

# The Comprehensive Addiction and Recovery Act of 2016 (S. 524): Comparison of Senateand House-Passed Versions

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## Summary

The Comprehensive Addiction and Recovery Act of 2016 (CARA; S. 524) aims to address the problem of opioid addiction in the United States. It passed the Senate (S. 524 ES) on March 10, 2016, and it passed the House with an amendment in the nature of a substitute (S. 524 EAH) on May 13, 2016. The two versions of the bill differ substantially. The scope of the differences may be illustrated by their structures: The Senate bill has 28 sections organized in 8 titles, whereas the House bill has 69 sections organized in 18 titles. This report discusses selected differences and similarities between the Senate- and House-passed versions of S. 524.

Both bills include provisions that would authorize new activities, provisions that would reauthorize and amend existing activities, and provisions that would codify activities already taking place. Few provisions, however, are directly comparable across the two bills. The bills include two parallel provisions, which share the same headings and would require or authorize similar activities: (1) Pain Management Best Practices Interagency Task Force and (2) Grants for Treatment of Pregnant and Postpartum Women.

More often, the two bills include provisions addressing the same theme in different ways. Common themes include comprehensive opioid abuse grants, accountability of grantees, veterans, criminal justice provisions, and access to naloxone to reverse opioid overdose.

Each bill also includes provisions for which the other bill has no comparable provisions; see **Appendix A** for a summary of the Senate bill and **Appendix B** for a summary of the House bill.

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## Background

The Comprehensive Addiction and Recovery Act of 2016 (CARA; S. 524) aims to address the problem of opioid addiction in the United States. It passed the Senate (S. 524 ES) on March 10, 2016,<sup>1</sup> and it passed the House with an amendment in the nature of a substitute (S. 524 EAH) on May 13, 2016.<sup>2</sup> The two versions of the bill differ substantially. The scope of the differences may be illustrated by their structures: The Senate bill has 28 sections organized in 8 titles, whereas the House bill has 69 sections organized in 18 titles.<sup>3</sup> This report discusses selected differences and similarities between the Senate- and House-passed versions of S. 524.

#### For More Information

CRS Report R43749, Drug Enforcement in the United States: History, Policy, and Trends CRS Report R43559, Prescription Drug Abuse CRS Report R42593, Prescription Drug Monitoring Programs CRS Report R44467, Federal Support for Drug Courts: In Brief CRS In Focus IF10400, Heroin Production in Mexico and U.S. Policy CRS In Focus IF10219, Opioid Treatment Programs and Related Federal Regulations

## **Comparison of Senate- and House-Passed CARA**

Both the House- and Senate-passed bills include provisions that would authorize new activities, provisions that would reauthorize and amend existing activities, and provisions that would codify activities already taking place. Few provisions, however, are directly comparable across the two bills. More often, the two bills include provisions addressing the same theme in different ways. Each bill also includes provisions for which the other bill has no comparable provisions; see **Appendix A** for a summary of the Senate bill and **Appendix B** for a summary of the House bill.

### **Parallel Provisions in Both Bills**

The bills include two parallel provisions, which share the same headings and would require or authorize similar activities: (1) Pain Management Best Practices Interagency Task Force and (2) Grants for Treatment of Pregnant and Postpartum Women.

#### Pain Management Best Practices Interagency Task Force

Both the Senate bill (Section 101) and the House bill (Title I) would require the Secretary of Health and Human Services (HHS) to convene an interagency task force to review, modify, and update best practices for prescribing pain medication and managing chronic and acute pain. Both bills would specify the membership, duties, limitations, and reporting requirements for the task force; however, each bill would specify such factors differently (except for task force limitations). The House version would also specify conditions of participation and consideration of other studies.

<sup>&</sup>lt;sup>1</sup> Congressional Record, vol. 162, part 39 (March 10, 2016), pp. S1404-S1416.

<sup>&</sup>lt;sup>2</sup> Congressional Record, vol. 162, part 76 (May 13, 2016), pp. H2355-H2374.

<sup>&</sup>lt;sup>3</sup> In both cases, some of the sections are short titles, findings, or definitions.

#### Grants for Treatment of Pregnant and Postpartum Women

Both the Senate bill (Section 501) and the House bill (Title X) would reauthorize and amend an existing grant program supporting residential treatment of pregnant and postpartum women with a primary diagnosis of a substance use disorder. Both bills would require the Director of the Center for Substance Abuse Treatment, within the Substance Abuse and Mental Health Services Administration (SAMHSA), to carry out a pilot program, which would be specified somewhat differently in each bill. The two bills would authorize different amounts to be appropriated over different periods. Both would allow up to 25% of the appropriated amount to be used for the pilot program grants; however, the House bill would make this conditional on the amount appropriated. The House bill would also include an offset.

## **Themes Addressed in Both Bills**

The two bills are similar with regard to authorizing comprehensive opioid abuse grants, setting forth provisions to require accountability of grantees, addressing opioid abuse among veterans, including criminal justice provisions, and increasing access to naloxone to reverse opioid overdose.

#### **Comprehensive Opioid Abuse Grants**

Both bills would amend existing law and authorize new grant activity and funds for states, tribes, and local governments to address opioid abuse. Both bills would authorize funds to be used for

- first responder training for the administration of opioid overdose reversal;
- treatment alternatives to incarceration (the bills specifically identify drug courts, veterans treatment courts,<sup>4</sup> and other alternatives);
- investigative activities to combat the unlawful distribution of opioids;
- prescription drug monitoring programs (state applicants only);<sup>5</sup>
- medication-assisted treatment programs;<sup>6</sup>
- prescription drug take-back activities;
- programs that address youth or juvenile substance abuse; and
- comprehensive opioid abuse response plans.

Notably, the bills would authorize these activities in different ways. Moreover, the House bill would authorize funds to go toward programs to use technology that provides a secure container for prescription drugs, whereas the Senate bill does not contain such a provision.

Both bills authorize funding for programs in HHS and the Department of Justice (DOJ). For further explanation of what grants would be authorized by these bills if enacted, see **Appendix A** and **Appendix B**.

<sup>&</sup>lt;sup>4</sup> For more information about drug courts and veterans treatment courts, see CRS Report R44467, *Federal Support for Drug Courts: In Brief.* 

<sup>&</sup>lt;sup>5</sup> For more information about prescription drug monitoring programs, see CRS Report R42593, *Prescription Drug Monitoring Programs*.

<sup>&</sup>lt;sup>6</sup> The House bill specifies that funds for medication-assisted treatment programs are to be used or operated by a criminal justice agency, whereas the Senate bill does not specify this.

#### Accountability of Grantees

Both bills would require various measures of grant accountability for programs that would be established by the bills as well as specific requirements for nonprofits. For example, both bills would require annual audits and other accountability of grantees receiving grants from DOJ. The House bill would go further in requiring an evaluation of performance for opioid abuse grant programs at both DOJ and HHS.

#### Veterans

If enacted, both bills would address the combined mental health and substance abuse treatment needs of justice-involved veterans, but they would do so in different ways. The House bill would amend 42 U.S.C. §3797aa (adult and juvenile collaboration programs) to include authorized assistance for veterans under DOJ.<sup>7</sup> Of note, since FY2013, the DOJ's Bureau of Justice Assistance has funded veterans treatment courts through the Drug Court Discretionary Grant Program.<sup>8</sup> The Senate bill does not have such a provision; rather, Section 503 of the Senate bill would amend 42 U.S.C. §3797aa *as it would be amended by a separate bill that has passed the Senate but has not been enacted* (S. 993).<sup>9</sup> Section 5 of S. 993 would amend 42 U.S.C. §3797aa by adding a new subsection (j) that would authorize a veterans treatment court program and define the term *qualified veteran* for participation in the program. Section 503 of CARA would further amend 42 U.S.C. §3797aa by expanding the *proposed* definition of a qualified veteran for participation in the veterans treatment court program (which would be authorized if S. 993 were enacted) to include those veterans who are discharged or released under dishonorable conditions if the reason, if known, is attributable to a substance use disorder.

The House bill would require the Secretary of Veterans Affairs (VA) to expand VA's Opioid Safety Initiative, implement education and training requirements for VA employees who prescribe opioids, establish protocols for the designation of a pain management team at each VA medical facility, ensure access to state prescription drug monitoring program (PDMP) data, maximize availability of naloxone, modify VA's Opioid Therapy Risk Report tool, and flag the health records of veterans at risk of opioid abuse, among other things. See **Appendix B** for further details on this provision. The Senate bill does not have such provisions.

#### **Criminal Justice Provisions (Non-grant)**

Both bills contain various provisions for federal law enforcement and courts, but not all provisions are opioid-related. For example, the House bill would authorize \$20 million in emergency federal law enforcement assistance funds for each fiscal year ending *after* FY2021. It would eliminate the current authorization (42 U.S.C. 10513(a)) of appropriations of \$20 million annually for DOJ to make grants to state and local governments for law enforcement

<sup>&</sup>lt;sup>7</sup> The House bill would authorize a veterans assistance program under DOJ that would support grants for (1) veterans treatment court programs; 2) peer-to-peer services or programs for qualified veterans; (3) practices that identify and provide services to qualified veterans who have been incarcerated; and (4) training programs to teach criminal justice, law enforcement, corrections, mental health, and substance abuse personnel how to identify and appropriately respond to incidents involving veterans. The Attorney General would give priority to applicants that (1) demonstrate collaboration between criminal justice, mental health, substance abuse, and veteran service agencies; (2) promote effective strategies to address risk of harm to qualified veterans and public safety; and (3) propose intervention with empirical support to improve outcomes for qualified veterans.

<sup>&</sup>lt;sup>8</sup> For more information, see CRS Report R44467, *Federal Support for Drug Courts: In Brief.* 

<sup>&</sup>lt;sup>9</sup> Comprehensive Justice and Mental Health Act of 2015 (S. 993).

emergencies. The House bill also would amend the Foreign Narcotics Kingpin Designation Act<sup>10</sup> to protect classified information from disclosure in the case of any judicial review in federal court of a determination made pursuant to such classified information. The Senate bill contains neither of these changes.

The Senate version of S. 524 would expand federal law to include new drug offenses, whereas the House bill does not contain such provisions. Of note, the Transnational Drug Trafficking Act of 2015 (S. 32) passed the Senate on October 7, 2015, and subsequently passed the House on May 10, 2016. It was incorporated into the Senate-passed CARA; however, its provisions were *not* included in the House-passed CARA.

#### Access to Naloxone to Reverse Opioid Overdose

Both bills aim to increase access to drugs (or devices) that can reverse the effects of an opioid overdose. Naloxone is the only such product currently on the market. The Senate bill includes a single provision (Section 202) focused on supporting administration of naloxone by appropriately trained first responders under specified circumstances. Relative to the Senate bill, the House bill takes a broader approach to increasing access to naloxone. In addition to including first responder training in naloxone administration as one of several allowable uses of grant funds under Title II, the House bill has two titles aimed at encouraging naloxone use by people who need not be first responders. Title IX focuses on co-prescribing naloxone along with prescription opioids. Title XIII would support co-prescribing, the use of standing orders (which allow a prescription drug such as naloxone to be dispensed to anyone meeting specified criteria), and public education about naloxone.

<sup>&</sup>lt;sup>10</sup> 21 U.S.C. §1903.

# Appendix A. Summary of Senate Version of CARA

The Comprehensive Addiction and Recovery Act of 2016 (CARA; S. 524 ES), as passed in the Senate, would authorize various initiatives and grants within the Department of Health and Human Services (HHS) and the Department of Justice (DOJ) that would address opioid abuse in the United States.

## Title I. Prevention and Education

#### Section 101. Development of Best Practices for the Use of Prescription Opioids

Section 101 would require the HHS Secretary, in cooperation with the Veterans Affairs (VA) and Defense Secretaries and the Administrator of the Drug Enforcement Administration (DEA), to convene an interagency task force to review, modify, and update best practices for prescribing pain medication and managing chronic and acute pain. Section 101 would specify the membership, duties, limitations, and reporting requirements for the task force.

#### Section 102. Awareness Campaigns

Section 102 would require the HHS Secretary, in coordination with the Attorney General, to "advance the education and awareness of the public, providers, patients, consumers, and other appropriate entities" regarding the risk of prescription drug abuse. It would require the Director of the Office of National Drug Control Policy (ONDCP), in coordination with the HHS Secretary, to establish a national drug awareness campaign that takes into account the association between prescription drug abuse and heroin use, emphasizes the effects of and similarities between heroin and prescription opioids, and raises public awareness regarding the dangers of fentanyl.<sup>11</sup>

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

Section 103 would replace a previously authorized grant program<sup>12</sup> and create a new grant program for organizations that have received a grant under the Drug Free Communities Act of 1997 and are in an area with documented higher rates of opioid abuse. It would allow the HHS Secretary, in coordination with the ONDCP Director, to make grants to eligible entities to implement comprehensive community-wide strategies to address the local drug crisis.

## Title II. Law Enforcement and Treatment

#### Section 201. Treatment Alternative to Incarceration Programs

Section 201 would allow the HHS Secretary, in coordination with the Attorney General, to award grants to state, tribal, and local governments or nonprofit organizations for the purpose of developing, implementing, or expanding treatment alternatives to incarceration (which would include a variety of pre-arrest and pre-booking treatment or diversionary programs) or to facilitate

<sup>&</sup>lt;sup>11</sup> Fentanyl is a prescription pain medication similar to morphine. See HHS, National Institutes of Health, National Institute on Drug Abuse, *Fentanyl*, at https://www.drugabuse.gov/drugs-abuse/fentanyl.

<sup>&</sup>lt;sup>12</sup> Part II of Title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. §§3797cc et seq.) would be amended by striking §2997 and inserting new language from §103 of CARA.

or enhance planning between state criminal justice and substance abuse systems to more effectively implement treatment alternatives to incarceration. Eligible participants would be individuals who (1) come into contact with the juvenile or criminal justice system or have been arrested or charged with an offense that is not a crime of violence<sup>13</sup> or a serious drug offense;<sup>14</sup> (2) have a current substance abuse or co-occurring mental health and substance abuse issue; and (3) are approved, based on their point of involvement in the juvenile or criminal justice system by the relevant officials. Section 201 would allow the HHS Secretary to use no more than \$5 million of the funds made available to SAMHSA for "criminal justice activities" to carry out the section for each of five fiscal years after enactment.

### Section 202. First Responder Training for the Use of Drugs and Devices That Rapidly Reverse the Effects of Opioids

Section 202 would allow the HHS Secretary, in coordination with the Attorney General, to award grants to state, local, and tribal governments to allow appropriately trained first responders to administer an opioid overdose reversal drug to an individual who (1) has experienced a prescription opioid or heroin overdose or (2) has been determined to have likely experienced a prescription opioid or heroin overdose. Funds under the program could be used to make Food and Drug Administration-approved opioid overdose reversal drugs or devices, such as naloxone, available to first responders; train first responders how to use an opioid overdose reversal drug or device; and establish processes, protocols, and mechanisms for referral to appropriate treatment. Section 202 would require the HHS Secretary to award technical assistance grants and conduct an evaluation of grants awarded under the section.

#### Section 203. Prescription Drug Take-Back Expansion

Section 203 would require the Attorney General, in coordination with the DEA Administrator, the HHS Secretary, and the ONDCP Director, to coordinate with covered entities (including but not limited to state, local, or tribal law enforcement agencies) to expand or make available disposal sites for unwanted prescription drugs.

#### Section 204. Heroin and Methamphetamine Task Forces

Section 204 would authorize the Attorney General to make grants to state law enforcement agencies to use task forces to investigate the trafficking and distribution of heroin, fentanyl, and prescription opioids and to investigate methamphetamine trafficking, laboratories, and precursor diversion.

## Title III. Treatment and Recovery

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

Section 301 would allow the HHS Secretary, acting through the Director of SAMHSA's Center for Substance Abuse Treatment and in coordination with the Attorney General and others, to award grants to state substance abuse agencies, units of local government, nonprofit

<sup>&</sup>lt;sup>13</sup> As defined at 18 U.S.C. §16.

<sup>&</sup>lt;sup>14</sup> As defined at 18 U.S.C. §924(e)(2)(A).

organizations, and Indian tribes or tribal organizations that have a high rate or have had a rapid increase in the use of heroin or other opioids, for the purposes of expanding addiction treatment, including medication-assisted treatment. Section 301 would require the HHS Secretary to ensure equitable geographic distribution of the grants and to carry out four "additional activities"—(1) evaluate the activities supported by the grants, (2) disseminate information from such evaluations, (3) provide technical assistance, and (4) fund only applications that specifically support recovery services.

### Section 302. Criminal Justice Medication-Assisted Treatment and Interventions Demonstration

Section 302 would allow the HHS Secretary, in coordination with the Attorney General, to award grants to states, units of local government, or Indian tribes to implement medication-assisted treatment (MAT) programs through courts, prisons, jails, or other agencies that administer criminal justice. Grants could be used for expenses related to a MAT program, training personnel and treatment providers on MAT, cross-training personnel providing behavioral health and health services, and the provision of recovery coaches, who are responsible for providing mentorship and transition plans to individuals reentering society following incarceration (or alternatives to incarceration). Section 302 would require the HHS Secretary, in coordination with the Attorney General and the Director of the National Institute on Drug Abuse, to provide technical assistance and training to grantees. It would allow the HHS Secretary to use no more than \$5 million of the funds made available to SAMHSA for "criminal justice activities" to carry out the section for each of five fiscal years after enactment.

#### Section 303. National Youth Recovery Initiative

Section 303 would allow the HHS Secretary, in coordination with the Secretary of Education, to award grants to high schools (as specified), institutions of higher education, recovery programs at nonprofit collegiate institutions, or nonprofit organizations for youth recovery support services.

#### Section 304. Building Communities of Recovery

Section 304 would allow the HHS Secretary to award grants to "recovery community organizations" (defined as nonprofit organizations wholly or principally governed by people in recovery, among other characteristics) for recovery services.

## Title IV. Addressing Collateral Consequences

#### Section 401. Correctional Education Demonstration Grant Program

Section 401 would allow the Attorney General to make grants to state, local, and tribal governments and nonprofit organizations to design, implement, and expand education programs for offenders in prisons, jails, and juvenile facilities.

#### Section 402. National Task Force on Recovery and Collateral Consequences

Section 402 would require the Attorney General, within 30 days of enactment, to establish a bipartisan Task Force on Recovery and Collateral Consequences to identify collateral consequences (i.e., "a penalty, disability, or disadvantage imposed ... as a result of criminal conviction but not as part of the judgment"); to examine any policy basis for such collateral consequences; and to examine the effect of such collateral consequences on individuals in

recovery resuming their personal and professional activities. Section 402 would require the task force to develop recommendations for proposed legislative and regulatory changes related to such collateral consequences. It would also require the task force to hold hearings, require testimony and attendance of witnesses, and secure information from federal departments or agencies. Finally, the task force, within one year of its first meeting, would be required to submit a report with findings and recommendations to the head of each relevant federal department or agency, the President, and the Vice President; these recipients would then be required to submit to Congress any legislative recommendations they consider appropriate.

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

#### Section 501. Improving Treatment for Pregnant and Postpartum Women

Section 501 would reauthorize and amend an existing grant program supporting residential treatment of pregnant and postpartum women with a primary diagnosis of a substance use disorder. It would require the Director of SAMHSA's Center for Substance Abuse Treatment to carry out a pilot program awarding competitive grants to state substance abuse agencies to enhance flexibility in the use of funds, help identify gaps in services, and encourage new approaches and models of service delivery. For the pilot program grants, the section would specify grant purposes, requirements for awarding grants, minimum services to be provided through the grants, maximum duration, and evaluation and reporting requirements. It would authorize to be appropriated for the existing program \$15.9 million for each of FY2016–FY2020. Up to 25% of the appropriated amount would be available to be used for the pilot program grants.

#### Section 502. Report on Grants for Family-Based Substance Abuse Treatment

Section 502 would require the Attorney General to submit an annual report to Congress that describes the number of grants awarded under Section 2921(1) of the Omnibus Crime Control and Safe Streets Act of 1968 (P.L. 90-351) and how these grants are used for family-based substance abuse treatment programs that serve as alternatives to incarceration. These programs enable custodial parents to receive treatment and services as a family.

#### Section 503. Veterans Treatment Courts

Section 503 would amend Section 2991(j) of the Omnibus Crime Control and Safe Streets Act of 1968 (P.L. 90-351) as Section 2991(j) would be amended by a separate bill that has passed the Senate but has not been enacted (S. 993, the Comprehensive Justice and Mental Health Act of 2015).<sup>15</sup> Section 5 of S. 993 would amend P.L. 90-351 by adding to the existing Section 2991 a new subsection (j) that would authorize several programs, including a veterans treatment court program, and would define the term *qualified veteran* for purposes of such programs. Section 503 of CARA would further amend P.L. 90-351 by changing the *proposed* definition of a qualified veteran for participation in the veterans treatment court program that would be authorized if S. 993 were enacted. Section 503 would expand the proposed definition to include those veterans who are discharged or released under dishonorable conditions if the reason, if known, is attributable to a substance use disorder.

<sup>&</sup>lt;sup>15</sup> Comprehensive Justice and Mental Health Act of 2015 (S. 993).

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

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

Section 601 would allow the Attorney General, in coordination with the HHS Secretary and in consultation with the ONDCP Director, to award grants to states (and combinations of states) to plan and implement an "integrated opioid abuse response initiative," allowing for both planning and implementation grants. For each year through FY2020, it would authorize the Attorney General to use up to \$5 million in unobligated balances from DOJ's General Administration account to carry out this section.

## Title VII. Miscellaneous

#### Section 701. GAO Report on IMD Exclusion

Section 701 would require a Government Accountability Office (GAO) report on how the Medicaid Institutions for Mental Disease (IMD) exclusion affects access to treatment for individuals with a substance use disorder.<sup>16</sup>

#### Section 702. Funding

Section 702 would authorize to be appropriated to the Attorney General and the HHS Secretary \$62 million for each year through FY2020 to carry out Part II of Title I of the Omnibus Crime Control and Safe Streets Act of 1968 (P.L. 90-351).

#### Section 703. Conforming Amendments

Section 703 includes conforming amendments.

#### Section 704. Grant Accountability

Section 704 would require various measures of grant accountability for programs that would be established by CARA and establish specific requirements for nonprofits.

# Section 705. Programs to Prevent Prescription Drug Abuse Under the Medicare Program

Section 705 would provide authority for (but not require) Medicare Part D plan sponsors to create a lock-in program to identify enrollees deemed at high risk of abusing prescription drugs and to limit such beneficiaries' choice of prescribers or pharmacies in order to better monitor their drug

<sup>&</sup>lt;sup>16</sup> The Social Security Act defines an IMD as "a hospital, nursing facility, or other institution of more than 16 beds, that is primarily engaged in providing diagnosis, treatment, or care of persons with mental diseases, including medical attention, nursing care, and related services." See Social Security Act §1905(i). For more information, see CRS In Focus IF10222, *Medicaid's Institutions for Mental Disease (IMD) Exclusion*. The Medicaid IMD exclusion generally applies to Medicaid-eligible individuals aged 21–64 who are patients in an IMD; such individuals cannot receive Medicaid coverage for services provided inside or outside the IMD.

use. Sponsors that do offer lock-in programs would provide beneficiaries deemed at risk of prescription drug abuse with notice of their status; consider beneficiaries' input on the allowable pharmacies and prescribers, so long as the beneficiaries' choices do not pose a risk of fraud or abuse; and provide beneficiaries the right to appeal and apply to terminate their at-risk status. Section 705 includes utilization management tools designed to prevent abuse of Part D drugs, such as retrospective utilization review and consultation with a Medicare Drug Integrity Contractor (MEDIC).

Section 705 would state the sense of Congress that Medicare Advantage organizations and Part D sponsors "should consider using e-prescribing and other health information technology tools to support combating fraud under MA-PD plans and the prescription drug plans under parts C and D of the Medicare Program." It would require a GAO report on the implementation of the section. In addition, it would require the HHS Secretary to submit to congressional committees a report on ways to improve upon the Medicare Part D appeals process.

## Title VIII. Transnational Drug Trafficking Act

#### Section 801. Short Title

Section 801 is the short title, Transnational Drug Trafficking Act.

# Section 802. Possession, Manufacture, or Distribution for Purposes of Unlawful Importations

Section 802 would make it unlawful to manufacture or distribute a Schedule I or II controlled substance, flunitrazepam, or listed chemical with the intent, knowledge, or reasonable cause to believe that it will then be unlawfully imported into the United States. The section would also make it unlawful to manufacture or distribute a listed chemical knowing or intending that the chemical will in turn be used to manufacture a controlled substance and knowing, intending, or having reasonable cause to believe that the controlled substance will then be unlawfully imported into the United States.

#### Section 803. Trafficking in Counterfeit Goods or Services

For the purposes of prosecuting an individual for trafficking in counterfeit goods or services (18 U.S.C. §2320), Section 803 would amend the list of offenses to include trafficking in a drug and knowingly using a counterfeit mark on or in connection with that drug. It would also amend the definition of a *counterfeit drug* to be a drug as defined by the Federal Food, Drug, and Cosmetic Act.

# Appendix B. Summary of House Version of CARA

The Comprehensive Addiction and Recovery Act of 2016 (CARA, S. 524 EAH) passed the House with an amendment in the nature of a substitute on May 13, 2016.<sup>17</sup> As shown in **Table B-1**, each of the 18 titles in the House-passed version of CARA previously passed the House as a standalone bill.

The summaries include information about Congressional Budget Office (CBO) cost estimates, where available. All of the included CBO estimates are based on the stand-alone bills, and many are based on the bills *as ordered to be reported*. The bills may have been amended between publication of the CBO cost estimates and passage of S. 524 EAH. As of this writing, CBO has not published a cost estimate for S. 524 EAH.

Title	Heading	Corresponding Stand-Alone Bill
Title I	Pain Management Best Practices Inter-Agency Task Force	H.R. 4641
Title II	Comprehensive Opioid Abuse Reduction Act	H.R. 5046
Title III	Jason Simcakoski PROMISE Act	H.R. 4063
Title IV	Kingpin Designation Improvement Act	H.R. 4985
Title V	Good Samaritan Assessment Act	H.R. 5048
Title VI	OPEN Act	H.R. 5052
Title VII	Infant Plan of Safe Care Improvement Act	H.R. 4843
Title VIII	NAS Healthy Babies Act	H.R. 4978
Title IX	Co-Prescribing to Reduce Overdoses Act	H.R. 3680
Title X	Improving Treatment for Pregnant and Postpartum Women Act	H.R. 3691
Title XI	Veteran Emergency Medical Technician Support Act	H.R. 1818
Title XII	John Thomas Decker Act	H.R. 4969
Title XIII	Lali's Law	H.R. 4586
Title XIV	Reducing Unused Medications Act	H.R. 4599
Title XV	Opioid Review Modernization Act	H.R. 4976
Title XVI	Examining Opioid Treatment Infrastructure Act	H.R. 4982
Title XVII	Opioid Use Disorder Treatment Expansion and Modernization Act	H.R. 4981
Title XVIII	National All Schedules Prescription Electronic Reporting Reauthorization Act	H.R. 1725

#### Table B-I. House Version of CARA: Titles and Corresponding Stand-Alone Bills

Source: CRS analysis of information on Congress.gov.

## Title I. Pain Management Best Practices Inter-Agency Task Force

Title I, Pain Management Best Practices Inter-Agency Task Force, would require the Secretary of Health and Human Services (HHS), in cooperation with the Veterans Affairs (VA) and Defense

<sup>&</sup>lt;sup>17</sup> Congressional Record, vol. 162, part 76 (May 13, 2016), pp. H2355-H2374.

Secretaries and the Administrator of the Drug Enforcement Agency (DEA), to convene an interagency task force to review, modify, and update best practices for prescribing pain medication and managing chronic and acute pain. Title I would specify the membership, conditions of participation, duties, consideration of other studies, limitations, and reporting requirements for the task force.

The corresponding stand-alone bill (H.R. 4641, which has no short title), as amended, passed the House by a vote of 412-4 on May 11, 2016.<sup>18</sup> CBO estimates that implementing the bill as ordered to be reported would cost \$2 million over the 2016-2021 period, assuming appropriation of the estimated amounts.<sup>19</sup>

## Title II. Comprehensive Opioid Abuse Reduction Act

Title II, Comprehensive Opioid Abuse Reduction Act, would amend the Omnibus Crime Control and Safe Streets Act of 1968 (P.L 90-351) to authorize the Attorney General to make grants to assist state and local governments and Indian tribes in addressing the national epidemic of opioid abuse, and for other purposes. Grant funds would go toward the following: treatment alternatives to incarceration (including specialized courts such as drug courts); planning and collaboration between state criminal justice agencies and substance abuse systems to address opioid abuse; training and resources for first responders' use of an opioid overdose reversal drug (e.g., naloxone); investigative activities related to unlawful distribution of opioids; medication-assisted treatment programs used or operated by a criminal justice agency; (for states only) prescription drug monitoring programs and interoperability with other states; programs to prevent and address opioid abuse by juveniles; integrated and comprehensive opioid response programs; programs to utilize technology that provides a secure container for prescription drugs; programs to prevent opioid abuse by veterans; and prescription drug take-back programs.

The Comprehensive Opioid Abuse Reduction Act of 2016 (H.R. 5046) would authorize a veterans assistance program under DOJ that would support grants for (1) veterans treatment court programs;<sup>20</sup> (2) peer-to-peer services or programs for qualified veterans; (3) practices that identify and provide services to qualified veterans who have been incarcerated; and (4) training programs to teach criminal justice, law enforcement, corrections, mental health, and substance abuse personnel how to identify and appropriately respond to incidents involving veterans. H.R. 5046 would authorize \$20 million in emergency federal law enforcement assistance funds for each fiscal year ending *after* FY2021. It would eliminate the current authorization<sup>21</sup> of appropriations of \$20 million annually for DOJ to make grants to state and local governments for law enforcement drug offenders to include pregnant women. It would require a Government Accountability Office (GAO) study and report on DOJ programs and research related to substance use disorders among adolescents and young adults.

<sup>&</sup>lt;sup>18</sup> Congressional Record, vol. 162, part 74 (May 11, 2016), pp. H2234-2247, 2253.

<sup>&</sup>lt;sup>19</sup> U.S. Congressional Budget Office, *H.R.* 4641, a bill 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, May 3, 2016, https://www.cbo.gov/publication/51519.

<sup>&</sup>lt;sup>20</sup> Of note, since FY2013, the DOJ, Bureau of Justice Assistance has funded veterans treatment courts through the Drug Court Discretionary Grant Program. For more information, see CRS Report R44467, *Federal Support for Drug Courts: In Brief.* 

<sup>&</sup>lt;sup>21</sup> 42 U.S.C. §10513(a).

H.R. 5046, as amended, passed the House by a vote of 413-5 on May 12, 2016.<sup>22</sup> CBO estimates that implementing the bill as ordered to be reported would have a net discretionary cost of \$248 million from 2017 to 2021 and \$167 million after 2021.<sup>23</sup>

## Title III. Jason Simcakoski PROMISE Act

Title III, Jason Simcakoski PROMISE Act, would require the VA Secretary to expand VA's Opioid Safety Initiative, implement education and training requirements for VA employees who prescribe opioids, establish protocols for the designation of a pain management team at each VA medical facility, ensure access to state prescription drug monitoring program (PDMP) data, maximize availability of naloxone, modify VA's Opioid Therapy Risk Report tool, and flag the health records of veterans at risk of opioid abuse. It would require the VA and Defense Secretaries to ensure that the Pain Management Working Group<sup>24</sup> focuses on specified issues, coordinates and consults with other entities as specified, and updates the clinical practice guideline for management of opioid therapy for chronic pain. In addition, it would require a GAO report on VA's Opioid Safety Initiative, a quarterly progress report from VA about actions taken to address GAO's outstanding findings and recommendations, an annual report from VA on opioid prescription rates, and an investigation by the Office of the Medical Inspector of the Veterans Health Administration when prescription rates are inconsistent with standards of appropriate and safe care. The title would require VA to share information with state PDMPs, and it would require the VA Secretary to limit the aggregate value of awards and bonuses.

The Promoting Responsible Opioid Management and Incorporating Scientific Expertise Act (PROMISE Act, H.R. 4063), as amended, passed the House by voice vote on May 10, 2016.<sup>25</sup> CBO estimates that implementing the bill as ordered to be reported would cost \$138 million over the 2017-2021 period, subject to appropriation of the necessary amounts.<sup>26</sup>

## Title IV. Kingpin Designation Improvement Act

Title IV, Kingpin Designation Improvement Act, would amend the Foreign Narcotics Kingpin Designation Act<sup>27</sup> to protect classified information from disclosure in the case of any judicial review in federal court of a determination made pursuant to such classified information. Specifically, it would authorize such classified information to be submitted to a reviewing court ex parte and in camera.<sup>28</sup>

<sup>&</sup>lt;sup>22</sup> Congressional Record, vol. 162, part 75 (May 12, 2016), pp. H2296-H2317.

<sup>&</sup>lt;sup>23</sup> U.S. Congressional Budget Office, H.R. 5046, *Comprehensive Opioid Abuse Reduction Act of 2016*, May 4, 2016, at https://www.cbo.gov/publication/51530.

<sup>&</sup>lt;sup>24</sup> 38 U.S.C. §320.

<sup>&</sup>lt;sup>25</sup> *Congressional Record*, vol. 162, part 73 (May 10, 2016), p. H2172. The title of the bill was amended so as to read: "A bill to improve the use by the Secretary of Veterans Affairs of opioids in treating veterans, and for other purposes."

<sup>&</sup>lt;sup>26</sup> U.S. Congressional Budget Office, *H.R. 4063, Promoting Responsible Opioid Management and Incorporating Scientific Expertise Act*, May 4, 2016, at https://www.cbo.gov/publication/51531.

<sup>&</sup>lt;sup>27</sup> 21 U.S.C. §1903.

<sup>&</sup>lt;sup>28</sup> Black's Law Dictionary (10<sup>th</sup> ed. 2014) defines ex parte as "Done or made at the instance and for the benefit of one party only, and without notice to, or argument by, anyone having an adverse interest; of, relating to, or involving court action taken or received by one party without notice to the other, usu. for temporary or emergency relief <an ex parte hearing> <an ex parte injunction>." It defines in camera as "1. In the judge's private chambers. 2. In the courtroom with all spectators excluded. 3. (Of a judicial action) taken when court is not in session.—Also termed (in reference to the opinion of one judge) in chambers."

The Kingpin Designation Improvement Act of 2016 (H.R. 4985) passed the House by voice vote on May 10, 2016.<sup>29</sup> CBO estimates that implementing the bill as ordered to be reported "would have no significant effect on the federal budget because it would have a negligible effect on the workload of the U.S. courts."<sup>30</sup>

## Title V. Good Samaritan Assessment Act

Title V, Good Samaritan Assessment Act, would require a GAO study on state Good Samaritan laws that pertain to treatment of opioid overdoses. Specifically, the study would report to Congress on (1) the extent to which the Director of National Drug Control Policy has reviewed Good Samaritan laws, including findings regarding effects of these laws; (2) efforts by the Director to encourage enactment of these laws; and (3) a compilation of these laws in effect in the states, territories, and the District of Columbia.<sup>31</sup>

The Good Samaritan Assessment Act of 2016 (H.R. 5048) passed the House by voice vote on May 10, 2016.<sup>32</sup> CBO estimates that implementing the bill as ordered to be reported "would have no significant effect on the federal budget because the information needed to complete the report is readily available and would not take significant time or resources to compile."<sup>33</sup>

## Title VI. OPEN Act

Title VI, OPEN Act, would evaluate how effective federal grant programs have been in addressing problems relating to opioid abuse—the bill appears to be referring to a DOJ grant program (the Comprehensive Opioid Abuse Grant Program) that would be enacted were H.R. 5046 to be enacted. It also refers to any program at HHS that provides grants for the primary purpose of providing assistance to address opioid abuse.

The Opioid Program Evaluation Act (OPEN Act; H.R. 5052), as amended, passed the House by a vote of 410-1 on May 10, 2016.<sup>34</sup> CBO estimates that implementing the bill as ordered to be reported would cost about \$4 million over the 2016-2021 period, assuming enactment of separate legislation establishing the grant program.<sup>35</sup>

<sup>&</sup>lt;sup>29</sup> Congressional Record, vol. 162, part 73 (May 10, 2016), pp. H2173-H2175.

<sup>&</sup>lt;sup>30</sup> U.S. Congressional Budget Office, H.R. 4985, *Kingpin Designation Improvement Act of 2016*, May 6, 2016, at https://www.cbo.gov/publication/51564.

<sup>&</sup>lt;sup>31</sup> According to the National Conference of State Legislatures, 35 states and the District of Columbia have enacted "some form of a Good Samaritan or 911 drug immunity law." Good Samaritan laws generally provide immunity from supervision violations or low-level drug offenses when an individual who observes or experiences an overdose calls for emergency assistance or otherwise seeks medical assistance. See National Conference of State Legislatures, *Drug Overdose Immunity and Good Samaritan Laws*, April 12, 2016, at http://www.ncsl.org/research/civil-and-criminal-justice/drug-overdose-immunity-good-samaritan-laws.aspx.

<sup>&</sup>lt;sup>32</sup> Congressional Record, vol. 162, part 73 (May 10, 2016), pp. H2179-2181.

<sup>&</sup>lt;sup>33</sup> U.S. Congressional Budget Office, H.R. 5048, *Good Samaritan Assessment Act of 2016*, May 4, 2016, at https://www.cbo.gov/publication/51560.

<sup>&</sup>lt;sup>34</sup> Congressional Record, vol. 162, part 73 (May 10, 2016), pp. H2181-2184.

<sup>&</sup>lt;sup>35</sup> U.S. Congressional Budget Office, H.R. 5052, *Opioid Program Evaluation Act*, May 5, 2016, at https://www.cbo.gov/publication/51533.

## Title VII. Infant Plan of Safe Care Improvement Act

Title VII, Infant Plan of Safe Care Improvement Act, aims to strengthen state processes and compliance related to the development of a safe plan of care for newborns affected by illegal substance abuse, withdrawal symptoms, or a Fetal Alcohol Spectrum Disorder.<sup>36</sup> The bill would amend the Child Abuse Prevention and Treatment Act (CAPTA)<sup>37</sup> to clarify that such plans are to address the infant's safety and well-being, including by addressing the substance abuse treatment needs of the infant and his/her parent(s) or caregiver(s). Among other things, the bill would additionally require the HHS Secretary to conduct specific monitoring of state compliance with this requirement and to maintain and disseminate (via the national clearinghouse on child abuse and neglect) information about best practices in developing such plans of safe care.

The Infant Plan of Safe Care Improvement Act (H.R. 4843), as amended, passed the House by a vote of 421-0 on May 11, 2016.<sup>38</sup> CBO estimates that implementing the bill as ordered to be reported would cost less than \$500,000 annually, subject to the availability of funds.<sup>39</sup>

## **Title VIII. NAS Healthy Babies Act**

Title VIII, NAS Healthy Babies Act, would require a GAO report on Neonatal Abstinence Syndrome (NAS). As amended in committee, it would also (1) exclude abuse-deterrent formulations of drugs from the definition of a *line extension* under Medicaid;<sup>40</sup> (2) limit disclosure of the means used in development as well as the algorithms used to identify fraud in Medicare, Medicaid, and the Children's Health Insurance Program; and (3) make \$5 million available to the Medicaid Improvement Fund for FY2021 and thereafter.

The Nurturing and Supporting Healthy Babies Act (NAS Healthy Babies Act; H.R. 4978), as amended, passed the House by voice vote on May 11, 2016.<sup>41</sup> CBO estimates that implementing the bill as ordered to be reported would not, on net, change direct spending over the 2017-2026 period and would have a discretionary cost of less than \$500,000 (subject to the availability of funds).<sup>42</sup>

## Title IX. Co-prescribing to Reduce Overdoses Act

Title IX, Co-Prescribing to Reduce Overdoses Act, would authorize grants to encourage coprescribing of naloxone (a drug to reverse the effects of opioid overdose) with prescription opioids and grants to support development of co-prescribing guidelines. It would specify eligible entities, application requirements, allowable uses of funds, program evaluations, and reporting

<sup>&</sup>lt;sup>36</sup> H.R. 4843 may be considered under suspension of the rules; see http://docs.house.gov/billsthisweek/20160509/ HR4843.pdf.

<sup>&</sup>lt;sup>37</sup> 42 U.S.C. §§5101 et seq.

<sup>&</sup>lt;sup>38</sup> Congressional Record, vol. 162, part 74 (May 11, 2016), pp. H2248-2253.

<sup>&</sup>lt;sup>39</sup> U.S. Congressional Budget Office, H.R. 4843, *Infant Plan of Safe Care Improvement Act*, May 6, 2016, at https://www.cbo.gov/publication/51537.

<sup>&</sup>lt;sup>40</sup> Whether a drug is considered a *line extension* affects the amount of the rebate drug manufacturers must offer under the Medicaid program. See Centers for Medicare & Medicaid Services, *Medicaid Drug Rebate Program*, at https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Medicaid-Drug-Rebate-Program.html.

<sup>&</sup>lt;sup>41</sup> Congressional Record, vol. 162, part 74 (May 11, 2016), pp. H2259-H2263.

<sup>&</sup>lt;sup>42</sup> U.S. Congressional Budget Office, H.R. 4978, *Nurturing and Supporting Healthy Babies Act*, May 9, 2016, at https://www.cbo.gov/publication/51551.

requirements. It includes an offset that would reduce by \$5 million the authorization of appropriation for specified activities of the Centers for Disease Control and Prevention (CDC).

The Co-Prescribing to Reduce Overdoses Act of 2016 (H.R. 3680), as amended, passed the House by voice vote on May 11, 2016.<sup>43</sup> CBO estimates that implementing the bill as ordered to be reported would, on net, reduce costs by \$1 million over the 2017-2021 period.<sup>44</sup>

## Title X. Improving Treatment for Pregnant and Postpartum Women Act

Title X, Improving Treatment for Pregnant and Postpartum Women Act, would reauthorize and amend an existing grant program supporting residential treatment of pregnant and postpartum women with a primary diagnosis of a substance use disorder. It would require the Director of SAMHSA's Center for Substance Abuse Treatment to carry out a pilot program awarding competitive grants to state substance abuse agencies to enhance flexibility in the use of funds, help identify gaps in services, and encourage new approaches and models of service delivery. For the pilot program grants, it would specify grant purposes, requirements for awarding grants, minimum services to be provided through the grants, maximum duration, and evaluation and reporting requirements. It would authorize to be appropriated for the existing program \$16.9 million for each of FY2017–FY2021. Up to 25% of the appropriated amount would be available to be used for the pilot program grants only if the amount appropriated for the fiscal year exceeds the amount appropriated for FY2016. To offset the cost, Title X would reduce by \$5 million the FY2017 authorization of appropriations for activities of the CDC.

The Improving Treatment for Pregnant and Postpartum Women Act of 2016 (H.R. 3691), as amended, passed the House by voice vote on May 11, 2016.<sup>45</sup> CBO estimates that implementing the bill as ordered to be reported would, on net, have a discretionary cost of \$65 million over the 2017-2021 period.<sup>46</sup>

## Title XI. Veteran Emergency Medical Technician Support Act

Title XI, Veteran Emergency Medical Technician Support Act, would require the HHS Secretary to award demonstration grants to states to help veterans who completed military emergency medical technician training during their military service meet state requirements to become an emergency medical technician by streamlining requirements and procedures. It would specify allowable uses of funds, eligibility, and reporting requirements. It would require that the program be carried out using amounts otherwise available for such purpose.

The Veteran Emergency Medical Technician Support Act of 2016 (H.R. 1818), as amended, passed the House by a vote of 415–1 on May 12, 2016.<sup>47</sup> CBO estimates that implementing the

<sup>&</sup>lt;sup>43</sup> Congressional Record, vol. 162, part 74 (May 11, 2016), pp. H2256-H2259.

<sup>&</sup>lt;sup>44</sup> U.S. Congressional Budget Office, H.R. 3680, *Co-Prescribing to Reduce Overdoses Act of 2015*, May 9, 2016, at https://www.cbo.gov/publication/51553.

<sup>&</sup>lt;sup>45</sup> Congressional Record, vol. 162, part 74 (May 11, 2016), pp. H2263-H2266.

<sup>&</sup>lt;sup>46</sup> U.S. Congressional Budget Office, H.R. 3691, *Improving Treatment for Pregnant and Postpartum Women Act of 2015*, May 9, 2016, at https://www.cbo.gov/publication/51550.

<sup>&</sup>lt;sup>47</sup> Congressional Record, vol. 162, part 75 (May 12, 2016), p. H2317.

bill as ordered to be reported would cost \$30 million over the 2017-2021 period, subject to the availability of funds.<sup>48</sup>

## Title XII. John Thomas Decker Act

Title XII, John Thomas Decker Act, would require the CDC to develop and disseminate informational materials and resources about youth sports injuries that might be treated with prescription opioids (potentially leading to addiction), including information about non-opioid treatment options, the dangers of opioid use and misuse, and how to seek addiction treatment.

The John Thomas Decker Act (H.R. 4969), as amended, passed the House by voice vote on May 11, 2016.<sup>49</sup> CBO estimates that implementing the bill as ordered to be reported would cost \$2 million over the 2017-2021 period, subject to the availability of funds.<sup>50</sup>

## Title XIII. Lali's Law

Title XIII, Lali's Law, would authorize grants to states (1) to develop standing orders (allowing naloxone to be dispensed to anyone meeting specified criteria); (2) to encourage pharmacies to dispense naloxone pursuant to standing orders; (3) to implement guidelines for prescribing opioids, co-prescribing naloxone, and discussing naloxone with patients; (4) to develop or adapt training materials related to the use of naloxone; and (5) to educate the public about naloxone. It would specify requirements and preference in awarding grants; terms of grants (e.g., duration and amount); and application and reporting requirements. It would authorize to be appropriated \$5 million for FY2017-FY2019 and limit the percentage of funds that may be used for administrative costs. In addition, it would include an offset that would reduce by \$5 million the authorization of appropriation for specified CDC activities.

Lali's Law (H.R. 4586), as amended, passed the House by a vote of 415-4 on May 12, 2016.<sup>51</sup> CBO estimates that implementing the bill as ordered to be reported would, on net, not affect spending over the 2017-2021 period.<sup>52</sup>

## Title XIV. Reducing Unused Medications Act

Title XIV, Reducing Unused Medications Act, would amend the Controlled Substances Act (CSA; 21 U.S.C. §§801 et seq.) to allow partial fills of prescriptions for controlled substances on Schedule  $II^{53}$  of the CSA at the request of the prescriber or the patient (subject to limitations).

The Reducing Unused Medications Act of 2016 (H.R. 4599), as amended, passed the House by voice vote on May 11, 2016.<sup>54</sup>

<sup>&</sup>lt;sup>48</sup> U.S. Congressional Budget Office, H.R. 1818, *Veteran Emergency Medical Technician Support Act of 2016*, May 6, 2016, at https://www.cbo.gov/publication/51556.

<sup>&</sup>lt;sup>49</sup> Congressional Record, vol. 162, part 74 (May 11, 2016), pp. H2268-H2270.

<sup>&</sup>lt;sup>50</sup> U.S. Congressional Budget Office, H.R. 4969, *John Thomas Decker Act of 2016*, May 9, 2016, at https://www.cbo.gov/publication/51552.

<sup>&</sup>lt;sup>51</sup> Congressional Record, vol. 162, part 75 (May 12, 2016), pp. H2317-H2318.

<sup>&</sup>lt;sup>52</sup> U.S. Congressional Budget Office, H.R. 4586, *Lali's Law*, May 9, 2016, at https://www.cbo.gov/publication/51554.

<sup>&</sup>lt;sup>53</sup> The CSA categorizes controlled substances into five schedules. Substances on Schedule I (e.g., heroin) have high risk of abuse and no accepted medical use. Those on Schedule II (e.g., hydrocodone) have high risk of abuse and an accepted medical use; they are the most tightly controlled of the prescription controlled substances.

<sup>&</sup>lt;sup>54</sup> Congressional Record, vol. 162, part 74 (May 11, 2016), pp. H2273-H2275.

## Title XV. Opioid Review Modernization Act

Title XV, Opioid Review Modernization Act, would require (1) referring new drug applications for opioids without abuse-deterrent properties to a Food and Drug Administration (FDA) advisory committee (with exceptions); (2) the HHS Secretary to seek recommendations from FDA's Pediatric Advisory Committee before approving labeling (or labeling changes) for opioids intended for pediatric use; (3) the HHS Secretary, acting through the FDA Commissioner, to develop recommendations for prescriber education as part of FDA's evaluation of the Risk Evaluation and Mitigation Strategy for extended-release and long-acting opioids; and (4) the FDA Commissioner to publish a final version of draft guidance entitled "General Principles for Evaluating the Abuse Deterrence of Generic Solid Oral Opioid Drug Products," within two years of the end of the public comment period.<sup>55</sup>

The Opioid Review Modernization Act (H.R. 4976) passed the House by voice vote on May 11, 2016.<sup>56</sup> CBO estimates that implementing the bill as ordered to be reported would "not have a significant budgetary effect because FDA is implementing similar requirements through their action plan on opioids."<sup>57</sup>

## Title XVI. Examining Opioid Treatment Infrastructure Act

Title XVI, Examining Opioid Treatment Infrastructure Act, would require a GAO report on treatment capacity, availability, and need. As amended, it also would require the GAO report to assess barriers to real-time reporting of drug overdoses and treatment availability for American Indians and Alaska Natives.

The Examining Opioid Treatment Infrastructure Act of 2016 (H.R. 4982), as amended, passed the House by voice vote on May 11, 2016.<sup>58</sup> CBO estimates that implementing the bill as ordered to be reported would cost less than \$500,000 over the 2017-2021 period, subject to the availability of funds.<sup>59</sup>

# Title XVII. Opioid Use Disorder Treatment Expansion and Modernization Act

Title XVII, Opioid Use Disorder Treatment Expansion and Modernization Act, would (1) expand the qualifying practitioners to treat opioid addiction with buprenorphine to include nurse practitioners or physician assistants; (2) raise the maximum number of patients a qualifying practitioner can treat from 100 to 250; (3) allow the HHS Secretary to recommend revoking or suspending DEA registration for practitioners who fail to comply; and (4) require reports to Congress on treatment services (the contents of which would be revised by an amendment).

 $<sup>^{55}</sup> See \ https://www.federalregister.gov/articles/2016/03/25/2016-06766/general-principles-for-evaluating-the-abuse-deterrence-of-generic-solid-oral-opioid-drugs-products.$ 

<sup>&</sup>lt;sup>56</sup> Congressional Record, vol. 162, part 74 (May 11, 2016), pp. H2276-H2280.

<sup>&</sup>lt;sup>57</sup> U.S. Congressional Budget Office, H.R. 4976, *Opioid Review Modernization Act of 2016*, May 9, 2016, at https://www.cbo.gov/publication/51555.

<sup>&</sup>lt;sup>58</sup> Congressional Record, vol. 162, part 74 (May 11, 2016), pp. H2275-H2276.

<sup>&</sup>lt;sup>59</sup> U.S. Congressional Budget Office, H.R. 4982, *Examining Opioid Treatment Infrastructure Act of 2016*, May 9, 2016, at https://www.cbo.gov/publication/51549.

The Opioid Use Disorder Treatment Expansion and Modernization Act (H.R. 4981), as amended, passed the House by voice vote on May 11, 2016.<sup>60</sup>

## **Title XVIII. National All Schedules Prescription Electronic Reporting Reauthorization Act**

Title XVIII, National All Schedules Prescription Electronic Reporting Reauthorization Act (NASPER Reauthorization Act), would reauthorize and amend the NASPER grant program, which is intended to support state PDMPs (and has not been funded in recent years).<sup>61</sup> It would amend the purpose of the grant program, increase the focus on interoperability of PDMPs, and revise requirements such as evaluation and reporting. Title XVIII would expand the definition of *state* for purposes of the program (currently each of the 50 states and the District of Columbia) to include "any commonwealth or territory of the United States." It also would make numerous text edits, such as replacing "implement or improve [PDMPs]" with "establish, improve, or maintain [PDMPs]" and replacing "public health" with "public health or public safety." It would authorize to be appropriated \$10 million for each of FY2016–FY2020.

The National All Schedules Prescription Electronic Reporting Reauthorization Act of 2015 (H.R. 1725) passed the House by voice vote on September 8, 2015.<sup>62</sup> CBO estimates that implementing the bill as ordered to be reported would cost \$43 million over the 2016–2020 period, assuming appropriation of authorized amounts.<sup>63</sup>

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<sup>&</sup>lt;sup>60</sup> Congressional Record, vol. 162, part 74 (May 11, 2016), pp. H2276-H2280.

<sup>&</sup>lt;sup>61</sup> See CRS Report R42593, Prescription Drug Monitoring Programs.

<sup>&</sup>lt;sup>62</sup> Congressional Record, vol. 161, part 128 (September 8, 2015), pp. H5796-H5798.

<sup>&</sup>lt;sup>63</sup> U.S. Congressional Budget Office, H.R. 1725, *National All Schedules Prescription Electronic Reporting Reauthorization Act of 2015*, August 14, 2015, at https://www.cbo.gov/publication/50735.