

The following chart reflects WHG’s analysis, by key policy area, of the major Congressional (House and Senate) opioid-focused legislation, as well as key Administration proposals in this regard. Specifically:

- **House:** Provisions included in [H.R. 6 \(summary; key provisions\)](#), the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act, which overwhelmingly passed (396-14) the House on June 22. The bill incorporates several dozen pieces of legislation passed by the House over the past two weeks – bills originating in the House Energy & Commerce (E&C) and Ways & Means (W&M) Committees – with some additional Judiciary Committee jurisdiction-related bills that advanced to the floor and were ultimately included in H.R. 6.
- **Senate:** Provisions included in the Senate [substitute amendment \(press release; section-by-section\)](#) to H.R. 6 passed 99-1 on Sept. 17. The legislation reflects over 70 proposals put forward by five Senate committees, including: Finance; Health, Education, Labor and Pensions (HELP); Judiciary; Commerce, Science and Transportation; and Banking, Housing, and Urban Affairs.
- **White House:** Policies encompassed in the White House’s [three-pronged plan](#) to address the opioid epidemic announced on Mar. 19.

KEY POLICY AREA	HOUSE (H.R. 6)	SENATE AMENDMENT TO H.R. 6	ADMINISTRATION (White House) See Regulatory Policies in Memo
PREVENTION & EDUCATION			
Community and Provider Education	<p>H.R. 6 includes provisions that aim to enhance opioid-focused community and/or provider education as categorized below.</p> <ul style="list-style-type: none"> • Hospitals and Providers – Secs. 6091, 6092, 6093, 6094, and 6095 incorporate H.R. 5774, the Combatting Opioid Abuse for Care in Hospitals (COACH) Act. These provisions require HHS to develop Medicare guidance on pain management and OUD prevention for hospitals; provide for opioid quality measures development; and provide for a technical expert panel (TEP) on reducing surgical setting opioid use and data collection on perioperative opioid use, among other provisions. 	<p>Title I: Opioid Crisis Response Act Subtitle D: Treatment and Recovery</p> <ul style="list-style-type: none"> • Technical Assistance on Opioid Alternatives – Directs HHS to provide technical assistance to hospitals and other acute care settings on alternatives to opioids for pain management, including best practices and strategies involving non-pharmacologic alternatives, including best practices that may address specific populations and conditions. Authorizes but does not appropriate \$5 million for each of FYs 2019-2023 (Section 1403). • Plans of Safe Care – Authorizes a state-based grant program to help child welfare agencies, hospitals with labor and delivery 	<p>The White House plan calls for a nationwide evidence-based campaign to raise public awareness about the dangers of prescription and illicit opioid use, as well as other drug use.</p>

	<ul style="list-style-type: none"> • QIOs/Prescriber Best Practices – Secs. 6051 and 6052 incorporate H.R. 5796, the Responsible Education Achieves Care and Healthy Outcomes for Users’ Treatment (REACH OUT) Act. These provisions direct CMS to work with Quality Improvement Organizations (QIOs) to engage in outreach with prescribers identified as clinical outliers to share best practices. • Medicare Beneficiary-Focused Outreach/Education – Secs. 6021 and 6022 incorporate H.R. 5685, the Medicare Opioid Safety Education Act. These provisions direct CMS to compile education resources for beneficiaries regarding opioid use, pain management, and alternative pain management treatments, and include these resources in the “Medicare and You” handbook. Additionally, secs. 6111, 6112, 6113, and 6114 incorporate elements of H.R. 5686, the Medicare Clear Health Options in Care for Enrollees (CHOICE) Act. These provisions require Part D PDPs to include information on the adverse effects of opioid overutilization and coverage of non-pharmacological therapies and non-opioid medications or devices used to treat pain. Similarly, these same sections incorporate H.R. 5775, the Providing Reliable Options for Patients and Educational Resources (PROPER) Act. These provisions require MA/Part D PDPs to include information on the risks associated with opioids; coverage of certain nonopioid treatments used to treat pain; and on the safe disposal of prescription drugs. • Pediatric Population – Secs. 8011 and 8012 incorporate H.R. 5889, the Recognizing Early Childhood Trauma 	<p>units, and specified state agencies to support plans of safe care for infants affected by substance abuse. Specifies elements of plans of safe care, including parent and caregiver engagement. Authorizes but does not appropriate \$60 million for each of FYs 2019-2023 (Section 1414).</p> <ul style="list-style-type: none"> • Prenatal Opioid Use – Within 60 days of enactment, calls for a Report to Congress by HHS on the implementation of the strategy for addressing prenatal opioid use, including neonatal abstinence syndrome. Reauthorizes Residential Treatment Programs for Pregnant and Post-Partum Women at a funding authorization of \$29.9 million annually for FYs 2019-2023 (Section 1418). • Early Interventions for Pregnant Women and Infants – Requires SAMHSA’s Center for Substance Abuse Prevention to develop educational materials for clinicians’ use with pregnant women on pain management during pregnancy. Calls for the implementation of recommendations conveyed in a 2017 HHS final report, “Protecting Our Infants Act: Final Strategy” (Section 1419). <p>Title I: Opioid Crisis Response Act Subtitle E: Prevention</p> <ul style="list-style-type: none"> • Comprehensive Pain Care Education – Requires grant recipients to create comprehensive education and training programs that include information regarding the dangers of opioid use disorders, early warning signs of OUDs, and safe disposal. Requires pain care programs to include and promote opioid alternatives that are non-addictive and non-pharmacologic. Ensures mental and 	
--	---	--	--

	<p>Related to Substance Abuse Act. The provisions require HHS to disseminate information to professionals working with young children on ways to recognize children impacted by trauma related to an adult’s substance use, and how to respond in a manner that will provide the best support for the child. Separately, secs. 8021 and 8022 incorporate H.R. 5890, the Assisting States’ Implementation of Plans of Safe Care Act. These provisions require HHS to provide states with enhanced guidance to support the implementation of their “plan of safe care” assurance, which is required under the Child Abuse Prevention and Treatment Act (CAPTA) and designed to address the needs of infants affected by prenatal substance abuse. Additionally, secs. 8031 and 8032 incorporate H.R. 5891. These provisions establish an interagency task force to develop a strategy on how federal agencies can implement a coordinated approach to responding to the opioid epidemic, focusing on the existing programs that support infants, children, and their families.</p> <ul style="list-style-type: none"> • Centers of Excellence – Secs. 7111 and 7112 incorporate H.R. 5261, the Treatment, Education, and Community Help (TEACH) to Combat Addiction Act. These provisions authorize HHS to designate and support Centers of Excellence and institutions of learning that champion SUD treatment and pain management education to improve how health professionals are taught about both SUD and pain. • State-Led Outreach, Education – Secs. 7151 and 7152 incorporate H.R. 5353, the Eliminating Opioid-Related Infectious Diseases Act. These provisions authorize CDC to undertake an injection drug use-associated infection elimination initiative 	<p>behavioral health education and training grant programs include trauma-informed care. (Section 1502)</p> <ul style="list-style-type: none"> • Amends CARA’s requirements regarding opioid-focused education and awareness campaigns for providers, patients and consumers. (Section 1503) • Patient Records & Information Sharing – Requires the identification or creation of model training programs and materials to help patients and families understand their rights to protect and obtain information, including in emergency situation. (Sections 1509, 1510) <p>Title II: HEAL Act of 2018 Subtitle A: Medicare</p> <ul style="list-style-type: none"> • Requires CMS to provide information within the Medicare & You handbook on opioid use and pain management, alternative non-opioid pain management treatments, and suggests beneficiaries talk with their physicians about opioid use and pain management. (Sec. 2101) 	
--	--	--	--

	and work with states to improve education, surveillance, and treatment of infections associated with injection drug-use.		
Focus on Overprescribing (e.g., Prescriber Limits)	<p>H.R. 6 includes provisions aimed at reducing overprescribing of opioids including those highlighted below. See also PDMP section.</p> <ul style="list-style-type: none"> • Pharmacist-Focused Efforts – Secs. 7011 and 7012 incorporate H.R. 4275, Empowering Pharmacists in the Fight Against Opioid Abuse Act. These provisions support the development and dissemination of materials giving pharmacists greater understanding and ability to decline to fill controlled substances when they suspect the prescriptions are fraudulent, forged, or appear to be for abuse or diversion. • Prescriber Patterns, Best Practices – Sec. 6065 incorporates H.R. 5716, the Commit to Opioid Medical Prescriber Accountability and Safety for Seniors (COMPASS) Act (See also: PASS Act, H.R. 5773, of which provisions were incorporated). This provision requires CMS to establish a prescriber threshold based on specialty and geographic area, which could designate a prescriber as an outlier opioid prescriber. CMS would then be responsible for notifying prescribers identified as outliers of their status. Additionally, secs. 6051 and 6052 incorporates H.R. 5796, the REACH OUT Act. The provisions direct CMS to work with QIOs to engage in outreach with prescribers identified as clinical outliers to share best practices. • Medicare Part D Policies – Sec. 6064 incorporates H.R. 5684, Protecting Seniors from Opioid Abuse Act (see also: PASS Act, H.R. 5773, of which provisions were incorporated). This provision adds 	<p>Title I: Opioid Crisis Response Act; Subtitle E: Prevention</p> <ul style="list-style-type: none"> • Study and Report on the Impact of Prescription Limits – Requires HHS to examine the impact of federal and state laws and regulations that limit the length, quality, or dose of opioid prescriptions. The intention of the study is to understand the impact of prescription limits on overdoses from prescription and illicit opioids, prevalence of opioid use disorders, access to necessary treatment, and impact of limits on diversion or misuse of controlled substances. (Section 1501) <p>Title II: HEAL Act of 2018 Subtitle A: Medicare</p> <ul style="list-style-type: none"> • Prescriber Outliers – Requires CMS to notify Part-D prescribers who are identified as statistical outliers when it comes to prescribing opioids as compared to their peers. The notification must include peer comparison details and CMS is directed to provide educational assistance to the outliers. (Sec. 2107) • Beneficiary Monitoring and Assistance – Requires CMS to identify beneficiaries enrolled in Medicare Part D with a history of opioid-related overdose and include them in its system for monitoring those potentially at-risk for prescription drug abuse, enables prescription drug plans to take steps that inform prescribers and dispensing pharmacies and facilitate improved care. (Sec. 2110) 	<p>The White House plan puts forth a Safer Prescribing Plan to cut nationwide opioid prescription fill by one-third within three years.</p> <p>Note that FDA Commissioner Scott Gottlieb gave remarks at the National Rx Drug Abuse and Heroin Summit pointing to new FDA analysis that suggests “that for many common surgical procedures, just a single day of opioids was sufficient.”</p>

	<p>beneficiaries at-risk for prescription drug abuse to the list of targeted beneficiaries to be eligible for medication therapy management (MTM) under Part D. Sec. 2006 incorporates H.R. 5675, Mandatory Lock-In, which builds off CARA to require Medicare PDP sponsors to establish drug management programs for at-risk beneficiaries. Sec. 2005 incorporates H.R. 3528, Every Prescription Conveyed Securely Act, requiring e-prescribing, with exceptions, for coverage of prescribed controlled substances under the Medicare Part D program. Secs. 6061 and 6062 incorporate H.R. 4841, the Standardizing Electronic Prior Authorization for Safe Prescribing Act, seeks to standardize electronic prior authorization for Medicare Part D prescription drugs. (This and other provisions incorporated as part of H.R. 5773, the PASS Act). Finally, secs. 6061, 6062, 6063, 6065, and 6064 incorporate provisions of H.R. 5773, the Preventing Addiction for Susceptible Seniors (PASS) Act. The PASS Act requires Medicare PDP sponsors to establish drug management programs for at-risk beneficiaries (“lock-in” programs); stipulates electronic prior authorization for covered Part D drugs; stipulates expanded eligibility for Part D medication therapy management (MTM) programs to include at-risk beneficiaries for prescription drug abuse; and calls for Medicare notifications to outlier prescribers of opioids, among other provisions.</p>		
<p>Preventive Services (e.g., Patient Screenings)</p>	<p>For H.R. 6, see throughout generally, including recommendations for screening for OUDs, as well as secs. 6091, 6092, 6093, 6094, and 6095 of the bill, which incorporate H.R. 5774 (COACH Act). These provisions include Medicare OUD prevention guidelines etc.</p>	<p>Title II: HEAL Act of 2018 Subtitle A: Medicare</p> <ul style="list-style-type: none"> Requires that the Medicare Initial Preventive Physical Examination and annual wellness visits to include a review of the beneficiary’s current opioid prescriptions and screenings for potential substance use disorders. (Sec. 2103) 	<p>The White House plan proposes to identify and treat offenders struggling with addiction in the criminal justice system by screening every Federal inmate for opioid addiction at intake.</p>

	<p>Additionally, sec. 2006 incorporates H.R. 5798, the Opioid Screening and Chronic Pain Management Alternatives for Seniors Act. This provision adds a review of current opioid prescriptions and, as appropriate, a screening for opioid use disorder as part of the Welcome to Medicare initial examination.</p>		
Workforce; Other	<p>Secs. 7141, 7142, 7143 and 7144 of H.R. 6 incorporate H.R. 5329, the Poison Center Network Enhancement Act. These provisions reauthorize the national network of Poison Control Centers that serve as the primary resource for poisoning information. These centers reduce ER visits and report year over year increases in all analgesic exposures, including opioids and sedatives.</p> <p>Sec. 8041 of H.R. 6 incorporates H.R. 5892, which calls for an Advisory Committee to advise the DOL on steps to address the impact of opioid abuse on the workplace.</p>	<p>Title I: Opioid Crisis Response Act Subtitle D: Treatment and Recovery</p> <ul style="list-style-type: none"> • Workforce Implications – Provides for grants of \$500,000 to \$5 million in a fiscal year under a Department of Labor initiative to assist with workforce training for people in communities demonstrating a opioid and substance abuse disorder increases of equal to or greater than the national average (Section 1410). • CAREER Act – Creates a grant program focused on assisting individuals transitioning to “independent living and the workforce,” with priority to states with high rates of overdoses and unemployment. Provides that funds may be used for specified purposes, such as hiring case managers, peer recovery support, and more, Authorizes but does not appropriate such sums as necessary for each of FYs 2019-2023 (Section 1411). • Report on Mental Health and Substance Abuse Parity – Requires CMS, DOL, and Treasury to provide further data in annual reporting to Congress regarding plans’ compliance with parity requirements, such as specific information on closed investigations and coordination between federal and state regulators (Section 1420). 	

		<p><i>Subtitle C: Medical Products & Controlled Substances Safety</i></p> <ul style="list-style-type: none"> • Strengthens coordination activities between FDA and US Customs and Border Protection (CBP) to improve detection and seizure of illegal drugs, provides infrastructure improvements, and FDA innovative detection technology and testing equipment. (Section 1303) • Clarifies FDA’s post-market authorities for drugs which may have reduced efficacy over time by modifying the definition of an adverse drug experience. (Section 1304) • Restricts entrance of illicit drugs by codifying existing FDA practice and debarring a person from importing a regulated product upon conviction of a related felony. (Section 1305) • Improves disposal of substances by hospice programs by providing certain health professionals the authority to dispose of controlled substances in hospice setting to reduce the risk of diversion or misuse. (Section 1307) • Requires the Government Accountability Office (GAO) to conduct a study and report on hospice programs’ written policies and procedures on the management and disposal of controlled substances in the home of an individual. (Section 1308) • Permits implantable or injectable substances to be delivered by a pharmacy directly to an administering practitioner. (Section 1309) 	
--	--	--	--

		<p><i>Subtitle E: Prevention</i></p> <ul style="list-style-type: none"> • Reauthorizes and expands CDC program to prevent and respond to infections commonly associated with illicit drug use including viral hepatitis, HIV, and ineffective endocarditis. Authorizes \$40 million per year for FY 2019 through 2023 for such programs. (Sec. 1512) • Authorizes the CDC to combat the opioid crisis by collecting, analyzing, and sharing a range of data regarding opioids and their impact, including grant and technical assistance support for state and local entities. Details are included in the data section at the end of this chart. • Creates an Interagency Task Force on Trauma-Informed Care to develop evidence-based and evidence-informed best practices to identify, prevent, and address the effects of trauma on infants, children, youth, and their families. Requires Congressional report and allows for data-sharing, grants, and efforts to ensure timely referral to trauma-informed age-appropriate care. <p>Title II: HEAL Act of 2018</p> <p><i>Subtitle A: Medicare</i></p> <ul style="list-style-type: none"> • Requires Medicare beneficiaries enrolled in Medicare Part D to have the right to automatically escalate their appeal to external review if CMS has identified them as potentially at-risk for Rx drug abuse and the PDP as affirmed its own decision at the initial appeal level. (Sec. 2111) 	
--	--	--	--

		<p>Title IV: Fighting Opioid Abuse in Transportation Act Subtitle A: Opioid Abuse in Transportation</p> <ul style="list-style-type: none"> • Rail Employee Testing – Requires the Department of Transportation to issue final rules within two years regarding controlled substances and alcohol testing for rail mechanical employees and yardmasters (Section 4102-4103). • Department of Transportation – By March 2019, requires DOT to make publicly available online a database of employer-reported drug and alcohol testing data for “each mode of transportation” that is updated annually. Calls for a GAO report within two years addressing the DOT’s Drug and Alcohol Testing Management Information System and the process used by the agency to collect and publicly report data (Section 4105). • Inclusion of Fentanyl in Workplace Testing – Within six months, requires HHS to determine whether to update the Mandatory Guidelines for Federal Workplace Drug Testing to include testing for fentanyl (Section 4106). • Hair Testing Guidelines – Requires HHS to regularly update Congress on the status of a final notice on scientific and technical guidelines for hair testing (Section 4107). • Mandatory Workplace Testing Using Oral Fluid –By December 2018, requires HHS to publish a final notice of Mandatory Guidelines for Federal Workplace Drug Testing Programs Using Oral Fluids based on the 2015 proposed notice. Calls for 	
--	--	--	--

		<p>“elimination of the risk” of positive test results caused by drug use of others and not by the individual tested (Section 4108).</p> <ul style="list-style-type: none"> • Electronic Recordkeeping – Within one year, requires HHS to ensure that each certified laboratory requesting approval for the use completely electronic Federal Drug Testing Custody and Control Forms receives such approval (Section 4109). • Status Report on Commercial Driver’s License Drug and Alcohol Clearinghouse – Requires annual reporting on the status of the clearinghouse, until implementation, by the Federal Motor Carrier Safety Administration (Section 4110). 	
RESEARCH AND FUNDING			
Non-Pharmacologic and/or Non-Opioid Pain Management	<p>H.R. 6 addresses research and/or funding for alternatives to opioid therapies, including:</p> <ul style="list-style-type: none"> • NIH Research Flexibility – Secs. 7041 and 7042 incorporate H.R. 5002, the Advancing Cutting Edge (ACE) Research Act, which grants NIH flexible authority to research new, non-addictive pain medications. • FDA Authority – Sec. 3001 incorporates H.R. 5806, the 21st Century Tools for Pain and Addiction Treatments Act. This provision directs the FDA to issue or update existing guidance on ways that the accelerated approval program and breakthrough therapy pathway can be used to bring novel non-addictive treatments for pain and addiction to patients. Additionally, secs. 7161 and 7162 incorporate H.R. 5473, the Better Pain Management through Better Data Act. These provisions directs the FDA to establish clear data collection methods for opioid-sparing labeling claims for 	<p>Title I: Opioid Crisis Response Act Subtitle B: Research and Innovation</p> <ul style="list-style-type: none"> • Advancing Cutting-Edge Research – Authorizes the National Institutes of Health (NIH) to leverage its “other transactions authority” for high-impact research that responds to public health threats, such as developing a non-addictive treatment for opioid use disorders (Section 1201). • Interagency Pain Research Coordinating Committee Changes – Broadens the purview of the Interagency Pain Research Coordinating Committee to encompass treatment and management of pain and related conditions, including information on best practices for non-pharmacologic treatments, non-addictive medication, and devices as well as identification of biomarkers, screening modalities, risk factors, and 	<p>The White House plan calls for research and development of new technologies and therapies designed to prevent addition and decrease the use of opioids for pain management. This includes supporting research and development for a vaccine to prevent opioid addiction and non-addictive pain management options.</p>

	<p>products that may replace, delay, or reduce the use of opioid analgesics.¹ Finally, Sec. 7221 incorporates H.R. 5811, FDA Long-term Efficacy Act. This provision enhances FDA’s authority and enforcement tools to ensure timely post-marketing studies for chronically administered opioids given currently limited data regarding long-term efficacy of opioids, increased addictive tendencies over time, and their overall place in treating pain.</p> <ul style="list-style-type: none"> • HHS/CMS Grants, Demonstrations – Secs. 7091 and 7092 incorporate H.R. 5197, the Alternatives to Opioids (ALTO) in the Emergency Department Act. These provisions establish a demonstration program to test alternative pain management protocols to limit to use of opioids in hospital emergency departments. Authorizes to be appropriated (but does not actually appropriate) \$10M for each of FYs 2019-2021 for these grants. Additionally, Secs. 6041 and 6042 incorporate H.R. 5605, the Advancing High Quality Treatment for Opioid Use Disorders in Medicare Act. These provisions create a demonstration project for an Alternative Payment Model (APM) for treating SUD, including the development of measures to evaluate the quality and outcomes of treatment. • Medicare Part B-Focused Policies – Sec. 2003 incorporates H.R. 5798, the Opioid Screening and Chronic Pain Management Alternatives for Seniors Act. This provision adds a pain assessment as part of the Welcome to Medicare initial examination, and provides intervention about nonopioid alternatives, as 	<p>early warning signs for substance abuse conditions. Provides for recommendations to NIH regarding avoidance of duplication in federal effort, dissemination of acute and chronic pain care information, and expansion of public-private partnerships. Calls for an NIH report on actions taken (Section 1202).</p> <p><i>Subtitle C: Medical Products & Controlled Substances Safety</i></p> <ul style="list-style-type: none"> • Clarifies the development and regulatory pathways of the Food and Drug Administration (FDA) for medical product manufacturers through guidance for new non-addictive medical products intended to treat pain or addiction. Requires the Agency to issue guidances and hold public meetings. (Section 1301) 	
--	--	---	--

¹ Note: Opioid sparing is defined as the development of novel, non-addictive analgesics and utilization of currently available non-addictive analgesics that may replace, delay, or reduce use of opioids.

	<p>appropriate. Additionally, sec. 2002 incorporates H.R. 5809, the Postoperative Opioid Prevention Act, which creates a temporary pass through payment to encourage the development of non-opioid drugs for post-surgical pain management in Medicare. Finally, sec. 2004 incorporates H.R. 5804, the Post-Surgical Injections as an Opioid Alternative Act. This provision seeks to incentivize post-surgical injections as a pain treatment alternative to opioids by reversing a reimbursement cut for these treatments.</p> <ul style="list-style-type: none"> ● Abuse-Deterrent Opioid Formulations – Secs. 6011 and 6012 incorporate H.R. 5582, the Abuse Deterrent Access Act, which directs CMS to evaluate the use of abuse-deterrent opioids in MA and Part D plans. <p>Additionally, sec. 2007 of H.R. 6 addresses certain payment reforms or benefit changes, including via incorporating language from H.R. 5776, the Medicare and Opioid Safe Treatment (MOST) Act. This provision stipulates Medicare coverage of certain services furnished by opioid treatment programs; reviews and adjustment payments under the Medicare hospital OPPS to avoid financial incentives to use opioids instead of non-opioid alternative treatments; studies the availability of MA supplemental benefits designed to treat or prevent SUDs; includes provisions to enhance access to clinical psychologist service via models led by CMMI, along with a GAO study and report on Medicare mental and behavioral health services; and directs HHS to conduct a report with recommendations on whether and how payment to Medicare Part A and B providers/suppliers related to the use of multi-disciplinary, evidence-based non-opioid treatments for acute and chronic pain management should be revised.</p>		
--	---	--	--

Funding for Naloxone	<p>H.R. 6 includes policies targeted toward enhancing access to naloxone treatment:</p> <ul style="list-style-type: none"> • Resources for Hospitals – Secs. 7081 and 7082 incorporate H.R. 5176, the Preventing Overdoses While in Emergency Rooms Act. These provisions provide resources for hospitals to develop protocols on discharging patients who have presented with an opioid overdose, addressing the provision of naloxone upon discharge, connection with peer-support specialists, and the referral to treatment and other services that best fit the patient’s needs. 		<p>The White House plan expresses the need to ensure first responders are supplied with naloxone.</p>
Other Funding (Grants etc.)	<p>H.R. 6 includes provisions that: (1) reinforce evidence-based standards for entities applying for federal mental health or SUD funding (sec. 7121 incorporates H.R. 5272, the Reinforcing Evidence-Based Standards Under Law in Treating Substance Abuse (RESULTS) Act); (2) authorize grants to federal, state, and local agencies for the establishment or operation of public health laboratories to detect fentanyl, its analogs, and other synthetic opioids (sec. 3002 incorporates H.R. 5580, the STOP Fentanyl Deaths Act); (3) build upon original CARA provisions by authorizing HHS to award grants to peer support specialist organizations for the development and expansion of recovery services (Secs. 7181 and 7182 incorporate H.R. 5587, the Peer Support Communities of Recovery Act); (4) create a student loan repayment program for a wide range of health professionals who agree to work as a SUD treatment professional in areas most in need of their services (sec. 7071 incorporates H.R. 5102, the Substance Use Disorder Workforce Loan Repayment Act); (5) clarifies grants related to serving people and organizations in Appalachia aimed at reducing drug abuse, including opioid abuse, in the region (secs. 8071 and 8072 incorporates H.R. 5294; and (6) reauthorizes the comprehensive opioid abuse grant program</p>	<p>Title I: Opioid Crisis Response Act Subtitle A: Reauthorization of Cures Funding</p> <ul style="list-style-type: none"> • Reauthorizes and aims to improves state targeted response grants from the 21st Century Cures Act to provide funding to Tribes and improve flexibility for states in using the grants. (Section 1101) <p>Title I: Opioid Crisis Response Act Subtitle D: Treatment and Recovery</p> <ul style="list-style-type: none"> • National Health Service Corps – Permits National Health Service Corps members to provide mental and behavioral health services in school and community-based setting for purposes of meeting obligations under Scholarship Program or Loan Repayment Program (Section 1416). • Loan Repayment – Authorizes but does not appropriate \$25 million (FYs 2019-2023) for purposes of Loan Repayment Program for substance abuse professionals practicing in shortage areas (Section 1417). <p>Title II: HEAL Act of 2018 Subtitle A: Medicare</p> <ul style="list-style-type: none"> • Adds \$65 million in funding to the Medicare Improvement Fund which supports CMS’ efforts to improve the 	

	through 2023 (secs. 8091 and 8092 incorporate H.R. 6029 , the REGROUP Act).	Medicare fee-for-service program (Sec. 2113)	
Other	Secs. 6031 and 6032 of H.R. 6 incorporate H.R. 5590 , the Opioid Addiction Action Plan Act, which requires CMS to establish an Action Plan , including studies, reports to Congress, and meetings with stakeholders, to address the opioid crisis.	<p>Title I: Opioid Crisis Response Act Subtitle B: Research and Innovation</p> <ul style="list-style-type: none"> Synthetic Drugs – Requires a Report to Congress by HHS on how psychoactive substances, such as synthetic drugs, affect adolescent and young adult health (Section 1203). <p>Title II: HEAL Act of 2018 Subtitle D: Synthetics Trafficking and Overdose Prevention</p> <ul style="list-style-type: none"> Establishing a \$1 fee on Inbound Express Mail Service items in order to generate funding to cover the cost of complying with new customs requirements. Splits the revenue between U.S. Customs and Customs Border Protection and the U.S. Postal Services. (Sec. 2402) <p>Title III: Judiciary Subtitle E: Opioid Quota Reform</p> <ul style="list-style-type: none"> Sets mandatory factors for DEA to consider when setting annual opioid quotas, including diversion, abuse, overdose deaths, and public health impacts, and requires DEA to explain health benefits if the agency approves any increase in annual opioid quotas. (Section 3501-3502) <p>Subtitle G: Sense of Congress</p> <ul style="list-style-type: none"> Expresses that the Federal Government must work to prevent patient brokers from taking advantage of individuals with substance use disorders, while ensuring that legitimate entities continue to assist individuals in need of treatment find reputable providers, sober living, or recovery homes. 	

TREATMENT AND RECOVERY SERVICES AND SUPPORTS			
Expanded Treatment Options – Including Evidence-based MAT, Enhanced Access to Buprenorphine	<p>H.R. 6 includes provisions that address:</p> <ul style="list-style-type: none"> • Buprenorphine Prescribing Authority – Sec. 3003 incorporates H.R. 3692, the Addiction Treatment Access Improvement Act. This provision: (1) makes the buprenorphine prescribing authority for Pas and NPs permanent; (2) temporarily allows APRNs to prescribe buprenorphine; (3) Permits a waived-practitioner to immediately start treating 100 patients at a time with buprenorphine (skipping the initial 30 patient cap) if the practitioner has board certification in addiction medicine or addiction psychiatry; or if practitioner provides MAT in a qualified practice setting. Advances the notion that medications, such as buprenorphine, in combination with counseling and behavioral therapies, provide a whole-patient approach to the treatment of opioid use disorder. • Comprehensive Opioid Recovery Centers (CORCs) – Secs. 7131 and 7132 incorporate H.R. 5327, the Comprehensive Opioid Recovery Centers Act, establishes CORCs to serve as models for comprehensive treatment and recovery, utilizing the full range of FDA-approved medications and evidence-based treatments. • Expanded Access in FQHCs, RHCs and Other Provisions (Including MA Supplemental Benefits) – Sec. 2007 incorporates H.R. 5776, the MOST Act (detailed above). This provision expands Medicare access to addiction treatment in FQHCs and RHCs, and studies the availability of MA supplemental benefits designed to treat or prevent SUDs, among other provisions. 	<p>Title I: Opioid Crisis Response Act <i>Subtitle D: Treatment and Recovery</i></p> <ul style="list-style-type: none"> • Comprehensive Opioid Recovery Centers – Authorizes a SAMHSA grant program with grants of up to five years with no fewer than 10 grants to be awarded. Entities may have preference if using technology enabled models, such as ECHO. Centers must provide specified treatment and recovery services, including a full continuum of services, all FDA-approved MATs, job training and assistance, onsite pharmacy, and periodic assessment, data reporting, and outreach activities. Authorizes (but does not appropriate) \$10 million annually for each of FYs 2019-2023 (Section 1401). • Medication-Assisted Treatment – Allows physicians to prescribe MAT who have graduated in good standing from an accredited school of allopathic osteopathic medicine during the preceding five-year period, submit a written notification to HHS, and successfully completed a curriculum that included specified elements. Directs HHS to consider how to ensure that an adequate number of pediatric specialists meet these requirements allowing for MAT prescribing (Section 1406). • Grant Program for Medical Schools re: MAT – Authorizes but does not appropriate \$4 million for each of FYs 2019-2023 for medical schools to develop curricula satisfying Section 1406's flexibility allowing medical school graduates to prescribe MAT if they meet specified criteria (Section 1407). • Flexibility in MAT Prescribing – Formalizes in statute that physicians are 	<p>The White House plan calls for expanded access to evidence-based addiction treatment in every state, particularly MAT for opioid addiction.</p>

		<p>able to prescribe MAT for up to 100 patients initially and then up to 275 patients if they meet specified requirements (Section 1408).</p> <p>Title I: Opioid Crisis Response Act; Subtitle E: Prevention</p> <ul style="list-style-type: none"> • Expanded Trauma-Informed Care for Children – Takes multiple steps to expand access to trauma-informed care for children including increasing the authorization level for Congress to fund the National Child Traumatic Stress Initiative, authorizing Congress to appropriate funding for grants to improve trauma support services and culturally-competent mental health care for children and youth in educational settings, and creating an interagency task force to develop best practices for trauma-informed identification, referral, and support for infants, children, youth, and families. (Secs. 1513-1515) <p>Title II: HEAL Act of 2018 Subtitle A: Medicare</p> <ul style="list-style-type: none"> • Requires HHS Secretary to conduct a five-year demonstration project to test Medicare coverage and payment for opioid use disorder (OUD) treatment services furnished by an eligible Opioid Treatment Program (OTP). An eligible OTP selected to participate would receive a bundled payment under Part B for OUD services. These services would include opioid agonist and antagonist treatment medication, counseling, individual and group treatment, toxicology testing, and other services deemed appropriate. HHS would be required to provide a report to Congress that includes evaluation within two years of completion. (Sec. 2109) 	
Extended Family and Other Recovery Supports	Secs. 7031 and 7032 of H.R. 6 incorporate H.R. 4684 , the Ensuring Access to Quality Sober Living Act. These provisions authorize	<p>Title I: Opioid Crisis Response Act Subtitle D: Treatment and Recovery</p>	The White House emphasizes providing addition treatment “on demand” to service

	<p>SAMHSA to develop, publish, and disseminate best practices for operating recovery housing that promotes a safe environment and sustained recovery from SUD. H.R. 6 also incorporates H.R. 5735, the Transitional Housing for Recovery in Viable Environments (THRIVE) Demonstration Program. This provision estimates a pilot program to allocate a portion of federal Section 8 Housing Choice vouchers directly to nonprofit organizations that provide housing, job training and continued support for individuals who are transitioning out of a substance abuse rehabilitation program and back into the workforce.</p> <p>Additionally, secs. 8081, 8082, 8083, and 8084 of H.R. 6 incorporate the House amendment to S. 1091, the Supporting Grandparents Raising Grandchildren Act, which establishes an Advisory Council to Support Grandparents Raising Grandchildren.</p>	<ul style="list-style-type: none"> • Communities of Recovery – Reauthorizes the Building Communities of Recovery program to encompass peer support networks (Section 1404). • Peer Support Technical Assistance Center – Requires SAMHSA to establish a National Peer-Run Training and Technical Assistance Center for Addiction Recovery Support geared toward providing technical assistance to recovery community organizations and peer support networks (Section 1405). • Recovery Housing – Directs HHS to identify or facilitate the issuance of best practices for sober-living houses, including consultation with applicable agencies and accreditors. Provides for development of “common indicators” for identifying operators that may be fraudulent (Section 1409). • Stable Housing Pilot – Authorizes but does not appropriate such sums as necessary (FYs 2019-2023) for a pilot program for states to “provide individuals in recovery from a substance abuse disorder stable, temporary housing” for up to two years. Provides that states would receive funding using a HUD-driven formula within 60 days of enactment (Section 1412). • Youth Prevention and Recovery – Directs HHS and the Department of Education, working with SAMHSA, HRSA, and others, to create a resource center providing technical assistance to communities on prevention, treatment, and recovery from substance abuse disorders among youth and young adults. Authorizes but does not appropriate such sums as 	<p>members, veterans and their families eligible for healthcare through the DoD or VA.</p>
--	--	---	---

		<p>necessary for FYs 2019-2023 (Section 1413).</p> <p>Title II: HEAL Act of 2018 Subtitle C: Human Services The Senate bill includes multiple provisions to expand access to family-focused treatment for patients and support for their children.</p> <ul style="list-style-type: none"> Family-focused Residential Treatment Programs are trauma-informed residential programs that offer SUD treatment to pregnant and postpartum women, parents, and guardians, and that allow children to stay with their parent(s) during treatment. Sec. 2301 requires HHS to issue guidance to states identifying opportunities to support family-focused residential treatment programs for SUD treatment. This includes opportunities and flexibilities under Section 1115 and 1915 waivers as well as a look at how states can coordinate Medicaid, foster care, and other HHS funding to support children residing with their parents in family-based treatment facilities. Section 2303 authorizes \$20 million for HHS to award to states to develop, enhance, or evaluate family-focused treatment programs to increase the number of evidence-based programs that help children at risk of entering foster care and subsequently qualify for funding under the <i>Family First Prevention Services Act</i>. Family Recovery and Reunification Model – Sec. 2302 calls on the Secretary to pilot and evaluate the implementation and impact of the recovery coach model, which is designed to help reunify families and protect children by working with parents or guardians that have temporarily lost custody of their children. Once complete, the Secretary will publicly report on the outcome of the pilot as well as the 	
--	--	--	--

		findings of the impact and implementation studies. If the analysis shows the program should be replicated, the Secretary will share recommendations for legislative and administrative actions. \$15 million is appropriated for FY 2019 and will remain available through FY 2026.	
Medicaid-Focused Policies	<p>In addition to Medicaid-focused components addressed throughout, key provisions in H.R. 6 include:</p> <ul style="list-style-type: none"> • Limited Repeal of Medicaid IMD Exclusion – Sec. 11002 incorporates H.R. 5797, the IMD CARE Act, allows state Medicaid programs from FYs 2019-2023 to remove the IMD exclusion for Medicaid beneficiaries aged 21-64 with a OUD. Medicaid would pay for up to 30 total days of care in an IMD during a 12-month period. Separately, secs. 5011 and 5012 incorporate H.R. 5800, which directs MACPAC to conduct a study on IMDs and Medicaid reimbursement, due no later than January 2020. • Medicaid Health Homes, Pharmacy Homes – Sec. 1007 incorporates H.R. 5810, the Medicaid Health HOME Act, which extends the enhanced match from eight quarters to 10 quarters for states to provide health home wrap-around services for treatment, if they meet quality, cost, and access targets set by CMS. Separately, sec. 1004 incorporates H.R. 5808, the Medicaid Pharmaceutical Home Act. Sec. 1004 requires state Medicaid programs to have a provider and pharmacist assignment program that identifies Medicaid beneficiaries at-risk for SUD and assigns them to a pharmacy home program. The provision sets reasonable limits on the number of prescribers and dispensers that beneficiaries may utilize. 	<p>Title II: HEAL Act of 2018 Subtitle A: Medicaid The Senate bill includes a range of Medicaid-related policies, many of which originated from the HELP bill (S. 2680).</p> <ul style="list-style-type: none"> • Pediatric Population – Sec. 2201 provides support for mothers and children by clarifying that states have the option to make Medicaid services available on an inpatient basis at a residential pediatric recovery center to infants with neonatal abstinence syndrome (NAS). • Peer Support Services – Sec. 2202 requires GAO to report on peer support services in Medicaid, including information on state Medicaid coverage for peer support services, relevant waivers and statutory authority, payment models utilized for reimbursement, and federal and state spending. The report will also include recommendations for legislative and administrative actions to improve access these services and reduce overall health costs. • Telehealth – Sec. 2203 requires CMS to issue guidance to states regarding state options for federal reimbursement for SUD assessment, MAT treatment, counseling, and medication management via telehealth, including services provided in school-based health centers via telehealth. The bill also requires GAO to evaluate children’s access to services and treatment for SUD under 	<p>The White House plan encourages a legislative change to the institutions of mental diseases “IMD exclusion,” and indicates it will continue approving state requests to waive the law in the interim.</p>

	<ul style="list-style-type: none"> ● CHIP Mental Health Parity – Secs. 5021 and 5022 incorporate H.R. 3192, the CHIP Mental Health Parity Act, which requires all CHIP plans to cover treatment of mental illness and SUDs. <p>Additional provisions in H.R. 6 include: (1) provide for the continuous Medicaid coverage of former foster youth (until age 26) even if they move to another state (sec. 1002, which incorporates H.R. 4998, Health Insurance for Former Foster Youth Act); (2) establish a demonstration project to provide an enhanced federal matching rate for state Medicaid expenditures related to the expansion of substance-use treatment and recovery services and provider capacity (sec. 1003, which incorporates H.R. 5477, Rural DOCS Act); (3) require state Medicaid programs to report on all core behavioral health measures (sec. 5001, which incorporates H.R. 5583); (4) provide federal Medicaid matching funds for medical services furnished to certain incarcerated individuals (secs. 5031 and 5032, which incorporates H.R. 4005) and address Medicaid coverage for juveniles while incarcerated (sec. 1001, which incorporates H.R. 1925); and (5) provide Medicaid coverage protections for pregnant and postpartum women in treatment (sec. 1006, which incorporates H.R. 5789).</p> <p>See also below re: pertinent Medicaid data-sharing policies included in H.R. 6.</p>	<p>Medicaid, and specifies that the evaluation must include analysis of provider reimbursement rates. Multiple reports outlining legislative and administrative options for improvement are required including (1) a CMS report on expanding best practices and reducing barriers to using services delivered via telehealth and remote patient monitoring for pediatric Medicaid populations, and (2) a comparison of pediatric services delivered in-person vs. via telehealth.</p> <ul style="list-style-type: none"> ● Non-opioid Alternatives – Sec. 2204 requires CMS to delineate guidance to states by Jan. 1, 2019 outlining mandatory and optional Medicaid services for non-opioid treatment and pain management, including evidence-based non-opioid pharmacological therapies and non-pharmacological therapies. ● Expanded Access to Buprenorphine, Naltrexone – Sec. 2205 directs GAO to study Medicaid barriers that impede beneficiary access to receiving SUD treatment medications, specifically: buprenorphine, naltrexone, and buprenorphine-naltrexone combinations. ● IMD Exclusion – Sec. 2206 allows states to receive federal Medicaid matching funds for otherwise coverable Medicaid items that are provided outside of the IMD, such as prenatal care, to a woman who: is eligible for Medicaid based on being pregnant, is a patient of IMD for receiving SUD treatment, and was enrolled in Medicaid immediately before becoming an IMD patient. Additionally, sec. 2207 allows for state flexibility to receive federal Medicaid payments for expenditures associated with the development of 	
--	---	---	--

		<p>managed care capitation rates for treatment in an IMD.</p> <ul style="list-style-type: none"> • MAT Utilization Controls – Sec. 2208 calls on MACPAC to study and report on utilization management controls that potentially impact access to MAT within both fee-for-service and risk-based managed care Medicaid. • Data-Sharing– Secs. 2209, 2210, and 2211 all pertain to data sharing. Sec. 2209 requires the Secretary to publish state statistics regarding the prevalence and treatment of SUD among FFS and managed care Medicaid beneficiaries, as well as to make such data available to researchers for analysis. Sec. 2210 clarifies state’s ability to access and share data from PDMPs with providers and managed care entities thus helping address the opioid crisis. Sec. 2211 requires reporting on all behavioral health quality measures included in the mandatory core set of adult health quality measures beginning in 2024. • Innovative Housing Services – Sec. 2212 required HHS to report on housing-related services and other innovative initiatives that are successfully being used by state Medicaid agencies to support SUD Medicaid patients that are homeless or at risk of becoming homeless. Sec. 2213 directs HHS to provide technical assistance to help states develop house-related services and care coordination for Medicaid clients with SUD either through state plan amendments or waivers. 	
Other	Secs. 8051 and 8052 of H.R. 6 incorporates H.R. 2147 , the Veterans Treatment Court Improvement Act of 2018, which seeks to enhance veterans’ access to Veterans Treatment Courts (VTCs). Separately, sec. 8061 directs the VA to increase the number of peer-to-peer	<p>Title I: Opioid Crisis Response Act Subtitle D: Treatment and Recovery</p> <ul style="list-style-type: none"> • Program for Support of Drug Overdose Patients – Requires HHS to identify or facilitate the development of best practices for emergency 	

	counselors providing counseling for women veterans . This provision was addressed as part of H.R. 2147 as well.	<p>treatment of drug overdoses; use of recovery coaches; care coordination, including referral after overdose; and provision of overdose reversal drugs. Establishes a grant program for care of patients who have experienced drug overdose, which may include implementation of best practices and connection to a continuum of services. Authorizes but does not appropriate such sums as necessary for each of FYs 2019-2023 (Section 1402).</p> <p>Title IV: Fighting Opioid Abuse in Transportation Act Subtitle B: Opioid Addiction Recovery Fraud Prevention</p> <ul style="list-style-type: none"> • False or Misleading Representations of Opioid Treatment Programs or Products – Provides it is “unlawful to make any deceptive representation with respect to the cost, price, efficacy, performance, benefit, risk, or safety of any opioid treatment program or opioid treatment product. Delineates parameters of FTC as well as state enforcement (Section 4203). 	
INFORMATION-SHARING, DATA TRACKING			
Information Sharing, Data Tracking, State PDMPs	<p>Certain provisions included in H.R. 6 aim to enhance information sharing and data tracking, including through enhanced use of state PDMPs to address the opioid crisis, namely:</p> <ul style="list-style-type: none"> • Patient Medical Records – Secs. 7051 and 7052 incorporates H.R. 5009, Jessie’s Law, which directs HHS to implement standards for display of opioid addiction in medical records. • State PDMPs – Secs. 7201, 7202, and 7203 incorporate H.R. 5812, the Creating Opportunities that Necessitate New and Enhanced Connections That Improve Opioid Navigation Strategies Act 	<p>Title I: Opioid Crisis Response Act; Subtitle E: Prevention</p> <ul style="list-style-type: none"> • Section 1504 authorizes the CDC to collect, analyze and disseminate data to help combat the opioid crisis including conducting direct data analysis as well as providing grants and technical assistance to help states, localities, and tribes improve data collection and utilization. • State PDMPs: Authorizes the CDC to help states improve their PDMPs, encourage inter-state data sharing, and support other evidence-based prevention strategies related to controlled substances. Authorizes \$486 million to be appropriated 	The White House plan calls for the leveraging of Federal funding opportunities to State and local jurisdictions to incentivize and improve nationwide overdoes tracking systems.

	<p>(CONNECTIONS) Act. These provisions authorize the CDC to carry out certain controlled substances overdose prevention and surveillance activities to improve data collection, timeliness, and accuracy for providers and dispensers in state-run PDMPs. Additionally, secs. 5041 and 50425899 incorporate H.R. 5801, the Medicaid PARTNERSHIP Act. These provisions require state Medicaid programs to integrate PDMP usage into a Medicaid provider's (including pharmacists) clinical workflow. Additionally, secs. 5041 and 5042: (1) require providers to check the PDMP before prescribing a Schedule II controlled substance; and (2) establish standard criteria that a PDMP must meet to be counted as a qualified PDMP and requires state Medicaid programs to report to CMS on several PDMP issues.</p> <ul style="list-style-type: none"> • Medicaid DUR Activities – Sec. 1005 incorporates H.R. 5799, the Medicaid DRUG Improvement Act. This provision requires all state Medicaid programs to implement Drug Utilization Review (DUR) activities, including limitations in place for opioid refills, monitoring of concurrent prescribing of opioids and other drugs (such as benzodiazepines and antipsychotics), and monitoring antipsychotic prescribing for children. • Nationwide Electronic Dashboard, Interagency SUD Coordinating Committee – Secs. 7021, 7022, and 7023 incorporate H.R. 4284 – the Indexing Narcotics, Fentanyl, and Opioids (INFO) Act. These provisions direct HHS to create a public and easily accessible electronic dashboard linking to all nationwide efforts to combat the opioid crisis. Also Creates an Interagency SUD Coordinating Committee. 	<p>annually from FY 2019-2024 for these purposes as well as to implement CARA section 102. Reauthorizes HHS' NASPER grant program to support state PDMPs including interoperability. (Secs. 1505, 1507)</p> <ul style="list-style-type: none"> • Adverse Childhood Experiences: authorizes the CDC to support state efforts to collect and report data on adverse childhood experiences (ACEs) utilizing existing public health surveys. (Section 1506) • Patient Medical Records – Like the House bill, incorporate Jessie's Law directing HHS to develop best practices for prominently displaying substance use treatment information in EHRs when requested by patients. (Section 1508) • Prenatal and Postnatal Health – Authorizes data collection and analysis regarding neonatal abstinence syndrome and other outcomes related to prenatal substance use, including support for state and local entities as they improve their abilities to track, collect, analyze and share such data. (Section 1511) • National Milestones to Measure Success – Requires national indicators to measure success curtailing the opioid crisis and reversing opioid-related morbidity and mortality. (Sec. 1516) <p>Title III: Judiciary Subtitle B: Using Data to Prevent Opioid Diversion</p> <ul style="list-style-type: none"> • Provides drug manufacturers and distributors with access to anonymized data from DEA's ARCOS to identify, report, and stop suspicious pharmacy orders of opioids. Secs. 3201-3204. 	
--	--	---	--

	<ul style="list-style-type: none"> • MA/Part D Plan Information Sharing – Sec. 6063 incorporates H.R. 5715, the Strengthening Partnerships to Prevent Opioid Abuse Act, would help to facilitate communication between MA organizations, Part D plan sponsors, and CMS relating to substantiated fraud, waste, and abuse investigations. (See also: PASS Act, H.R. 5773, of which provisions were incorporated). 		
Fraud and Abuse/Program Integrity/Oversight	<p>Various H.R. 6 provisions focus on enhancing enforcement tools to respond to the opioid epidemic, including:</p> <ul style="list-style-type: none"> • Illicit Drugs – Secs. 7001 and 7002 incorporate H.R. 449, the Synthetic Drug Awareness Act. These provisions require the Surgeon General to report on synthetic drugs’ public health impact on youth ages 12-18. Secs. 7191, 7192, 7193, and 7194 incorporate H.R. 5752, the Stop Illicit Drug Importation Act. These provisions streamline and enhance FDA’s tools to intercept illegal products including illicit or unapproved drugs entering the U.S through International Mail Facilities (IMFs). Secs. 7101, 7102, 7103, 7104, 7105, and 7106 incorporate H.R. 5228, the Stop Counterfeit Drugs by Regulating and Enhancing Enforcement Now (SCREEN) Act. These provisions provide FDA with stronger recall and seizure authority, among other things, to disrupt the entry of counterfeit and illicit drugs through IMFs. Also, secs. 8001, 8002, 8003, 8004, 8005, 8006, 8007, 8008, and 8009 incorporate H.R. 5788, the Securing the International Mail Against Opioids Act of 2018. These provisions provide for the processing by U.S. Customs and Border Protection of certain international mail shipments and requires the provision of advance electronic information on international mail shipments of mail, among other provisions. Finally, 	<p>Title II: HEAL Act of 2018 Subtitle A: Medicare</p> <ul style="list-style-type: none"> • Requires CMS to establish a web-based portal to enhance communication between the agency, MA plans, MA-PDs and stand alone prescription drug plans and Medicare Drug Integrity Contractors, with the intention of strengthening the ability to address fraud, waste, and abuse (Sec. 2106) • Enhances the CMS-run Open Payments, or “sunshine”, program by expanding the types of professional who a drug and device manufacturer provides something of value to include: physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, and certified nurse midwives. Ends the prohibition that prevents the inclusion of the unique identification number, for all professionals and other entities. (Sec. 2108) <p>Subtitle D: Synthetics Trafficking and Overdose Prevention</p> <ul style="list-style-type: none"> • Mechanisms to Reduce and Intercede Trafficked Synthetic Drugs via the U.S. Mail System – Directs the Commissioner of the Customs and Border Protection (CBP) and the Postmaster General, to collaborate to identify and develop technology that will improve the detection of synthetic opioids entering the U.S. by mail. Adds requirements and protections regarding the USPS’ use and transmission 	<p>The Administration proposes to reduce supplies of heroin, other illicit opioids, and precursor chemicals by engaging with China and expanded cooperation with Mexico.</p> <p>The plan proposes to advance the DOJ’s Prescribing Interdiction and Litigation (PIL) Task Force by expanding efforts to prosecute “corrupt or criminally negligent doctors, pharmacies, and distributors” and deploy appropriate actions to hold opioid manufacturers accountable for unlawful practices.</p> <p>The plan calls for strengthened criminal penalties for dealing and trafficking in fentanyl and other opioids through use of the death penalty “where appropriate under current law.” It also calls on Congress to pass legislation to reduce the threshold of drugs needed to invoke mandatory minimum sentences.</p>

	<p>H.R. 6 incorporates H.R. 2851, the Stop the Importation & Trafficking of Synthetic Analogues (SITSA) Act, which provides law enforcement with tools to help address illicit synthetic drugs, like fentanyl, while updating scheduling guidelines regarding synthetic drugs.</p> <ul style="list-style-type: none"> • Pharmacy Fraud – Secs. 6101 and 6102 incorporates H.R. 5676, the Stop Excessive Narcotics in our Retirement (SENIOR) Communities Protection Act. These provisions authorize the suspension of payments by Medicare prescription drug plans and MA-PD plans pending investigations of credible allegations of fraud by pharmacies. • MedPAC Report – Secs. 6071 and 6072 incorporates H.R. 5723, the Expanding Oversight of Opioid Prescribing and Payment Act, which requires MedPAC to report on Medicare opioid payment, adverse incentives, and data. 	<p>of advance electronic data (AEDs) to the CBP regarding merchandise from international mail arriving in the U.S. Adds additional mechanisms to strengthen Congressional oversight as well as requirements regarding assigning all costs to foreign shippers or entities, reporting on violations of any requirements, establishing civil penalties for postal shipments, and more. Directs the State Department to ensure the U.S. is in compliance with international postal requirements while also maintaining the U.S.’ ability to secure AED even if such agreements change. (Sec. 2403-2408)</p> <p>Title III: Judiciary Subtitle A: Access to Increased Drug Disposal</p> <ul style="list-style-type: none"> • Establishes a grant program under which the Attorney General provides grants to five States to increase participation of eligible collectors in drug take-back and disposal programs. Sec. 3201-3204. <p>Subtitle B: Using Data to Prevent Opioid Diversion</p> <ul style="list-style-type: none"> • Provides drug manufacturers and distributors with access to anonymized data from DEA’s ARCOS to identify, report, and stop suspicious pharmacy orders of opioids. Secs. 3201-3204. <p>Subtitle C: Substance Abuse Prevention</p> <ul style="list-style-type: none"> • Aims to prevent substance abuse and reduce demand for illicit narcotics, in part via reauthorization of the White House Office of National Drug Control Policy (ONDCP). Other provisions would reauthorize the Drug-Free Communities program (Sec. 3303); the National Community Anti-Drug Coalition Institute (Sec. 3304); the High-Intensity Drug Trafficking Area program (Sec. 3305); funding for the drug court program (Sec. 	
--	--	---	--

		<p>3306-3307); and more. Sec. 3315 authorizes SAMHSA to establish Sobriety Treatment and Recovery Teams (START) grants.</p> <p><i>Subtitle D: Synthetic Abuse and Labeling of Toxic Substances (SALTS)</i></p> <ul style="list-style-type: none"> Amends the Controlled Substances Act to establish factors that may be considered as evidence to determine whether a controlled substance analogue is intended for human consumption and whether a defendant knew the substance was intended to be consumed by injection, inhalation, or ingestion. (Sec. 3401-3401.) <p><i>Subtitle F: Preventing Drug Diversion</i></p> <ul style="list-style-type: none"> Improves drug diversion prevention efforts by requiring registrants to design systems to identify and report suspicious orders, and requiring the DEA to establish a database to collect all suspicious orders and share this information with States. (Section 3601-3602) 	
Health IT	<p>H.R. 6 includes a provision at sec. 6001 that would incentivize adoption and use of CEHRT among behavioral health providers (incorporating H.R. 3331).</p>	<p>Title II: HEAL Act of 2018</p> <p><i>Subtitle A: Medicare</i></p> <ul style="list-style-type: none"> Electronic Prescribing – Requires physicians and other practitioners to prescribe Part-D covered controlled substances electronically. Directs CMS to outline exceptions to the e-prescribing requirement as well as consequences for not complying. (Sec. 2104) Electronic Prior Authorizations – Requires a standard format for prior authorizations related to Part D prescriptions that are prescribed electronically with the intention of increasing efficiency and timely access to necessary prescription drugs. (Sec. 2105) Incentive Payments for Behavioral Health Usage of EHRs – Clarifies CMS 	

		may test payment and delivery models that offer incentive payments to behavioral health providers for adopting EHRs technologies such as electronic documentation and information exchange. (Sec. 2112)	
Telehealth	<p>H.R. 6 includes provisions related to telehealth, such as:</p> <ul style="list-style-type: none"> • Secs. 7171 and 7172 incorporate H.R. 5483, the Special Registration for Telemedicine Clarification Act. These provisions direct HHS to promulgate interim final regulations to implement an existing law which permits the AG to issue a special registration to health care providers to prescribe controlled substances via telemedicine in legitimate emergency situations, such as a lack of access to an in-person specialist. • Sec. 2001 incorporates H.R. 5603, the Access to Telehealth Services for Opioid Use Disorder Act, which instructs CMS to evaluate the utilization of telehealth services in treating opioid use disorder. 	<p>Title I: Opioid Crisis Response Act Subtitle D: Treatment and Recovery</p> <ul style="list-style-type: none"> • Controlled Substance Prescribing Via Telemedicine – Requires DEA final regulations within one year providing parameters for special registration for the prescribing of controlled substances through telemedicine (Section 1415). <p>Title II: HEAL Act of 2018 Subtitle A: Medicare</p> <ul style="list-style-type: none"> • Expands Telehealth – Expands the use of telehealth services for the treatment of OUD and other substance use disorders. Eliminates the originating site requirement for telehealth services furnished to Medicare beneficiaries receiving treatment for SUDs. Allows payments for substance abuse disorder treatment via telehealth at originating sites. (Sec. 2102) 	
Packaging and Safe Disposal	<p>Safe disposal-focused policies addressed by H.R. 6 include:</p> <ul style="list-style-type: none"> • Secs. 5041 and 5042, which incorporates H.R. 5041, the Safe Disposal of Unused Medication Act. • Secs. 7211 and 7212, which incorporates H.R. 5687, the Securing Opioids and Unused Narcotics with Deliberate (SOUND) Disposal and Packaging Act. These provisions: (1) direct FDA to work with manufacturers to establish programs for efficient return or destruction of unused Schedule II drugs, with an emphasis on opioids; (2) facilitate utilization of packaging to reduce opioid overprescribing; and (3) require GAO to 	<p>Title I: Opioid Crisis Response Act Subtitle C: Medical Products & Controlled Substances Safety</p> <ul style="list-style-type: none"> • Clarifies FDA’s authority to require drug manufacturers to package certain opioids to allow for a set treatment duration and to require manufacturers to give patients simple and safe options to dispose of unused opioids. (Section 1302) <p>Title III: Judiciary Subtitle A: Access to Increased Drug Disposal</p> <ul style="list-style-type: none"> • Establishes a grant program under which the Attorney General provides grants to five States to increase participation of eligible collectors in drug take-back and disposal programs. (Sec. 3201-3204.) 	

	<p>study safe disposal of unused opioids and other medications.</p> <ul style="list-style-type: none">• Secs. 6111, 6112, 6113, and 6114 incorporates H.R. 5775, the PROPER Act, which among other provisions, requires Medicare MTM programs and MA in-home health risk assessments (HRAs) to include information about the safe disposal of prescription drugs.		
--	---	--	--