

# Comprehensive Addiction and Recovery Act of 2016 (S. 524)

## Conference Report: A Section-by-Section Analysis

**Conference Report signed by:** Reps. Upton (R-MI), Pitts (R-PA), Lance (R-NJ), Guthrie (R-KY), Kinzinger (R-IL), Bucshon (R-IN), Brooks (R-IN), Goodlatte (R-VA), Sensenbrenner (R-WI), Smith (R-TX), Marino (R-PA), Collins (R-GA), Trott (R-MI), Bishop (R-MI), McCarthy (R-CA), Barletta (R-PA), Carter (R-GA), Bilirakis (R-FL), Walorski (R-IN), Meehan (R-PA), and Dold (R-IL); Sens. Grassley (R-IA), Alexander (R-TN), Hatch (R-UT), and Sessions (R-AL)

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## ***Title I: Prevention and Education***

### **Section 101: Task Force on Pain Management**

This section creates an **inter-agency task force to develop a set of best practices for chronic and acute pain management and prescribing pain medication**. The task force will review: existing research; recommendations from relevant conferences; efforts at the State and local levels to develop pain management strategies; management strategies for high risk populations; the Centers for Disease Control's (CDC) Guideline for Prescribing Opioids for Chronic Pain; and private sector, State, and local efforts related to pain management. The task force will also review public comments and develop a strategy for disseminating the best practices to stakeholders.

The Secretary of Health and Human Services (HHS) would lead the task force in cooperation with the Secretary of Veterans Affairs (VA) and Secretary of Defense. Other representatives on the task force would include the

representatives of HHS, VA, Department of Defense, and the Office of National Drug Control Policy (ONDCP). This section also calls for the task force to include prescribers, pharmacists, experts in the pain and addiction research fields, pain management professional organizations, advocacy groups, and representatives of the mental health and substance use disorder treatment communities. The task force will not have rulemaking authority. The task force will convene no later than 2 years after enactment of this Act, and will sunset after 3 years.

### Section 102: Awareness Campaigns

This section calls for the Secretary of Health and Human Services (HHS) to advance the education and awareness of the public regarding opioid use disorders. The campaign will take into account the association between prescription opioid misuse and heroin use, emphasizing the similarities between prescription opioids and heroin. The campaign will also raise awareness about the risks of fentanyl.

### Section 103: Community-Based Coalition Enhancement Grants to Address Local Drug Crises

This section authorizes the Director of ONDCP, in coordination with the Administrator of SAMHSA, to make grants to eligible entities to **implement comprehensive community-wide strategies to address local drug crises**. Eligible entities will be organizations that have received a grant under the Drug Free Communities Act of 1997 and that have documented higher than average rates of local opioid misuse methamphetamine use. “Local drug crises” refers to areas with a sudden, documented increase in the misuse of opioids or methamphetamines, or rates of misuse of prescription opioids or methamphetamines that are significantly higher than the national average.

Applicants must submit to the Director of ONDCP a detailed, comprehensive, multi-sector plan for addressing the local drug crises. Federal funds received under this section should supplement other federal and non-federal funding sources, not supplant them. A grant under this section will be subject to the same evaluation requirements and procedures as the Drug-Free Communities Act of 1997, and may also include an evaluation of the effectiveness at reducing abuse of opioids or methamphetamines. This section authorizes to be appropriated \$5 million for each of fiscal years 2017 through 2021.

### Section 104: Information Materials and Resources to Prevent Addiction Related to Youth Sports Injuries

This section calls for the Secretary of HHS to make publicly available a report on the extent to which informational materials and resources are available to adolescents, families, and relevant health care providers regarding youth with sports injuries for which opioids may be prescribed. Within one year of publishing the report, the Secretary will facilitate the development of and then make publicly available informational materials and resources on youth with sports injuries for which opioids may be prescribed. The materials will focus on the risks associated with opioid use and misuse, alternative treatment options, and how to seek treatment for addiction.

### Section 105: Assisting Veterans with Military Emergency Medical Training to Meet Requirements for Becoming Civilian Health Care Professionals

This section amends Part B of title III of the Public Health Service Act by adding a section on “Assisting Veterans with Military Emergency Medical Training to Meet Requirements for Becoming Civilian Health Care Professionals.” Under this section, the Secretary of HHS, in consultation with the Secretary of Labor, would award demonstration grants to States to streamline State requirements and procedures in order to assist veterans who held health certain medical specialties in the military to meet certification, licensure, and other requirements applicable to civilian health care professions. Funds would be used to determine the extent to which requirements for health care professions in the State are equivalent to: requirements for the education, training, and skill level of veterans who served in medical related fields while a member of the Armed Forces; identify methods for veterans who served in medical related fields while in the Armed Forces to forgo or meet any equivalent State requirements; and develop or expand career pathways at higher education institutions to support veterans in meeting requirements. Upon the completion of the demonstration program, the Secretary will submit to Congress a report on the program. No additional funds are authorized to be appropriated to carry out this section. The demonstration program will sunset after 5 years.

### Section 106: FDA Opioid Action Plan

This section requires that any application of a new opioid drug be referred to an FDA advisory committee for recommendations prior to FDA approval. The referral to an advisory committee is not required if the Secretary of HHS: finds that referral is not in the interest of promoting public health; finds that referral is not necessary based on a review of the relevant scientific information; and submits a notice containing the rationale for such findings to Congress. This section also calls for the Secretary to convene the Pediatric Advisory Committee of the FDA to receive recommendations on the labeling of opioids for pediatric populations prior to approval.

This section also calls for the Secretary, acting through the Commissioner of Food and Drugs, as part of the FDA's evaluation of the Extended-Release/Long-Acting Opioid Analgesics Risk Evaluation and Mitigation Strategy, to develop **recommendations regarding prescriber education on opioids**. Additionally, this section requires that the Commissioner of Food and Drugs publish in the Federal Register the final version of the guidance entitled "General Principles for Evaluating the Abuse Deterrence of Generic Solid Oral Opioid Drug Products."

### Section 107: Improving Access to Overdose Treatment

This section amends part D of title V of the Public Health Service Act by adding a section on "Grants for Reducing Overdose Deaths." Under this section the Secretary of HHS would award **grants to expand access to drugs or devices for opioid overdose reversal**. Eligible entities would include federally qualified health centers, opioid treatment programs, or any other entity that the Secretary deems appropriate. Grant funds could be used to: (1) establish a program for prescribing a drug or device for overdose reversal; (2) train and provide resources for health care providers and pharmacists on the prescribing of overdose reversal drugs or devices; (3) purchase overdose reversal drugs or devices for distribution; (4) offset the co-payments and other cost sharing associated with overdose reversal drugs or devices; and (5) establish protocols to connect patients who have experienced a drug overdose with appropriate treatment, including medication-assisted treatment and appropriate counseling and behavioral therapies. Within 5 years of the first grant award, the Secretary will submit a report to Congress on the outcomes achieved by the grant programs. This section authorizes to be appropriated \$5 million for FY 2017-2021.

This section also calls for the Secretary to provide information to prescribers within federally qualified health centers and the health care facilities of the Indian Health Service, on best practices for prescribing or co-prescribing an overdose reversal drug or device, including for patients receiving chronic opioid therapy and patients being treated for opioid use disorders. The Secretary of Defense may provide information to prescribers within the Department of Defense on best practices for prescribing or co-prescribing an overdose reversal drug or device, and the Secretary of the VA may do the same for prescribers within the Department of Veterans Affairs medical facilities.

### Section 108: NIH Opioid Research

This section authorizes the Director of the NIH to intensify and coordinate fundamental, translational, and clinical research of the NIH with respect to the understanding of pain; the discovery and development of therapies for chronic pain; and the development of alternatives to opioids for effective pain treatments.

### Section 109: National All Schedules Prescription Electronic Reporting (NASPER) Reauthorization

This section amends Section 3990 of the Public Health Services Act by adding that grants to establish, implement, or improve a State controlled substance monitoring program will be administered by the Secretary "in consultation with the Administrator of SAMHSA and the Director of the CDC." Language is also added that would require grant applicants to include in their application information on **how the substance monitoring program jointly works with the applicant's respective State substance abuse agency** to ensure information collected and maintained by the controlled substance monitoring program is used to inform the provision of clinically appropriate substance use disorder services to individuals in need. This section would also add language on interoperability of controlled substance monitoring programs.

Additionally, this section would require grantees to submit to the Secretary aggregate data. This data would

allow the Secretary to evaluate the success of the State’s program, and prepare and submit a report to Congress. A new section would also be added on prescriber and dispenser education and access to the monitoring system.

This section authorizes \$10 million for each of fiscal years 2017 through 2021.

### Section 110: Opioid Overdose Reversal Medication Access and Education Grant Programs

This section amends part D of title V of the Public Health Service Act by adding a section on “Opioid Overdose Reversal Medication Access and Education Grant Programs.” In this grant program, the Secretary of HHS would award grants to States to: (1) implement strategies for pharmacists to dispense an opioid overdose reversal drug or device pursuant to a standing order; (2) encourage pharmacies to dispense opioid overdose reversal medication pursuant to a standing order; (3) develop or provide training materials on the administration of an opioid overdose reversal drug or device; and (4) educate the public concerning the availability of overdose reversal drugs or devices. A grant may be awarded only if the State involved has authorized standing orders to be issued for overdose reversal drugs or devices. Grantees must at least annually submit a report to the Secretary on the number of pharmacies in the State that dispense an opioid overdose reversal drug or device under a standing order. This section defines the term ‘standing order’ as 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. A grant under this section will last for a period of 3 years. This section authorizes \$5 million for FY 2017-FY 2019.

## Title II: Law Enforcement and Treatment

### Section 201: Comprehensive Opioid Abuse Grant Program

This section amends title I of the Omnibus Crime Control and Safe Streets Act of 1968 by adding a section on the “Comprehensive Opioid Abuse Grant Program.” In this grant program, the Attorney General would make grants to States, local governments, and Indian tribes for any of the following activities:

- Developing, implementing, or expanding a treatment alternative to incarceration program (may include prebooking or postbooking components; training for criminal justice agency personnel on substance use disorders and co-occurring mental illness and substance use disorders; a mental health court; a drug court; a veterans treatment court; a focus on parents whose incarceration could result in their children entering the child welfare system; and a community-based substance use diversion program sponsored by a law enforcement agency)
- In the case of a State, facilitating or enhancing planning and **collaboration between State criminal justice agencies and State substance abuse agencies** in order to more efficiently and effectively carry out activities or services that address opioid abuse. The State substance abuse agency is defined as the agency that manages the substance Abuse Prevention and Treatment (SAPT) Block Grant.
- Providing training and resources for first responders on carrying and administering—as well as purchasing—an opioid overdose reversal drug or device.
- Locating or investigating illicit activities related to the unlawful distribution of opioids.
- **Developing, implementing, or expanding a medication-assisted treatment program used or operated by a criminal justice agency.**
- In the case of a State, developing, implementing, or expanding a prescription drug monitoring program.
- Developing, implementing, or expanding a program to prevent and address opioid abuse by juveniles.
- Developing, implementing, or expanding a program to utilize technology that provides a secure container for prescription drugs.
- Developing, implementing, or expanding a prescription drug take-back program.
- Developing, implementing, or expanding an integrated and comprehensive opioid abuse response program.

Applications to the Attorney General must include: (1) a certification that Federal funds made available under this part will not be used to supplant State, local, or tribal funds; (2) assurance that the applicant will maintain and report data, records, and information as the Attorney General may reasonably require; (3) certification that the activities or services to be funded by the grant meet all requirements, all the information contained in the



application is correct, there has been appropriate coordination with affected agencies, and the applicant will comply with all provisions of this section and applicable Federal laws; and (4) assurance that the applicant will work with the Drug Enforcement Administration to develop an integrated and comprehensive strategy to address opioid abuse.

Additionally, this section calls for the Comptroller General to conduct a study and submit to Congress a report on how Federal agencies, through grant programs, are addressing prevention of, treatment for, and recovery from, substance use among adolescents and young adults.

A grant under this section may be no longer than 4 years. This section authorizes \$103,000,000 for each of fiscal years 2017 through 2021.

### Section 202: First Responder Training

This section amends Part D of Title V of the Public Health Service Act to add a new section: "Sec. 546 First Responder Training." This section authorizes the Secretary of HHS to make grants available to States, local governments, or Indian tribal governments. Funding will allow first responders and members of other key community sectors to administer an opioid overdose reversal drug or device.

The grant application to the Secretary of HHS will describe the evidence-based methodology and outcome measurements that will be used for program evaluation, and explain how such measurements will provide valid measures of the impact of the program. The application will describe how the program could be broadly replicated. It will also identify agencies that the program will coordinate, and describe how law enforcement agencies will coordinate with their SSA and State mental health agency to identify protocols and resources for victims and families.

The Secretary of HHS will conduct an evaluation of grants to determine the number of first responders equipped with an opioid overdose reversal drug or device. The evaluation will also determine the number of opioid overdoses reversed by first responders and key community sectors receiving training and supplies of opioid overdose reversal drugs and devices through the grant program. Additionally, the evaluation will determine the number of calls for service related to opioid overdose, and the extent to which overdose victims and families receive information about treatment services and available data describing treatment admissions.

This section authorizes \$12 million for each of fiscal years 2017 through 2021.

### Section 203: Prescription Drug Take Back Expansion

This section authorizes the Attorney General, in coordination with the Administrator of DEA, Secretary of HHS, and Director of ONDCP, to make grants to a variety of entities to **expand or create disposal sites for unwanted prescription medications**. Eligible applicants include:

- State, local, or tribal law enforcement agency;
- Manufacturer, distributor, or reverse distributor of prescription medications;
- Retail pharmacy;
- Registered narcotic treatment program;
- Hospital or clinic with an on-site pharmacy;
- Eligible long-term care facility; or
- Any other entity authorized by the DEA to dispose of prescription medications.

## Title III: Treatment and Recovery

### Section 301: Evidence-Based Prescription Opioid and Heroin Treatment and Interventions Demonstration

This section amends title V of the Public Health Service Act to add "Sec. 514B Evidence-Based Prescription Opioid and Heroin Treatment and Interventions Demonstration." The section authorizes the Secretary of HHS, to **award grants to State substance abuse agencies**, units of local government, nonprofit organizations, and Indian tribes

or tribal organizations that have a high rate or rapid increase in the use of heroin or other opioids. Funds will be used to **expand activities, including the availability of medication-assisted treatment (MAT) and other clinically appropriate services**. MAT is defined in this legislation as the use of medications approved by the FDA in combination with counseling and behavioral therapies. The Secretary will evaluate the activities of grantees, disseminate significant results from the evaluation, provide technical assistance, and fund applications that specifically support recovery services as a critical component of the grant program.

This section authorizes \$25 million for each of fiscal years 2017 through 2021.

### Section 302: Building Communities of Recovery

This section amends Part D Title V of the Public Health Service Act to add “Sec. 547 Building Communities of Recovery.” This section authorizes the Secretary of HHS to award **grants to recovery community organizations to develop, expand, and enhance recovery services**. “Recovery community organizations” are nonprofits that mobilize resources within and outside the recovery community to increase long-term recovery and that are wholly or principally governed by people in recovery who reflect the community served. Federal grant funds may not exceed 50% of total program costs. Funds may be used to: develop, expand, and enhance community and Statewide recovery support services; build connections between recovery support services and networks, including treatment programs, mental health providers, primary care providers, and others; reduce the stigma associated with substance use disorders; and to conduct public education and outreach on issues related to substance use disorders and recovery. This can include education on the signs of addiction, the resources available for people with substance use disorders and those in recovery, and the medical consequences of substance use disorders, including neonatal abstinence syndrome (NAS). This section authorizes \$1 million for each of fiscal years 2017 through 2021.

### Section 303: Medication-Assisted Treatment for Recovery from Addiction

This section amends Section 303 of the Controlled Substance Act related to practitioners dispensing narcotic drugs for narcotic treatment. In the prescriber’s notification to the Secretary of HHS of their intent to prescribe buprenorphine, they must certify that: the practitioner is a qualifying practitioner; they have the capacity to provide directly, by referral, all drugs approved by the FDA for the treatment of opioid use disorder, as well as appropriate counseling and other ancillary services; and the total number of patients of the practitioner at any one time will not exceed the applicable number. The applicable number is 30 in the first year, and 100 if the practitioner submits a second notification to the Secretary of the need and intent of the practitioner to treat up to 100 patients. The Secretary may by regulation change the applicable number. Additionally, 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.

This section adds to the criteria of a “qualifying practitioner” the following: (1) the physician holds a board certification in addiction psychiatry or addiction medicine from the American Board of Medical Specialties; and (2) the physician holds an addiction certification or board certification from the American Society of Addiction Medicine or the American Board of Addiction Medicine. With regard to physician training, the physician must have completed at least 8 hours of training 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. Training should include opioid maintenance and detoxification; appropriate clinical use of all drugs approved by the FDA; initial and periodic patient assessments (including substance use monitoring); individualized treatment planning, overdose reversal, and relapse prevention; counseling and recovery support services; staffing roles and considerations; diversion control; and other best practices, as identified by the Secretary.

The term ‘qualifying practitioner’ is defined as a **qualifying physician or qualifying other practitioner, which means a nurse practitioner or physician assistant** who satisfies each of the following:

- The nurse practitioner or physician assistant is licensed under State law to prescribe schedule III, IV, or V

medications for the treatment of pain.

- The nurse practitioner or physician assistant has completed at least 24 hours of initial training 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; or has 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.
- 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.

Nothing in the section preempts any State law that: (1) permits a qualifying practitioner to dispense narcotic drugs for maintenance or detoxification treatment to a total number of patients that is more than 30 or less than the total number applicable to the qualifying practitioner if a State enacts a law modifying such total number and the Attorney General is notified by the State of such modification; or (2) requires a qualifying practitioner to comply with additional requirements relating to the dispensing of narcotic drugs, including requirements relating to the practice setting in which the qualifying practitioner practices and education, training, and reporting requirements.

This section also calls for the Secretary to update the treatment improvement protocol containing best practice guidelines for the treatment of opioid-dependent patients in office-based settings. Additionally, the Secretary will review the provision of opioid use disorder treatment services provided in opioid treatment programs and other specialty and non-specialty settings, and then submit a report on findings to Congress. The Attorney General and the Secretary must update regulations regarding practitioners to include nurse practitioners and physician assistants within 18 months of enactment of this Act.

#### *Title IV: Addressing Collateral Consequences*

##### **Section 401: GAO Report on Recovery and Collateral Consequences**

This section directs the Comptroller General to submit to Congress a report that: (1) describes **the collateral consequences for individuals with convictions for nonviolent drug-related offenses**; (2) describes the effect of the collateral consequences on individuals in resuming their personal and professional activities; (3) discusses policy bases and justifications for imposing collateral consequences on individuals convicted of nonviolent drug-related offenses; and (4) provides perspectives on the potential for mitigating the effect of the collateral consequences on individuals who are participating in or have completed a recovery program. A collateral consequence is defined as: (1) a penalty, disability, or disadvantage imposed upon an individual as a result of a criminal conviction for a drug-related offense automatically by operation of law; or by authorized action of an administrative agency or court on a case-by-case basis; and (2) not a direct consequence imposed as part of the judgment of a court at sentencing, including a term of imprisonment or community supervision, or a fine.

#### *Title V: Addiction and Treatment Services for Women, Families, and Veterans*

##### **Section 501: Improving Treatment for Pregnant and Postpartum Women**

This section amends Section 508 of the Public Health Service Act by reauthorizing the Residential Treatment Program for Pregnant and Postpartum Women. This section authorizes the Director of the Center for Substance Abuse Treatment (CSAT) within SAMHSA to prioritize awards for the residential services grant program to programs serving rural areas, areas with a health professional shortage, and areas with a shortage of family-based treatment options.

Additionally, this section authorizes the Director of CSAT to carry out a pilot program making competitive **grants available to State substance abuse agencies to enhance flexibility in the use of funds for family-**



**based services for pregnant and postpartum women** with a primary diagnosis of a substance use disorder. Funds will help SSAs address gaps in services to women across the continuum of care, including in non-residential settings, and promote new approaches and evidence-based models of service delivery.

The Director of CSAT will specify minimum services that should be made available to women through the pilot program, which will be based on recommendations from stakeholders, including SSAs, health care providers, and individuals in recovery from a substance use disorder. The minimum services will include individual, group, and family counseling, as well as follow-up services to assist women in preventing a relapse. The minimum services may—but do not have to—include:

- Prenatal and postpartum health care.
- Referrals for necessary hospital services.
- For the infants and children of the woman-
  - pediatric health care, including treatment for any perinatal effects of maternal substance abuse and including screenings regarding the physical and mental development of the infants and children;
  - counseling and other mental health services, in the case of children; and
  - comprehensive social services.
- Providing supervision of children during periods in which the woman is engaged in therapy or in other necessary health or rehabilitative activities.
- Training in parenting.
- Counseling on the human immunodeficiency virus and on acquired immune deficiency syndrome.
- Counseling on domestic violence and sexual abuse.
- Counseling on obtaining employment, including the importance of graduating from a secondary school.
- Reasonable efforts to preserve and support the family units of the women, including promoting the appropriate involvement of parents and others, and counseling the children of the women.
- Planning for and counseling to assist reentry into society, both before and after discharge, including referrals to any public or nonprofit private entities in the community involved that provide services appropriate for the women and the children of the women.
- Case management services, including-
  - assessing the extent to which authorized services are appropriate for the women and their children;
  - in the case of the services that are appropriate, ensuring that the services are provided in a coordinated manner; and
  - assistance in establishing eligibility for assistance under Federal, State, and local programs providing health services, mental health services, housing services, employment services, educational services, or social services.

The Director of the Center for Behavioral Health Statistics and Quality (CBHSQ), in cooperation with grant recipients, will conduct an evaluation of the pilot program, beginning one year after the first grant is awarded. The Director of CBHSQ, in coordination with the Director of CSAT, will then submit an evaluation report to the relevant committees of the Senate and House of Representatives. The report will include information on pilot program outcomes, including any reductions in the use of substances, engagement in treatment services, retention in the appropriate level of care, and access to medications approved by the Food and Drug Administration (FDA) for the treatment of substance use disorders in combination with counseling. Although this section calls for the pilot program to sunset after 5 years, the report to Congress would include a recommendation by the Director of CSAT as to whether the pilot program should be extended beyond 5 years.

This section authorizes \$16,900,000 for each of fiscal years 2017 through 2021 to carry out the reauthorized residential services grant program for pregnant and postpartum women. Of those funds, not more than 25 percent of the funds appropriated to the residential services grant program may be used to implement the pilot program. The pilot program would not move forward unless funding for the overall program is above the FY 2016 level (\$15,900,000).

### Section 502: Veterans' Treatment Courts

This section amends Section 2991 of the Omnibus Crime Control and Safe Streets Act of 1968 by adding that the Attorney General, in consultation with the Secretary of Veterans Affairs, may award grants to establish or expand veterans treatment court programs; peer-to-peer services or programs for qualified veterans; practices that identify and provide treatment, rehabilitation, legal, transitional, and other appropriate services to qualified veterans who have been incarcerated; or 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. In awarding grants under this subsection, the Attorney General may prioritize applications that: demonstrate collaboration between and joint investments by criminal justice, mental health, substance abuse, and veterans service agencies; promote effective strategies to identify and reduce the risk of harm to qualified veterans and public safety; and propose interventions with empirical support to improve outcomes for qualified veterans. Those veterans dishonorably discharged due to a substance use disorder are eligible to participate in this program. The Attorney General may prioritize applications that demonstrate collaboration with State substance abuse agencies.

### Section 503: Infant Plan of Safe Care

This section amends Section 103 of the Child Abuse Prevention and Treatment Act (CAPTA) by adding that the Secretary of HHS will maintain and disseminate information about the best practices relating to the development of plans of safe care for infants born and identified as being affected by substance abuse or withdrawal symptoms, or a Fetal Alcohol Spectrum Disorder. Section 106 of CAPTA is amended by adding that a State plan will (1) ensure the safety and well-being of an infant following release from the care of health care providers, including through **addressing the health and substance use disorder treatment needs of the infant and affected family or caregiver**; and (2) the development and implementation by the State of monitoring systems regarding the implementation of plans to determine whether and in what manner local entities are providing, in accordance with State requirements, referrals to and delivery of appropriate services for the infant and affected family or caregiver. Section 106 CAPTA is also amended by adding to the contents of data reports the number of infants for whom a plan of safe care was developed, and for whom a referral was made for appropriate services, including services for the affected family or caregiver. This section amends title I of CAPTA by adding a section on monitoring and oversight.

### Section 504: GAO Report on Neonatal Abstinence Syndrome (NAS)

This section calls for the Comptroller General to submit to Congress a report on NAS. The report will include information on the prevalence of NAS, Medicaid coverage of NAS treatment, costs associated with NAS treatment, utilization of various care settings under State Medicaid programs for NAS treatment, as well as best practices for NAS treatment. The report will also include recommendations for improvements that will ensure access to treatment for infants with NAS under State Medicaid programs.

## *Title VI: Incentivizing State Comprehensive Initiatives to Address Opioid and Heroin Abuse*

### Section 601: State Demonstration Grants for Comprehensive Opioid Abuse Response

This section authorizes the Secretary of HHS to award **grants to States and combinations of States to implement an integrated opioid abuse response initiative**. For the purposes of this section, a "prescriber of a Schedule II, III, or IV controlled substance" does not include a prescriber that dispenses the substance for use on the premises, in a hospital emergency room, for a certified opioid treatment program, or in other situations that the Secretary may identify. Comprehensive response plans will include:

- Educational efforts around heroin and opioid use, treatment, and recovery.
- A comprehensive prescription drug monitoring program (PDMP) to track the dispensing of Schedule II, III, or IV controlled substances.
- Developing, implementing, or expanding the opioid treatment program of the State by:
  - Expanding programs for medication-assisted treatment (MAT);
  - Developing, implementing, or expanding programs to screen and treat individuals who are in treatment for prescription drug and opioid use disorders for hepatitis C and HIV;
  - Developing, implementing, or expanding recovery support services in high schools and higher

education institutions.

- Developing, implementing, and expanding programs to prevent opioid overdose death.
- Raising awareness of the public, patients, and others regarding opioid use disorders.

This section authorizes \$5 million for each of fiscal years 2017 through 2021.

### ***Title VII: Miscellaneous***

#### **Section 701: Grant Accountability and Evaluations**

This section amends title I of the Omnibus Crime Control and Safe Streets Act of 1968 to add “Sec. 3026. Grant Accountability.” This section defines the term “applicable committees” as:

- For the Attorney General and any other official of the Department of Justice, the Committee on the Judiciary of both the Senate and the House of Representatives.
- For the Secretary of Health and Human Services and any other official of the Department of Health and Human Services, means, the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives.

This section covers **accountability provisions for all grants awarded within this Act**, including audit requirements, nonprofit organization requirements, conference expenditures, and annual certification. Additionally, this section requires that the Attorney General or Secretary of Health and Human Services compare potential grant awards with other grants awarded under this Act to determine if duplicate grant awards are awarded for the same purpose.

#### **Section 702: Partial Fills of Schedule II Controlled Substances**

This section amends section 309 of the Controlled Substances Act by adding that a prescription for a controlled substance in schedule II may be partially filled if: (A) it is not prohibited by State law; (B) the prescription is written and filled in accordance with this title, regulations prescribed by the Attorney General, and State law; (C) the partial fill is requested by the patient or the practitioner that wrote the prescription; and (D) the total quantity dispensed in all partial fillings does not exceed the total quantity prescribed. Remaining portions of a partially filled prescription may be filled within 30 days after the date on which the prescription is written. In emergency situations, the remaining portions of a partially filled prescription may be filled within 72 hours after the prescription is issued.

#### **Section 703: Good Samaritan Assessment**

This section calls for the Comptroller General to submit to Congress a report on the extent to which the Director of National Drug Control Policy has reviewed Good Samaritan laws, and any findings from the review; efforts by the Director to encourage the enactment of Good Samaritan laws; and a compilation of Good Samaritan laws in effect in the States, the territories, and the District of Columbia.

#### **Section 704: Programs to Prevent Prescription Drug Abuse Under Medicare Parts C and D**

This section amends Section 1860D–4(c) of the Social Security Act by adding that a Prescription Drug Plan (PDP) sponsor may establish a drug management program for Medicare part D beneficiaries who are at risk of prescription drug misuse. The program will require that individuals at-risk are sent notices that they have been identified as at-risk, information on addiction treatment services, State and federal public health resources that address prescription drug abuse, and other information. The section also requires a GAO report on the implementation and effectiveness of the at-risk beneficiaries for prescription drug abuse drug management programs authorized by this section.

#### **Section 705: Excluding Abuse-Deterrent Formulations of Prescription Drugs from the Medicaid Additional Rebate Requirement for New Formulations of Prescription Drugs**

This section amends by adding that “line extension” means, with respect to a drug, a new formulation of the drug, such as an extended release formulation, but does not include an abuse-deterrent formulation of the drug (as determined by the Secretary), regardless of whether the abuse-deterrent formulation is an extended release formulation.

**Section 706: Limiting Disclosure of Predictive Modeling and Other Analytics Technologies to Identify and Prevent Waste, Fraud, and Abuse**

This section amends Title XI of the Social Security Act by adding a new section on Disclosure of Predictive Modeling and Other Analytics Technologies to Identify and Prevent Waste, Fraud, and Abuse. In implementing provisions with respect to covered algorithms, the covered algorithms used or will be exempt from disclosure. Additionally, a State agency may not use or disclose covered algorithms except for purposes of administering the State plan under the Medicaid program or the State child health plan under the Children’s Health Insurance Program. This section defines a covered algorithm as a predictive modeling or other analytics technology, as used to identify and prevent waste, fraud, and abuse with respect to the Medicare program, the Medicaid program, and the Children’s Health Insurance Program; and it includes the mathematical expressions utilized in the application of such technology and the means by which the technology is developed.

**Section 707: Medicaid Improvement Fund**

This section amends section 1941 of the Social Security Act by adding that \$5 million will be available to the Fund for fiscal year 2021 and thereafter.

**Section 708: Sense of the Congress Regarding Treatment of Substance Abuse Epidemics**

The Sense of Congress is that experience and research demonstrate that a fiscally responsible approach to substance use disorder epidemics is to treat them as public health emergencies that require prevention, treatment, and recovery.

***Title VIII: Kingpin Designation Improvement***

**Section 801: Protection of Classified Information in Federal Court Challenges Relating to Designations Under Narcotics Kingpin Designation Act**

This section amends section 804 of the Foreign Narcotics Kingpin Designation Act by adding that in any judicial review, if the determination was based on classified information, that information may be submitted to the reviewing court ex parte and in camera.

***Title IX: Department of Veterans Affairs***

**Section 901: Short Title**

This section is identified as the Jason Simcakoski Memorial and Promise Act.

**Section 902: Definitions**

This section provides definitions for “controlled substance,” “State,” “complementary and integrative health,” and “opioid receptor antagonist.”

**Subtitle A—Opioid Therapy and Pain Management**

**Section 911: Improvement of Opioid Safety Measures by Department of Veterans**

This section calls for the Secretary of Veterans Affairs to expand the Opioid Safety Initiative of the Department of Veterans Affairs to include all medical facilities of the Department. The Secretary of HHS will establish guidance to ensure that VA health care providers use the Opioid Therapy Risk Report tool of the Department of Veterans Affairs before initiating opioid therapy to treat a patient. The Secretary will also establish enhanced standards with respect to the use of routine and random urine drug tests for patients before and during opioid therapy to help prevent substance abuse, dependence, and diversion. In carrying out the Opioid Safety Initiative of the Department, the Secretary will require all employees of the Department responsible for prescribing opioids to receive education and training. Also in carrying out the Opioid Safety Initiative, the director of each medical facility of the Department will identify and designate a pain management team of health care professionals.

**Section 912: Strengthening of Joint Working Group on Pain Management of the Department of Veterans Affairs and the Department of Defense**

This section calls for the Secretary of Veterans Affairs and the Secretary of Defense to 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) 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 in treating such individuals.
- (4) The concurrent use and practice by health care providers of each Department of opioids and prescription drugs to treat mental health disorders, including benzodiazepines.
- (5) The use of care transition plans by health care providers of each Department to address case management issues for patients receiving opioid therapy who transition between inpatient and outpatient care.
- (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 properly screen, identify, refer, and treat patients with substance use disorders who are seeking treatment for acute and chronic pain management conditions.

The Secretary of Veterans Affairs and the Secretary of Defense must ensure that the working group: coordinates their activities with other relevant working groups; consults with other relevant Federal agencies, including the Centers for Disease Control and Prevention; and consults with the Department of Veterans Affairs and the Department of Defense (DOD) with respect to the VA/DOD Clinical Practice Guideline for Management of Opioid Therapy for Chronic Pain.

#### **Section 913: Review, Investigation, and Report on Use of Opioids in Treatment by Department of Veterans Affairs**

This section calls for the Comptroller General to 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 Opioid Safety Initiative of the Department of Veterans Affairs and the opioid prescribing practices of health care providers of the Department.

#### **Section 914: Mandatory Disclosure of Certain Veteran Information to State Controlled Substance Monitoring Programs**

This section amends section 5701 of title 38 of United States Code by requiring the disclosure of certain veteran information to the State drug monitoring program.

#### **Section 915: Elimination of Copayment Requirement for Veterans Receiving Opioid Antagonists or Education on Use of Opioid Antagonists**

This section amends section 38 of United States Code by adding that co-payments do not apply to opioid antagonists for a veteran who is at high risk for overdose of a specific medication or substance in order to reverse the effect of an overdose.

### **Subtitle B—Patient Advocacy**

#### **Section 921: Community Meetings on Improving Care Furnished by Department of Veterans Affairs**

This section calls for the Secretary of HHS to ensure that every 90 days each VA medical facility and each VA community-based outpatient clinic hosts a community meeting open to the public on improving health care. Each meeting must be attended by Director of the Veterans Integrated Service Network in which the medical facility or community-based outpatient clinic is located.

#### **Section 922: Improvement of Awareness of Patient Advocacy Program and Patient Bill of Rights of Department of Veterans Affairs**

This section calls for the Secretary of Veterans Affairs to publicly display the purposes of the Patient Advocacy Program of the Department and the contact information for the patient advocate.



**Section 923: Comptroller General Report on Patient Advocacy Program of Department of Veterans Affairs**

This section requires the Comptroller General to 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 Patient Advocacy Program of the Department of Veterans Affairs.

**Section 924: Establishment of Office of Patient Advocacy of the Department of Veterans Affairs**

This section establishes the Office of Patient Advocacy within the Department within the Office of the Under Secretary for Health. The Office will be headed by the Director of the Office of Patient Advocacy, who will ensure that patient advocates: advocate on behalf of veterans with respect to health care received and sought by veterans; carry out the responsibilities specified in this Act; and receive training in patient advocacy.

**Subtitle C—Complementary and Integrative Health**

**Section 931: Expansion of Research and Education on and Delivery of Complementary and Integrative Health to Veterans**

This section establishes the "Creating Options for Veterans' Expedited Recovery" or the "COVER Commission." The Commission will examine the evidence-based therapy treatment model used by the Secretary of Veterans Affairs for treating mental health conditions of veterans and the potential benefits of incorporating complementary and integrative health treatments available in non-Department facilities.

**Section 932: Expansion of Research and Education on and Delivery of Complementary and Integrative Health to Veterans**

This section calls for the Secretary of Veterans Affairs to develop a plan to expand the scope of the effectiveness of research and education on, and delivery and integration of, complementary and integrative health services into the health care services provided to veterans.

**Section 933: Pilot Program on Integration of Complementary and Integrative Health and Related Issues for Veterans and Family Members of Veterans**

This section calls for the Secretary of HHS to establish a pilot program to assess the feasibility and advisability of using complementary and integrative health and wellness-based programs to complement the provision of pain management and other health care services, including mental health care services, to veterans. Within 30 months after the start of the pilot program, the Secretary will submit to Congress a report on the findings and conclusions of the program.

**Subtitle D—Fitness of Health Care Providers**

**Section 941: Additional Requirements for Hiring of Health Care Providers by Department of Veterans Affairs**

This section addresses the Secretary of Veterans Affairs' requirements for health care providers applying for a job at the VA. The Secretary of the VA will require from the medical board of each State in which a health care provider has a medical license information on any violation of the medical license requirements in the past 20 years. The Secretary will also require information on whether the health care provider has entered into any settlement agreement for a disciplinary charge relating to the practice of medicine.

**Section 942: Provision of Information on Health Care Providers of Department of Veterans Affairs to State Medical Boards**

This section calls for the Secretary of the VA to provide to the medical board of the State(s) in which a health care provider is licensed detailed information on any medical license violation, regardless of whether or not the State board has formally requested such information.

**Section 943: Report on Compliance by Department of Veterans Affairs with Reviews of Health Care Providers Leaving the Department or Transferring to Other Facilities**

This section calls for the Secretary of Veterans Affairs to submit to Congress a report on the compliance by the Department of Veterans Affairs with the policy of the Department to conduct a review of each health care provider of the Department who transfers to another medical facility of the Department, resigns, retires, or is

terminated to determine whether there are any concerns, complaints, or allegations of violations relating to the medical practice of the health care provider; and to take appropriate action with respect to any concern, complaint, or allegation.

**Subtitle E—Other Matters**

**Section 951: Modification to Limitation on Awards and Bonuses**

This section amends section 705 of the Veterans Access, Choice, and Accountability Act of 2014. This amended section calls for the Secretary of Veterans Affairs to ensure that the aggregate amount of awards and bonuses paid by the Secretary in a fiscal year or any other awards or bonuses do not exceed a certain amount. This section additionally states that the Sense of Congress is that this limitation on awards and bonuses should not disproportionately impact lower-wage employees.