

Description of the Chairman's Mark

**The Helping to End Addiction and Lessen (HEAL)
Substance Use Disorders Act of 2018**

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Title I—Medicare

Section 101: Medicare Opioid Safety Education

Current Law

On an annual basis, the Secretary of Health & Human Services (HHS Secretary) is required to prepare and distribute a public notice that provides an explanation of Medicare benefits. This benefit-related overview must explain the scope of medical services that are—and are not—covered by Medicare. The annual notice must also contain information regarding specified Medicare beneficiary rights, responsibilities, and educational resources (Social Security Act (SSA) Section 1804). During preparation of the notice, the HHS Secretary is required to consult with health insurers and groups representing seniors. The completed notice must be delivered to all individuals entitled to benefits under Medicare Parts A or B.

To meet the notice requirement, the Centers for Medicare & Medicaid Services (CMS) produces a “handbook” entitled *Medicare & You* (CMS Product No. 10050). The handbook is mailed to Medicare beneficiaries in late September, prior to the Part C Medicare Advantage (MA) and Medicare Part D open enrollment period. *Medicare & You* is also publicly available on the CMS website, where beneficiaries can opt out of receiving a physical copy of the handbook and instead choose electronic delivery for future releases. In addition to setting forth the statutory requirements, the handbook includes other Medicare information, such as answers to frequently asked questions and lists of available health and drug plans.

Proposed Provision

The Chairman’s Mark would add a new SSA Section 1804(d) requiring the HHS Secretary to compile and provide the following in the annual *Medicare & You* handbook for open enrollment periods after January 1, 2019: references to educational resources on opioid use and pain management; a description of categories of alternative, non-opioid Medicare-covered pain management treatments; and a suggestion that beneficiaries talk to their physicians about opioid use and pain management.

Section 102: Expanding Telehealth Response to Ensure Addiction Treatment

Current Law

Telehealth services covered for Medicare beneficiaries under Part B are subject to SSA Section 1834(m), which places restrictions on the location, provider, telehealth technology, and certain other parameters. The facility where the beneficiary is located is referred to as the *originating site*, and the site where the practitioner is located is referred to as the *distant site*. Medicare makes a payment to the physician or practitioner at the distant site for rendering the telehealth service, and a separate facility fee to the originating site. SSA Section 1834(m) requires that telehealth services must be provided from a qualifying originating site in a rural health professional shortage area (HPSA) or a county not included in a Metropolitan Statistical Area (MSA), or from an entity that participates in a federal telemedicine demonstration project. Qualifying originating sites include an office of a physician or practitioner, a critical access hospital (CAH), a rural health clinic, a federally qualified health center, a hospital, a hospital- or CAH-based renal dialysis center, a skilled nursing facility, or a community mental health center. Under Part C, MA plans must provide telehealth services to the extent that they are a covered service under Medicare Part B.

Bipartisan Budget Act of 2018 (BBA 18, P.L. 115-123) expanded telehealth under Medicare in four ways: (1) by increasing the opportunities for physicians and practitioners participating in certain accountable care organizations (ACOs) to receive telehealth payments, beginning January 1, 2020 (BBA 18 Section

50324); (2) by eliminating certain originating site restrictions for telehealth services for diagnosis, evaluation or treatment of the symptoms of an acute stroke, beginning January 1, 2019 (BBA 18 Section 50325); (3) by allowing MA plans to provide additional telehealth benefits (minus capital and infrastructure costs), which are treated as if they are benefits required under original Medicare) for payment purposes starting in plan year 2020 (BBA 18 Section 50323); and (4) by permitting Medicare patients with end-stage renal disease (ESRD) on home dialysis to receive monthly clinical assessments at home or at freestanding dialysis facilities via telehealth without regard to geographic location, beginning January 1, 2019 (BBA 18 Section 50302).

Proposed Provision

The Chairman’s Mark would amend SSA Section 1834(m) to eliminate the statutory originating site requirements for services furnished via telehealth for the purpose of treating substance use disorders, beginning January 1, 2019. Thus, the provision would allow payment for these telehealth services when furnished to a beneficiary at an originating site without regard to its geographic location or facility type. However, no facility fee would be paid unless the site meets the existing statutory originating site requirements. The HHS Secretary would be given authority to implement this provision through an interim final rule. No later than five years after enactment, the HHS Secretary would be required to report to Congress on the impact of this modification on health care utilization and health outcomes related to substance use disorders.

Section 103: Comprehensive Screenings for Seniors

Current Law

Medicare beneficiaries are entitled to annual “wellness” visits. The first, furnished in the first year of enrollment, is the Initial Preventive Physical Examination (IPPE), often called the “Welcome to Medicare” visit (SSA Section 1861(ww)). Annually thereafter, beneficiaries are entitled to an annual wellness visit (AWV) and personalized prevention plan services (SSA Section 1861(hhh)). Regulations at 42 C.F.R. Part 410, Subpart B specify the required elements for the IPPE and AWV, respectively, which include the following: the provision of a health assessment; a suite of physical measurements (e.g., blood pressure); education, counseling, and referral for additional preventive services that are covered separately; and consultative services, such as end-of-life planning (upon agreement with the patient) and screenings for depression and alcohol misuse.

Proposed Provision

The Chairman’s Mark would amend the authorities for the IPPE and AWV in SSA Section 1861 for services furnished on or after January 1, 2019 to include the following for each:

- A review of the beneficiary’s current opioid prescriptions, defined as (1) a review of potential risk factors for opioid use disorder; (2) an evaluation of pain severity and the treatment plan; (3) the provision of information on non-opioid treatment options; and (4) referral to a pain management specialist, as appropriate; and
- Screening for potential substance use disorders that includes a referral for treatment, as appropriate.

Section 104: Every Prescription Conveyed Securely

Current Law

Under Medicare Part D, private insurers and other sponsors enter into annual contracts with CMS to provide a defined package of outpatient drug benefits in some or all of the 34 Part D regions and U.S. territories. As part of program requirements, Part D plans must support an electronic prescription (e-prescribing) program, which is defined by CMS as the use of electronic media to transmit prescription or prescription-related information between a prescriber, dispenser, pharmacy benefit manager, and/or health plan, either directly or through an intermediary, including an e-prescribing network. Technical transmission requirements for e-prescribing networks are based on standards set by the National Council for Prescription Drug Programs (NCPDP SCRIPT) and other outside organizations. Physicians and pharmacies that transmit e-prescriptions and related communications with Part D plans must comply with CMS standards.

Further, the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA, Public Law 110-275) established an incentive payment program to encourage physician uptake of e-prescribing through bonus payments that transitioned to payment penalties after a period of time. This e-prescribing incentive program was sunset at the end of calendar year 2013 as physician e-prescribing was incorporated as a requirement into the broader Electronic Health Record Incentive Program, commonly referred to as the “meaningful use” program.

Proposed Provision

The Chairman’s Mark would amend SSA Section 1860D-4(e) to require that health care practitioners use e-prescribing for Part D-covered drugs that are Schedule II, III, IV, or V controlled substances, as classified under the Controlled Substances Act (P.L. 91-513), beginning on January 1, 2021.

The HHS Secretary would be required to define circumstances, through rulemaking that involves public comment, when the requirement may be waived, including:

- cases where the prescriber and dispenser are the same entity;
- a prescription that cannot be transmitted electronically due to the constraints of the most recently implemented version of NCPDP SCRIPT standard;
- a prescription issued by a practitioner who has received a maximum one-year waiver (or renewal of a waiver) of the e-prescribing requirement due to demonstrated economic hardship, technological limitations not reasonably within the control of the practitioner, or other exceptional circumstances;
- a situation where a practitioner reasonably determines that it would be impractical for the individual involved to obtain substances prescribed by electronic prescription in a timely manner, and such delay would adversely impact the individual’s medical condition;
- a prescription that allows for dispensing of a non-patient specific prescription pursuant to a standing order, approved protocol for drug therapy, collaborative drug management, or comprehensive medication management, in response to a public health emergency, or other circumstances;
- a prescription under a research protocol;
- a prescription that the Food and Drug Administration (FDA) requires to contain certain elements that cannot be accomplished with electronic prescribing, such as a drug with risk evaluation and mitigation strategies; and

- a prescription for an individual who receives hospice care that is not covered under the hospice benefit or a prescription for an individual who is a resident of a nursing home and is dually eligible for both Medicare and Medicaid.

Part D sponsors and pharmacists would not be required to verify that prescribers have a waiver from the e-prescribing requirements.

The requirements would not affect the ability of a Part D plan to cover, or a pharmacist to dispense, Part D drugs from otherwise valid written, oral, or fax prescriptions. The requirements also would not affect the ability of a Part D enrollee to designate a specific pharmacy to dispense a drug. The HHS Secretary has authority to enforce penalties and consequences for noncompliance that are established through rulemaking that involves public comment.

Section 105: Standardizing Electronic Prior Authorization for Safe Prescribing

Current Law

CMS regulations and contract provisions require that Medicare Part D plans' e-prescribing systems allow for the exchange of specific information about a prescription such as enrollee eligibility, plan benefits, the drug being prescribed or dispensed, other drugs listed in a medication history, and the availability of lower cost, therapeutically appropriate alternatives (if any). Technical transmission requirements for e-prescribing networks are based on the NCPDP SCRIPT standards and other organizations' standards. Physicians and pharmacies that transmit e-prescriptions and related communications electronically with Part D plans must comply with CMS standards. Congress, through MIPPA, established an incentive payment program to encourage physician uptake of e-prescribing that was sunset at the end of calendar year 2013 as the physician e-prescribing was added to the broader Electronic Health Record Incentive Program, commonly referred to as the "meaningful use" program, as a required element.

In addition, Part D plans may implement formulary-level safety edits for beneficiaries using high levels of opioids that can include prior authorization requirements. Prior authorization typically requires the prescriber to provide additional information to demonstrate that the prescription is clinically justified before the plan determines it will cover it. The latest version of the NCPDP SCRIPT allows for prior authorizations, but it has not yet been adopted by CMS for Part D transactions.

Proposed Provision

The Chairman's Mark would amend SSA Section 1860D-4(e) to require that Part D e-prescribing systems allow for processing of formulary prior authorizations using a standard format, beginning no later than January 1, 2021. The standard format would have to provide for secure electronic transmission of (1) a prior authorization request from a prescribing health care professional for a covered Part D drug for an enrollee to the plan sponsor, and (2) a response from the plan to the prescribing professional.

The HHS Secretary would define the technical standards for the electronic prior authorization format in consultation with:

- the NCDPC;
- other standard-setting organizations determined by the HHS Secretary; and
- stakeholders, including plan sponsors, health care professionals, and health information technology software vendors.

A facsimile, a proprietary payer portal that does not meet standards specified by the HHS Secretary, or an electronic form would not be treated as electronic transmissions.

Section 106: Strengthening Partnerships to Prevent Opioid Abuse

Current Law

Medicare Part C (MA) plans and Part D prescription drug plans (PDPs) are required under SSA Section 1860D-4(c)(1)(D) to establish compliance programs to prevent, detect, and correct fraud, waste, and abuse. The HHS Secretary is required to establish contracts with Medicare Drug Integrity Contractors (MEDICs) to support Medicare Parts C and D program integrity activities. CMS, the HHS Secretary, and the MEDICs audit MA and PDP plans to ensure their compliance programs meet Medicare requirements and investigate MA and PDP reports of provider and supplier fraud, waste, and abuse activities. MA and PDPs may, but are not required to, report to the HHS Secretary or MEDICs information about provider or supplier fraud, waste, or abuse activities. The HHS Secretary may share provider and supplier fraud, waste, or abuse information among other MA and PDP plans, but is not required to disseminate that information.

The HHS Secretary is authorized to impose civil monetary penalties on individuals, organizations, agencies, or other entities that engage in improper conduct and may also be required in some situations, or may elect in other situations, to exclude these individuals, organizations, or other entities from participating in federal health programs. In addition, the HHS Secretary may suspend provider or supplier payments based on credible allegations of fraud.

Proposed Provision

The Chairman's Mark would add a new SSA Section 1859(i) requiring the HHS Secretary to establish a secure Internet website portal within two years of enactment. The HHS Secretary would use the website portal to communicate and facilitate data sharing with MA and PDP plans and MEDICs. The website portal would enable MA and PDP plans to refer suspicious fraud, waste, and abuse activities by providers and suppliers to MEDICs for the purpose of initiating or assisting in investigations.

This provision would require the HHS Secretary to use the website portal to disseminate to MA and PDP plans information on providers and suppliers who were recently referred for fraud, waste, and abuse; were excluded or had a payment suspension; had their Medicare participation revoked; or had been subject to administrative actions for similar activities.

The HHS Secretary would be required to specify through rulemaking that involves public comment what constitutes suspected fraud, waste, and abuse for the purposes of the portal.

The HHS Secretary would be required to disseminate quarterly reports to MA and PDP plans on fraud, waste, and abuse schemes and suspicious activity trends reported through the website portal. The quarterly reports would be required to maintain the anonymity of the plans submitting information and to include administrative actions, opioid overprescribing information, and other data determined appropriate by the HHS Secretary, in consultation with stakeholders.

The provision makes clear that none of the above actions would prohibit referrals to the HHS OIG or other law enforcement entities.

The Chairman's Mark would amend SSA Section 1857(e)(4)(C) and 1860D-4 to require MA organizations and prescription drug plans (PDPs) to submit to the HHS Secretary, beginning with plan year 2021, information on credible evidence of suspected fraud and other actions related to inappropriate opioid prescribing. Before January 1, 2021, in consultation with stakeholders, the HHS Secretary would be required to establish a process for MA organizations and PDPs to submit the required information on inappropriate opioid prescribing. To implement the suspected fraud information reporting process, the HHS Secretary would be required to issue regulations that would define the term "inappropriate prescribing of opioids," and determine the information plans would be required to submit.

Section 107: Commit to Opioid Medical Prescriber Accountability and Safety for Seniors

Current Law

The Part D statute does not require identification of practitioners who may be prescribing an excessive amount of opioids, as compared to their peers. CMS has recently initiated steps using its general administrative authority to identify the practitioners who prescribe significantly more opioids than their peers and to notify them of their “outlier” status. Additional efforts to use Part D prescription claims data to track practitioner opioid prescribing and patient utilization include:

- The CMS Overutilization Monitoring System (OMS) reviews Part D prescription drug claims to identify at-risk beneficiaries who are using high dosages of opioids (over a specified period of time) provided by multiple prescribers or pharmacies. CMS uses the OMS to verify that Part D sponsors that have established opioid management programs have effective systems.
- A CMS determination that requires Part D plans to reject prescriptions from practitioners who are on a special HHS preclusion list. The preclusion list, which takes effect January 1, 2019, pertains to: individuals and entities whose Medicare billing and participation privileges have been revoked for misconduct or crimes; and individuals who have engaged in behavior for which CMS could have revoked their privileges had they been enrolled in Medicare.

Proposed Provision

The Chairman’s Mark would amend SSA Section 1860D-4(c)(4) to direct the HHS Secretary, after consultation with stakeholders, to establish a program that notifies Part D opioid prescribers identified as statistical outliers compared to their peers and aims to improve prescribing consistent with the medical evidence. The peer comparison would be made against prescribers in the same specialty, with the Secretary having the discretion to also compare within the same geographic area.

CMS would use the National Provider Identifier (NPI), the unique identifier for providers used for Medicare transactions and other purposes, on Part D claims to assess practitioners’ Part D prescribing patterns. Certain data would be excluded from the process for identifying prescribers as statistical outliers including: claims for Part D covered drugs for individuals in hospice care, claims for Part D covered drugs for individuals being treated for cancer, and claims by prescribers who are under investigation by CMS or the HHS Office of Inspector General (OIG).

Using a threshold for determining what constitutes a statistical outlier opioid prescriber, no later than January 1, 2021, the HHS Secretary would be required to provide annual notification to prescribers identified as such outliers (during the period that a prescriber is identified as a statistical outlier) including: (1) information on how a prescriber compares to other prescribers within the same specialty and, if determined appropriate by the Secretary, geographic area; (2) information on evidence-based opioid prescribing guidelines, identified with input from stakeholders; and (3) other information determined by the Secretary. The HHS Secretary could expand the required notifications to include concurrent prescriptions of other covered Part D drugs that may produce side effects when used in combination with opioids. Beginning five years after the notifications first go into effect, the Secretary could change the frequency of the notifications based on stakeholder input and changes in opioid prescribing utilization and trends.

If the HHS Secretary were to determine that a prescriber is persistently identified as a statistical outlier prescriber of opioids, the Secretary would be required to connect the prescriber with an entity that provides technical or educational resources on opioid prescribing guidelines. A prescriber could be required to enroll in the program, for a period determined by the HHS Secretary. At least once a year, the

HHS Secretary would be required to communicate information on such prescribers to Part D plan sponsors.

In addition, the HHS Secretary would be required to make aggregate information on the opioid outlier prescriber program available on the CMS website without identifying any specific prescriber.

Section 108: Fighting the Opioid Epidemic with Sunshine

Current Law

SSA Section 1128G requires applicable drug, device, biological, or medical supply manufacturers that make a payment or other transfer of value to a “covered recipient” to annually report information on such transactions to the HHS Secretary. A covered recipient is defined as a physician or a teaching hospital, but the definition does not include physicians who are employees of applicable manufacturers. Categories of reportable payments and transfers of value include amounts for research, gifts, entertainment, consulting fees, grants, meals, or travel. Certain items are exempt from disclosure, including certain very small payments or transfers of value, samples intended for patient use, loans of a covered device for a short-term time period, and educational materials for direct patient use. Additionally, the HHS Secretary is generally required to have procedures in place to ensure public availability of submitted information, including through a searchable Internet website. This reporting program established by the HHS Secretary is referred to as the Open Payments program.

Section 1128G requires applicable manufacturers to report the NPI of covered recipients in their submission of information about payments and transfers of value to the HHS Secretary. The statute, however, prohibits the display of NPIs on the Open Payments program website.

Proposed Provision

The Chairman’s Mark would amend SSA Section 1128G(e)(6) to expand the definition of covered recipient to encompass physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, and certified nurse midwives (excluding employees of applicable manufacturers). Accordingly, applicable manufacturers would be required to submit information on payments or other transfers of value to these types of health care professionals. The amendments made by this section would apply to information required to be submitted on or after January 1, 2021.

The Chairman’s Mark would also sunset the prohibition on the inclusion of NPIs of covered recipients on the Open Payments website, beginning with the display of information required to be submitted on or after January 1, 2021.

Title II—Medicaid

Section 201: Caring Recovery for Infants and Babies

Current Law

Medicaid is a joint federal-state program that finances the delivery of primary and acute medical services, as well as long-term services and supports, for a diverse low-income population. Each state has a Medicaid state plan that describes how the state will administer its Medicaid program. The benefits covered under Medicaid (*medical assistance*), described generally in SSA Section 1905, include both mandatory and optional services.

One mandatory Medicaid service is the early and periodic screening, diagnostic, and treatment services (EPSDT) benefit for children under the age of 21. EPSDT is a broad benefit including periodic screenings

(comprehensive child health assessments, including physical examinations, preventive dental services, vision and hearing testing, appropriate immunizations, and laboratory tests), certain interperiodic screenings, diagnosis, and treatment. *Treatment* under EPSDT includes any services included as medical assistance in federal law that are necessary to correct or ameliorate physical and mental illnesses or conditions identified through the screening services.

Federal law does not specifically require states to furnish Medicaid benefits to address *neonatal abstinence syndrome* (NAS), which is a term for withdrawal symptoms an infant may experience because of prenatal use of opioids or other substances by the mother. A United States Government Accountability Office report issued in October 2017, *Newborn Health: Federal Action Needed to Address Neonatal Abstinence Syndrome* (GAO-18-32), noted that more than 80% of NAS cases are paid for by Medicaid. The report found that most infants with NAS in the United States are treated in a hospital setting, often in the neonatal intensive care unit. Medicaid pays for this care through its inpatient hospital benefit. In addition, some state Medicaid programs cover treatment of NAS in outpatient clinics and programs or in special neonatal withdrawal centers.

Proposed Provision

The Chairman’s Mark would amend SSA Section 1902 in order to clarify that states have the option to make Medicaid services available on an inpatient or outpatient basis at a residential pediatric recovery center to infants with NAS. A *residential pediatric recovery center* would be defined as a “center or facility that furnishes items and services for which medical assistance is available under the state plan to infants with the diagnosis of neonatal abstinence syndrome without any other significant medical risk factors.” Covered services could include not only services to infants, but also services to mothers or other caretakers provided that those services are otherwise covered under the Medicaid state plan or waiver of such plan, such as counseling or referrals for services, activities to encourage caregiver-infant bonding, or training on caring for such infants.

The Chairman’s Mark would take effect as of the date of enactment, and would apply to Medicaid services furnished on or after that date, regardless of whether final regulations implementing the provision have been promulgated by that date.

Section 202: Peer Support Enhancement and Evaluation Review

Current Law

Peer support services are a behavioral health model of care that consists of qualified peer support providers helping individuals with their recovery including from substance use disorders. State Medicaid agencies have the option to offer peer support services under Medicaid. CMS’ State Medicaid Director Letter #07-011 (Aug. 15, 2007) indicated that states that have chosen to cover these services have done so either under the Medicaid state plan, under the authority of SSA Section 1905(a)(13) (“other diagnostic, screening, preventive, and rehabilitative services”); or as part of a waiver under SSA Section 1915(b) or 1915(c).

Proposed Provision

The Chairman’s Mark would create a standalone requirement that the Comptroller General of the United States (“Comptroller General”), within two years after the date of enactment, submit a report on the provision of peer support services in Medicaid to Congress. The report must include information on state Medicaid programs’ coverage of peer support services, including (1) the mechanisms (statutory authority or waivers) through which states may cover peer support; (2) the populations to which such coverage has been provided; (3) payment models used by states; and (4) federal and state spending. The report must also provide other information specified in the section relating to access to care, health outcomes, and

costs. Finally, the report must include recommendations for legislative and administrative actions to improve access to peer support services under Medicaid.

Section 203: Medicaid Substance Use Disorder Treatment via Telehealth

Current Law

State Medicaid programs provide for a variety of types of telehealth services, which can include the use of a broad range of electronic information and telecommunications technologies to support remote clinical health care, patient and professional health-related education, and other health care delivery functions.

Proposed Provision

The Chairman's Mark would create standalone requirements for CMS and the Comptroller General to conduct various activities to evaluate and strengthen the provision of telehealth services in Medicaid.

The Chairman's Mark would define various terms for purposes of the provision. *Telehealth services* would be defined broadly to include remote patient monitoring and other modalities such as live video, store-and-forward, mobile health, telephonic consultation, and electronic consultation. *School-based health center* would be defined the same way the term is defined for purposes of the State Children's Health Insurance Program (CHIP), in SSA Section 2110(c)(9).

The Chairman's Mark would require CMS, within one year after enactment, to issue guidance to states on state options for federal reimbursement of states' expenditures for substance use disorder (SUD) services and treatment using telehealth including: (1) services addressing high-risk individuals including, at the least, American Indians and Alaska Natives, adults under age 40, and individuals with a history of nonfatal overdose; (2) provider education on providing SUD services using the hub and spoke model, through managed care contracts, through administrative claiming for disease management activities, and under Delivery System Reform Incentive Payment programs; and (3) services furnished through school-based health centers.

The Chairman's Mark would require the Comptroller General to evaluate children's access to SUD services under Medicaid and submit a report summarizing the evaluation and making recommendations for appropriate legislative and administrative action to Congress within one year after enactment. The evaluation must include analysis of (1) options for improving access to and outcomes of SUD services, including by expanding the use of telehealth in school-based health centers, particularly in health professional shortage areas and medically underserved areas; and (2) Medicaid provider rates for SUD services.

The Chairman's Mark would require CMS to issue a report to Congress identifying best practices and potential solutions for reducing barriers to the use of telehealth SUD services for children under Medicaid and publish it on the HHS website within one year after enactment.

Section 204: Enhancing Patient Access to Non-Opioid Treatment Options

Current Law

The benefits covered under Medicaid include both mandatory and optional services. Examples of mandatory Medicaid services include inpatient hospital services, physician services, pregnancy-related services, services furnished by federally-qualified health centers, and services under the EPSDT benefit for children under the age of 21. Examples of optional services under Medicaid include prescription drugs; physical, occupational, and speech therapies; personal care services; and other diagnostic, screening, preventive and rehabilitative services.

State Medicaid programs vary in the scope of pain management services offered. All states currently offer a Medicaid outpatient prescription drug benefit, even though the benefit is optional to states. The drug benefit in general is broad, encompassing most prescription drugs and many non-prescription, over-the-counter drugs. Most non-pharmacological pain management services, ranging from physical therapy to chiropractic services to acupuncture, are optional to states under Medicaid.

Proposed Provision

The Chairman's Mark would create a standalone requirement that CMS, by January 1, 2019, issue one or more final guidance documents to states, or to update existing guidance documents, regarding mandatory and optional items and services that state Medicaid programs may furnish, under the state plan or a waiver of the state plan, for non-opioid treatment and management of pain, including evidence-based non-opioid pharmacological therapies and non-pharmacological therapies.

Section 205: Assessing Barriers to Opioid Use Disorder Treatment

Current Law

States are required to cover many health care and related services and supplies for Medicaid beneficiaries, though some services and supplies are optional benefits, such as outpatient prescription drugs. Even though Medicaid drug coverage is broad, state Medicaid programs may use drug utilization management tools to help administer the outpatient drug benefit and control drug expenditures. Physician administered drugs are covered under Medicaid's medical benefit, rather than the outpatient drug benefit. Most state Medicaid programs use a buy-and-bill methodology to pay for physician administered drugs, where physicians purchase drugs, then bill the state Medicaid program after the drugs are administered to Medicaid beneficiaries.

SUD treatment often utilizes prescription drugs or drug combinations that block or reduce the effect of controlled substances, such as methadone, buprenorphine, and buprenorphine-naloxone combinations. State coverage of SUD treatment drugs varies, but all states cover some SUD drugs under some circumstances, which may be determined by a formulary or by prior authorization.

Proposed Provision

The Chairman's Mark would create a standalone requirement that the Comptroller General study Medicaid barriers that impede beneficiary access to receiving SUD treatment medications, in particular, buprenorphine, naltrexone, and buprenorphine-naltrexone combination products. The Comptroller General would be required to study the barriers to Medicaid beneficiaries receiving SUD medications under various drug distribution models such as buy-and-bill as well as addressing options for Medicaid programs to use in reducing or removing SUD drug treatment barriers. The Comptroller General would be required to study SUD-treatment drug distribution models on purchasing, storage, and administration; pharmacist dispensing of SUD drugs; and ordering, prescribing, and obtaining SUD treatment drugs from specialty pharmacies. The Comptroller General would be required to evaluate how each model presents barriers or could be used by state Medicaid programs to reduce barriers to providing SUD treatments by examining what is known about the effect of each distribution model on Medicaid beneficiary access to SUD drugs, differential Medicaid costs, and provider willingness to provide SUD drug services. The Comptroller General would be required to submit a report to Congress on SUD barriers and to include appropriate recommendations for legislative and administrative action within 15 months of the enactment date.

Section 206: Help for Moms and Babies

Current Law

The scope and types of pregnancy-related services that are offered to pregnant women under Medicaid may vary both within and across states by Medicaid eligibility pathway. Pregnancy-related services can range from pregnancy-related services only, to full Medicaid benefit coverage.

Medicaid's low-income pregnancy-related eligibility pathways require states to provide pregnancy-related services to pregnant women with incomes up to 133% of the federal poverty level, or to pregnant women at higher income levels at state option. For these women (i.e., those who are Medicaid-eligible on the basis of being pregnant), at a minimum benefit coverage must include prenatal care, labor and delivery, and 60 days of postpartum care. Women who are otherwise eligible for Medicaid (e.g., under a low-income parent, adult, or disability pathway) and who become pregnant are entitled to the Medicaid services specified in the state plan. States may also extend coverage to pregnant woman through the use of the Section 1115 waiver authority. Coverage for such women is specified in the waiver special terms and conditions.

The *institutions for mental disease* (IMD) exclusion is a long-standing policy under Medicaid that prohibits the federal government from providing federal Medicaid matching funds to states for services rendered to certain Medicaid-eligible individuals aged 21 through 64, including pregnant women, who are patients in IMDs, which are institutions with more than 16 beds that primarily provide services to persons with mental diseases, including substance use disorders. When a Medicaid-eligible individual aged 21 through 64 is a patient in an IMD, he or she cannot receive Medicaid coverage for services provided inside or outside the IMD.

Proposed Provision

The Chairman's Mark would amend SSA Section 1905(a) to permit states to receive federal Medicaid matching funds for otherwise coverable Medicaid items or services that are provided outside of the IMD, such as prenatal care, to a woman who (1) is eligible for Medicaid on the basis of being pregnant (through 60 days postpartum); (2) is a patient in an IMD for the purpose of receiving treatment for a substance use disorder; and (3) was enrolled in Medicaid immediately before becoming a patient in an IMD or becomes Medicaid-eligible while a patient in an IMD.

The effective date for this provision would be the date of enactment. If the HHS Secretary determines that state legislation (other than legislation appropriating funds) would be needed in order for the state to meet a specific statutory requirement for this provision, then the state plan would not be regarded as failing to comply with the requirement before the first day of the first calendar quarter beginning after the close of the first regular session of the state legislature beginning after enactment.

Section 207: Securing Flexibility to Treat Substance Use Disorders

Current Law

The IMD exclusion is a long-standing policy under Medicaid that prohibits the federal government from providing federal Medicaid matching funds to states for services rendered to certain Medicaid-eligible individuals aged 21 through 64 who are patients in IMDs, which are defined as institutions with more than 16 beds, that are primarily engaged in providing diagnosis, treatment, or care of persons with mental diseases.

One exception to the IMD exclusion provided through regulation (42 C.F.R. §438.6(e)) is that states are allowed to provide IMD coverage under Medicaid managed care in certain circumstances. Specifically,

states may make monthly payments to managed care organizations for enrollees aged 21 through 64 who are patients in an IMD “in lieu of” other services covered under the Medicaid state plan, as long as the length of stay in the IMD is no more than 15 days during the month of the payment. In setting managed care capitation rates, states may include the utilization of services at IMDs, but for the cost of these services, the state must use the cost of the same services through providers included in the Medicaid state plan rather than the cost of the IMD services.

Proposed Provision

The Chairman’s Mark would amend SSA Section 1903(m) to allow states to receive federal Medicaid payments for expenditures included in the development of managed care capitation rates for treatment described under 42 C.F.R. Section 438.6(e).

Section 208: Removing Lifetime Limits under Medicaid on Medication-Assisted Treatment for Substance Use Disorders

Current Law

SUD treatment often relies on prescription drugs or drug combinations that block or reduce the effect of controlled substances. Medication-assisted treatment (MAT) is a form of SUD treatment that requires counseling or therapy in addition to prescription drugs. State Medicaid coverage of MAT drugs varies, but all states cover some MAT drugs under some circumstances typically through a formulary or by prior authorization. Most state Medicaid programs impose some utilization limits on beneficiary access to MAT drugs. State utilization controls on MAT drugs may include restrictions on the maximum daily drug dose that beneficiaries may receive, duration of initial treatment, requirements for reassessment, treatment plan adherence, and maximum lifetime limits. As part of such utilization controls, states must provide a process for accessing a covered drug including MAT if otherwise medically necessary.

Proposed Provision

The Chairman’s Mark would amend SSA Section 1927(d) to prohibit states from employing maximum lifetime limits as a utilization control mechanism on Medicaid covered MAT treatments approved by the Food and Drug Administration used in SUD treatment. The prohibition would be effective on the first day of the first calendar quarter that begins after the date of enactment. Where legislation is required to amend the state Medicaid plan, then the state plan would not be regarded as failing to comply with the requirement before the first day of the first calendar quarter that begins after the close of the first state legislative session after the enactment date.

Section 209: Opioid Addiction Treatment Programs Enhancement

Current Law

SSA Section 1903(r) requires states to operate Medicaid mechanized claims information retrieval systems that allow for the efficient and effective administration of the Medicaid state plan. The Balanced Budget Act of 1997 (P.L. 105-33) required states to submit electronic claims data, enrollee encounter data, and other supporting information through the Medicaid Statistical Information System (MSIS). The Patient Protection and Affordable Care Act (P.L. 111-148, as amended) expanded the state Medicaid data reporting requirements to include data elements that the HHS Secretary determines necessary for program integrity, program oversight, and administration. These additional data reporting requirements resulted in CMS’ transition from MSIS to the Transformed-Medicaid Statistical Information System (T-MSIS). T-MSIS expands the data states are required to submit to CMS to include information on providers, third-party payers, and managed care plans.

The Freedom of Information Act (5 U.S.C. §552) requires agencies to publish a notice of their systems of records in the *Federal Register* for any records under control of the agency whereby information is retrieved by the name of an individual, an identifying number, or some other identifier that is assigned to an individual. This *Federal Register* notice outlines policies and procedures to protect the security and privacy of the data and is generally referred to as a System of Records Notice (SORN). The SORN associated with the MSIS system is SORN 09-70-0541, and includes information such as the kinds of records contained in the data system, the purpose of the data system, the categories of data users (e.g. federal or state agency or individual or organization for a research project), and the purpose of such uses.

Proposed Provision

The Chairman's Mark would create a standalone requirement that the HHS Secretary publish a report on the prevalence of SUDs among Medicaid enrollees and the SUD treatment services provided to Medicaid enrollees, including certain specified information. The provision would require CMS to publish this report, including information for each state, and to the extent available, for the District of Columbia, and the five territories (i.e., Puerto Rico, the U.S. Virgin Islands, Guam, the Commonwealth of the Northern Mariana Islands, and American Samoa), on the agency website not later than 12 months after the date of enactment of this Act. CMS would be required to issue annual updates not later January 1 for each calendar year through 2024.

The reports would be required to rely on T-MSIS data that is no more than 12 months old as of the report publication date, and as appropriate, would be required to include information on data quality and completeness, including caveats on data limitations to inform the appropriate uses for the information.

The Chairman's Mark would also require the HHS Secretary to publish a SORN in the *Federal Register* for the specified data to outline the policies and procedures to protect the security and privacy of the data that, at a minimum meet the MSIS system privacy and security policies in SORN 09-70-0541. The data specified in the SORN would be made available to researchers and states and sufficient to analyze the prevalence of SUDs and SUD treatment services by service type and by treatment setting for Medicaid enrollees in the 50 states, the District of Columbia, and the five territories. The HHS Secretary would be required to initiate the SUD data sharing activities outlined in the SORN no later than January 1, 2019.

Section 210: Better Data Sharing to Combat the Opioid Crisis

Current Law

Prescription drug monitoring programs (PDMPs) are statewide electronic databases that compile designated information on controlled substances generally dispensed within states. PDMP data are made available to individuals or organizations as authorized under state law; these may include prescribers, law enforcement officials, licensing boards, and others.

Even though most states have PDMPs, there is no requirement for a state to operate a PDMP and there is considerable variation in how they are administered, who can access data, what data are collected, and other factors. In addition, there is variation in the underlying information technology used in PDMPs that can make data sharing among states difficult.

The Health Insurance Portability and Accountability Act of 1996 (HIPAA, P.L. 104-191) required the HHS Secretary to develop regulations to protect the privacy and security of certain health information. The privacy rule established standards to protect certain individual health information, whereas the security rule established national standards to protect the privacy of health information that is held or transferred electronically. Under HIPAA, certain stricter privacy requirements were established to protect individually identifiable information received or acquired by federally-assisted substance abuse programs.

State Medicaid programs are required to comply with HIPAA privacy and security provisions as well as to safeguard the use and disclosure of Medicaid beneficiary information.

Proposed Provision

The Chairman’s Mark would amend SSA Section 1903(m) to clarify state Medicaid programs may have reasonable access to one or more state-administered or accessed PDMP databases to the extent Medicaid program access is permitted under state law. In addition, as permitted under state law, the Chairman’s Mark also clarifies that state Medicaid programs may facilitate reasonable access to state administered or accessed PDMP databases and to share the PDMP database information with Medicaid-enrolled providers and Medicaid managed care entities

Any state Medicaid program, individual, or entity that accessed or obtained information from PDMP databases would be subject to applicable state and federal security and privacy protections and laws. This amendment would be effective on the date of enactment.

Title III- Human Services

Section 301: Supporting Family-Focused Residential Treatment

Current Law

Under Medicaid, the federal government requires states to cover certain mandatory populations and benefits, but allows states to cover other optional populations and services. Due to this flexibility, there is substantial state variation in factors such as Medicaid eligibility and covered benefits. In addition, several waiver authorities (included in SSA Sections 1115 and 1915) allow states to cover additional populations and services not otherwise covered under the state plan.

The Foster Care, Prevention, and Permanency program (Title IV-E of the SSA, also known as the Title IV-E program) is a joint federal-state program that funds assistance, including certain case management activities, for eligible children who are removed from their parents and placed in foster care (for their safety), as well as ongoing assistance to eligible children leaving foster care for new permanent homes via adoption or legal guardianship. As amended by the Family First Prevention Services Act (Title VII, Division E of P.L. 115-123) and beginning with October 1, 2018, children in foster care who are residing with their parents in a licensed family-based residential treatment center that provides trauma-informed substance use disorder treatment, parenting skills training, parent education, and individual and family counseling, are eligible for Title IV-E foster care support for up to 12 months.

Proposed Provision

The Chairman’s Mark would require the HHS Secretary, within 180 days of enactment of the section, to issue guidance on how states may use existing Medicaid and Title IV-E program authorities (including Medicaid waivers) to support substance use disorder treatment via family-focused residential treatment programs, including the placement of foster children with their parents in such programs. It would define a *family-focused residential treatment program* as a trauma-informed residential program that primarily provides substance use disorder treatment to pregnant and postpartum women, as well as parents and guardians, and that “to the extent appropriate and applicable” allows children to reside with such women, their parents or guardians, during the treatment.

The guidance would need to discuss how funding under Medicaid, the Title IV-E program, and other HHS-administered programs can be used and coordinated to support SUD treatment and related services provided in a family focused residential treatment program. These include MAT, counseling, parenting training, non-emergency transportation for care of children residing in the program, transitional services

for families leaving the program, and others. Before issuing the guidance, the HHS Secretary would need to consult with the various HHS divisions that administer substance use disorder or child welfare programs, as well as solicit input from a range of relevant public and private stakeholders.

Section 302: Improving Recovery and Reunifying Families

Current Law

The Promoting Safe and Stable Families Program (PSSF, Title IV-B, Subpart 2 of the SSA) authorizes funding to states for the provision of services that support and preserve families, aid in reuniting children and their families, and promote and support adoption. Under SSA Section 435, the HHS Secretary is required to conduct evaluations of programs supported under the PSSF program, and may conduct evaluations of other state, local, or federally funded programs designed to achieve the same purposes as the PSSF program. Funding for this evaluation work is annually reserved out of capped mandatory funding, as well as any discretionary funding provided for the PSSF program.

Proposed Provision

The Chairman’s Mark would amend SSA Section 435 to authorize a one-time mandatory appropriation of \$15 million (to remain available across eight years, i.e., FY 2019-FY2026) for the support of a “family recovery and reunification program replication project.” In carrying out this project, the HHS Secretary would be required to award a contract or grant to one or more eligible entities to conduct an evaluation of a family recovery and reunification program. The program must use a recovery coach model and include services and assistance designed to ensure that parents or guardians with a substance use disorder (and who have temporarily lost custody of their children) receive treatment and other services to support their recovery and allow them to be reunited with their children. Further, the HHS Secretary must ensure the program impacts are evaluated via a random assignment experiment that measures multiple relevant indicators (e.g., time to recovery, safety of reunifications, parental substance use, persistence of parental treatment engagement and recovery, costs, and others). Finally, in addition to reports on the pilot phase, impact study, and implementation of the family recovery and reunification program, the HHS Secretary would be required to publish (on an HHS-maintained website) a report that analyzes the program’s impacts, and if warranted, includes a replication plan with any recommendations for legislative and administrative actions the HHS Secretary determines to be appropriate.

Section 303: Building Capacity for Family-Focused Residential Treatment

Current Law

As amended by the Family First Prevention Services Act (Title VII, Division E of P.L. 115-123) and effective with October 1, 2019, states may elect to use the Foster Care, Prevention, and Permanency program (under Title IV-E of the SSA) to provide 12 months of trauma-informed services to families with children at imminent risk of entering foster care and to pregnant or parenting teens in foster care. Prevention services that may be supported under this Title IV-E program option are trauma-informed and evidence-based substance use and mental health treatment services and in-home parent skills programs, including parent education, parenting skills training, and individual and family counseling. However, to be eligible for Title IV-E support, the prevention services and programs offered must meet certain criteria that define them as “promising,” “supported” or “well-supported.” Further, Title IV-E support for these services and programs will only be available to the extent that at least 50% of the total (state and federal) prevention spending for these activities meets the highest evidence standard (i.e., “well-supported”).

Proposed Provision

The Chairman’s Mark would require the HHS Secretary to make grants to eligible public and private entities to develop, enhance or evaluate family-focused residential treatment programs for the purpose of increasing the availability of programs that meet the evidence-based practice criteria for Title IV-E prevention services (as added by the Family First Prevention Services Act). For this purpose, it would authorize a one-time discretionary appropriation of \$20 million (to remain available across five years, FY2019-FY2023) and would require any evaluation funded (in whole or in part with these dollars) to be designed to help determine if the family-focused residential treatment program being carried out would qualify as “promising,” “supported” or “well-supported” under Title IV-E.

For this purpose, the Chairman’s Mark would define a “family-focused residential treatment program” as a trauma-informed residential program that primarily provides substance use disorder treatment to pregnant and postpartum women, as well as parents and guardians, and which, “to the extent appropriate and applicable,” allows children to reside with their parents or guardians during the treatment. Entities eligible to receive funding to develop, enhance or evaluate such programs would be defined to include state, county, local or tribal health or child welfare agencies; private nonprofit organizations; research organizations; treatment service providers; public or non-profit institutions of higher education; or other entities specified by the HHS Secretary.