



H.R. 6 –Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act (Rep. Walden R-OR)

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FLOOR SCHEDULE:

Scheduled for consideration on June 22, 2018 under a structured rule.

The rule would provide for consideration of <u>Rules Committee Print 115-76</u> (consisting of Titles I – IV), as amended by <u>Rules Committee Print 115-78</u> (Titles V – VIII). The bill would also consider as adopted a <u>manager's amendment</u> to the Rules Committee Print 115-78 (making technical corrections).

The rule would make in order eight amendments to the bill, which are described below.

The rule would further direct the Clerk to, in the engrossment of H.R. 6, add the texts of H.R. 2851, the Stop the Importation and Trafficking of Synthetic Analogues Act of 2017, H.R. 5735, the THRIVE Act, and H.R. 5797, the Individuals in Medicaid Deserve Care that is Appropriate and Responsible in its Delivery Act, as passed by the House as a new matter at the end of H.R. 6 and to make technical and conforming modifications in the engrossment.

TOPLINE SUMMARY: H.R. 6 would provide Medicaid, Medicare and public health reforms in order to provide relief for certain individuals with substance use disorders including: opioids and analogues of opioids, cocaine and other illegal substances. The legislation generally includes the text of other standalone bills, many of which have passed the House.

COST: The <u>Congressional Budget Office</u> estimates that H.R. 6 would reduce direct spending by \$1.111 billion, reduce revenues by \$164 million, and would reduce the deficit by \$947 million over the FY 2018 – 2028 period.

CONSERVATIVE CONCERNS:

- Expand the Size and Scope of the Federal Government? Certain sections of this legislation authorize and create new government programs. Certain sections of this legislation authorize new authorities to the Secretary of Health and Human Services, as well as new authorities to the FDA. Certain sections of this legislation expand Medicaid and Medicare coverage.
- **Encroach into State or Local Authority?** Some conservatives may feel that certain provisions and sections of this legislation would be more appropriately handled by the state and local governments, or by market forces and civil society.
- **Delegate Any Legislative Authority to the Executive Branch?** Some conservatives may be concerned that certain provisions and sections of this legislation would authorize new rulemaking authority, and requirements to issue guidance for the Secretary of Health and Human Services. Some conservatives may be concerned with the delegation of new authority to the FDA.
- Contain Earmarks/Limited Tax Benefits/Limited Tariff Benefits? No.

DETAILED SUMMARY AND ANALYSIS:

<u>H.R. 6</u> would provide Medicaid, Medicare and public health reforms in order to provide relief for certain individuals with substance use disorders including: opioids and analogues of opioids, cocaine and other illegal substances. The legislation generally includes the text of other stand-alone bills, many of which have passed the House. The bills numbers referenced in each section below reference the bill where the legislative language originated.

Title I - Medicaid Provisions to Address the Opioid Crisis

Sec 101. – At-Risk Youth Medicaid Protection (H.R. 1925)

This section would require state Medicaid programs not to terminate eligibility for medical assistance under the State plan for an individual who is an eligible juvenile because the juvenile is an inmate of a public institution, but may suspend the coverage during the period the juvenile is an inmate.

The state shall, prior to the individual's release conduct a redetermination of eligibility. If the State determines that the individual continues to meet the eligibility requirements for medical assistance, the State shall restore coverage for medical assistance upon the individual's release.

According to <u>CBO</u>, this section would increase outlays by \$75 million over the FY 2018 – 2028 period.

Sec 102. – Health Insurance for Former Foster Youth (H.R. 4998)

This section would provide health coverage for former foster care children up to age 26.

According to $\underline{\text{CBO}}$, this section would increase outlays by \$171 million over the FY 2018 – 2028 period.

Sec 103. – Demonstration to increase substance use provider capacity under the Medicaid program (H.R. 5477)

This Section would require CMS to conduct a 54-month demonstration project to increase the treatment capacity of providers in participating States to provide substance use disorder treatment or recovery services under the State plan.

According to <u>CBO</u>, this section would increase outlays by \$256 million over the FY 2018 – 2028 period.

Sec 104. – Drug management program for at-risk beneficiaries (H.R. 5808)

This section would require State Medicaid programs to run a qualified drug management program under which a State may enroll certain at-risk beneficiaries for substance use disorder identified by the State under the program. This section also details the conditions for enrollment, notification, and re-enrollment.

According to <u>CBO</u>, this section would reduce outlays by \$13 million over the FY 2018 – 2028 period.

Sec 105. - Medicaid drug review and utilization (H.R. 5799)

This section would build upon already in place Medicaid drug review and utilization requirements.

The State would be required to have safety edits for subsequent fills for opioids and a claims review automated process that indicates when an individual enrolled under the State plan is prescribed a subsequent fill of opioids in excess of any limitation that may be identified by the State. Additionally, the State would be required to have safety edits on the maximum daily morphine equivalent that be prescribed for the treatment of chronic pain, as well as a claims review automated process. Finally, the State would be required to have a claims review automated process that monitors when an individual enrolled under the State plan is currently prescribed opioids, benzodiazepines, and antipsychotics.

This section also contains a provision to monitor antipsychotic medications prescribed to children.

According to CBO, this section would increase outlays by \$5 million over the FY 2018 – 2028 period.

Sec 106. – Guidance to improve care for infants with neonatal abstinence syndrome and their mothers and GAO report (H.R. 5789)

This section would require the Secretary of Health and Human Services to provide guidance to improve care for infants with neonatal abstinence syndrome and their families.

This section would require the Government Accountability Office to conduct a study addressing gaps in coverage for pregnant women with substance abuse disorder under the Medicaid program, and gaps in coverage for postpartum women with substance use disorder who had coverage during their pregnancy.

Sec 107. – Medicaid health homes for opioid-use disorder Medicaid enrollees (H.R. 5810)

This section would extend the enhanced matching rate for certain substance use disorder treatment in Medicaid Health Homes from eight quarters by an addition two quarters for a total of 10 quarters.

States which extend the matching rate would be required to submit a report to the Secretary of Health and Human services on the quality of care provided, with a focus on the outcomes relevant to the recovery of each individual; the access of the individual to health care; and the total expenditures of each participant for their health care.

According to $\underline{\text{CBO}}$, this section would increase outlays by \$509 million over the FY 2018 – 2028 period.

Title II - Medicare Provisions to Address the Opioid Crisis

Sec 201. – Authority not to apply certain Medicare telehealth requirements in the case of certain treatment of a substance use disorder or co-occurring mental health disorder (H.R. 5603)

This section would provide the Secretary of Health and Human Services with rulemaking authority to expand telehealth services for individuals diagnosed with a substance use disorder, or a mental health disorder that is co-occurring with a substance use disorder.

This section would also require that the Secretary submit a report to Congress not later than five years after the date of the enactment of this legislation, which would describe the utilization of telehealth services, and the outcomes.

According to CBO, this section would increase outlays by \$11 million over the FY 2018 – 2028 period.

Sec 202. – Encouraging the use of non-opioid analysesics for the management of postsurgical pain (H.R. 5809)

This section would expand a pass-through payment system from three to five years under Medicare for the use of non-opioid pain management drugs.

According to $\underline{\text{CBO}}$, this section would increase outlays by \$180 million over the FY 2018 – 2028 period.

Sec 203. – Requiring a review of current opioid prescriptions for chronic pain and screening for opioid use disorder to be included in the Welcome to Medicare initial preventive physical examination (H.R. 5798)

This section would require a review of current opioid prescriptions and screening for opioid use disorder to be included in the Welcome to Medicare initial preventive physical examination, before an individual can enter the Medicare program.

This section would also require qualified practitioners to: 1) review the beneficiary's potential risk factors for opioid use disorder; (2) evaluate the beneficiary's level of pain; (3) provide the beneficiary information regarding non-opioid treatment options; and (4) provide a referral for additional treatment, where appropriate.

According to <u>CBO</u>, this section would increase outlays by \$5 million over the FY 2018 – 2028 period.

Sec 204. – Modification of payment for certain outpatient surgical services (H.R. 5804)

This section seeks to give patients and providers more pain management options by reversing reimbursement cuts for certain treatments in the Ambulatory Service center setting.

This section would incentivize post-surgical injections as a pain treatment alternative to opioids by reversing a reimbursement cut for these treatments in the Ambulatory Service Center setting, as well as to collect data on a subset of codes related to these treatments.

According to <u>CBO</u>, this section would increase outlays by \$108 million over the FY 2018 – 2028 period.

Sec 205. – Requiring e-prescribing for coverage of covered part D controlled substances (H.R. 3528)

This section would require e-prescribing for coverage of prescribed controlled substances under the Medicare Part D program.

This section would provide the Secretary of Health and Human Services with rulemaking authority to specify circumstances to which the Secretary may waive the e-prescribing requirements for certain specified circumstances.

According to CBO, this section would reduce outlays by \$250 million over the FY 2018 – 2028 period.

Sec 206. – Requiring PDPs under Medicare to establish drug management programs for at-risk beneficiaries (H.R. 5675)

This section would require prescription drug plan sponsors under Medicare to establish drug management programs for at-risk beneficiaries.

According to <u>CBO</u>, this section would reduce outlays by \$60 million over the FY 2018 – 2028 period.

Sec 207. – Medicare coverage of certain services furnished by opioid treatment programs (H.R. 5776)

This section would expand Medicare to include Opioid Treatment Programs for the purposes of delivering Medication-Assisted treatment. Medicare would pay the Opioid Treatment Programs through bundled payments.

This section would also require the Secretary of Health and Human Services to provide an annual update to the bundled payment amounts.

According to <u>CBO</u>, this section would increase outlays by \$250 million over the FY 2018 – 2028 period.

Title III - Other Health Provisions to Address the Opioid Crisis

Sec 301. – Clarifying FDA regulation of non-addictive pain and addiction therapies (H.R. 5806)

This section would require the FDA to hold not less than one public meeting to address the challenges and barriers of developing non-addictive medical products intended to treat pain or addiction.

This section would also require the Secretary of Health and Human Services to issue guidance on to help address challenges to developing non-addictive medical products to treat pain or addiction, including how such products may be eligible for accelerated approval or breakthrough therapy designation.

Sec 302. – Surveillance and Testing of Opioids to Prevent Fentanyl Deaths (H.R. 5580)

This section would authorize the Secretary of Health and Human Services to establish a program to award grants to Federal, State, and local agencies to support the establishment or operation of public health laboratories to detect fentanyl, its analogues and other synthetic opioids.

Sec 303. – Allowing for more flexibility with respect to medication-assisted treatment for opioid use disorders (H.R. 3692)

This section would make permanent the prescribing authority for physician assistants and nurse practitioners and permits a waivered practitioner to immediately start treating from 30 to 100 patients at a time with buprenorphine, which is an opioid medication used to treat opioid addiction.

This section makes the buprenorphine prescribing authority for physician's assistants and nurse practitioners permanent.

This section also requires the Secretary of Health and Human Services to submit a report to the congress that assesses the care provided by qualifying practitioners who are treating, in the case of physicians, 100 or more patients, and in the case of qualifying practitioners who are not physicians, 30 or more patients.

According to <u>CBO</u>, this section would increase outlays by \$395 million over the FY 2018 – 2028 period.

Title VI - Offsets

Sec 401. - Promoting value in Medicaid managed care

This section would provide for an incentive for States to voluntarily adopt a medical loss ratio requirement for their Medicaid managed care organizations at a rate of 85 percent.

According to CBO, this section would reduce outlays by \$2.275 billion over the FY 2018 – 2028 period.

Sec 402. – Extending period of application of Medicare secondary payer rules for individuals with ESRD

This section would extend the limited time period that employer health plans are the primary payer for beneficiaries with end-stage renal disease from 30 months to 33 months. The provision would apply for items and services furnished beginning January 1, 2020.

According to CBO, this section would reduce outlays by \$344 million over the FY 2018 – 2028 period.

Sec. 403 – Requiring reporting by group health plans of prescription drug coverage information for purposes of identifying primary payer situations under the Medicare program

This section would extend mandatory reporting requirements to include prescription drug coverage in order to better coordinate benefits related to Medicare Part D. Starting in 2020, this extension would ensure that all prescription drug coverage provided by group health plans that is primary to

Medicare coverage is communicated to HHS and to Part D sponsors, thereby permitting sponsors to comply with the statutory Medicare secondary payer requirements.

According to <u>CBO</u>, this section would reduce outlays by \$45 million over the FY 2018 – 2028 period.

Title V - Other Medicaid Provisions

Sec. 5001 – <u>H.R. 5583</u>, to amend title XI of the Social Security Act to require states to annually report on certain adult health quality measures, and for other purposes

This section would require state Medicaid programs to report on the behavioral health measures that are included in CMS's 2018 Core Set of Adult Health Care Quality Measures for Medicaid.

According to CBO, "most states have systems in place for reporting such measures to the federal government."

Sec. 5011, 5012 - H.R. 5800, the Medicaid IMD ADDITIONAL INFO Act

These sections would direct the Medicaid and CHIP Payment and Access Commission (MACPAC) to conduct a study on institutions for mental disease (IMD) that receive Medicaid reimbursement. The study would be required to report on the requirements and standards that state Medicaid programs have for IMDs.

MACPAC, considering input from stakeholders, will summarize the findings and make recommendations on improvements and best practices and data collection. The report would be due no later than January 2020.

Sec. 5021, 5022 - H.R. 3192, the CHIP Mental Health Parity Act

These sections would require comprehensive mental health and substance use disorder services as a mandatory benefit under the CHIP program for pregnant women and children.

Specifically, this section would amend the CHIP program to include coverage of mental health services necessary to prevent, diagnose, and treat a broad range of mental health symptoms and disorders, including substance use disorders. This legislation would prohibit States from imposing financial or utilization limits on mental health treatment that are lower than limits places on physical health treatment.

Sec. 5031, 5032 - <u>H.R. 4005</u>, the Medicaid Reentry Act

These sections would direct the Secretary of Health and Human Services to convene a stakeholder group that will produce a report of best practice for states to consider in health care related transitions for inmates of public institutions.

This section would require the Secretary to issue guidance for demonstration projects to inmates to receive medical assistance under Medicaid during the 30-day period preceding release from a public institution.

Sec. 5041, 5042 - H.R. 5801, the Medicaid PARTNERSHIP Act

These sections would require providers who are permitted to prescribe controlled substances and who participate in Medicaid to query prescription drug monitoring programs (PDMPs) before prescribing controlled substances to Medicaid patients beginning October 1, 2021.

This section would also require each State to include in the annual report submitted to the Secretary, beginning in 2023, a percentage of covered providers who check the prescription drug history of a covered individual through a qualified prescription drug monitoring program before prescribing a controlled substance, as well as the types of controlled substances prescribed. Additionally, CMS would be required to publish a report including guidance for States on how States can increase the percentage of covered providers who use qualified prescription drug monitoring programs; and best practices for how States and covered providers should use such qualified prescription drug monitoring programs to reduce the occurrence of abuse of controlled substances.

This section would increase the Federal medical assistance percentage, or Federal matching rate, for expenditures by the State for administrative costs to implement a prescription drug management program during the period beginning October 1, 2018, and ending September 30, 2021, if the state has in place agreements with all contiguous states allowing providers in contiguous states to access the program. The increase in the Federal medical assistance percentage, or Federal matching rate would be prohibited from resulting in exceeding a 100 percent rate. However, the increase that may be provided is not specified by the legislation.

This section would require CMS to issue guidance on best practices on the use of prescription drug monitoring programs and on privacy of Medicaid beneficiary information.

Title VI - Other Medicaid Provisions

Sec. $6001 - \underline{\text{H.R. 3331}}$, To amend title XI of the Social Security Act to promote testing of incentive payments for behavioral health providers for adoption and use of certified electronic health record technology

Obamacare created the Center for Medicare and Medicaid Innovation (CMMI) "to test models that improve care, lower costs, and better align payment systems to support patient-centered practices."

This section would add a model to make incentive payments to behavioral health providers to adopt and use electronic health record technology.

According to CBO, "it is already clear to CMMI that it has that authority" under current law.

Sec. 6011, 6012 - H.R. 5582, the Abuse Deterrent Access Act of 2018

These sections would require a report from the Secretary of Health and Human Services (HHS) regarding the adequacy of access to abuse-deterrent opioid formulations for individuals with chronic pain for Medicare patients.

Sec. 6021, 6022 - H.R. 5685, the Medicare Opioid Safety Education Act

These sections would direct the Centers for Medicare and Medicaid Services (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.

Sec. 6031, 6032 - H.R. 5590, the Opioid Addiction Action Plan Act

These sections would require the Secretary of HHS to develop an action plan by January 1, 2019, for increasing access to medication-assisted treatment among Medicare and Medicaid enrollees.

The Secretary of HHS, in collaboration with the Pain Management Best Practices Inter-Agency Task Force, would be required to develop an action plan that provides recommendations on changes to the Medicare and Medicaid program for all medication-assisted treatment of opioid addiction and other therapies that manage chronic and acute pain, as well as recommendations to minimize the risk of opioid addiction. Additionally, this action plan would be required to enhance the coverage and reimbursement of medication-assisted treatment for opioid addiction.

Finally, this section would require the Centers for Medicare and Medicaid Services to convene a stakeholders group to receive public comment on the action plan.

Sec. 6041, 6042 – <u>H.R. 5605</u>, the Advancing High Quality Treatment for Opioid Use Disorders in Medicare Act

These sections would establish a four-year demonstration program to increase access to treatment for opioid use disorder.

The purpose of this program would be to increase access of applicable beneficiaries to opioid use disorder treatment services; improve physical and mental health outcomes for such beneficiaries; and to reduce Medicare expenditures. The demonstration would provide incentive payments and funding for care management services based on criteria such as patient engagement, use of evidence based treatments, and treatment length and intensity.

Under this section, the Secretary of HHS would be directed to encourage other payers to coordinate payments for opioid use disorder treatments and to evaluate the extent to which the demonstration reduces hospitalizations, increases the use of medication-assisted treatments, and improves the health outcomes of individuals with opioid use disorders during and after the demonstration.

The Comptroller General of the United States would be required to submit a report to the Secretary and Congress regarding an evaluation of this program.

This section would provide for the transfer from the Federal Supplementary Medical Insurance Trust Fund of \$5 million to the Centers for Medicare & Medicaid Services Program Management Account for administrative expenses. The bill would also provide for the transfer from the Federal Supplementary Medical Insurance Trust Fund of \$10 million each fiscal year over the FY 2021 – 2024 period for making payments under the program.

This section would allow the Secretary to waive any provision of the title to carry out the program.

This section would require prescriptions for controlled substances on Schedule II, III, IV, and V under Medicare Part D to be transmitted by a practitioner electronically beginning in 2021. The bill would allow this provision to be waived under certain circumstances.

According to <u>CBO</u>, this would increase outlays by \$107 million over the FY 2018 – 2028 period.

Sec. 6051, 6052 - H.R. 5796, the REACH OUT Act of 2018

These sections would allow the Secretary of Health and Human Services to award grants to certain organizations that provide technical assistance and education to high-volume prescribers of opioids.

The purpose of the grants would be to educate and provide outreach to prescribers of opioids about best practices for prescribing opioids; to educate about non-opioid pain management therapies; and to reduce the amount of opioid prescriptions prescribed by prescribers of opioids. In order to be considered for a grant, the eligible entity shall submit an application to the Secretary containing the information that the Secretary shall require as determined by the Secretary.

This section would provide for the transfer of \$75 million from the Federal Supplementary Medical Insurance Trust Fund to the Centers for Medicare & Medicaid Services Program Management Account to implement the grant.

This section would also make modifications to the federal share for Medicaid managed care between FY 2026 – 2028.

Sec. 6061, 6062, 6063, 6065, 6064 – H.R. 5773, the PASS Act of 2018

These sections would require Medicare Part D prescription drug plans to provide drug management programs for Medicare beneficiaries who are at risk for prescription drug abuse.

This section would require health care professionals to submit prior authorization requests electronically, starting on January 1, 2021, for drugs covered under Medicare Part D. Additionally, this legislation would expend medication therapy management programs under Medicare Part D to include beneficiaries who are at risk for prescription drug abuse.

Finally, this section would require the Secretary of Health and Human Services to establish a secure Internet portal to allow Health and Human Services, Medicare Advantage plans, and Medicare Part D plans to exchange information about fraud, waste, and abuse among providers and supplier no later than two years after enactment. H.R. 5773 also would require organizations with Medicare Advantage contracts to submit information on investigations related to providers suspected of prescribing large volumes of opioids through a process established by the Secretary no later than January 2021.

Sec. 6071, $6072 - \underline{\text{H.R. } 5723}$, the Expanding Oversight of Opioid Prescribing and Payment Act of 2018

This section would require the Medicare Payment Advisory Commission to report on opioid payment, adverse incentives, and data under the Medicare program.

The report to Congress would include payments for pain treatment, incentives for prescribing opioids in inpatient and outpatient settings, and documented tracking of opioid use from Medicare claims data.

This section specifies that no additional funds are authorized to be appropriated to carry out the requirements of the bill, and that the requirements shall be carried out using amounts otherwise authorized.

Sec. 6081, 6082, 6083, 6084, 6085, 6086 – <u>H.R. 6110</u>, the Dr. Todd Graham Pain Management, Treatment, and Recovery Act of 2018

These sections would require the Secretary of Health and Human Services to conduct a review of payments under the Medicare Outpatient Prospective Payment System for opioids and evidence-based non-opioid alternatives for pain management with a goal of ensuring that there are not

financial incentives to use opioids instead of non-opioid alternatives. The Secretary would be required to consider the extent to which revisions such as the creation of additional groups of outpatient department services to classify procedures that utilize opioids and non-opioid alternatives separately would reduce payment incentives for opioids instead of non-opioids. If the Secretary identifies revisions, the bill would require the Secretary to begin making them beginning on January 1, 2020. The Secretary would be required to focus on covered outpatient department services, ambulatory payment classifications that primarily include surgical services, and other services determined by the Secretary which general involve treatment for pain management.

Additionally, this section would expand access under Medicare for addiction treatment at Federally Qualified Health Centers. The payment for these treatments will be subject to available appropriated funds, and the amount will be determined by the Secretary. The bill would provide \$6 million in mandatory funding for this purpose to remain available until expended. Further, access to similar opioid addiction treatment will be expanded to certain Rural Health Clinics. The bill would provide \$2 million in mandatory funding for this purpose to remain available until expended.

This section would require a study on the availability of supplemental health care benefits designed to treat or prevent substance use disorders under Medicare Advantage plans.

According to <u>CBO</u>, this would increase outlays by \$8 million over the FY 2018 – 2028 period.

Sec. 6091, 6092, 6093, 6094, 6095 - H.R. 5774, the COACH Act of 2018

These sections would require the Secretary of Health and Human Services to develop and publish an online guide by January 1, 2019, on pain management strategies and opioid use disorder prevention strategies with respect to individuals entitled to benefits under Medicare Part A. The Secretary would be required to consult with relevant stakeholders including: medical professional organizations, providers and suppliers of services, health care consumers or groups representing such consumers, and other entities determined appropriate by the Secretary.

This section would require the Secretary to establish a technical expert panel for the purposes of reviewing quality measures relating to opioids and opioid use disorders, including care, prevention, diagnosis, health outcomes, and treatment furnished to individuals with opioid use disorders. This panel shall, not later than one year after its establishment, provide a report to the Secretary on its findings.

Further, this section also would require the Secretary to establish an additional technical expert panel on reducing surgical setting opioid use, and to collect data on perioperative opioid use; and to report on diagnosis-related group codes that have the highest volume of surgeries and the availability of associated data regarding post-operative opioid use, including prescription patterns and rates of consumption. This panel would be required to include medical and surgical specialty societies and hospital organizations.

This section would require the Secretary to post all guidance published by the HHS on or after January 1, 2016, relating to prescribing opioids applicable to Medicare Part A and B beneficiaries to a public website.

Sec. 6101, 6102 - H.R. 5676, the SENIOR Communities Protection Act of 2018

These sections would authorize the suspension of payments by Medicare prescription drug plans and Medicare Advantage Prescription Drug plans, pending investigation of credible allegations of fraud by pharmacies.

This section also clarifies that a fraud hotline tip, as defined by the Secretary of Health and Human Services, without further evidence shall not be treated as sufficient evidence for a credible allegation of fraud.

The changes made by the bill would be applicable to plan years beginning January 1, 2020.

According to CBO, this would reduce outlays by \$9 million over the FY 2018 – 2028 period.

Sec. 6111, 6112, 6113, 6114 – <u>H.R. 5775</u>, the Providing Reliable Options for Patients and Educational Resources (PROPER) Act

These sections would require prescription drug plans that provide coverage under Medicare Part D to furnish information to beneficiaries about the risks of opioid use and the availability of alternative treatments for pain.

The section also would require Medicare Advantage plans and prescription drug plans to provide information regarding safe disposal of controlled substances in home health risk assessments and medication therapy management programs.

This section also would make changes to pain-related questions on the Hospital Consumer Assessment of Healthcare Providers and Systems survey. Specifically, the survey may not include questions about communication by hospital staff with an individual about such individual's pain unless such questions take into account whether an individual experiencing pain was informed about risks associated with the use of opioids and about non-opioid alternatives for treatment of pain.

Title VII - Other Health Provisions

Sec. 7001, 7002 - H.R. 449, Synthetic Drug Awareness Act of 2017

These sections would require the U.S. Surgeon General to submit a comprehensive report to Congress on the public health effects of the rise in synthetic drug use among youth aged 12 to 18.

Synthetic drugs, such as synthetic cannabinoids (Spice, K2), cathinones (Bath Salts), and psychedelic phenethylamines (N-Bomb) are produced in labs and can have chemical structures that can be either identical to or different from naturally occurring drugs. Their effects are designed to mimic or enhance those of natural drugs. Synthetic drugs can be modified to circumvent the Drug Enforcement Administration's (DEA) scheduling regime. Fentanyl, a substance that is 50 times more potent than heroin and 100 times more potent than morphine, has numerous analogs. Before DEA's recently issued order to schedule all fentanyl-related compounds under Schedule I, when the agency would temporarily control one given fentanyl substance, illicit manufacturers abroad would produce new analogs through minor structural modifications to be smuggled and distributed as a purportedly "non-controlled substances."

Sec. 7011, 7012 – <u>H.R. 4275</u>, Empowering Pharmacists in the Fight Against Opioid Abuse Act

These sections would require the Department of Health and Human Services (HHS) to develop and disseminate training programs and materials for pharmacists, health care providers, and patients on circumstances where a pharmacist may decline to fill a prescription he feels is fraudulent or is indicative of diversion.

Sec. 7021, 7022, 7023 – <u>H.R. 4284</u>, Indexing Narcotics, Fentanyl, and Opioids (INFO) Act of 2017

These sections would direct the Department of Health and Human Services to create a public and easily accessible electronic dashboard linking to all of the nationwide efforts and strategies to combat the opioid crisis.

Additionally, this legislation would create an Interagency Substance Use Disorder Coordinating Committee to review and coordinate opioid use disorder and other substance use disorder research, services, and prevention activities across all relevant Federal agencies, evaluate the effectiveness of these activities, and make specific recommendations for actions that agencies can take to better coordinate the administration of services for patients with opioid use disorder and substance abuse disorder. The Committee would terminate after six years.

Sec. 7031, 7032 - <u>H.R. 4684</u>, the Ensuring Access to Quality Sober Living Act of 2017 These sections would require the Substance Abuse and Mental Health Services Administration

(SAMHSA) to develop, publish, and disseminate best practices, including model laws, for operating recovery housing that promotes a safe environment for sustained recovery from substance use disorder (SUD).

This section would authorize the appropriation of \$3 million over the FY 2019 – 2021 period.

Sec. 7041, 7042 - <u>H.R. 5002</u>, ACE Research Act

These sections would provide the National Institutes of Health (NIH) with new authority to conduct "high impact cutting-edge research that fosters scientific creativity and increases fundamental biological understanding leading to the prevention, diagnosis, or treatment of diseases and disorders, or research urgently required to respond to a public health threat."

Sec. 7051, 7052 - H.R. 5009, Jessie's Law

These sections would require the Department of Health and Human Services (HHS) to develop and disseminate best practices regarding the prominent display of substance use disorder (SUD) history in patient records of patients who have previously provided this information to a health care provider and who request the display of the information.

This section would also require HHS to annually develop and disseminate information to health care providers regarding permitted disclosures of information to families, caregivers, and health care providers.

Sec. 7061, 7062 - H.R. 5041, Safe Disposal of Unused Medication Act,

The Controlled Substances Act requires persons who manufacture, distribute, or dispense controlled substances to register with the Department of Justice.

These sections would provide that an employee of a hospice program to handle and dispose of controlled substances for the person receiving the care without having to register with the Department of Justice.

This section would require training for hospice employees and would require hospice programs to have written policies regarding disposal of controlled substances.

Sec. 7071 – <u>H.R. 5102</u>, Substance Use Disorder Workforce Loan Repayment Act of 2018

This section would create a loan repayment program for substance use disorder treatment providers.

Specifically, this section would offer student loan repayment of up to \$250,000 for participants who agree to work as a substance use disorder treatment professional in areas most in need of their services. The program would be available to a wide range of direct care providers, including physicians, registered nurses, social workers, and other behavioral health professionals.

This section would authorize the appropriation of \$25 million for each year over the FY 2019 – 2028 period.

Sec. 7081, 7082 – <u>H.R. 5176</u>, Preventing Overdoses While in Emergency Rooms (POWER) Act of 2018

These sections would require the Department of Health and Human Services (HHS) to establish a program to develop protocols for discharging patients who have presented with an opioid overdose.

This section would establish a grant to up to 20 health care sites to carry out the program. Grants would be used to establish polices to address the administration of overdose reversal medication and best practices for treating overdoses, and could be used to hire medical professionals, establishing models of care, and other uses.

This section would authorize the appropriation of \$50 million for the FY 2019 – 2023 period.

Sec. 7091, 7092 – <u>H.R. 5197</u>, Alternatives to Opioids (ALTO) in the Emergency Department Act

These sections would require the Department of Health and Human Services (HHS) to carry out a demonstration program to award grants to hospitals and emergency departments to develop, implement, enhance, or study alternative pain management protocols and treatments that limit the use and prescription of opioids in emergency departments.

This section would authorize appropriation of \$10 million each fiscal year of the FY 2019 – 2021 period.

Sec. 7101, 7102, 7103, 7104, 7105, 7106 – <u>H.R. 5228</u>, the Stop Counterfeit Drugs by Regulating and Enhancing Enforcement Now (SCREEN) Act

These sections would provide authority for Food and Drug Administration (FDA) to authority destroy certain drugs imported into the United States through the mail. The bill would increase the maximum dollar amount of drugs that may be destroyed, if the FDA Commissioner determines it is in the interest of public health.

This section would allow the FDA to order a distributer of a drug to cease distribution of the drug upon a determination that use, consumption, or exposure to the drug may present an imminent or substantial 15 hazard to the public health. The bill would provide an informal hearing within 10 days for the person subject to the order. The bill would allow the FDA to recall the drug.

This section would allow the FDA to seize all drugs being offered for importation by a manufacturer, distributor, or importer as adulterated or misbranded, if the FDA "identifies a pattern of adulterated or misbranded drugs being offered for import from the same manufacturer, distributor, or importer."

This section would establish a new FDA Opioid and Substance Use Epidemic Response Fund "to strengthen and facilitate the Food and Drug Administration's efforts to address the opioid and substance use epidemic." The bill would transfer \$110 million annually over the FY 2019 – 2023 period from the General Fund of the Treasury to the new Fund. The bill would authorize appropriations from the Fund as high as the annual transfer. The bill would provide that for FY 2019 – 2023, the total amount of appropriations out of the Fund shall be subtracted from the CBO estimate of discretionary Budget Authority and Outlays and the amount transferred to the Fund shall be reduced by the same amount in order to offset the budgetary effects of the appropriations for CBO scoring purposes. The bill would limit the applicability of transfer authority provided in appropriations bills to require that the funds appropriated from the Fund be limited to the uses specified by the bill.

This section would allow the FDA to refuse an application for a new drug "if the drug is or contains a controlled substance for which a listing in any schedule is in effect under the Controlled Substances Act or that is permanently scheduled pursuant to section 201 of such Act, on the basis of information submitted to him as part of the application, or upon the basis of any other information before him with respect to such drug, the drug is unsafe for use due to the risks of abuse or misuse or there is insufficient information to show that the drug is safe for use considering such risks." The bill would allow the FDA to withdraw approval of a drug if the Secretary finds "that, in the case of a drug that is or contains a controlled substance for which a listing in any schedule is in effect under the Controlled Substances Act or that is permanently scheduled pursuant to section 201 of such Act, on the basis of new information before him with respect to such drug, evaluated together with the information available to him when the application was approved, that the drug is unsafe for use due to the risks of abuse or misuse."

Sec. 7111, 7112 - H.R. 5261, TEACH to Combat Addiction Act of 2018

These section would allow for the designation of Regional Centers of Excellence in Substance Use Disorder Education. Eligible entities would include health systems, medical schools, teaching hospitals, and other health profession schools.

This section would authorize the appropriation of \$4 million for each year over the FY 2019 – 2023 period.

Sec. 7121 – <u>H.R. 5272</u>, a bill to ensure that programs and activities that are funded by a grant, cooperative agreement, loan, or loan guarantee from the Department of Health and Human Services, and whose purpose is to prevent or treat a mental health or substance use disorder, are evidence-based

This section would direct the Substance Abuse and Mental Health Services Administration (SAMHSA) to provide guidance for entities applying for substance use disorder and mental illness grants, including guidance to grantees on how best to articulate the rationale for a given program or activity.

Sec. 7131, 7132 - H.R. 5327, Comprehensive Opioid Recovery Centers Act 2018

These sections would establish grants for at least ten Comprehensive Opioid Recovery Centers (CORCs) that would serve as models for comprehensive treatment and recovery. CORCs would utilize

the full range of FDA-approved medications and evidence-based treatments, have strong linkages with the community, generate meaningful outcomes data, and dramatically improve the opportunities for individuals to establish and maintain long-term recovery as productive members of society.

This section would authorize the appropriation of \$10 million each year over the FY 2019 – 2023 period.

Sec. 7141, 7142, 7143, 7144 – <u>H.R. 5329</u>, the Poison Center Network Enhancement Act of 2018

These sections would reauthorize the national network of Poison Control Centers, which offer free, confidential, and expert medical advice 24 hours a day, seven days a week. Often times these programs serve as the primary resource for poisoning information and help reduce Emergency Room visits through in-home treatment.

This section would reauthorize a public awareness campaign regarding poison control centers.

This section would reauthorize the Poison Control Center Grant Program.

This section would authorize a total of \$30.1 million annually over the FY 2019 – 2023 period for these activities.

Sec. 7151, 7152 – <u>H.R. 5353</u>, Eliminating Opioid-Related Infectious Diseases Act of 2018

These sections would reauthorize and expand a program to provide grants to public and nonprofit entities to:

- Cooperate with the States and Indian tribes in implementing or maintaining a surveillance system to determine the incidence of infections commonly associated with illicit drug use, including infections commonly associated with injection drug use
- Identify, counsel, and offer testing to individuals who are at risk of infections as a result of injection drug use, receiving blood transfusions prior to July 1992, or other risk factors.
- Provide appropriate referrals for counseling, testing, and medical treatment of at risk individuals
- Develop and disseminate public information and education programs for the detection and control of infections
- Improve the education, training, and skills of health professionals in the detection and control of infections and the coordination of treatment of addiction and infectious diseases

This section would allow the Centers for Disease Control and Prevention (CDC) to carry out programs, including by grants, to provide for improvements to clinical-laboratory procedures.

This section would authorize the appropriation of \$40 million in each fiscal year over the FY 2019 – 2023 period.

Sec. 7161, 7162 - <u>H.R. 5473</u>, the Better Pain Management Through Better Data Act of 2018

These sections would require the Food and Drug Administration (FDA) to conduct a public meeting and issue one or more guidances to address alternative methods for data collection on opioid sparing, alternative methods for inclusion of such data in product labeling; and investigations other than

clinical trials, including partially controlled studies and objective trials without matched controls such as historically controlled analyses, open-label studies, and meta-analyses, on opioid sparing for inclusion in product labeling.

The terms "opioid sparing" refer to the use of drugs or devices that reduce pain while enabling the reduction, replacement, or avoidance of oral opioids.

Sec. 7171, 7172 – <u>H.R. 5483</u>, Special Registration for Telemedicine Clarification Act of 2018

Current law permits the Attorney General 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. The waiver process has never been implemented through regulation.

These sections would require interim final regulations to be promulgated within one year after enactment of the bill.

Sec. 7181, 7182 - H.R. 5587, the Peer Support Communities of Recovery Act

These sections would expand the Building Communities of Recovery grant program. The bill would authorize the Department of Health and Human Services to award grants to peer support specialist organizations for the development and expansion of recovery services.

This section would authorize appropriations of \$15 million for each fiscal year over the 2019 – 2023 period. This is an increase from the \$1 million that is currently authorized for this program.

Sec. 7191, 7192, 7193, 7194 – H.R. 5752, the Stop Illicit Drug Importation Act of 2018 According to CRS, "Under current law, FDA, in collaboration with the Customs and Border Protection Agency, is authorized to inspect, detain, and refuse entry to imported drugs, devices, food, and other products under its jurisdiction. Recently, FDA Commissioner Gottlieb and others have highlighted challenges associated with diverted opioids or illegal drugs that enter the United States through international mail facilities, including issues with inspecting the high volume of items entering these facilities and procedural difficulties in determining whether a particular product violates the FD&C Act before it may be refused entry or destroyed."

These sections would expand the definition of what is considered a drug under the FDA's authority to detain, refuse, and destroy drugs to include articles that contain an active ingredient in an approved drug, contain an active ingredient that is under clinical investigation, or contain a substance that has a chemical structure that is substantially similar to such an active ingredient.

This section would allow the FDA to refuse importation of "articles of concern" that would include an article that contains a drug or substance for which in the previous 24 months the Secretary of Health and Human Services has initiated the process to schedule it under the Controlled Substances Act.

This section would modify the procedures regarding articles seized by the FDA due to being adulterated or misbranded.

This section would provide for the disbarment of individuals importing controlled substances under certain circumstances.

Sec. 7201, 7202, 7203 – <u>H.R. 5812</u>, the Creating Opportunities that Necessitate New and Enhanced Connections That Improve Opioid Navigation Strategies (CONNECTIONS) Act

These sections would allow the Centers for Disease Control and Prevention (CDC) to award grants to states and local governments, and provide training and technical assistance to states and local governments for evidenced based prevention activities, including prescription drug monitoring programs, health system interventions, evaluating interventions, and public awareness education regarding opioids.

This section would also allow the CDC to provide grants to carry out controlled substance overdose surveillance, including enhancing data reporting.

This section would require the CDC to support states use of Prescription Drug Monitoring Programs.

This section would authorize the appropriation of \$486 million each year over the FY 2019 – 2023 period for these grants and the Prescription Drug Monitoring Program.

Sec. 7211, 7212 - H.R. 5687, the SOUND Disposal and Packaging Act

These sections would authorize the Sectary, after consultation with relevant stakeholders, to issue an order requiring the holder of a covered application to implement or modify one or more technologies, controls, or measures with respect to the packaging or disposal of one or more drugs identified in the covered application. This would be implemented if the Secretary determines such technologies, controls, or measures to be appropriate to help mitigate the risk of abuse or misuse of such drug or drugs, including by reducing the availability of unused drugs. In addition, this bill will facilitate utilization of packaging that may reduce overprescribing, diversion, or abuse of opioids.

Finally, this section would require the Government Accountability Office (GAO) to study new and innovative technologies that claim to be able to dispose of opioids safely and other unused medications. GAO would review and detail the effectiveness of these disposal methods.

Sec. 7221 – <u>H.R. 5811</u>, to amend the Federal Food, Drug, and Cosmetic Act with respect to post approval study requirements for certain controlled substances, and for other purposes

This section would allow the FDA to require that pharmaceutical manufacturers study certain drugs after they are approved to assess any potential reduction in those drugs' effectiveness for the conditions of use prescribed, recommended, or suggested in labeling.

The Secretary would only be able to require a post-approval study, studies, or clinical trial if the Secretary becomes aware of new safety information; and if the Secretary determines that new effectiveness information exists. New effectiveness information is defined as: new information about the effectiveness of the drug, including a new analysis of existing information derived in a clinical trial; an adverse event report; peer-reviewed biomedical literature; and data derived from the postmarket risk identification system. The study wouldn't be considered a new clinical investigation for purposes of providing exclusivity for a drug.

Title VIII - Miscellaneous

Sec. 8001, 8002, 8003, 8004, 8005, 8006, 8007, 8008, 8009 – <u>H.R. 5788</u>, the Synthetics Trafficking and Overdose Prevention (STOP) Act of 2018

These sections would require the Secretary of Treasury to promulgate regulations that would require the United States Postal Service (USPS) to transmit advance electronic data (AED) to U.S. Customs and Border Protection (CBP) for international shipments by the USPS. The AED requirements would be phased in with target percentages that increase over time. By the end of 2018, the percentage of shipments that would have to meet the AED requirement would be set at 70 percent overall, and 100 percent of shipments from China.

By the end of 2020, 100 percent of packages would have to meet the AED requirement. The bill would allow the Commissioner of CBP to exclude a country from the AED requirement if the Commissioner determines that a country does not have the capacity to collect and transmit advance electronic data, represents a low risk for shipments that violate relevant U.S. laws and regulations, and accounts for low volumes of mail shipments that can be effectively screened for compliance with relevant U.S. laws and regulations through an alternate means. The Commissioner would reevaluate such exclusions annually.

The USPS and CBP would be required to refuse shipments after December 31, 2020, that are not transmitted with required AED. The bill gives the USPS and CBP discretion to take remedial action instead of refusing shipment. Remedial action can include destruction, seizure, controlled delivery or other law enforcement initiatives, or correction of the failure to provide the information.

This section would create, starting in 2020, a new customs fee of one dollar to be applied on Inbound Express Mail Service (EMS) items. Collected fees would be split between CBP and USPS, for the costs of customs processing associated with the new requirements. The fee could be adjusted annually beginning in FY 2021 to an amount commensurate with the costs of services provided in connection with the customs processing of Inbound EMS items.

This section would require the Department of Homeland Security and USPS to jointly submit to Congress a report on compliance with the requirements established in this bill.

This section would require the Department of Homeland Security and USPS to develop a joint strategic plan detailing specific performance measures for achieving transmission of AED and for the percentage of targeted mail presented by USPS to CBP for inspection. The bill would also require the Department of Homeland Security and USPS to develop a joint strategic plan detailing the extent to which U.S. Customs and Border Protection and the United States Postal Service are engaged in capacity building efforts, describing plans for future capacity building efforts, and assessing how capacity building has increased the ability of U.S. Customs and Border Protection and the Postal Service.

This section would also require the Government Accountability Office (GAO) to submit a report on the extent and quality of progress made by the USPS in complying the bill's AED requirements.

This section would direct the Secretary of State, in the event that the requirements under the bill are determined to be in violation of obligations of the United States under any postal treaty, convention, or other international agreement to negotiate to amend the relevant provisions of the agreement so that the United States is no longer in violation.

This section would require the USPS and CBP to collaborate to identify and develop technology for the detection of illicit fentanyl, other synthetic opioids, and other narcotics and psychoactive substances entering the United States by mail.

This section would direct the USPS to ensure that all costs associated with complying with this Act are charged directly to foreign shippers or foreign postal operators.

This section would set up a civil penalty against the USPS if the USPS accepts a shipment in violation of the bill's AED requirements after December 31, 2020. The bill would direct CBP to reduce or dismiss the penalty if the USPS has a low error rate in compliance with this Act, is cooperating with CBP, or has taken remedial action to prevent future violations. If CBP determines that the USPS has repeatedly committed violations, it shall impose civil penalties until corrective action, satisfactory to CBP is taken. The bill would require the CBP to annually report on violations occurring in the last year.

According to <u>CBO</u>, this section would increase outlays by \$30 million over the FY 2018 – 2028 period.

Sec. 8011, 8012 - <u>H.R. 5889</u>, the Recognizing Early Childhood Trauma Related to Substance Abuse Act of 2018

These sections would require the secretary of Health and Human Services to disseminate information, resources, and technical assistance to early childhood education providers on ways to properly recognize children who are impacted by drug abuse-related trauma and how to appropriately respond.

The goals of the resources provided must be to educate early childhood education providers on identifying early signs and risk factors, suggest communication tools and practices for traumainformed care, provide options to responding to children, and promoting whole-family and multigenerational approaches to prevent separation.

Sec. 8021, 8022 – <u>H.R. 5890</u>, the Assisting States' Implementation of Plans of Safe Care Act

These sections would require the Secretary of Health and Human Services to provide written guidance and technical assistance to support states in implementing parts of <u>42 U.S.C. 5106a</u> of the Child Abuse Prevention and Treatment Act, which provides grants to states for child abuse or neglect prevention and treatment.

This section requires the guidance to: (1) enhance understanding of requirements and flexibilities; (2) address challenges with developing and implementing plans of safe care; (3) disseminate best practices related to developing and implementing plans of safe care; (4) support collaboration between health care providers, social service agents, public health agencies and the child welfare system, (5) prevent separation and support reunification of families; (6) recommend treatment approaches for serving infants, pregnant women, and post-partum women whose infants may be affected by substance use (7) support state efforts to develop technology systems; (8) help states improve the long term safety and well-being of young children and families.

This section does not amend requirements of the Child Abuse Prevention and Treatment Act.

Sec. 8031, 8032 – <u>H.R. 5891</u>, the Improving the Federal Response to Families Impacted by Substance Use Disorder Act

These sections would establish an Interagency Task Force to Improve the Federal Response to Families Impacted by Substance Use Disorders to identify and recommend ways for federal agencies to coordinate substance abuse disorder and opioid crisis responses.

The task force would be comprised of 12 federal officials from each of the following departments:

- Secretary of Health and Human Services: two members
- Secretary of Education: two members
- Secretary of Agriculture: two members
- Secretary of Labor: two members
- The additional four federal officials/members of the taskforce and the chairperson are to be appointed by the Secretary of Health and Human Services

The taskforce members may not receive pay, allowances or benefits as a result of their service on the taskforce.

The duties of the taskforce are to: (1) solicit input from stakeholders to inform the taskforce's activities; (2) develop a collaboration strategy for the federal response to substance abuse disorders; (3) evaluate and recommend partnerships, professional development or best practices based on that strategy; and, (4) consider evidence–based best practices related to identifying and supporting families at risk of substance abuse exposure.

This section prevents the application of the <u>Federal Advisory Committee Act</u> to the task force.

This section requires the taskforce to prepare a detailed action plan and report to Congress. The taskforce must also submit a report to governors describing opportunities for partnerships. The reports must be made available online and must be released within 9 months of enactment. The taskforce will terminate 30 days after the reports have been disseminated.

Administrative expenses are to be paid out of the existing Department of Health and Human Services appropriations.

Sec. 8041 – <u>H.R. 5892</u>, to establish an Advisory Committee on Opioids and the Workplace to advise the Secretary of Labor on actions the Department of Labor can take to address the impact of opioid abuse on the workplace

This section would require the Secretary of Labor to establish an Advisory Committee on Opioids and the Workplace to advise the secretary on actions the Department of Labor can take to provide informational resources and best practices on how to address the impact of opioid abuse on the workplace and support workers suffering from opioid abuse.

The advisory committee would be comprised of 19 individuals:

- Employer representatives: four members
- Worker representatives: four members (two must be appointed by labor organizations)
- Representatives of health benefits, employee assistance, and workers' compensation plans, and workplace health and safety professionals: three members
- Treatment and recovery experts: 8 members. 1 member may be a state or local government agency representative

The secretary would appoint the chairperson and members of the committee would serve for three years. Members of the committee must serve without compensation.

The committee would advise the secretary on actions the department can take to provide informational resources and best practices on how to address the impact of opioid abuse on the workplace and support workers suffering from opioid abuse. In doing so, the committee must take into account: (1) evidence-based policies and best-practices regarding opioid abuse; (2) the effect of opioid abuse on workplace safety; (3) the impact of opioid abuse on productivity and absenteeism; (4) the extent to which alternative pain management treatments should be covered by employer health plans; (5) the legal requirements the protection of employee privacy and nondiscrimination; (6) interactions of opioids with other substance abuse disorders; (7) additional benefits or available resources to employees abusing opioids that promote worker retention or reentry; (8) initiatives that promote early identification of opioid abuse; (9) workplace policies that reduce stigmatization; and, (10) legal requirements of the Mental Health Parity and Addiction Equity Act and other laws related to health coverage of substance abuse and mental health services and medications.

This section requires the committee to submit a report to the secretary and appropriate congressional committees before the committee's termination.

This section prevents the application of the <u>Federal Advisory Committee Act</u> to the committee.

The bill does not authorize any funds to be appropriated; expenses are to be paid with funds appropriated to department management within the Department of Labor.

This section appoints three ex officio, non-voting member appointed by the secretary from agencies within the Department of Health and Human Services.

The committee would terminate three years after enactment.

Sec. 8051, 8052 – <u>H.R. 2147</u>, the Veterans Treatment Court Improvement Act of 2018 These sections aim to avoid unnecessary criminalization of mental illness and extended incarceration among veterans by ensuring that eligible, justice-involved veterans have timely access to VA services. This program would provide support services to veterans involved in the criminal justice system.

This section would require the Department of Veterans Affairs (VA) to hire at least 50 Veterans Justice Outreach (VJO) Specialists, place each one at an eligible VA medical center, and ensure that each serves as part of a justice team in a veterans treatment court or other veteran-focused court. The bill would require the Secretary to ensure that each VJO specialist otherwise meets the VA hiring guidelines.

According to <u>CBO</u>, "VA reports that currently it is working to hire at least 50 additional specialists for the VJO program," and that the bill would codify the VA's current plan.

This section would establish criteria for an eligible VA medical center, including working within a local criminal justice system for justice-involved veterans, maintaining an affiliation with one or more veterans treatments courts or other veterans-focused courts, and either routinely provides VJO specialists to serve as part of a justice team in a veterans treatment court or establishes a plan to do so. The bill would require that placement of VJO specialists be prioritized for VA medical centers that have or intend to have an affiliation with a veterans treatment court.

Additionally, this section would require the VA and GAO to submit reports to Congress on the VJO program.

Sec. $8061 - \underline{\text{H.R. 4635}}$, to direct the Secretary of Veterans Affairs to increase the number of peer-to-peer counselors providing counseling for women veterans, and for other purposes

According to <u>CBO</u>, "Under current law, VA operates the Peer Support Counseling Program where veterans voluntarily provide support to fellow veterans on issues related to mental health care and readjustment."

This section would require the Department of Veterans Affairs (VA) to attempt to recruit women as peer counselors.

Specifically, this section would direct VA to place an emphasis on appointing and training volunteer peer counselors for women veterans who suffered sexual trauma while in the Armed Forces, experience post-traumatic stress disorder, are homeless or at risk of becoming homeless, or are otherwise at increased risk of suicide.

This section would require the Secretary to conduct outreach to inform women veterans about the program and the assistance available. Further, the Secretary shall coordinate with community organizations, State and local governments, education institutions, local businesses and organizations that provide legal assistance in order to carry out this program.

This section would specify that no additional funds are authorized to be appropriated by the bill and that the VA shall carry out the requirements of the bill using funds otherwise made available to the Secretary.

Additionally, the Secretary would be required to submit a report to the Congress providing an assessment of the program.

Sec. 8071, 8072 - H.R. 5294, the Treating Barriers to Prosperity Act of 2018

These sections would clarify that the <u>Appalachian Regional Commission</u> may provide technical assistance to, make grants to, enter into contracts with, or provide amounts to individuals and entities in the Appalachian region for projects to address drug abuse, including opioid abuse. The bill specifically allows activities to facilitate the sharing of best practices, initiate programs to reduce harm to the workforce and economic growth, attract healthcare services and workers, and develop infrastructure.

This section would prevent more than 50 percent of the cost of the activity from being provided using funds appropriated under this section, unless the county is designated 'distressed' under 40 U.S.C. 14526, in which case 80 percent may be provided, or designated 'at-risk' under 40 U.S.C. 14526, in which case 70 percent may be provided. A current list of counties that have been designated as 'distressed' may be found here.

Grants may be provided in combination with other federal grants and other sources. The bill would allow grants to be used to increase the federal share under other programs, as the Appalachian Regional Commission determines appropriate.

Sec. 8081, 8082, 8083, 8084 – <u>House Amendment to S. 1091</u>, the Supporting Grandparents Raising Grandchildren

These sections would establish an Advisory Council to Support Grandparents Raising Grandchildren. The advisory council would be comprised of the following members, or their designee:

- The Secretary of Health and Human Services
- The Secretary of Education
- The Administrator of the Administration for Community Living
- The Director of the Centers of Disease Control and Prevention
- The Assistant Secretary for Substance Abuse and Mental Health Services Administration
- The Assistant Secretary for the Administration for Children and Families
- A grandparent raising a grandchild
- An older relative caregiver of children
- The head of other federal departments or agencies, as identified by the Secretary of Health and Human Services as appropriate

The lead agency would be the Department of Health and Human Services.

The advisory council would be required to disseminate to the public information, resources and best practices available to help grandparent and older relatives meet the needs of children in their care, and maintain their own health and well-being.

This section would require the advisory council to consider the needs of those affected by the opioid crisis.

This section would require the advisory council to submit a report to the appropriate committees, state agencies, and to the public, online. The advisory council must submit a follow-up report within two years of submitting the first report.

This section would require the advisory council to establish a process to receive public input.

This section prevents the application of the <u>Federal Advisory Committee Act</u> to the committee.

No funds are authorized to carry out the bill, and the council shall terminate three years after enactment.

Sec. 8091, 8092 - H.R. 6029, the REGROUP Act of 2018

The <u>Comprehensive Opioid Abuse Program</u> (COAP) was authorized through the <u>Comprehensive Addiction and Recovery Act of 2016</u>, to provide grants and assistance to state and local governments in combatting the opioid epidemic. Eligible applicants <u>include</u> first responder partnerships, technology-assisted treatment projects, system-level diversion projects, statewide planning, coordination, and implementation projects, Harold Rogers Prescription Drug Monitoring Program (PDMP) Implementation and Enhancement Projects, and Public Safety, Behavioral Health, and Public Health Information-sharing Partnerships. This program was originally authorized at \$103 million per fiscal year through 2021.

These sections would reauthorize the program through 2023 in the amount of \$330 million per fiscal year. This funding level was already appropriated through H.R. 1625, the Consolidated Appropriations Act.

AMENDMENTS:

- 1. <u>(#22) Rep. Walden (R-OR)</u>: would clarify that nothing in the review of current opioid prescriptions for chronic pain and screening for opioid use disorder in the Welcome to Medicare Initial Preventive Physical Examination would be construed to prohibit separate payment for structured assessment and intervention services for substance abuse furnished to an individual on the same day as an initial preventive physical examination.
- 2. (#9) Rep. Dunn (R-FL): would strike language expanding the classes of health care workers who are authorized to dispense narcotics for narcotic treatment, including a qualifying other practitioner, who is a nurse practitioner or physician assistant.
- 3. (#16) Rep. Barton (R-TX): would direct the Commissioner of Food and Drugs to develop high-quality, evidence-based opioid analgesic prescribing guidelines for the indication-specific treatment of acute pain in the relevant therapeutic areas where such guidelines do not exist. The amendment would require the Commissioner of Food and Drugs to gather input through a public workshop and comment period, and to provide a report to Congress on how such guidelines will be used to protect the public health.
- 4. (#11) Rep. Curtis (R-UT): would require a report to Congress from the Secretary of Health and Human Services, in coordination with the Centers for Disease Control and Prevention, the National Institutes of Health, and the Substance Abuse and Mental Health Services Administration on opioids prescribing practices for pregnant women and recommendations for such practices; that provides recommendations for identifying and reducing opioids misuse during pregnancy; on prescription opioid misuse during pregnancy in urban and rural areas; on prescription opioid use during pregnancy for the purpose of medication-assisted treatment in urban and rural areas; evaluating current utilization of non-opiate pain management practices in place of prescription opioids during pregnancy; providing guidelines encouraging the use of non-opioid pain management practices during pregnancy when safe and effective; and that provides recommendations for increasing public awareness and education of opioid use disorder in pregnancy, including available treatment resources in urban and rural areas.
- 5. (#12) Rep. Keating (D-MA): would direct the Secretary of Health and Human Services to issue guidelines for prescribing an opioid overdose reversal drug. In issuing guidelines, the Secretary would address: co-prescribing an opioid overdose reversal drug in conjunction with any prescribed opioid; dosage safety; prescribing an opioid overdose reversal drug to an individual other than a patient; standing orders; other distribution, education, and safety measures as determined necessary.
- 6. (#6) Rep. Meadows (R-NC): would require the Government Accountability Office (GAO) to complete a study and submit a report to Congress on health care policy changes that may have contributed to the increase in opioid overdoses and deaths during the 10 years preceding the bill's enactment. The study would include a review of health care-related legislative, administrative, and judicial decisions by officers and employees of the Federal Government that have affected access to pain management strategies with an emphasis on pharmaceuticals as well as other measures.
- 7. <u>(#19) Rep. Waters (D-CA)</u>: would require the Secretary of Health and Human Services to conduct a survey of all entities that receive Federal funding for the purpose of providing substance use disorder treatment services. The survey would direct such entities to provide

the following information: the length of time the entity has provided substance use disorder treatment services; a detailed description of the patient population served by the entity, including but not limited to the number of patients, type of addictions, geographic area served, as well as gender, racial, ethnic and socioeconomic demographics of such patients; a detailed description of the types of addiction for which the entity has the experience, capability, and capacity to provide such services; an explanation of how the entity handles patients requiring treatment for a substance use disorder that the organization is not able to treat; a description of what is needed, in the opinion of the entity, in order to improve the entity's ability to meet the addiction treatment needs of the communities served by that entity, based on the identified needs of the communities served, a description of unmet needs and inadequate services and how such needs and services could be better addressed through additional Federal, State, or local government resources or funding to treat addiction to methamphetamine, crack cocaine, other types of cocaine, heroin, opioids, and other commonly abused drugs. The amendment would require a report to Congress on the survey.

8. (#14) Rep. Turner (R-OH): would prohibit the Substance Abuse and Mental Health Services Administration from establishing, maintaining, or implementing any memorandum of understanding or other policy that prohibits or restricts the Administration's provision or support of substance abuse treatment or related services for incarcerated individuals, so long as such provision or support is statutorily authorized for such type of treatment or services; and not statutorily prohibited or restricted with respect to incarcerated individuals.

COMMITTEE ACTION:

The bill was introduced on June 13, 2018, and was referred to the House Committee on Energy and Commerce; the House Committee on Ways and Means; and the House Committee on the Judiciary. No further action was taken on H.R. 6 as introduced. However legislative action, including hearings, markups, and floor passage were held for many of the underlying sections.

ADMINISTRATION POSITION:

No Statement of Administration Policy is available at this time.

CONSTITUTIONAL AUTHORITY:

"Congress has the power to enact this legislation pursuant to the following: This bill is enacted pursuant to the power granted to Congress under Article I, Section 8 of the United States Constitution."

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