

Senate Opioid Bills
Last updated June 21, 2018

Committee Origin	Bill Number	Bill Title	Bill Description	Bill Status/Last Action
Judiciary				
	S. 2645	Access to Increased Drug Disposal Act of 2018	<ul style="list-style-type: none"> Establishes a demonstration program, under which, the DEA provides grants to eligible States to increase participation in drug take-back programs 	Advanced out of Judiciary committee. Ordered to be reported without amendment to the Senate floor 5/24/18
	S. 2535	Opioid Quota Reform Act	<ul style="list-style-type: none"> Amends the Controlled Substances Act to strengthen DEA discretion in fixing and adjusting production and manufacturing quotas for fentanyl, oxycodone, hydrocodone, oxymorphone, and hydromorphone 	Advanced out of Judiciary committee. Ordered to be reported with amendment to the Senate floor 5/24/18
	S. 2789	Substance Abuse Prevention Act	<ul style="list-style-type: none"> Reauthorizes the Office of National Drug Control Policy, Drug-Free Communities Program, the National Community Anti-Drug Coalition Institute, High-Intensity Drug Trafficking Area Program, and the Drug Court Program. The law includes additional provisions and amendments to prevent substance abuse and reduce demand for illicit narcotics. 	Advanced out of Judiciary committee. Ordered to be reported with amendment to the Senate floor 5/24/18
	S. 207	Synthetic Abuse and Labeling of Toxic Substances (SALTS) Act of 2017	<ul style="list-style-type: none"> Amends the Controlled Substances Act to set forth factors that may be considered as evidence to determine whether a controlled substance analogue is intended for human consumption 	Advanced out of Judiciary committee. Ordered to be reported without amendment to the Senate floor 5/24/18
	S. 2838	Using Data to Prevent Opioid Diversion Act of 2018	<ul style="list-style-type: none"> Requires the DEA to report certain information on distribution of opioids, and for other purposes 	Advanced out of Judiciary committee. Ordered to be reported with amendment to the Senate floor 5/24/18
	S. 2837	Preventing Drug Diversion Act of 2018	<ul style="list-style-type: none"> Improves the systems for identifying the diversion of controlled substances and increases civil penalties 	Referred to Judiciary Committee 5/14/18
HELP				
	S. 2680 The Opioid Crisis Response Act of 2018	<p><u>Title I: Reauthorization of Cures Funding</u> <i>1. Sec. 101. State Response to the opioid abuse crisis</i></p> <p><u>Title II: Research and Innovation</u> <i>1. Sec. 201. Advancing Cutting Edge Research</i></p>	<ul style="list-style-type: none"> Reauthorizes State targeted response grants through 2021 and expands grant eligibility to Indian tribes. 	Advanced out of HELP Committee after unanimous vote 5/7/18 Placed on Senate Legislative Calendar under

2. *Sec. 202. Pain Research*

Title III: Medical Products and Controlled Substances Safety

1. *Sec. 301. Clarifying FDA regulation of non-addictive pain products*

2. *Sec. 302. Clarifying FDA packaging authorities*

3. *Sec. 303. Strengthening FDA and CBP coordination and capacity*

4. *Sec. 304. Clarifying FDA post-market authorities*

5. *Sec. 305. Restricting entrance of illicit drug.*

- Increases NIH flexibility to use “other transactional authority” for approval of high impact, cutting-edge research in response to public health threats.
- Amends the mission and reporting requirements for the Interagency Pain Research Coordinating Committee to better address issues related to the opioid crisis and improve scientific understanding of pain.
- Requires the FDA to clarify regulatory pathways, hold public meetings, and issue guidance documents to address: (1) Expedited Pathways, (2) Pain Endpoints, (3) Opioid Sparing, and (4) Risk-Benefit Related to Misuse and Abuse
- Clarifies FDA’s authority to require drug manufacturers to package certain drugs for set treatment durations. Additionally, clarifies FDA authorities to require manufacturers to give patients simple and safe options to dispose of unused opioids.
- Acting through the Commissioner of Food and Drugs, the Secretary will coordinate with the Secretary of Homeland Security to carry out activities related to customs and border protection and response to illegal controlled substances and drug imports, including at sites of import.
- Modifies the definition of an adverse drug experience
- Any package, discovered or received upon import, in violation of the Controlled Substances Act, the Controlled Substances Import and Export Act, the Federal Food, Drug and Cosmetics Act, or any other applicable law, shall transfer such package to U.S. Customs and Boarder Protection.

General Orders, 5/7/18.
Calendar No. 398

- 6. *Sec. 306. First responder training*
- 7. *Sec. 307. Disposal of controlled substances of hospice patients*
- 8. *Sec. 308. GAO study and report on hospice safe drug management*
- 9. *Sec. 309. Delivery of a controlled substance by a pharmacy to be administered by injection or implantation*

Title IV: Treatment and Recovery

Sec. 401. Comprehensive opioid recovery centers.

Sec. 402. Program to support coordination and continuation of care for drug overdose patients

Sec. 403. Alternatives to opioids.

Sec. 404. Building communities of recovery.

- Expands grant program under the Comprehensive Addiction and Recovery Act (CARA), allowing first responders to administer a drug or device to treat an opioid overdose
- Allows certain employees of qualified hospice programs the legal authority to dispose of controlled substances after a patient's death
- Requires GAO to conduct a study on the requirements applicable to and the challenges of hospice programs with regard to the management and disposal of controlled substances in the home of an individual
- Permits implantable or injectable buprenorphine products, and intrathecal pumps, to be delivered by a pharmacy to an administering practitioner
- Authorizes a grant program for entities to establish or operate a comprehensive opioid recovery center and would require centers to serve as a resource for the community
- Requires the Secretary to identify best practices and establish a grant program for the provision of care, overdose reversal medication, and follow-up services to an individual after an overdose.
- Requires the Secretary of HHS to provide technical assistance to hospitals, and other acute care settings, related to the use of alternatives to opioids for pain management and for certain patient populations

Sec. 405. Peer support technical assistance center.

Sec. 406. Medication-assisted treatment for recovery from addiction.

Sec. 407. Grant program.

Sec. 408. Allowing for more flexibility with respect to medication-assisted treatment for opioid use disorders.

Sec. 409. National recovery housing best practices.

Sec. 410. Addressing economic and workforce impacts of the opioid crisis.

Sec. 411. Youth prevention and recovery.

- The Secretary will award grants to recovery community organizations to enable organizations to develop, expand, and enhance recovery services.
- The Secretary, acting through the Assistant Secretary for SMHSA, shall establish or operate a National Peer-Run Training and Technical Assistance Center for Addiction Recovery Support. The Center shall provide technical assistance and support to recovery community organizations and peer support networks, related to substance use disorder
- Amends physician good standing under Waivers for Maintenance or Detoxification Treatment of the Controlled Substances Act
- The established grant program will be available to accredited school of allopathic medicine or osteopathic medicine and teaching hospitals to support the development of curricula that meet the requirements under the Controlled Substances Act, as amended.
- Codifies the ability for qualified physicians to prescribe MAT for up to 275 patients
- Requires HHS to issue best practices for entities operating recovery housing facilities
- In support of state and local communities affected by the opioid crisis, the pilot program will provide grants to eligible entities to address economic and workforce impacts associated with a high rate of substance use disorder.

Sec. 412. Plans of safe care.

Sec. 413. Regulations relating to special registration for telemedicine.

Sec. 414. National Health Service Corps behavioral and mental health professionals providing obligated service in schools and other community based settings.

Sec. 415. Loan repayment for substance use disorder treatment providers.

Sec. 416. Protecting moms and infants.

Sec. 417. Early interventions for pregnant women and infants.

- In consultation with the Department of Education, the Secretary of HHS is required to disseminate best practices and issue grants for prevention of and recovery from substance use disorder for children, adolescents, and young adults.
- Authorizes grants to states to improve and coordinate their response to ensure the safety, permanency, and well-being of infants affected by substance use. Facilitates collaboration and coordination between the agencies responsible for carrying out plans, and extends critical state technical assistance programs.
- Amends the Controlled Substances Act to allow qualified providers to prescribe controlled substances in limited circumstances via telemedicine. Not later than 1 year after the date of enactment, the Attorney general shall promulgate final regulations specifying the limited circumstance in which a special registration may be issued, and the procedure for obtaining a special registration
- Allows mental and behavioral health providers participating in the Scholarship Program or Loan Repayment Program to provide services in schools and other community-based setting
- This provision provides loan repayment to substance use disorder treatment providers, including masters level, licensed substance use disorder counselors, for participating in SUD treatment facilities and other health care settings in underserved areas
- Requires the Secretary of HHS to submit a report on the implementation of the Final Strategy of the Protecting Our Infants Act of 2015
- In coordination with the CDC, the Center for Substance Abuse Prevention will develop education materials for clinicians to use

Sec. 418. Report on investigations regarding parity in mental health and substance use disorder benefits.

Title V: Prevention

1. *Sec. 501. Study on prescribing limits.*

2. *Sec. 502. Programs for health care workforce.*

3. *Sec. 503. Education and awareness campaigns.*

4. *Sec. 504. Enhanced controlled substance overdoses data collection, analysis, and dissemination.*

5. *Sec. 505. Preventing overdoses of controlled substances.*

with pregnant women for shared decision making regarding main management during pregnancy

- Amends Section 13003 of the 21st Century Cures Act, applicable with respect to the second annual report and each such annual report thereafter.
- No later than two years after the date of enactment of this Act, the Secretary of HHS is required to examine the impact of federal and state laws regulating the length, quantity, or dosage of opioid prescriptions and submit a report on these laws; including the impact of overdose rates, diversion, and individuals for whom opioids are medically appropriate
- Updates and improves resources for pain care providers to assess, diagnose, prevent, treat, and manage acute or chronic pain, as well as to detect early warning signs of opioid use disorders. Additionally, the provision updates mental and behavioral health training programs to include trauma-informed care
- The provision shall advance education and awareness regarding the risks related to misuse and abuse of opioids, which may include developing or improving existing program, conducting activities, and awarding grants that advance the education and awareness of the public, including providers, patients, and consumers
- The program will provide training, technical assistance, and support to States, localities, and tribes to collect, analyze, and disseminate controlled substance overdose data

6. *Sec. 506. CDC surveillance and data collection for child, youth, and adult trauma.*

7. *Sec. 507. Reauthorization of NASPER.*

8. *Sec. 508. Jessie's law.*

9. *Sec. 509. Development and dissemination of model training programs for substance use disorder patient records.*

10. *Sec. 510. Communication with families during emergencies.*

11. *Sec. 511. Prenatal and postnatal health.*

12. *Sec. 512. Surveillance and education regarding infections associated with illicit drug use and other risk factors.*

- Program awards grants to carry out and expand any prevention activities, including, but not limited to, PDMPs, innovative projects, and research
- Director of CDC, in cooperation with the States, may collect and report data on adverse childhood experiences through the Behavioral Risk Surveillance System, the Youth Risk Behavioral System, and other relevant public health surveys or questionnaires
- Reauthorizes NASPER through 2026
- Requires HHS to develop best practices for prominently displaying patient's history of opioid abuse in electronic health records, when requested by the patient
- No later than one year after the date of the enactment of this act, the Secretary is to identify model training programs on how to protect and appropriately disclose confidential substance use disorder medical records for health care providers, patients, and their families
- Promotes awareness of authorizes disclosure during emergencies. Health care providers will be notified annually regarding permitted disclosure during emergencies, including overdoses, of certain health information to families and caregivers under Federal health care privacy laws and regulations
- Authorizes data collection and analysis on neonatal abstinence syndrome and other long-term outcomes related to prenatal substance abuse and misuse, including prenatal opioid abuse and misuse

		<p>13. <i>Sec. 513. Task force to develop best practices for trauma-informed identification, referral, and support.</i></p> <p>14. <i>Sec. 514. Grants to improve trauma support services and mental health care for children and youth in educational settings.</i></p> <p>15. <i>Sec. 515. National Child Traumatic Stress Initiative</i></p>	<ul style="list-style-type: none"> • Program supports state and federal efforts to collect data on infections commonly associated with illicit drug use, and identify and assist patients who may be at increased risk of infection • Establishes the Interagency Task Force on Trauma-Informed Care that shall identify, evaluate, and make recommendations regarding best practice with respect to children and youth, and their families as appropriate, who have experienced or are at risk of experiencing trauma • Authorizes award grants to, or enter into contract cooperative agreements with qualified entities, for the purpose of increasing student access to evidence-based trauma support services and mental health care by developing innovative initiatives, activities, or programs to link local school systems with local trauma informed support and mental health systems • Amends Section 582(j) of the Public Health Service Act, authorizing \$53,887,000 for each fiscal years 2019 through 2023 	
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Finance

<p>The Helping to End Addiction and Lessen (HEAL) Substance Use Disorders Act of 2018</p>	<p><u>Title I: Medicare</u></p> <p>1. <i>Sec. 101 Medicare Opioid Safety Education</i></p> <p>2. <i>Sec 102. Expanding the use of telehealth services for the treatment of opioid use disorder and other substance use disorders</i></p>		<ul style="list-style-type: none"> • Adds new SSA Section 1804(d), requiring the Secretary of HHS to compile and provide references to educational resources on opioid use and pain management; a description of categories of alternative, non-opioid Medicare-covered pain management treatments; and a suggestion that beneficiaries talk to their physicians about opioid use and pain management. Resources and references will be added to the Medicare and You Handbook for open enrollment periods after January 1, 2019. • Eliminates certain statutory originating site requirements for services furnished via telehealth for the purpose of treating substance use disorders, beginning January 1, 2019. The provision would allow payment for these telehealth services when furnished 	<p>Senate Finance Committee advanced HEAL Act out of committee 6/12/2018</p>
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to a beneficiary at an originating site, including the beneficiary's home, without regard to its geographic location

3. *Sec. 103 Comprehensive screenings for seniors*

- Amends the authorities for the IPPE and AWP, for services furnished after 1/1/19, to include: a review of the beneficiary's current opioid prescriptions, including potential risk factors for opioid use disorder; and evaluation of pain severity and the treatment plan; the provision of information on non-opioid treatment options; and referral to a pain management specialist; and screening for potential substance use disorders that includes a referral for treatment.

4. *Sec. 104 Every prescription conveyed securely*

- Requires that health care practitioners use e-prescribing for Part D-covered drugs that are Schedule II, III, IV, or V controlled substances, as classified under the Controlled Substances Act, beginning on January 1, 2021.

5. *Sec. 105 Standardizing Electronic Prior Authorization for Safe Prescribing*

- Require that Part D e-prescribing systems allow for processing of formulary prior authorizations using a standard format, beginning no later than January 1, 2021. The standard format must provide secure electronic transmission of (1) a prior authorization request from a prescribing health care professional for a covered Part D drug for an enrollee to the plan sponsor, and (2) a response from the plan to the prescribing professional

6. *Sec. 106 Strengthening partnerships to prevent opioid abuse*

- The Secretary of HHS will establish a secure Internet website portal within two years of enactment. The website portal will communicate and facilitate data sharing with MA and PDP plans and MEDICs

7. *Sec. 107 Commit to opioid medical prescriber accountability and safety for seniors*

- Directs the Secretary of HHS, after consultation with stakeholders, to establish a program that notifies Part D opioid prescribers identified as statistical outliers compared to their peers and aims to improve prescribing consistent with the medical evidence.

8. *Sec. 108 Fighting the opioid epidemic with sunshine*

9. *Sec. 109 Opioid treatment program demonstration (Cassidy#1, Nelson, Cardin amendment)*

10. *Sec. 110 Medicare Improvement Fund*

Title II: Medicaid

1. *Sec. 201 Caring recovery for infants and babies*

2. *Sec. 202 Peer support enhancement and evaluation review*

- Expands the definition of covered recipient to encompass physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, and certified nurse midwives; applicable manufacturers will be required to submit information on payments or other transfers of value to these types of health care professionals. The amendments made by this section would apply to information required to be submitted on or after January 1, 2021
- Secretary of HHS will conduct a demonstration to test coverage and payment for opioid use disorder treatment services furnished by Opioid Treatment Programs (OTP), to begin no later than January 1, 2021 and run for a five-year period
- The Chairman’s Mark would deposit \$50 million into the Medicare Improvement Fund (MIF)
- Clarifies that states have the option to make Medicaid services available on an inpatient or outpatient basis at a residential pediatric recovery center to infants with NAS. Covered services include not only services to infants, but also services to mothers or other caretakers provided that those services are otherwise covered under the Medicaid state plan or waiver of such plan, such as counseling or referrals for services, activities to encourage caregiver-infant bonding, or training on caring for such infants
- The Comptroller General, within two years after the date of enactment, is required to submit a report on the provision of peer support services in Medicaid to Congress. The report must include information on state Medicaid programs’ coverage of peer support services, including (1) the mechanisms (statutory authority or waivers) through which states may cover peer support; (2) the populations to which such coverage has been provided; (3) payment models used by states; and (4) federal and state spending

3. *Sec. 203 Medicaid substance use disorder treatment via telehealth*

4. *Sec. 204 Enhancing patient access to non-opioid treatment options*

5. *Sec. 205 Assessing barriers to opioid use disorder treatment*

6. *Sec. 206 Help for mom and babies*

7. *Sec. 207 Securing flexibility to treat substance use disorders*

8. *Sec. 208 MACPAC Study and report on MAT utilization controls under state Medicaid programs*

- CMS and the Comptroller General are required to conduct various activities to evaluate and strengthen the provision of telehealth services in Medicaid

- By 1/1/19, CMS us required to issue one or more final guidance documents to states, or to update existing guidance documents, regarding mandatory and optional items and services that state Medicaid programs may furnish, under the state plan or a waiver of the state plan, for non-opioid treatment and management of pain, including evidence-based non-opioid pharmacological therapies and non-pharmacological therapies.

- Requires the Comptroller General study Medicaid barriers that impede beneficiary access to receiving SUD treatment medications, in particular, buprenorphine, naltrexone, and buprenorphine-naltrexone combination products

- Permits states to receive federal Medicaid matching funds, for otherwise coverable Medicaid items or services, that are provided outside of the IMD to a woman who (1) is eligible for Medicaid on the basis of being pregnant (through 60 days postpartum); (2) is a patient in an IMD for the purpose of receiving treatment for a substance use disorder; and (3) was enrolled in Medicaid immediately before becoming a patient in an IMD or becomes Medicaid-eligible while a patient in an IMD.

- Amend SSA Section 1903(m), allowing states to receive federal Medicaid payments for expenditures included in the development of managed care capitation rates for treatment described under 42 C.F.R. Section 438.6(e).

9. *Sec. 209 Opioid addiction treatment programs enhancement*

10. *Sec. 210 Better data sharing to combat the opioid crisis*

11. *Sec. 211 Mandatory reporting with respect to adult behavioral health measures (Cassidy #2, Brown #2 amendment)*

12. *Sec. 212 Report on Housing-related services and supports for individuals with substance use disorders under Medicaid (Cardin #4, Isakson amendment)*

- Requires the Medicaid and CHIP Payment and Access Commission (MACPAC), within one year after the date of enactment, make publicly available a report on states' Medicaid programs for utilization control policies for medication-assisted treatment.
- Requires the Secretary of HHS to publish a report on the prevalence of SUDs among Medicaid enrollees and the SUD treatment services provided to Medicaid enrollees, including certain specified information. CMS would be required to issue annual updates not later January 1 for each calendar year through 2024.
- Clarifies that state Medicaid programs may have reasonable access to one or more state-administered or accessed PDMP databases to the extent Medicaid program access is permitted under state law. Additionally, as permitted under state law, clarifies that state Medicaid programs may facilitate reasonable access to state administered or accessed PDMP databases and to share the PDMP database information with Medicaid-enrolled providers and Medicaid managed care entities
- Requires states to report quality measures related to behavioral health included in the core set of adult health quality measures beginning in 2024. Additionally, the Secretary of HHS will be required to maintain such behavioral health measures within its core set for purposes of state reporting requirements.
- Within one year after the date of enactment, the Secretary of HHS is required to issue a report on innovative initiatives and strategies that states may use under Medicaid to provide housing-related services and supports to beneficiaries with substance use disorders who are at risk of homelessness.

13. *Sec. 213 Technical assistance and support for state strategies to provide house-related supports under Medicaid (Cardin #4, Isakson amendment)*

Title III: Human Services

1. *Sec. 301 Supporting family-focused residential treatment*

2. *Sec. 302 Improving recovery and reunifying families*

3. *Sec. 303 Building capacity for family focused residential treatment*

- Requires the Secretary of HHS to provide technical assistance and support to states seeking to provide housing-related supports and services and care coordination services under Medicaid to beneficiaries with substance use disorders, and issue a report detailing an action plan to do so within 180 days after enactment.

- Requires the Secretary of HHS, within 180 days of enactment of the section, to issue guidance on how states may use existing Medicaid and Title IV-E program authorities (to support substance use disorder treatment via family-focused residential treatment programs, including the placement of foster children with their parents in such programs

- Authorizes a one-time mandatory appropriation of \$15 million, to remain available across eight years, i.e., FY 2019-FY2026, for the support of a “family recovery and reunification program replication project.” The HHS Secretary is required to publish a report that analyzes the program’s impacts, and if warranted, includes a replication plan with any recommendations for legislative and administrative actions the HHS Secretary determines to be appropriate.

- Requires the HHS Secretary to make grants to eligible public and private entities to develop, enhance or evaluate family-focused residential treatment programs for the purpose of increasing the availability of programs that meet the evidence-based practice criteria for Title IV-E prevention services. Authorize a one-time discretionary appropriation of \$20 million, to remain available across five years, FY2019-FY2023, and would require any

Amendments to HEAL Act

1. *Toomey Amendment #1: Encouraging Appropriate Prescribing for Victims of Overdose in Medicare Act, *Passed on a 16-11 vote*

2. *Brown Amendment #3: Lock-in-Auto Escalation, *Passed on a voice vote*

evaluation funded (in whole or in part with these dollars) to be designed to help determine if the family-focused residential treatment program being carried out would qualify as “promising,” “supported” or “well-supported” under Title IV-E

- This amendment modifies the current Medicare drug management program and Medicaid drug use review programs to encourage appropriate prescribing for victims of opioid-related overdoses. No later than 1/1/21, CMS will be required to identify enrollees with a history of opioid-related overdose, as well as beneficiaries “potentially at-risk” for prescription drug abuse
- Amends section 704 (the “lock-in” provision) of the Comprehensive Addiction and Recovery Act (CARA) to clarify that beneficiaries who are included in a Part D plan “lock-in” have the option to auto-escalate their appeals.