;".

SEC. 703. STATE PLANS.

Section 106(b)(2)(B)(iii) of the Child Abuse Prevention and Treatment Act (42 U.S.C. 5106a(b)(2)(B)(iii)) is amended by inserting before the semicolon at the end the following: "to ensure the safety and well-being of such infant following release from the care of healthcare providers, including through—

"(I) addressing the health and substance use disorder treatment needs of the infant and affected family or caregiver; and

"(II) the development and implementation by the State of monitoring systems regarding the implementation of such plans to determine whether and in what manner local entities are pro-

viding, in accordance with State requirements, referrals to and delivery of appropriate services for the infant and affected family or caregiver".

SEC. 704. DATA REPORTS.

(a) IN GENERAL.—Section 106(d) of the Child Abuse Prevention and Treatment Act (42 U.S.C. 5106a(d)) is amended by adding at the end of the following:

"(17)(A) The number of infants identified under subsection (b)(2)(B)(ii).

"(B) The number of infants for whom a plan of safe care was developed under subsection (b)(2)(B)(iii).

"(C) The number of infants for whom a referral was made for appropriate services, including services for the affected family or caregiver, under subsection (b)(2)(B)(iii).".

(b) REDESIGNATION.—Effective on May 29, 2017, section 106(d) of the Child Abuse Prevention and Treatment Act (42 U.S.C. 5106a(d)) is amended by redesignating paragraph (17) (as added by subsection (a)) as paragraph (18).

SEC. 705. MONITORING AND OVERSIGHT.

(a) AMENDMENT.—Title I of the Child Abuse Prevention and Treatment Act (42 U.S.C. 5101 et seq.) is further amended by adding at the end the following:

"SEC. 114. MONITORING AND OVERSIGHT.

"The Secretary shall conduct monitoring to ensure that each State that receives a grant under section 106 is in compliance with the requirements of section 106(b), which—

"(1) shall—

"(A) be in addition to the review of the State plan upon its submission under section 106(b)(1)(A); and

"(B) include monitoring of State policies and procedures required under clauses (ii) and (iii) of section 106(b)(2)(B); and

"(2) may include—

"(A) a comparison of activities carried out by the State to comply with the requirements of section 106(b) with the State plan most recently approved under section 432 of the Social Security Act;

"(B) a review of information available on the Website of the State relating to its compliance with the requirements of section 106(b);

"(C) site visits, as may be necessary to carry out such monitoring; and

"(D) a review of information available in the State's Annual Progress and Services Report most recently submitted under section 1357.16 of title 45, Code of Federal Regulations (or successor regulations).".

(b) TABLE OF CONTENTS.—The table of contents in section 1(b) of the Child Abuse Prevention and Treatment Act (42 U.S.C. 5101 note) is amended by inserting after the item relating to section 113, the following:

"Sec. 114. Monitoring and oversight.".

SEC. 706. RULE OF CONSTRUCTION.

Nothing in this Act, or the amendments made by this Act, shall be construed to authorize the Secretary of Health and Human Services or any other officer of the Federal Government to add new requirements to section 106(b) of the Child Abuse Prevention and Treatment Act (42 U.S.C. 5106a(b)), as amended by this Act.

TITLE VIII—NAS HEALTHY BABIES ACT

SEC. 801. SHORT TITLE.

This title may be cited as the "Nurturing And Supporting Healthy Babies Act" or as the "NAS Healthy Babies Act".

SEC. 802. GAO REPORT ON NEONATAL ABSTINENCE SYNDROME (NAS).

(a) IN GENERAL.—Not later than 1 year after the date of the enactment of this Act, the Comptroller General of the United States shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Finance and the Committee on Health, Education, Labor and Pensions of the Senate a report on neonatal abstinence syndrome (in this section referred to as "NAS") in the United States.

(b) INFORMATION TO BE INCLUDED IN REPORT.—Such report shall include information on the following:

(1) The prevalence of NAS in the United States, including the proportion of children born in the United States with NAS who are eligible for medical assistance under State Medicaid programs under title XIX of the Social Security Act at birth and the costs associated with NAS through such programs.

(2) The services for which coverage is available under State Medicaid programs for treatment of infants with NAS.

(3) The settings (including inpatient, outpatient, hospital-based, and other settings) for the treatment of infants with NAS and the reimbursement methodologies and costs associated with such treatment in such settings.

(4) The prevalence of utilization of various care settings under State Medicaid programs for treatment of infants with NAS and any Federal barriers to treating such infants under such programs, particularly in non-hospital-based settings.

(5) What is known about best practices for treating infants with NAS.

(c) RECOMMENDATIONS.—Such report also shall include such recommendations as the Comptroller General determines appropriate for improvements that will ensure access to treatment for infants with NAS under State Medicaid programs.

SEC. 803. EXCLUDING ABUSE-DETERRENT FORMULATIONS OF PRESCRIPTION DRUGS FROM THE MEDICAID ADDITIONAL REBATE REQUIREMENT FOR NEW FORMULATIONS OF PRESCRIPTION DRUGS.

(a) IN GENERAL.—The last sentence of section 1927(c)(2)(C) of the Social Security Act (42 U.S.C. 1396r–8(c)(2)(C)) is amended by inserting before the period at the end the following: ", but does not include an abuse-deterrent formulation of the drug (as determined by the Secretary), regardless of whether such abuse-deterrent formulation is an extended release formulation".

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply to drugs that are paid for by a State in calendar quarters beginning on or after the date of the enactment of this Act.

SEC. 804. LIMITING DISCLOSURE OF PREDICTIVE MODELING AND OTHER ANALYTICS TECHNOLOGIES TO IDENTIFY AND PREVENT WASTE, FRAUD, AND ABUSE.

(a) IN GENERAL.—Title XI of the Social Security Act is amended by inserting after section 1128J (42 U.S.C. 1320a–7k) the following new section:

"SEC. 1128K. DISCLOSURE OF PREDICTIVE MODELING AND OTHER ANALYTICS TECHNOLOGIES TO IDENTIFY AND PREVENT WASTE, FRAUD, AND ABUSE.

"(a) REFERENCE TO PREDICTIVE MODELING TECHNOLOGIES REQUIREMENTS.—For provisions relating to the use of predictive modeling and other analytics technologies to identify and prevent waste, fraud, and abuse with respect to the Medicare program under title XVIII, the Medicaid program under title XIX, and the Children's Health Insurance Program under title XXI, see section 4241 of the Small Business Jobs Act of 2010 (42 U.S.C. 1320a–7m).

"(b) LIMITING DISCLOSURE OF PREDICTIVE MODELING TECHNOLOGIES.—In implementing such provisions

under such section 4241 with respect to covered algorithms (as defined in subsection (c)), the following shall apply:

"(1) NONAPPLICATION OF FOIA.—The covered algorithms used or developed for purposes of such section (including by the Secretary or a State (or an entity operating under a contract with a State)) shall be exempt from disclosure under section 552(b)(3) of title 5, United States Code.

"(2) LIMITATION WITH RESPECT TO USE AND DISCLOSURE OF INFORMATION BY STATE AGENCIES.—

"(A) IN GENERAL.—A State agency may not use or disclose covered algorithms used or developed for purposes of such section except for purposes of administering the State plan (or a waiver of the plan) under the Medicaid program under title XIX or the State child health plan (or a waiver of the plan) under the Children's Health Insurance Program under title XXI, including by enabling an entity operating under a contract with a State to assist the State to identify or prevent waste, fraud, and abuse with respect to such programs.

"(B) INFORMATION SECURITY.—A State agency shall have in effect data security and control policies that the Secretary finds adequate

to ensure the security of covered algorithms used or developed for purposes of such section 4241 and to ensure that access to such information is restricted to authorized persons for purposes of authorized uses and disclosures described in subparagraph (A).

"(C) PROCEDURAL REQUIREMENTS.—State agencies to which information is disclosed pursuant to such section 4241 shall adhere to uniform procedures established by the Secretary.

"(c) COVERED ALGORITHM DEFINED.—In this section, the term 'covered algorithm'—

"(1) means a predictive modeling or other analytics technology, as used for purposes of section 4241(a) of the Small Business Jobs Act of 2010 (42 U.S.C. 1320a–7m(a)) to identify and prevent waste, fraud, and abuse with respect to the Medicare program under title XVIII, the Medicaid program under title XIX, and the Children's Health Insurance Program under title XXI; and

"(2) includes the mathematical expressions utilized in the application of such technology and the means by which such technology is developed.".

(b) CONFORMING AMENDMENTS.—

(1) MEDICAID STATE PLAN REQUIREMENT.—Section 1902(a) of the Social Security Act (42 U.S.C. 1396a(a)) is amended—

(A) in paragraph (80), by striking "and" at the end;

(B) in paragraph (81), by striking the period at the end and inserting "; and"; and

(C) by inserting after paragraph (81) the following new paragraph:

"(82) provide that the State agency responsible for administering the State plan under this title provides assurances to the Secretary that the State agency is in compliance with subparagraphs (A), (B), and (C) of section 1128K(b)(2).".

(2) STATE CHILD HEALTH PLAN REQUIREMENT.—Section 2102(a)(7) of the Social Security Act (42 U.S.C. 1397bb(a)(7)) is amended—

(A) in subparagraph (A), by striking ", and" at the end and inserting a semicolon;

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

(C) by adding at the end the following new subparagraph:

"(C) to ensure that the State agency involved is in compliance with subparagraphs (A), (B), and (C) of section 1128K(b)(2).".

SEC. 805. MEDICAID IMPROVEMENT FUND.

Section 1941(b)(1) of the Social Security Act (42 U.S.C. 1396w–1(b)(1)) is amended to read as follows:

"(1) IN GENERAL.—There shall be available to the Fund, for expenditures from the Fund for fiscal year 2021 and thereafter, $5,000,000.".

TITLE IX—CO-PRESCRIBING TO REDUCE OVERDOSES ACT

SEC. 901. SHORT TITLE.

This title may be cited as the "Co-Prescribing to Reduce Overdoses Act of 2016".

SEC. 902. OPIOID OVERDOSE REVERSAL DRUGS PRESCRIBING GRANT PROGRAM.

(a) ESTABLISHMENT.—

(1) IN GENERAL.—Not later than 6 months after the date of the enactment of this Act, the Secretary of Health and Human Services may establish, in accordance with this section, a 5-year opioid overdose reversal drugs prescribing grant program (in this Act referred to as the "grant program").

(2) MAXIMUM GRANT AMOUNT.—A grant made under this section may not be for more than $200,000 per grant year.

(3) ELIGIBLE ENTITY.—For purposes of this section, the term "eligible entity" means a federally qualified health center (as defined in section 1861(aa) of the Social Security Act (42 U.S.C. 1395x(aa)), an opioid treatment program under part 8 of title 42, Code of Federal Regulations, any practitioner dispensing narcotic drugs pursuant to section 303(g) of the Controlled Substances Act (21 U.S.C. 823(g)), or any other entity that the Secretary deems appropriate.

(4) PRESCRIBING.—For purposes of this section and section 3, the term "prescribing" means, with respect to an opioid overdose reversal drug, such as naloxone, the practice of prescribing such drug—

(A) in conjunction with an opioid prescription for patients at an elevated risk of overdose;

(B) in conjunction with an opioid agonist approved under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) for the treatment of opioid abuse disorder;

(C) to the caregiver or a close relative of patients at an elevated risk of overdose from opioids; or

(D) in other circumstances, as identified by the Secretary, in which a provider identifies a patient is at an elevated risk for an intentional or unintentional drug overdose from heroin or prescription opioid therapies.

(b) APPLICATION.—To be eligible to receive a grant under this section, an eligible entity shall submit to the Secretary of Health and Human Services, in such form and manner as specified by the Secretary, an application that describes—

(1) the extent to which the area to which the entity will furnish services through use of the grant is experiencing significant morbidity and mortality caused by opioid abuse;

(2) the criteria that will be used to identify eligible patients to participate in such program; and

(3) how such program will work to try to identify State, local, or private funding to continue the program after expiration of the grant.

(c) USE OF FUNDS.—An eligible entity receiving a grant under this section may use the grant for any of the following activities, but may use not more than 20 percent

of the grant funds for activities described in paragraphs (4) and (5):

(1) To establish a program for prescribing opioid overdose reversal drugs, such as naloxone.

(2) To train and provide resources for health care providers and pharmacists on the prescribing of opioid overdose reversal drugs, such as naloxone.

(3) To establish mechanisms and processes for tracking patients participating in the program described in paragraph (1) and the health outcomes of such patients.

(4) To purchase opioid overdose reversal drugs, such as naloxone, for distribution under the program described in paragraph (1).

(5) To offset the co-pays and other cost sharing associated with opioid overdose reversal drugs, such as naloxone, to ensure that cost is not a limiting factor for eligible patients.

(6) To conduct community outreach, in conjunction with community-based organizations, designed to raise awareness of prescribing practices, and the availability of opioid overdose reversal drugs, such as naloxone.

(7) To establish protocols to connect patients who have experienced a drug overdose with appropriate

treatment, including medication assisted treatment and appropriate counseling and behavioral therapies.

(d) EVALUATIONS BY RECIPIENTS.—As a condition of receipt of a grant under this section, an eligible entity shall, for each year for which the grant is received, submit to the Secretary of Health and Human Services information on appropriate outcome measures specified by the Secretary to assess the outcomes of the program funded by the grant, including—

(1) the number of prescribers trained;

(2) the number of prescribers who have co-prescribed an opioid overdose reversal drug, such as naloxone, to at least one patient;

(3) the total number of prescriptions written for opioid overdose reversal drugs, such as naloxone;

(4) the percentage of patients at elevated risk who received a prescription for an opioid overdose reversal drug, such as naloxone;

(5) the number of patients reporting use of an opioid overdose reversal drug, such as naloxone; and

(6) any other outcome measures that the Secretary deems appropriate.

(e) REPORTS BY SECRETARY.—For each year of the grant program under this section, the Secretary of Health and Human Services shall submit to the appropriate com-

mittees of the House of Representatives and of the Senate a report aggregating the information received from the grant recipients for such year under subsection (d) and evaluating the outcomes achieved by the programs funded by grants made under this section.

SEC. 903. PROVIDING INFORMATION TO PRESCRIBERS IN CERTAIN FEDERAL HEALTH CARE AND MEDICAL FACILITIES ON BEST PRACTICES FOR PRESCRIBING OPIOID OVERDOSE REVERSAL DRUGS.

(a) IN GENERAL.—Not later than 180 days after the date of enactment of this Act, the Secretary of Health and Human Services (in this section referred to as the "Secretary") may, as appropriate, provide information to prescribers within federally qualified health centers (as defined in paragraph (4) of section 1861(aa) of the Social Security Act (42 U.S.C. 1395x(aa))), and the health care facilities of the Indian Health Service, on best practices for prescribing opioid overdose reversal drugs, such as naloxone, for patients receiving chronic opioid therapy, patients being treated for opioid use disorders, and other patients that a provider identifies as having an elevated risk of overdose from heroin or prescription opioid therapies.

(b) NOT ESTABLISHING A MEDICAL STANDARD OF CARE.—The information on best practices provided under

this section shall not be construed as constituting or establishing a medical standard of care for prescribing opioid overdose reversal drugs, such as naloxone, for patients described in subsection (a).

(c) ELEVATED RISK OF OVERDOSE DEFINED.—In this section, the term "elevated risk of overdose" has the meaning given such term by the Secretary, which—

(1) may be based on the criteria provided in the Opioid Overdose Toolkit published by the Substance Abuse and Mental Health Services Administration (SAMHSA); and

(2) may include patients on a first course opioid treatment, patients using extended-release and long-acting opioid analgesics, and patients with a respiratory disease or other co-morbidities.

SEC. 904. AUTHORIZATION OF APPROPRIATIONS.

There is authorized to be appropriated to carry out this title $5,000,000 for the period of fiscal years 2017 through 2021.

SEC. 905. CUT-GO COMPLIANCE.

Subsection (f) of section 319D of the Public Health Service Act (42 U.S.C. 247d–4) is amended by inserting before the period at the end the following: "(except such dollar amount shall be reduced by $5,000,000 for fiscal year 2018)".

TITLE X—IMPROVING TREATMENT FOR PREGNANT AND POSTPARTUM WOMEN ACT

SEC. 1001. SHORT TITLE.

This title may be cited as the "Improving Treatment for Pregnant and Postpartum Women Act of 2016".

SEC. 1002. REAUTHORIZATION OF RESIDENTIAL TREATMENT PROGRAMS FOR PREGNANT AND POSTPARTUM WOMEN.

Section 508 of the Public Health Service Act (42 U.S.C. 290bb–1) is amended—

(1) in subsection (p), in the first sentence, by inserting "(other than subsection (r))" after "section"; and

(2) in subsection (r), by striking "such sums" and all that follows through "2003" and inserting "$16,900,000 for each of fiscal years 2017 through 2021".

SEC. 1003. PILOT PROGRAM GRANTS FOR STATE SUBSTANCE ABUSE AGENCIES.

(a) IN GENERAL.—Section 508 of the Public Health Service Act (42 U.S.C. 290bb–1) is amended—

(1) by redesignating subsection (r), as amended by section 2, as subsection (s); and

(2) by inserting after subsection (q) the following new subsection:

"(r) PILOT PROGRAM FOR STATE SUBSTANCE ABUSE AGENCIES.—

"(1) IN GENERAL.—From amounts made available under subsection (s), the Director of the Center for Substance Abuse Treatment shall carry out a pilot program under which competitive grants are made by the Director to State substance abuse agencies to—

"(A) enhance flexibility in the use of funds designed to support family-based services for pregnant and postpartum women with a primary diagnosis of a substance use disorder, including opioid use disorders;

"(B) help State substance abuse agencies address identified gaps in services furnished to such women along the continuum of care, including services provided to women in nonresidential based settings; and

"(C) promote a coordinated, effective, and efficient State system managed by State substance abuse agencies by encouraging new approaches and models of service delivery.

"(2) REQUIREMENTS.—In carrying out the pilot program under this subsection, the Director shall—

"(A) require State substance abuse agencies to submit to the Director applications, in such form and manner and containing such information as specified by the Director, to be eligible to receive a grant under the program;

"(B) identify, based on such submitted applications, State substance abuse agencies that are eligible for such grants;

"(C) require services proposed to be furnished through such a grant to support family-based treatment and other services for pregnant and postpartum women with a primary diagnosis of a substance use disorder, including opioid use disorders;

"(D) not require that services furnished through such a grant be provided solely to women that reside in facilities;

"(E) not require that grant recipients under the program make available through use of the grant all services described in subsection (d); and

"(F) consider not applying requirements described in paragraphs (1) and (2) of subsection (f) to applicants, depending on the circumstances of the applicant.

"(3) REQUIRED SERVICES.—

"(A) IN GENERAL.—The Director shall specify a minimum set of services required to be made available to eligible women through a grant awarded under the pilot program under this subsection. Such minimum set—

"(i) shall include requirements described in subsection (c) and be based on the recommendations submitted under subparagraph (B); and

"(ii) may be selected from among the services described in subsection (d) and include other services as appropriate.

"(B) STAKEHOLDER INPUT.—The Director shall convene and solicit recommendations from stakeholders, including State substance abuse agencies, health care providers, persons in recovery from substance abuse, and other appropriate individuals, for the minimum set of services described in subparagraph (A).

"(4) DURATION.—The pilot program under this subsection shall not exceed 5 years.

"(5) EVALUATION AND REPORT TO CONGRESS.—The Director of the Center for Behavioral Health Statistics and Quality shall fund an evaluation of the pilot program at the conclusion of the first grant

cycle funded by the pilot program. The Director of the Center for Behavioral Health Statistics and Quality, in coordination with the Director of the Center for Substance Abuse Treatment shall submit to the relevant committees of jurisdiction of the House of Representatives and the Senate a report on such evaluation. The report shall include at a minimum outcomes information from the pilot program, including any resulting reductions in the use of alcohol and other drugs; engagement in treatment services; retention in the appropriate level and duration of services; increased access to the use of medications approved by the Food and Drug Administration for the treatment of substance use disorders in combination with counseling; and other appropriate measures.

"(6) STATE SUBSTANCE ABUSE AGENCIES DEFINED.—For purposes of this subsection, the term 'State substance abuse agency' means, with respect to a State, the agency in such State that manages the Substance Abuse Prevention and Treatment Block Grant under part B of title XIX.".

(b) FUNDING.—Subsection (s) of section 508 of the Public Health Service Act (42 U.S.C. 290bb–1), as amended by section 1002 and redesignated by subsection (a), is further amended by adding at the end the following new sen-

tence: "Of the amounts made available for a year pursuant to the previous sentence to carry out this section, not more than 25 percent of such amounts shall be made available for such year to carry out subsection (r), other than paragraph (5) of such subsection. Notwithstanding the preceding sentence, no funds shall be made available to carry out subsection (r) for a fiscal year unless the amount made available to carry out this section for such fiscal year is more than the amount made available to carry out this section for fiscal year 2016.".

SEC. 1004. CUT-GO COMPLIANCE.

Subsection (f) of section 319D of the Public Health Service Act (42 U.S.C. 247d–4) is amended by striking "through 2018" and inserting "through 2016, $133,300,000 for fiscal year 2017, and $138,300,000 for fiscal year 2018".

TITLE XI—VETERAN EMERGENCY MEDICAL TECHNICIAN SUPPORT ACT

SEC. 1101. SHORT TITLE.

This title may be cited as the "Veteran Emergency Medical Technician Support Act of 2016".

SEC. 1102. ASSISTING VETERANS WITH MILITARY EMERGENCY MEDICAL TRAINING TO MEET REQUIREMENTS FOR BECOMING CIVILIAN EMERGENCY MEDICAL TECHNICIANS.

Part B of title III of the Public Health Service Act (42 U.S.C. 243 et seq.) is amended by inserting after section 314 the following:

"SEC. 315. ASSISTING VETERANS WITH MILITARY EMERGENCY MEDICAL TRAINING TO MEET REQUIREMENTS FOR BECOMING CIVILIAN EMERGENCY MEDICAL TECHNICIANS.

"(a) PROGRAM.—The Secretary shall establish a program consisting of awarding demonstration grants to States to streamline State requirements and procedures in order to assist veterans who completed military emergency medical technician training while serving in the Armed Forces of the United States to meet certification, licensure, and other requirements applicable to becoming an emergency medical technician in the State.

"(b) USE OF FUNDS.—Amounts received as a demonstration grant under this section shall be used to prepare and implement a plan to streamline State requirements and procedures as described in subsection (a), including by—

"(1) determining the extent to which the requirements for the education, training, and skill level of

emergency medical technicians in the State are equivalent to requirements for the education, training, and skill level of military emergency medical technicians; and

"(2) identifying methods, such as waivers, for military emergency medical technicians to forgo or meet any such equivalent State requirements.

"(c) ELIGIBILITY.—To be eligible for a grant under this section, a State shall demonstrate that the State has a shortage of emergency medical technicians.

"(d) REPORT.—The Secretary shall submit to the Congress an annual report on the program under this section.

"(e) FUNDING.—No additional funds are authorized to be appropriated for the purpose of carrying out this section. This section shall be carried out using amounts otherwise available for such purpose.".

TITLE XII—JOHN THOMAS DECKER ACT

SEC. 1201. SHORT TITLE.

This title may be cited as the "John Thomas Decker Act of 2016".

SEC. 1202. INFORMATION MATERIALS AND RESOURCES TO PREVENT ADDICTION RELATED TO YOUTH SPORTS INJURIES.

(a) TECHNICAL CLARIFICATION.—Effective as if included in the enactment of the Children's Health Act of 2000 (Public Law 106–310), section 3405(a) of such Act (114 Stat. 1221) is amended by striking "Part E of title III" and inserting "Part E of title III of the Public Health Service Act".

(b) AMENDMENT.—Title III of the Public Health Service Act is amended by inserting after part D of such title (42 U.S.C. 254b et seq.) the following new part E:

"PART E—OPIOID USE DISORDER

"SEC. 341. INFORMATION MATERIALS AND RESOURCES TO PREVENT ADDICTION RELATED TO YOUTH SPORTS INJURIES.

"(a) REPORT.—The Secretary shall—

"(1) not later than 24 months after the date of the enactment of this section, make publicly available a report determining the extent to which informational materials and resources described in subsection (b) are available to teenagers and adolescents who play youth sports, families of such teenagers and adolescents, nurses, youth sports groups, and relevant health care provider groups; and

"(2) for purposes of educating and preventing addiction in teenagers and adolescents who are injured playing youth sports and are subsequently prescribed an opioid, not later than 12 months after such report is made publicly available and taking into consideration the findings of such report, develop and, in coordination with youth sports groups, disseminate informational materials and resources described in subsection (b) for teenagers and adolescents who play youth sports, families of such teenagers and adolescents, nurses, youth sports groups, and relevant health care provider groups.

"(b) MATERIALS AND RESOURCES DESCRIBED.—For purposes of this section, the informational materials and resources described in this subsection are informational materials and resources with respect to youth sports injuries for which opioids are potentially prescribed and subsequently potentially lead to addiction, including materials and resources focused on the dangers of opioid use and misuse, treatment options for such injuries that do not involve the use of opioids, and how to seek treatment for addiction.

"(c) NO ADDITIONAL FUNDS.—No additional funds are authorized to be appropriated for the purpose of carrying out this section. This section shall be carried out using amounts otherwise available for such purpose.".

TITLE XIII—LALI'S LAW

SEC. 1301. SHORT TITLE.

This title may be cited as "Lali's Law".

SEC. 1302. OPIOID OVERDOSE REVERSAL MEDICATION ACCESS AND EDUCATION GRANT PROGRAMS.

(a) TECHNICAL CLARIFICATION.—Effective as if included in the enactment of the Children's Health Act of 2000 (Public Law 106–310), section 3405(a) of such Act (114 Stat. 1221) is amended by striking "Part E of title III" and inserting "Part E of title III of the Public Health Service Act".

(b) AMENDMENT.—Title III of the Public Health Service Act is amended by inserting after part D of such title (42 U.S.C. 254b et seq.) the following new part E:

"PART E—OPIOID USE DISORDER

"SEC. 341. OPIOID OVERDOSE REVERSAL MEDICATION ACCESS AND EDUCATION GRANT PROGRAMS.

"(a) GRANTS TO STATES.—The Secretary may make grants to States for—

"(1) developing standing orders for pharmacies regarding opioid overdose reversal medication;

"(2) encouraging pharmacies to dispense opioid overdose reversal medication pursuant to a standing order;

"(3) implementing best practices for persons authorized to prescribe medication regarding—

"(A) prescribing opioids for the treatment of chronic pain;

"(B) co-prescribing opioid overdose reversal medication with opioids; and

"(C) discussing the purpose and administration of opioid overdose reversal medication with patients;

"(4) developing or adapting training materials and methods for persons authorized to prescribe or dispense medication to use in educating the public regarding—

"(A) when and how to administer opioid overdose reversal medication; and

"(B) steps to be taken after administering opioid overdose reversal medication; and

"(5) educating the public regarding—

"(A) the public health benefits of opioid overdose reversal medication; and

"(B) the availability of opioid overdose reversal medication without a person-specific prescription.

"(b) CERTAIN REQUIREMENT.—A grant may be made under this section only if the State involved has authorized

standing orders regarding opioid overdose reversal medication.

"(c) PREFERENCE IN MAKING GRANTS.—In making grants under this section, the Secretary shall give preference to States that—

"(1) have not issued standing orders regarding opioid overdose reversal medication;

"(2) authorize standing orders that permit community-based organizations, substance abuse programs, or other nonprofit entities to acquire, dispense, or administer opioid overdose reversal medication;

"(3) authorize standing orders that permit police, fire, or emergency medical services agencies to acquire and administer opioid overdose reversal medication;

"(4) have a higher per capita rate of opioid overdoses than other applicant States; or

"(5) meet any other criteria deemed appropriate by the Secretary.

"(d) GRANT TERMS.—

"(1) NUMBER.—A State may not receive more than one grant under this section.

"(2) PERIOD.—A grant under this section shall be for a period of 3 years.

"(3) AMOUNT.—A grant under this section may not exceed $500,000.

"(4) LIMITATION.—A State may use not more than 20 percent of a grant under this section for educating the public pursuant to subsection (a)(5).

"(e) APPLICATIONS.—To be eligible to receive a grant under this section, a State shall submit an application to the Secretary in such form and manner and containing such information as the Secretary may require, including detailed proposed expenditures of grant funds.

"(f) REPORTING.—Not later than 3 months after the Secretary disburses the first grant payment to any State under this section and every 6 months thereafter for 3 years, such State shall submit a report to the Secretary that includes the following:

"(1) The name and ZIP Code of each pharmacy in the State that dispenses opioid overdose reversal medication under a standing order.

"(2) The total number of opioid overdose reversal medication doses dispensed by each such pharmacy, specifying how many were dispensed with or without a person-specific prescription.

"(3) The number of pharmacists in the State who have participated in training pursuant to subsection (a)(4).

"(g) DEFINITIONS.—In this section:

"(1) OPIOID OVERDOSE REVERSAL MEDICATION.—The term 'opioid overdose reversal medication' means any drug, including naloxone, that—

"(A) blocks opioids from attaching to, but does not itself activate, opioid receptors; or

"(B) inhibits the effects of opioids on opioid receptors.

"(2) STANDING ORDER.—The term 'standing order' means a document prepared by a person authorized to prescribe medication that permits another person to acquire, dispense, or administer medication without a person-specific prescription.

"(h) AUTHORIZATION OF APPROPRIATIONS.—

"(1) IN GENERAL.—To carry out this section, there is authorized to be appropriated $5,000,000 for the period of fiscal years 2017 through 2019.

"(2) ADMINISTRATIVE COSTS.—Not more than 3 percent of the amounts made available to carry out this section may be used by the Secretary for administrative expenses of carrying out this section.".

SEC. 1303. CUT-GO COMPLIANCE.

Subsection (f) of section 319D of the Public Health Service Act (42 U.S.C. 247d–4) is amended by inserting before the period at the end the following: "(except such dol-

lar amount shall be reduced by $5,000,000 for fiscal year 2017)".

TITLE XIV—REDUCING UNUSED MEDICATIONS ACT

SEC. 1401. SHORT TITLE.

This title may be cited as the "Reducing Unused Medications Act of 2016".

SEC. 1402. PARTIAL FILLS OF SCHEDULE II CONTROLLED SUBSTANCES.

(a) IN GENERAL.—Section 309 of the Controlled Substances Act (21 U.S.C. 829) is amended by adding at the end the following:

"(f) PARTIAL FILLS OF SCHEDULE II CONTROLLED SUBSTANCES.—

"(1) PARTIAL FILLS.—

"(A) IN GENERAL.—A prescription for a controlled substance in schedule II may be partially filled if—

"(i) it is not prohibited by State law;

"(ii) the prescription is written and filled in accordance with the Controlled Substances Act (21 U.S.C. 801 et seq.), regulations prescribed by the Attorney General, and State law;

"(iii) the partial fill is requested by the patient or the practitioner that wrote the prescription; and

"(iv) the total quantity dispensed in all partial fillings does not exceed the total quantity prescribed.

"(B) OTHER CIRCUMSTANCES.—A prescription for a controlled substance in schedule II may be partially filled in accordance with section 1306.13 of title 21, Code of Federal Regulations (as in effect on the date of enactment of the Reducing Unused Medications Act).

"(2) REMAINING PORTIONS.—

"(A) IN GENERAL.—Except as provided in subparagraph (B), remaining portions of a partially filled prescription for a controlled substance in schedule II—

"(i) may be filled; and

"(ii) shall be filled not later than 30 days after the date on which the prescription is written.

"(B) EMERGENCY SITUATIONS.—In emergency situations, as described in subsection (a), the remaining portions of a partially filled pre-

scription for a controlled substance in schedule II—

"(i) may be filled; and

"(ii) shall be filled not later than 72 hours after the prescription is issued.".

(b) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to affect the authority of the Attorney General to allow a prescription for a controlled substance in schedule III, IV, or V of section 202(c) of the Controlled Substances Act (21 U.S.C. 812(c)) to be partially filled.

TITLE XV—OPIOID REVIEW MODERNIZATION ACT

SEC. 1501. SHORT TITLE.

This title may be cited as the "Opioid Review Modernization Act of 2016".

SEC. 1502. FDA OPIOID ACTION PLAN.

Chapter V of the Federal Food, Drug, and Cosmetic Act is amended by inserting after section 569 of such Act (21 U.S.C. 350bbb–8) the following:

"SEC. 569–1. OPIOID ACTION PLAN.

"(a) NEW DRUG APPLICATION.—

"(1) IN GENERAL.—Subject to paragraph (2), prior to the approval pursuant to an application under section 505(b) of a new drug that is an opioid and does not have abuse-deterrent properties, the Sec-

retary shall refer the application to an advisory committee of the Food and Drug Administration to seek recommendations from such advisory committee.

"(2) PUBLIC HEALTH EXEMPTION.—A referral to an advisory committee under paragraph (1) is not required with respect to a new drug if the Secretary—

"(A) finds that such a referral is not in the interest of protecting and promoting public health;

"(B) finds that such a referral is not necessary based on a review of the relevant scientific information; and

"(C) submits a notice containing the rationale for such findings to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives.

"(b) PEDIATRIC OPIOID LABELING.—The Secretary shall convene the Pediatric Advisory Committee of the Food and Drug Administration to seek recommendations from such Committee regarding a framework for the inclusion of information in the labeling of drugs that are opioids relating to the use of such drugs in pediatric populations before the Secretary approves any labeling or change to label-

ing for any drug that is an opioid intended for use in a pediatric population.

"(c) SUNSET.—The requirements of subsections (a) and (b) shall cease to be effective on October 1, 2022.".

SEC. 1503. PRESCRIBER EDUCATION.

Not later than 1 year after the date of the enactment of this Act, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, as part of the Food and Drug Administration's evaluation of the Extended-Release/Long-Acting Opioid Analgesics Risk Evaluation and Mitigation Strategy, and in consultation with relevant stakeholders, shall develop recommendations regarding education programs for prescribers of opioids pursuant to section 505–1 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355–1), including recommendations on—

(1) which prescribers should participate in such programs; and

(2) how often participation in such programs is necessary.

SEC. 1504. GUIDANCE ON EVALUATING THE ABUSE DETERRENCE OF GENERIC SOLID ORAL OPIOID DRUG PRODUCTS.

Not later than 2 years after the end of the period for public comment on the draft guidance entitled "General

Principals for Evaluating the Abuse Deterrence of Generic Solid Oral Opioid Drug Products" issued by the Center for Drug Evaluation and Research of the Food and Drug Administration in March 2016, the Commissioner of Food and Drugs shall publish in the Federal Register a final version of such guidance.

TITLE XVI—EXAMINING OPIOID TREATMENT INFRASTRUCTURE ACT

SEC. 1601. SHORT TITLE.

This title may be cited as the "Examining Opioid Treatment Infrastructure Act of 2016".

SEC. 1602. STUDY ON TREATMENT INFRASTRUCTURE.

Not later than 24 months after the date of enactment of this Act, the Comptroller General of the United States shall initiate an evaluation, and submit to Congress a report, of the inpatient and outpatient treatment capacity, availability, and needs of the United States, which shall include, to the extent data are available—

(1) the capacity of acute residential or inpatient detoxification programs;

(2) the capacity of inpatient clinical stabilization programs, transitional residential support services, and residential rehabilitation programs;

(3) the capacity of demographic specific residential or inpatient treatment programs, such as those designed for pregnant women or adolescents;

(4) geographical differences of the availability of residential and outpatient treatment and recovery options for substance use disorders across the continuum of care;

(5) the availability of residential and outpatient treatment programs that offer treatment options based on reliable scientific evidence of efficacy for the treatment of substance use disorders, including the use of Food and Drug Administration-approved medicines and evidence-based nonpharmacological therapies;

(6) the number of patients in residential and specialty outpatient treatment services for substance use disorders;

(7) an assessment of the need for residential and outpatient treatment for substance use disorders across the continuum of care;

(8) the availability of residential and outpatient treatment programs to American Indians and Alaska Natives through an Indian health program (as defined by section 4 of the Indian Health Care Improvement Act (25 U.S.C. 1603)); and

(9) the barriers (including technological barriers) at the Federal, State, and local levels to real-time reporting of de-identified information on drug overdoses and ways to overcome such barriers.

TITLE XVII—OPIOID USE DISORDER TREATMENT EXPANSION AND MODERNIZATION ACT

SEC. 1701. SHORT TITLE.

This title may be cited as the "Opioid Use Disorder Treatment Expansion and Modernization Act".

SEC. 1702. FINDING.

The Congress finds that opioid use disorder has become a public health epidemic that must be addressed by increasing awareness and access to all treatment options for opioid use disorder, overdose reversal, and relapse prevention.

SEC. 1703. OPIOID USE DISORDER TREATMENT MODERNIZATION.

(a) IN GENERAL.—Section 303(g)(2) of the Controlled Substances Act (21 U.S.C. 823(g)(2)) is amended—

(1) in subparagraph (B), by striking clauses (i), (ii), and (iii) and inserting the following:

"(i) The practitioner is a qualifying practitioner (as defined in subparagraph (G)).

"(ii) With respect to patients to whom the practitioner will provide such drugs or combinations of drugs, the practitioner has the capacity to provide directly, by referral, or in such other manner as determined by the Secretary—

"(I) all schedule III, IV, and V drugs, as well as unscheduled medications approved by the Food and Drug Administration, for the treatment of opioid use disorder, including such drugs and medications for maintenance, detoxification, overdose reversal, and relapse prevention, as available; and

"(II) appropriate counseling and other appropriate ancillary services.

"(iii)(I) The total number of such patients of the practitioner at any one time will not exceed the applicable number. Except as provided in subclause (II), the applicable number is 30.

"(II) The applicable number is 100 if, not sooner than 1 year after the date on which the practitioner submitted the initial notification, the practitioner submits a second notification to the Secretary of the need and intent of the practitioner to treat up to 100 patients.

"(III) The Secretary may by regulation change such total number.

"(IV) The Secretary may exclude from the applicable number patients to whom such drugs or combinations of drugs are directly administered by the qualifying practitioner in the office setting.

"(iv) If the Secretary by regulation increases the total number of patients which a qualifying practitioner is permitted to treat pursuant to clause (iii)(II), the Secretary shall require such a practitioner to obtain a written agreement from each patient, including the patient's signature, that the patient—

"(I) will receive an initial assessment and treatment plan and periodic assessments and treatment plans thereafter;

"(II) will be subject to medication adherence and substance use monitoring;

"(III) understands available treatment options, including all drugs approved by the Food and Drug Administration for the treatment of opioid use disorder, including their potential risks and benefits; and

"(IV) understands that receiving regular counseling services is critical to recovery.

"(v) The practitioner will comply with the reporting requirements of subparagraph (D)(i)(IV).";

(2) in subparagraph (D)—

(A) in clause (i), by adding at the end the following:

"(IV) The practitioner reports to the Secretary, at such times and in such manner as specified by the Secretary, such information and assurances as the Secretary determines necessary to assess whether the practitioner continues to meet the requirements for a waiver under this paragraph.";

(B) in clause (ii), by striking "Upon receiving a notification under subparagraph (B)" and inserting "Upon receiving a determination from the Secretary under clause (iii) finding that a practitioner meets all requirements for a waiver under subparagraph (B)"; and

(C) in clause (iii)—

(i) by inserting "and shall forward such determination to the Attorney General" before the period at the end of the first sentence; and

(ii) by striking "physician" and inserting "practitioner";

(3) in subparagraph (G)—

(A) by amending clause (ii)(IV) to read as follows:

"(IV) The physician has, with respect to the treatment and management of opiate-dependent patients, completed not less than 8 hours of training (through classroom situations, seminars at professional society meetings, electronic communications, or otherwise) that is provided by the American Society of Addiction Medicine, the American Academy of Addiction Psychiatry, the American Medical Association, the American Osteopathic Association, the American Psychiatric Association, or any other organization that the Secretary determines is appropriate for purposes of this subclause. Such training shall address—

"(aa) opioid maintenance and detoxification;

"(bb) appropriate clinical use of all drugs approved by the Food and Drug Administration for the treatment of opioid use disorder;

"(cc) initial and periodic patient assessments (including substance use monitoring);

"(dd) individualized treatment planning; overdose reversal; relapse prevention;

"(ee) counseling and recovery support services;

"(ff) staffing roles and considerations;

"(gg) diversion control; and

"(hh) other best practices, as identified by the Secretary."; and

(B) by adding at the end the following:

"(iii) The term 'qualifying practitioner' means—

"(I) a qualifying physician, as defined in clause (ii); or

"(II) during the period beginning on the date of the enactment of the Opioid Use Disorder Treatment Expansion and Modernization Act and ending on the date that is 3 years after such date of enactment, a qualifying other practitioner, as defined in clause (iv).

"(iv) The term 'qualifying other practitioner' means a nurse practitioner or physician assistant who satisfies each of the following:

"(I) The nurse practitioner or physician assistant is licensed under State law to prescribe

schedule III, IV, or V medications for the treatment of pain.

"(II) The nurse practitioner or physician assistant satisfies one or more of the following:

"(aa) Has completed not fewer than 24 hours of initial training addressing each of the topics listed in clause (ii)(IV) (through classroom situations, seminars at professional society meetings, electronic communications, or otherwise) provided by the American Society of Addiction Medicine, the American Academy of Addiction Psychiatry, the American Medical Association, the American Osteopathic Association, the American Nurses Credentialing Center, the American Psychiatric Association, the American Association of Nurse Practitioners, the American Academy of Physician Assistants, or any other organization that the Secretary determines is appropriate for purposes of this subclause.

"(bb) Has such other training or experience as the Secretary determines will demonstrate the ability of the nurse practitioner

or physician assistant to treat and manage opiate-dependent patients.

"(III) The nurse practitioner or physician assistant is supervised by or works in collaboration with a qualifying physician, if the nurse practitioner or physician assistant is required by State law to prescribe medications for the treatment of opioid use disorder in collaboration with or under the supervision of a physician.

The Secretary may review and update the requirements for being a qualifying other practitioner under this clause."; and

(4) in subparagraph (H)—

(A) in clause (i), by inserting after subclause (II) the following:

"(III) Such other elements of the requirements under this paragraph as the Secretary determines necessary for purposes of implementing such requirements."; and

(B) by amending clause (ii) to read as follows:

"(ii) Not later than 1 year after the date of enactment of the Opioid Use Disorder Treatment Expansion and Modernization Act, the Secretary shall update the treatment improvement protocol containing best practice guidelines for

the treatment of opioid-dependent patients in office-based settings. The Secretary shall update such protocol in consultation with experts in opioid use disorder research and treatment.".

(b) RECOMMENDATION OF REVOCATION OR SUSPENSION OF REGISTRATION IN CASE OF SUBSTANTIAL NONCOMPLIANCE.—The Secretary of Health and Human Services may recommend to the Attorney General that the registration of a practitioner be revoked or suspended if the Secretary determines, according to such criteria as the Secretary establishes by regulation, that a practitioner who is registered under section 303(g)(2) of the Controlled Substances Act (21 U.S.C. 823(g)(2)) is not in substantial compliance with the requirements of such section, as amended by this Act.

(c) OPIOID DEFINED.—Section 102(18) of the Controlled Substances Act (21 U.S.C. 802(18)) is amended by inserting "or 'opioid'" after "The term 'opiate'".

(d) REPORTS TO CONGRESS.—

(1) IN GENERAL.—Not later than 2 years after the date of enactment of this Act and not less than over every 5 years thereafter, the Secretary of Health and Human Services, in consultation with the Drug Enforcement Administration and experts in opioid use disorder research and treatment, shall—

(A) perform a thorough review of the provision of opioid use disorder treatment services in the United States, including services provided in opioid treatment programs and other specialty and nonspecialty settings; and

(B) submit a report to the Congress on the findings and conclusions of such review.

(2) CONTENTS.—Each report under paragraph (1) shall include an assessment of—

(A) compliance with the requirements of section 303(g)(2) of the Controlled Substances Act (21 U.S.C. 823(g)(2)), as amended by this Act;

(B) the measures taken by the Secretary of Health and Human Services to ensure such compliance;

(C) whether there is further need to increase or decrease the number of patients a waivered practitioner is permitted to treat, as provided for by the amendment made by subsection (a)(1);

(D) the extent to which, and proportions with which, the full range of Food and Drug Administration-approved treatments for opioid use disorder are used in routine health care settings

and specialty substance use disorder treatment settings;

(E) access to, and use of, counseling and recovery support services, including the percentage of patients receiving such services;

(F) changes in State or local policies and legislation relating to opioid use disorder treatment;

(G) the use of prescription drug monitoring programs by practitioners who are permitted to dispense narcotic drugs to individuals pursuant to a waiver under section 303(g)(2) of the Controlled Substances Act (21 U.S.C. 823(g)(2));

(H) the findings resulting from inspections by the Drug Enforcement Administration of practitioners described in subparagraph (G); and

(I) the effectiveness of cross-agency collaboration between Department of Health and Human Services and the Drug Enforcement Administration for expanding effective opioid use disorder treatment.

SEC. 1704. SENSE OF CONGRESS.

It is the Sense of Congress that, with respect to the total number of patients that a qualifying physician (as defined in subparagraph (G)(iii) of section 303(g)(2) of the

Controlled Substances Act (21 U.S.C. 823(g)(2)) can treat at any one time pursuant to such section, the Secretary of Health and Human Services should consider raising such total number to 250 patients following a third notification to the Secretary of the need and intent of the physician to treat up to 250 patients that is submitted to the Secretary not sooner than 1 year after the date on which the physician submitted to the Secretary a second notification to treat up to 100 patients.

SEC. 1705. PARTIAL FILLS OF SCHEDULE II CONTROLLED SUBSTANCES.

(a) IN GENERAL.—Section 309 of the Controlled Substances Act (21 U.S.C. 829) is amended by adding at the end the following:

"(f) PARTIAL FILLS OF SCHEDULE II CONTROLLED SUBSTANCES.—

"(1) PARTIAL FILLS.—

"(A) IN GENERAL.—A prescription for a controlled substance in schedule II may be partially filled if—

"(i) it is not prohibited by State law;

"(ii) the prescription is written and filled in accordance with the Controlled Substances Act (21 U.S.C. 801 et seq.), reg-

ulations prescribed by the Attorney General, and State law;

"(iii) the partial fill is requested by the patient or the practitioner that wrote the prescription; and

"(iv) the total quantity dispensed in all partial fillings does not exceed the total quantity prescribed.

"(B) OTHER CIRCUMSTANCES.—A prescription for a controlled substance in schedule II may be partially filled in accordance with section 1306.13 of title 21, Code of Federal Regulations (as in effect on the date of enactment of the Reducing Unused Medications Act of 2016).

"(2) REMAINING PORTIONS.—

"(A) IN GENERAL.—Except as provided in subparagraph (B), remaining portions of a partially filled prescription for a controlled substance in schedule II—

"(i) may be filled; and

"(ii) shall be filled not later than 30 days after the date on which the prescription is written.

"(B) EMERGENCY SITUATIONS.—In emergency situations, as described in subsection (a),

the remaining portions of a partially filled prescription for a controlled substance in schedule II—

"(i) may be filled; and

"(ii) shall be filled not later than 72 hours after the prescription is issued.".

(b) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to affect the authority of the Attorney General to allow a prescription for a controlled substance in schedule III, IV, or V of section 202(c) of the Controlled Substances Act (21 U.S.C. 812(c)) to be partially filled.

TITLE XVIII—NATIONAL ALL SCHEDULES PRESCRIPTION ELECTRONIC REPORTING REAUTHORIZATION ACT

SEC. 1801. SHORT TITLE.

This title may be cited as the "National All Schedules Prescription Electronic Reporting Reauthorization Act of 2015".

SEC. 1802. AMENDMENT TO PURPOSE.

Paragraph (1) of section 2 of the National All Schedules Prescription Electronic Reporting Act of 2005 (Public Law 109–60) is amended to read as follows:

"(1) foster the establishment of State-administered controlled substance monitoring systems in order to ensure that—

"(A) health care providers have access to the accurate, timely prescription history information that they may use as a tool for the early identification of patients at risk for addiction in order to initiate appropriate medical interventions and avert the tragic personal, family, and community consequences of untreated addiction; and

"(B) appropriate law enforcement, regulatory, and State professional licensing authorities have access to prescription history information for the purposes of investigating drug diversion and prescribing and dispensing practices of errant prescribers or pharmacists; and".

SEC. 1803. AMENDMENTS TO CONTROLLED SUBSTANCE MONITORING PROGRAM.

Section 399O of the Public Health Service Act (42 U.S.C. 280g–3) is amended—

(1) in subsection (a)—

(A) in paragraph (1)—

(i) in subparagraph (A), by striking "or";

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

(iii) by adding at the end the following:

"(C) to maintain and operate an existing State-controlled substance monitoring program."; and

(B) in paragraph (3), by inserting "by the Secretary" after "Grants awarded";

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

"(b) MINIMUM REQUIREMENTS.—The Secretary shall maintain and, as appropriate, supplement or revise (after publishing proposed additions and revisions in the Federal Register and receiving public comments thereon) minimum requirements for criteria to be used by States for purposes of clauses (ii), (v), (vi), and (vii) of subsection (c)(1)(A).";

(3) in subsection (c)—

(A) in paragraph (1)(B)—

(i) in the matter preceding clause (i), by striking "(a)(1)(B)" and inserting "(a)(1)(B) or (a)(1)(C)";

(ii) in clause (i), by striking "program to be improved" and inserting "program to be improved or maintained";

(iii) by redesignating clauses (iii) and (iv) as clauses (iv) and (v), respectively;

(iv) by inserting after clause (ii) the following:

"(iii) a plan to apply the latest advances in health information technology in order to incorporate prescription drug monitoring program data directly into the workflow of prescribers and dispensers to ensure timely access to patients' controlled prescription drug history;";

(v) in clause (iv), as redesignated, by inserting before the semicolon at the end "and at least one health information technology system such as an electronic health records system, a health information exchange, or an e-prescribing system"; and

(vi) in clause (v), as redesignated, by striking "public health" and inserting "public health or public safety";

(B) in paragraph (3)—

(i) by striking "If a State that submits" and inserting the following:

"(A) IN GENERAL.—If a State that submits";

(ii) by striking the period at the end and inserting "and include timelines for full implementation of such interoperability. The State shall also describe the manner in which it will achieve interoperability between its monitoring program and health information technology systems, as allowable under State law, and include timelines for implementation of such interoperability."; and

(iii) by adding at the end the following:

"(B) MONITORING OF EFFORTS.—The Secretary shall monitor State efforts to achieve interoperability, as described in subparagraph (A).."; and

(C) in paragraph (5)—

(i) by striking "implement or improve" and inserting "establish, improve, or maintain"; and

(ii) by adding at the end the following: "The Secretary shall redistribute any funds that are so returned among the remaining grantees under this section in accordance with the formula described in subsection (a)(2)(B).";

(4) in subsection (d)—

(A) in the matter preceding paragraph (1)—

(i) by striking "In implementing or improving" and all that follows through "(a)(1)(B)" and inserting "In establishing, improving, or maintaining a controlled substance monitoring program under this section, a State shall comply, or with respect to a State that applies for a grant under subparagraph (B) or (C) of subsection (a)(1)"; and

(ii) by striking "public health" and inserting "public health or public safety"; and

(B) by adding at the end the following:

"(5) The State shall report to the Secretary on—

"(A) as appropriate, interoperability with the controlled substance monitoring programs of Federal departments and agencies;

"(B) as appropriate, interoperability with health information technology systems such as electronic health records systems, health information exchanges, and e-prescribing systems; and

"(C) whether or not the State provides automatic, real-time or daily information about a patient when a practitioner (or the designee of a practitioner, where permitted) requests information about such patient.";

(5) in subsections (e), (f)(1), and (g), by striking "implementing or improving" each place it appears and inserting "establishing, improving, or maintaining";

(6) in subsection (f)—

(A) in paragraph (1)—

(i) in subparagraph (B), by striking "misuse of a schedule II, III, or IV substance" and inserting "misuse of a controlled substance included in schedule II, III, or IV of section 202(c) of the Controlled Substance Act"; and

(ii) in subparagraph (D), by inserting "a State substance abuse agency," after "a State health department,"; and

(B) by adding at the end the following:

"(3) EVALUATION AND REPORTING.—Subject to subsection (g), a State receiving a grant under subsection (a) shall provide the Secretary with aggregate data and other information determined by the Secretary to be necessary to enable the Secretary—

"(A) to evaluate the success of the State's program in achieving its purposes; or

"(B) to prepare and submit the report to Congress required by subsection (l)(2).

"(4) RESEARCH BY OTHER ENTITIES.—A department, program, or administration receiving non-identifiable information under paragraph (1)(D) may make such information available to other entities for research purposes.";

(7) by redesignating subsections (h) through (n) as subsections (j) through (p), respectively;

(8) in subsections (c)(1)(A)(iv) and (d)(4), by striking "subsection (h)" each place it appears and inserting "subsection (j)";

(9) by inserting after subsection (g) the following:

"(h) EDUCATION AND ACCESS TO THE MONITORING SYSTEM.—A State receiving a grant under subsection (a) shall take steps to—

"(1) facilitate prescriber and dispenser use of the State's controlled substance monitoring system;

"(2) educate prescribers and dispensers on the benefits of the system both to them and society; and

"(3) facilitate linkage to the State substance abuse agency and substance abuse disorder services.

"(i) CONSULTATION WITH ATTORNEY GENERAL.—In carrying out this section, the Secretary shall consult with the Attorney General of the United States and other relevant Federal officials to—

"(1) ensure maximum coordination of controlled substance monitoring programs and related activities; and

"(2) minimize duplicative efforts and funding.";

(10) in subsection (l)(2)(A), as redesignated by paragraph (7)—

(A) in clause (ii), by inserting "; established or strengthened initiatives to ensure linkages to substance use disorder services;" before "or affected patient access"; and

(B) in clause (iii), by inserting "and between controlled substance monitoring programs and health information technology systems" before ", including an assessment";

(11) by striking subsection (m) (relating to preference), as redesignated by paragraph (7);

(12) by redesignating subsections (n) through (p), as redesignated by paragraph (7), as subsections (m) through (o), respectively;

(13) in subsection (m)(1), as redesignated by paragraph (12), by striking "establishment, implementation, or improvement" and inserting "establishment, improvement, or maintenance";

(14) in subsection (n), as redesignated by paragraph (12)—

(A) in paragraph (5)—

(i) by striking "means the ability" and inserting the following: "means—

"(A) the ability";

(ii) by striking the period at the end and inserting "; or"; and

(iii) by adding at the end the following:

"(B) sharing of State controlled substance monitoring program information with a health information technology system such as an electronic health records system, a health information exchange, or an e-prescribing system.";

(B) in paragraph (7), by striking "pharmacy" and inserting "pharmacist"; and

(C) in paragraph (8), by striking "and the District of Columbia" and inserting ", the District of Columbia, and any commonwealth or territory of the United States"; and

(15) by amending subsection (o), as redesignated by paragraph (12), to read as follows:

"(o) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there is authorized to be appropriated $10,000,000 for each of fiscal years from 2016 through 2020.".

Amend the title so as to read: ''An Act to authorize the Attorney General and Secretary of Health and Human Services to award grants to address the national epidemics of prescription opioid abuse and heroin use, and to provide for the establishment of an inter-agency task force to review, modify, and update best practices for pain management and prescribing pain medication, and for other purposes.''.

Attest:

Clerk.

114TH CONGRESS
2D SESSION

S. 524

AMENDMENTS