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House Amendment to the Senate Amendment to 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:

TOPLINE SUMMARY: House Amendment to the Senate Amendment to 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 stand-alone bills, many of which have passed the House.

COST: The Congressional Budget Office estimates that the House Amendment to the Senate Amendment to H.R. 6 would reduce direct spending by $82 million, reduce revenues by $81 million, and would reduce the deficit by $2 million over the FY 2019 - 2028 period.

The CBO report does not provide estimates for authorizations for appropriations included in the bill.

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:

Below is a summary of notable provisions of the House Amendment to the Senate Amendment to H.R. 6.

A section by section and a one page summary from the Energy and Commerce Committee can be found here.

Title I – Medicaid Provisions to Address the Opioid Crisis

Sec. 1001. 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.

Sec. 1002. Health insurance for former foster youth (H.R. 4998).

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

Sec. 1003. 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.

Sec. 1004. 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.

Sec. 1005. 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. 1006. 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 additional 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 CBO, this section would increase mandatory outlays by $509 million over the FY 2019 – 2028 period.

Sec. 1007. Caring recovery for infants and babies.

This section would extend the enhanced matching rate for certain qualified activities for Medicaid health homes targeted towards Medicaid recipients with substance abuse disorders from eight quarters to 10 quarters.

This section would also require state Medicaid programs to provide coverage for medication-assisted treatment.

The provisions in this section would take effect on the date of the enactment of this legislation and shall apply to medical assistance furnished on or after that date, without regard to final regulations.

Sec. 1008. Peer support enhancement and evaluation review.

This section would direct the GAO to submit a report to the Congress regarding: 1) Information on State coverage of peer support, including mechanisms through which States may provide coverage, including through existing statutory authority or through waivers; the populations to which States have provided such coverage; the payment models; and information on Federal and State spending under Medicaid for peer support serviced; and 2) information on selected State experiences in providing medical assistance for peer support services under State Medicaid plans and whether States measure the effects of providing such assistance with respect to: improving access to behavioral health services; improving early detection, and preventing worsening, of behavioral health disorders; reducing chronic and comorbid conditions; and reducing overall health costs.

This section would also include recommendation for such legislative and administration actions related to improving services.

Sec. 1009. Medicaid substance use disorder treatment via telehealth.

This section would direct CMS to issue guidance to states on options for providing services via telehealth that address substance use disorders under Medicaid, including in school-based health centers. The guidance would be issued by the Secretary of Health and Human Services.

This section would also require the GAO to conduct a study on children's access to services and treatment for substance use disorders under Medicaid. Additionally, a report would be required to be sent to Congress containing the evaluation of the study.

Sec. 1010. Enhancing patient access to non-opioid treatment options.

This section would require the Secretary of Health and Human Services to issue one or more final guidance documents, or update existing guidance documents, to States regarding mandatory and optional items and services that may be provided under Medicaid for non-opioid treatment and management of pain, including, but not limited to, evidence-based non-opioid pharmacological therapies and non-pharmacological therapies.

Sec. 1011. Assessing barriers to opioid use disorder treatment.

This section would direct the GAO to analyze and issue a report to Congress on access to substance use disorder treatment medications under various drug distribution models, such as "buy-and-bill".

This section states that the report would need to be sent not later than 15 months after the enactment of this act.

Sec. 1012. Help for moms and babies.

This section would modify the IMD care act by aiming to address the prohibition on Medicaid from paying for otherwise coverable Medicaid services for certain adults while in institutions for mental disease.

This section would take effect on the date of enactment of this legislation.

Sec. 1013. Securing flexibility to treat substance use disorders.

This section would aim to clarify flexibilities around Medicaid's IMD exclusion where managed care plans may provide alterative services in lieu of other services that are not permitted under the state plan.

This section would also codify certain regulations permitting managed care plans to cover treatment in an IMD for a certain number of days in a month in lieu of other types of services.

Sec. 1014. MACPAC study and report on MAT utilization controls under State Medicaid programs.

This section would direct the Medicaid and CHIP Payment and Access Commission to conduct a study and analysis of utilization control policies applied to medication-assisted treatment for substance use disorders under State Medicaid programs, including policies and procedures applied both in fee-for-service Medicaid and in risk-based managed care Medicaid.

The report shall be made public not one year after the date of the enactment of this Act.

Sec. 1015. Opioid addiction treatment programs enhancement.

This section would require the Secretary of Health and Human Services to publish a data book detailing, for each state, statistics on the prevalence and treatment of substance abuse disorder

among Medicaid beneficiaries, including beneficiaries receiving treatment under fee-for-service and managed care arrangements.

This section specifies what the content of the report shall contain.

This section specifies that the content of the report shall be updated annually.

This section requires such data to be made available to researchers in the same manner in which precursor data had been made available in the past, including relevant privacy and security protections.

Sec. 1016. Better data sharing to combat the opioid crisis.

This section would aim to clarify states' ability to access and share data from prescription drug monitoring program databases.

This section contains provisions on security and privacy.

The provisions in this section would take effect on the date of the enactment of this legislation.

Sec. 1017. Report on innovative State initiatives and strategies to provide housing-related services and supports to individuals struggling with substance use disorders under Medicaid.

This section would require the Secretary of Health and Human Services to issue a report to Congress describing innovative State initiatives and strategies for proving housing-related services and supports under a State Medicaid program to individuals with substance use disorders who are experiencing or at risk of experiencing homelessness.

Sec. 1018. Technical assistance and support for innovative State strategies to provide housing-related supports under Medicaid.

This section would require the Secretary of Health and Human Services to provide technical assistance and support to States regarding the development and expansion of innovative State strategies to provide housing-related supports and services and care coordination services under Medicaid to individuals with substance use disorder.

This section states that the report shall be issued not later than 180 days after the date of the enactment of this legislation.

Title II – Medicare Provisions to Address the Opioid Crisis

Sec. 2001. Expanding the use of telehealth services for the treatment of opioid use disorder and other substance use disorders.

This section would expand the use of telehealth services by eliminating certain statutory originating site requirements for telehealth services furnished to Medicare beneficiaries for the treatment of substance use disorders and co-occurring mental health disorders, beginning July 1, 2019.

This section would also allow payment for those services furnished via telehealth at originating sites, including a beneficiary's home, regardless of geographic location.

This section specifies that a report must be sent to Congress not later than five years after the enactment of this legislation.

This section specifies that that the Secretary of Health and Human Services shall provide a transfer of funds from the Federal Supplementary Medical Insurance Trust Fund an amount of $3 million to the Centers for Medicare & Medicaid Services Program Management Account to remain available until expended.

Sec. 2002. Comprehensive screenings for seniors.

This section would increase screening for opioid use disorder and other substance use disorders among Medicare beneficiaries, during Medicare wellness and preventive care visits, facilitating early detection and treatment.

This provisions contained in this section would apply on or after January 1, 2020.

Sec. 2003. Every prescription conveyed securely. (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 mandatory outlays by $250 million over the FY 019 – 2028 period.

Sec. 2004. Requiring prescription drug plan sponsors 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.

Sec. 2005. 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.

Sec. 2006. Encouraging appropriate prescribing under Medicare for victims of opioid overdose.

This section would require CMS to identify beneficiaries enrolled in Medicare Part D with a history of opioid-related overdose and include them in the definition of beneficiaries potentially at-risk for prescription drug abuse under the Part D Drug Management Program.

Sec. 2007. Automatic escalation to external review under a Medicare part D drug management program for at-risk beneficiaries.

This section would require that a beneficiary enrolled in Medicare Part D who is identified as potentially at-risk for prescription drug abuse (or who is subsequently identified as at-risk) can automatically escalate an appeal of such designation to an entity external to the prescription drug plan if the plan affirms its own decision at the initial appeal level.

The provisions in this section would apply beginning not later than January 1, 2021.

Sec. 2008. Suspension of payments by Medicare prescription drug plans and MA–PD plans pending investigations of credible allegations of fraud by pharmacies. (H.R. 5676)

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.

Title III – FDA and Controlled Substance Provisions

Subtitle A – FDA Provisions

Chapter 1 – In General

Sec. 3001. 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 helping 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. 3002. Evidence-based opioid analgesic prescribing guidelines and report ((#16) Rep. Barton (R-TX)).

This section 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.

Chapter 2 – Stop Counterfeit Drugs by Regulating and Enhancing Enforcement Now (H.R. 5228)

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 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."

Chapter 3 – Stop Illicit Drug Importation. (H.R. 5752)

Sec. 3022. Restricting entrance of illicit drugs.

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."

This section 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.

Subtitle B – Controlled Substance Provisions

CHAPTER 1—More Flexibility with Respect to Medication-Assisted Treatment for Opioid Use Disorders

Sec. 3201. Allowing for more flexibility with respect to medication-assisted treatment for opioid use disorders.

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 CBO, this section would increase mandatory outlays by $395 million.

Sec. 3202. Medication-assisted treatment for recovery from substance use disorder.

This section would aim to ensure physicians who have recently graduated in good standing from an accredited school of allopathic or osteopathic medicine, and who meet the other training requirements to prescribe medication-assisted treatment, to obtain a waiver to prescribe medication-assisted treatment.

This section would outline the credentials needed, including a successfully completed allopathic or osteopathic medicine curriculum.

The section would contain provisions regarding the treatment of children with substance use disorders.

Sec. 3203. Grants to enhance access to substance use disorder treatment.

This section would require the Secretary of Health and Human Services to establish a new grant program under which the Secretary shall be able to make grants to accredited schools of allopathic medicine or osteopathic medicine and teaching hospitals located in the United States.

This section would authorize $4 million for each of fiscal years 2019 through 2023.

Sec. 3204. Delivery of a controlled substance by a pharmacy to be administered by injection or implantation.

This section would provide updates to Federal Law in order to allow for implantable or injectable controlled substances of maintenance or detoxification treatment to be delivered by a pharmacy to an administering practitioner while maintaining proper controls, such as storage and record keeping.

This section would require that the Comptroller General submit a study on these provisions to the Congress not later than 2 years after the enactment of this legislation.

Chapter 2—Empowering Pharmacists in The Fight Against Opioid Abuse

Sec. 3212. Programs and materials for training on certain circumstances under which a pharmacist may decline to fill a prescription. (H.R. 4275)

This section 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.

Chapter 3 – Safe Disposal of Unused Medication

Sec. 3222. Disposal of controlled substances of a hospice patient by employees of a qualified hospice program. (H.R. 5041)

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. 3223. GAO study and report on hospice safe drug management.

This section would require the GAO to conduct a study on the requirements applicable to, and challenges of, hospice programs with regard to the management and disposal of controlled substances in the home of an individual.

This section would outline the necessary contents of the report to be sent to Congress not later than 18 months after the date of the enactment of this legislation.

Chapter 4 – Special Registration for Telemedicine Clarification, (H.R. 5687)

Sec. 3232. Regulations relating to a special registration for telemedicine.

This section 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 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.

Chapter 5 – Synthetic Abuse and Labeling of Toxic Substances

Sec. 3241. Controlled substance analogues.

This section would amend the Controlled Substances Act to set forth factors that may be considered as evidence to determine whether a controlled substance analogue is intended for human consumption.

Chapter 6 – Access to Increased Drug Disposal

These sections would provide authority to the Attorney General of the United States to award grants to States in order to enable the States to increase the participation of eligible collectors as authorized collectors.

These sections would outline the guidelines for a State to submit application to the Attorney General; outline the State's ability to use the grants; the eligibility for grants; the duration of grants; the accountability requirements from the State to be sent in a report to the Attorney General; the duration of such program; and the authorization of funds to be appropriated to the Attorney General as such sums as may be necessary to carry out this section.

Chapter 7 – Using Data to Prevent Opioid Diversion

These sections would aim to increase the transparency in the use of Automated Reports and Consolidated Ordering System (ACROS) by providing drug manufacturers and distributors with access to anonymized information through ARCOS to help drug manufacturers and distributors identify, report, and stop suspicious orders of opioids, which will in turn reduce diversion rates.

This section would outline civil penalties for violation of provisions in these sections.

This section would require a report to be sent to the Congress by the Attorney General not later than one year after the enactment of this legislation. The report shall include information on how the Attorney General is using such data, including whether the Attorney General is looking at aggregate orders from individual pharmacies to multiple distributers that in total are suspicious, even if no individual order rises to the level of a suspicious order to a given distributer.

Chapter 8 –Opioid Quota Reform

Sec. 3282. Strengthening considerations for DEA opioid quotas.

This section would establish mandatory factors for the DEA to consider when setting annual opioid quotas, including diversion, abuse, overdose deaths, and public health impacts.

This section would also require the DEA to explain public health benefits if DEA approves any increase in annual opioid quota.

This section also requires the Attorney General to submit certain annual reports to the Congress relating to the provisions of these sections.

Chapter 9 – Preventing Drug Diversion

Sec. 3292. Improvements to prevent drug diversion.

This section would require registrants to design systems to identify and report suspicious orders of opioids. They also require DEA to establish a database for the collection of all suspicious orders reported by all registrants, and to share suspicious order information with the States.

This section would also require a one-time report to be sent to Congress relating to provisions in this section.

Title IV – Offsets

Sec. 4001. 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 mandatory outlays by $2.71 billion over the FY 2019 – 2028 period.

Sec. 4002. 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 CBO, this section would reduce mandatory outlays by $45 million over the FY 2019 – 2028 period.

Sec. 4003. Additional Religious Exemption from Health Coverage Responsibility Requirement. (H.R. 1201)

This section would expand the religious conscience exemption to include any individual "who relies solely on a religious method of healing, and for whom the acceptance of medical health services would be inconsistent with the religious beliefs of the individual." This would primarily apply to members of the Christian Scientist religion.

This legislation passed the House on July 24, 2018, by voice vote.

According to CBO, this section would reduce mandatory outlays by $26 million over the FY 2019 – 2028 period.

Sec. 4004. Modernizing the Reporting of Biological and Biosimilar Products.

This section would ensure that patent agreements regarding biosimilars are accurately reported to the Federal Trade Commission.

This section comes from Sec. 3 of S. 2554, which passed the House on September 25, 2018, by voice vote.

According to CBO, this section would reduce mandatory outlays by $41 million over the FY 2019 – 2028 period.

Title V – Other Medicaid Provisions

Subtitle A – Mandatory Reporting with Respect to Adult Behavioral Health Measures

Sec. 5001. Mandatory reporting with respect to adult behavioral health measures (H.R. 5583).

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."

Subtitle B – Medicaid IMD Additional Info

Sec. 5012. MACPAC exploratory study and report on institutions for mental diseases requirements and practices under Medicaid (H.R. 5800).

This 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.

Subtitle C – CHIP Mental Health and Substance Use Disorder Parity (H.R. 3192).

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.

Subtitle D– Medicaid Reentry (H.R. 4005)

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.

Subtitle E– Medicaid Partnership (H.R. 5801)

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.

Subtitle F– IMD CARE Act

Sec. 5052. State option to provide Medicaid coverage for certain individuals with substance use disorders who are patients in certain institutions for mental diseases.

This section would provide state Medicaid programs with the option to cover care in certain Institutions for Mental Diseases (IMD), which may be otherwise non-federally-reimbursable under the IMD exclusion, for Medicaid beneficiaries aged 21 to 64 with a substance use disorder for fiscal years 2019 to 2023.

This section would outline the services provided.

This section would outline State reporting requirements.

According to CBO, this section, which only provides the benefit for four years, would increase mandatory spending by $1.048 billion over the FY 2019 – 2028 period.

Title VI – Other Medicare Provisions

Subtitle A – Testing of Incentive Payments for Behavioral Health Providers for Adoption and Use of Certified Electronic Health Record Technology

Sec. 6001. Testing of incentive payments for behavioral health providers for adoption and use of certified electronic health record technology. (H.R. 3331)

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.

Subtitle B – Abuse Deterrent Access (H.R. 5582)

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.

Subtitle C – Medicare Opioid Safety Education (H.R. 5685)

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.

Subtitle D – Opioid Addiction Action Plan (H.R. 5590)

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.

Subtitle E – Advancing High Quality Treatment for Opioid Use Disorders in Medicare (H.R. 5605)

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.

Subtitle F – Advancing High Quality Treatment for Opioid Use Disorders in Medicare (H.R. 5796)

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.

Subtitle G – Preventing Addiction for Susceptible Seniors. (H.R. 5773)

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.

Subtitle H – Preventing Addiction for Susceptible Seniors. (H.R. 5723)

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.

Subtitle I – Preventing Addiction for Susceptible Seniors. (H.R. 6110)

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.

Subtitle J – Combating Opioid Abuse for Care in Hospitals. (H.R. 5774)

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.

Subtitle K – Providing Reliable Options for Patients and Educational Resources. (H.R. 5775)

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.

Subtitle L – Fighting the Opioid Epidemic with Sunshine

Sec. 6111. Fighting the opioid epidemic with sunshine.

This section would aim to enhance the CMS sunshine program by expanding the types of professionals for whom a drug and device manufacturer are required to report when the manufacturer provides something of value to include: physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, and certified nurse midwives.

Title VII – Public Health Provisions

Subtitle A – Awareness and Training

Sec. 7001. Report on effects on public health of synthetic drug use.

This section 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. 7002. First responder training.

This section would expand a grant program authorized by the Comprehensive Addiction and Recovery Act, which is designed to allow first responders to administer a drug or device to treat an opioid overdose.

This section would authorize $36 million for each of fiscal years 2019 through 2023.

Subtitle B – Pilot Program for Public Health Laboratories To Detect Fentanyl and Other Synthetic Opioids

Sec. 7011. Pilot program for public health laboratories to detect fentanyl and other synthetic opioids.

This section would establish a pilot program for public health laboratories to detect fentanyl and other synthetic opioids.

This section would authorize $15 million for each of fiscal years 2019 through 2023.

Subtitle C – Indexing Narcotics, Fentanyl, and Opioids

Sec. 7021. Establishment of substance use disorder information dashboard.
This section 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.

Sec. 7022. Interdepartmental Substance Use Disorders Coordinating Committee.
This section would require the Secretary of Health and Human Services to establish an interdepartmental committee to coordinate federal activities related to substance use disorders.

This section would outline whom would be a part of such a committee, as well as their duties.

This section states that the Committee shall terminate on the date that is six years after the date of which the Committee is established.

Sec. 7023. National milestones to measure success in curtailing the opioid crisis.
This section would require the Secretary of Health and Human Services to develop or identify existing national indicators to measure success in curtailing the opioid crisis and significantly reversing the incidence and prevalence of opioid misuse and abuse and opioid-related morbidity and mortality in the United States within five years of enactment.

This section would provide an outline for what those national milestones shall be.

This section would require an annual update to be sent to the Congress on the requirements of this section.

Sec. 7024. Study on prescribing limits.
This section would require the Secretary of Health and Human Services, not later than two years after the enactment of this legislation, to conduct a study on prescribing limits. That report would be sent to the appropriate Congressional committees.

Subtitle D – Ensuring Access to Quality Sober Living. (H.R. 4684)

Sec. 7031. National recovery housing best practices.
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.

Subtitle E – Advancing Cutting Edge Research. (H.R. 5002)
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."

Subtitle F – Jessie's Law. (H.R. 5009)

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. 7053. Development and dissemination of model training programs for substance use disorder patient records.

This section would require the Secretary of Health and Human Services to identify model programs and materials to better train and educate providers, patients and families regarding the permitted uses and disclosures of patient records related to treatment for substance use disorders.

This section would outline the requirements of the model programs.

This section would authorize 1) $4 million for fiscal year 2019; 2) $2 million for each of fiscal years 2020 and 2021; and 3) $1 million for each of fiscal years 2022 and 2023.

Subtitle G – Protecting Pregnant Women and Infants

Sec. 7061. Report on addressing maternal and infant health in the opioid crisis.

This section would require a report to be conducted by the Secretary of Health and Human Service regarding maternal and infant health in the opioid crisis.

This section outlines the requirements of such a report.

Sec. 7062. Protecting moms and infants.

This section would require the Secretary of Health and Human Services to issue and periodically update a report regarding the implementation of the recommendations in the strategy relating to prenatal opioid use, including neonatal abstinence syndrome, developed pursuant to the Protecting Our Infants Act of 2015.

This section would also reauthorize the Residential Treatment for Pregnant and Postpartum Women grant program.

Sec. 7063. Early interventions for pregnant women and infants.

This section would require the Center for Substance Abuse Prevention to develop educational materials for clinicians to use with pregnant women for shared decision-making regarding pain management during pregnancy.

Sec. 7064. Prenatal and postnatal health.

This section would authorize data collection and analysis of neonatal abstinence syndrome and other outcomes related to prenatal substance abuse and misuse, including prenatal opioid abuse and misuse.

Sec. 7065. Plans of safe care.
This provision authorizes the Secretary to provide support for states to collaborate and improve plans of safe care for substance-exposed infants.

This section would provide guidance for the distribution of such funds, as well as the use of such funds.

This section would repeal the Abandoned Infants Assistance Act of 1988.

Subtitle H – Substance Use Disorder Treatment Workforce

Sec. 7071. Loan repayment program for substance use disorder treatment workforce.
This section would require the Secretary of Health and Human Services to enter into six-year loan repayment agreements with substance use disorder treatment professionals in mental health professional shortage areas or counties that have been hardest hit by drug overdoses.

This section would outline the maximum an individual may receive as a loan not to exceed $250,000.

This section would outline who is eligible for such a loan.

This section would require a report to be sent to Congress not later than 5 years after the enactment of the legislation relating to provisions of this section.

Sec. 7072. Clarification regarding service in schools and other community-based settings.
This provision would allow mental and behavioral health providers participating in the National Health Service Corps to provide care at a school or other community-based setting located in a health professional shortage area as part of their obligated service requirements.

Sec. 7073. Programs for health care workforce.
This section would provide programs and training which support the education of for health care workers which that include information on the dangers of opioid abuse, early warning signs of opioid use disorders, safe disposal options, and other innovative deactivation mechanisms.

This section would also make certain updates to Mental and Behavior Health Education and Training Programs.

Subtitle I – Preventing Overdoses While in Emergency Rooms. (H.R. 5176)

Sec. 7081. Program to support coordination and continuation of care for drug overdose patients.
This section 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.

Subtitle J – Alternatives to Opioids in the Emergency Department. (H.R. 5197)

Sec. 7091. Emergency department alternatives to opioids demonstration program.

This section 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.

Subtitle K – Treatment, Education, and Community Help to Combat Addiction. (H.R. 5261)

Sec. 7101. Establishment of regional centers of excellence in substance use disorder education.

This 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. 7102. Youth prevention and recovery.

This section would require the Secretary of Health and Human Services to establish the Centers of Excellence to support the improvement of health professional training resources related to substance use disorder prevention, treatment, and recovery.

Subtitle L – Treatment, Education, and Community Help to Combat Addiction. (H.R. 5272)

Sec. 7111. Information from National Mental Health and Substance Use Policy Laboratory.

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.

Subtitle M—Comprehensive Opioid Recovery Centers. (H.R. 5327)

Sec. 7121. Comprehensive opioid recovery centers.

This section 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.

Subtitle N—Trauma-Informed Care

Sec. 7131. CDC surveillance and data collection for child, youth, and adult trauma.

This section would authorize the Centers for Disease Control to support state efforts to collect and report data on adverse childhood experiences through existing public health surveys.

This section would authorize $2 million for each of fiscal years 2019 through 2023.

Sec. 7132. Task force to develop best practices for trauma-informed identification, referral, and support.

This section would establish a task force, to be known as the Interagency Task Force on Trauma-Informed Care that shall identify, evaluate, and make recommendations regarding: 1) best practices with respect to children and youth, and their families as appropriate, who have experienced or are at risk of experiencing trauma; and 2) ways in which Federal agencies can better coordinate to improve the Federal response to families impacted by stance use disorders and other forms of trauma.

This section would outline the membership of such a task force, as well as the duties of the task force.

This section outlines certain reports to be reported to Congress on the findings of the task force.

Sec. 7133. National Child Traumatic Stress Initiative.

This section increases the authorization level for the National Child Traumatic Stress Initiative to a level of $63.887 million for each of fiscal years 2019 through 2023.

Sec. 7134. Grants to improve trauma support services and mental health care for children and youth in educational settings.

This section would authorize the Secretary of Education, in coordination with the Assistant Secretary for Mental Health and Substance Use, to make grants to link educational agencies with mental health systems in order to increase student access to evidence-based trauma support services to help prevent and mitigate trauma that children and youth experience

This section would outline the duration of such a program, as well as the guidelines for the use of such funds.

This section would outline the application process for such grants.

This section would authorize $50 million for each of fiscal years 2019 through 2023.

Sec. 7135. Recognizing early childhood trauma related to substance abuse.

This section would require the Secretary of Health and Human Services to disseminate information, resources, and if requested, technical assistance to early childhood care and education providers and professionals working with young children on ways to recognize and respond appropriately to early childhood trauma, including trauma related to substance use.

Subtitle O— Eliminating Opioid Related Infectious Diseases. (H.R. 5353)

Sec. 7141. Reauthorization and expansion of program of surveillance and education regarding infections associated with illicit drug use and other risk factors.

This section 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.

Subtitle P— Peer Support Communities of Recovery

Sec. 7151. Building communities of recovery.

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.

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

Sec. 7152. Peer support technical assistance center.

This section would require that the Secretary of Health and Human Services to establish or operate a National Peer-Run Training and Technical Assistance Center for Addiction Recovery Support, to provide technical assistance and support to recovery community organizations and peer support networks providing peer support services related to substance use disorder.

This section would authorize $1 million for each of fiscal years 2019 through 2023.

Subtitle Q – Creating Opportunities That Necessitate New and Enhanced Connections That Improve Opioid Navigation Strategies. (H.R. 5812)

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.

Subtitle R – Review of Substance Use Disorder Treatment Providers Receiving Federal Funding

Sec. 7171. Review of substance use disorder treatment providers receiving Federal funding.

This section would require the Secretary of Health and Human Services to conduct a review of entities that receive Federal funding for the provision of substance use disorder treatment services. This section would outline the requirements of the review.

This section would also require a report to be sent to Congress regarding a plan to address inadequacies in services or funding identified as a result of the review.

Subtitle S – Other Health Provisions

Sec. 7181. State response to the opioid abuse crisis.

This section would reauthorize the state targeted response grants from the 21st Century Cures Act to provide funding to the Tribes and to improve flexibility for state using the grants.

This section would require a report to Congress regarding the purposes and use of grants made available in this section.

This section would authorize $500 million for each of fiscal years 2019 through 2021.

Sec. 7182. Report on investigations regarding parity in mental health and substance use disorder benefits.

This section would require that the Assistant Secretary of Labor of the Employee Benefits Security Administration to provide additional information in annual reports to Congress on mental health parity compliance.

Sec. 7183. CAREER Act.
This section would require the Secretary of Health and Human Services to continue or establish a program to support individuals in recovery from a substance use disorder transition to independent living and the workforce.

This section would also require a report to Congress detailing how grant funding was used, including the number of individuals who received services and an evaluation of the effectiveness of the activities conducted by the grantee with respect to outcomes of the population of individuals with substance use disorder who receive services from the grantee; and recommendations related to best practices for health care professionals to support individuals in substance use disorder treatment or recovery to live independently and participate in the workforce.

This section would authorize $5 million for each of fiscal years 2019 through 2023.

Title VIII – Miscellaneous

Subtitle A—Synthetics Trafficking and Overdose Prevention. (H.R. 5788)

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.

Subtitle B—Opioid Addiction Recovery Fraud Prevention

Sec. 8023. Unfair or deceptive acts or practices with respect to substance use disorder treatment service and products.

This section would state that unfair or deceptive acts with respect to substance use disorder treatment services, or substance use disorder treatment products are subject to civil penalties for first time violations by the Federal Trade Commission.

Subtitle D—Peer Support Counseling Program for Women Veterans. (H.R. 4635)

Sec. 8051. Peer support counseling program for women veterans.

According to CBO, "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.

Subtitle E—Treating Barriers to Prosperity. (H.R. 5294)

These sections would clarify that the Appalachian Regional Commission 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.

Subtitle F—Pilot Program to Help Individuals in Recovery from a Substance Use Disorder Become Stably Housed

Sec. 8071. Pilot program to help individuals in recovery from a substance use disorder become stably housed.

This section would authorize a new pilot program to provide certain individuals in recovery from a substance use disorder with stable and temporary housing.

This section provides guidelines for who shall qualify for such housing.

This section provides information for the use of the funds authorized by this section.

Subtitle G—Human Services

Sec. 8081. Supporting family-focused residential treatment.

This section would require the Secretary of Health and Human Services to develop and issue guidance to states identifying opportunities to support family-focused residential substance abuse treatment program options.

This section would provide an outline for the requirements of such options

Sec. 8082. Improving recovery and reunifying families.

This section would establish a program for parents with children in foster care due to a parental substance abuse. This section would outline the purpose and components of such a program.

This section would appropriate $15 million for fiscal year 2019, which shall remain available through fiscal year 2026.

Sec. 8083. Building capacity for family-focused residential treatment.

This section would authorize the Secretary of Health and Human Services to develop, enhance, or evaluate family-focused treatment programs to increase the number of evidence-based programs that will later qualify for funding under Family First Prevention Services Act.

This section would authorize $20 million for fiscal year 2019, which shall remain available through fiscal year 2023.

Subtitle H—Reauthorizing and Extending Grants for Recovery from Opioid Use Programs. (H.R. 6029)

The Comprehensive Opioid Abuse Program (COAP) was authorized through the Comprehensive Addiction and Recovery Act of 2016, to provide grants and assistance to state and local governments in combatting the opioid epidemic. Eligible applicants include 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 for FY 2018 through H.R. 1625, the Consolidated Appropriations Act.

Subtitle I—Fighting Opioid Abuse in Transportation

Sec. 8102. Alcohol and controlled substance testing of mechanical employees.

This section would require the Secretary of Transportation to publish a rule to apply drug and controlled substance testing requirements to all employees of railroad carriers who perform mechanical activities.

Sec. 8103. Department of Transportation public drug and alcohol testing database.

This section would require the Secretary of Transportation to establish and make publicly available on its website a database of drug and alcohol testing data reported by employers for each mode of transportation and to update the database annually, while protecting commercially sensitive data and ensuring individual employers and employees are not identified.

Sec. 8104. GAO report on Department of Transportation's collection and use of drug and alcohol testing data.

This section would require that not later than two years after the enactment of Sec 8102, the Comptroller General would be required to: 1) review the Department of Transportation Drug and Alcohol Testing Management Information System; and 2) submit the review to Congress.

This section would outline the contents of the report, as well as include any recommendations for improvements.

Sec. 8105. Transportation Workplace Drug and Alcohol Testing Program; addition of fentanyl and other substances.

This section would provide for mandatory guidance for the Transportation Workplace Drug and Alcohol Testing Program. Specifically, within six months, the Secretary of Health and Human Services shall determine whether the inclusion of fentanyl on the panel of drugs authorized for testing is justified and, if justified, requires the Secretary to issue a revision to HHS mandatory guidelines to include fentanyl on the testing panel.

This section would also state that if an expansion is deemed justified, a report shall be sent to Congress on those justifications.

Sec. 8106. Status reports on hair testing guidelines.

This section would require the Secretary of Health and Human Service to provide a report to Congress on the status of the final notice for the scientific and technical guidelines for hair testing, within 60 days of enactment of this legislation and every year thereafter, until the agency publishes a final notice of guidelines for hair testing.

Sec. 8107. Mandatory Guidelines for Federal Workplace Drug Testing Programs using Oral Fluid.

This section would require the Secretary of Health and Human Services, not later than December 31, 2018, to issue final notice of the Mandatory Guidelines for the Federal Workplace Drug Testing Programs using Oral fluid.

Sec. 8108. Electronic recordkeeping.

This section would require that the Secretary of Health and Human Services, not later than one year after the date of the enactment of this legislation, to ensure each certified laboratory that requests the use of paperless electronic chain of custody forms receives approval.

This section also provides a requirement to the Secretary of Transportation to issue a final rule authoring the use of electronic signatures for all paperless chain of custody forms.

Sec. 8109. Status reports on Commercial Driver's License Drug and Alcohol Clearinghouse.

This section requires the Federal Motor Carrier Safety Administration to submit a report to Congress on the implementation of the final rule for the Commercial Driver's Drug and Alcohol Clearinghouse,

within 60 days of enactment of this bill and every year thereafter, until January 6, 2020 or such rule is fully implemented.

Subtitle J—Eliminating Kickbacks in Recovery

Sec. 8122. Criminal penalties.

This section would make it illegal to knowingly and willfully pay or receive kickbacks in return for referring a patient to a recovery home or clinical treatment facilities.

This section would provide that the penalty would not be more than $200,000, as well as imprisonment for not more than 10 years.

This section would provide authority to the Attorney General, in consultation with the Secretary of Health and Human Services to issue and update regulation relating to this section.

Subtitle K—Substance Abuse Prevention

These sections would reauthorize the Office of National Drug Control Policy; the Drug-Free Communities Program; the National Community Anti-Drug Coalition Institute; the High-Intensity Drug Trafficking Area Program; and the drug court program from fiscal years 2018 to 2023.

Sec. 8207. Drug court training and technical assistance.

This section would provide an authorization of $2 million for each of fiscal years 2018 through 2023 for drug court training and technical assistance.

Sec. 8208. Drug overdose response strategy.

This section provides and outline for how to implement a drug overdose response strategy in high intensity drug tracking areas on a nationwide basis.

Sec. 8209. Protecting law enforcement officers from accidental exposure.

This section would provide grants in an amount of not more than $10 million to provide supplemental competitive grants to high intensity drug trafficking areas that have experienced high seizures of fentanyl and new psychoactive substances.

Sec. 8210. COPS Anti-Meth Program.

This section would authorize the Attorney General to use amounts otherwise appropriated to carry out this section to make competitive grants, in amounts of not less than $1 million for a fiscal year, to State law enforcement agencies with high seizures of precursor chemicals, finished methamphetamine, laboratories, and laboratory dump seizures for the purpose of locating or investigating illicit activities, such as precursor diversion, laboratories, or methamphetamine traffickers.

Sec. 8211. COPS anti-heroin task force program.

This section would authorize the Attorney General to use amounts otherwise appropriated to carry out this section, or other amounts as appropriated, to make competitive grants to State law enforcement agencies in States with high per capita rates of primary treatment admissions, for the purpose of locating or investigating illicit activities, through Statewide collaboration, relating to the distribution of heroin, fentanyl, or carfentanil or relating to the unlawful distribution of prescription opioids.

Sec. 8212. Comprehensive Addiction and Recovery Act education and awareness.
This section would authorize the Secretary of Health and Human Services to make grants to entities that focus on addiction and substance use disorders and specialize in family and patient services, advocacy for patients and families, and educational information.

This section would outline the allowable uses for such grants.

Sec. 8213. Reimbursement of substance use disorder treatment professionals.
This section would require that the Comptroller General, not later than January 1, 2020, to submit a report to Congress examining how substance use disorder services are reimbursed.

Sec. 8214. Sobriety Treatment and Recovery Teams (START).
This section would authorize the Secretary of Health and Human Services to make grants to States, units of local government, or tribal governments to establish or expand Sobriety Treatment and Recovery Team or other similar programs to determine the effectiveness of pairing social workers or mentors with families that are struggling with a substance use disorder and child abuse or neglect in order to help provide peer support, intensive treatment, and child welfare services to such families.

This section would outline the allowable uses for such grants, as well as requirements for such programs.

Sec. 8215. Provider education.
Sec. 8218. Emerging threats committee, plan, and media campaign.
Sec. 8219. Drug interdiction.
Sec. 8220. GAO Audit.
Sec. 8221. National Drug Control Strategy.
Sec. 8222. Technical and conforming amendments to the Office of National Drug Control Policy Reauthorization Act of 1998.
These sections would require the Attorney General to provide a plan related to the medical registration coordination required by Senate Report 114-239, which accompanied the Veterans Care Financial Protection Act of 2017.

This section would require certain federal agencies to complete a plan for educating and training medical practitioners in best practices for prescribing controlled substances and focusing on upcoming threats through the establishment of an Emerging Threats Coordinator and Committee to monitor emerging drug threats in coordination with state, local, and tribal governments.

This section would require that not later than four years after the date of enactment of this Act, and every 4 years after, the Comptroller general shall conduct an audit relating to the programs and operations of: 1) the Office; and 2) certain programs within the office.

The report would be submitted to the Congress.

COMMITTEE ACTION:
H.R. 6 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. Legislative action, including hearings, markups, and floor passage were held for many of the underlying sections of the bill.

H.R. 6 passed the House on June 22, 2018, by a vote of 396-14.

The legislation was subsequently passed by the Senate with an amendment on September 17, 2018, by a vote of 99-1.

ADMINISTRATION POSITION:

No Statement of Administration Policy is available at this time for the House Amendment to the Senate Amendment to H.R. 6.

The original Statement of Administration Policy for H.R. 6 as originally considered in the House can be found here.

The Statement of Administration Policy for H.R. 6 as considered in the Senate can be found here.

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."

NOTE: *RSC Legislative Bulletins are for informational purposes only and should not be taken as statements of support or opposition from the Republican Study Committee.*

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