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NEWLY ENACTED OPIOID LAW: HOW DOES IT IMPACT PROVIDERS?

On October 25, 2018, the president signed a wide-ranging bipartisan legislative package to address the opioid epidemic. The enactment of the Substance Use–Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act, or the SUPPORT for Patients and Communities Act, (the "Act") follows a lengthy process in both the Senate and House of Representatives, uniting numerous policy proposals of many lawmakers aiming to address the epidemic.

The Act comes approximately one year after the president declared the opioid crisis a national emergency. This version of the measure overwhelmingly passed the Senate 98 to 1 on October 3, 2018 after easily passing the House of Representatives by a vote of 393 to 8. The Act aims to curb the growing opioid public health crisis with several measures touching upon many aspects of the epidemic, increasing access to prevention programs, enabling a number of substance abuse interventions and providing additional funding for addiction treatments. Its provisions include expanding the availability of addiction treatment, making it more difficult for illicit synthetic opioids to pass through the border and increasing research related to non-opioid, non-addictive pain treatments. In addition, the Act also clarifies regulations regarding the Medicaid Institution for Mental Diseases ("IMD") exclusion, which prohibited the use of Medicaid financing for care provided to most adult patients in mental health and substance use hospitals and other facilities. The Act provides flexibility to the exclusion by codifying regulations allowing managed care plans to cover treatment in an IMD for limited periods under certain circumstances.

A Congressional Budget Office estimate expects that the Act will cost the federal government $29 million over the period of 2019-2028 through increased direct spending. However, the actual budgeting for many programs implemented as byproducts of this legislation will require future appropriations by Congress. Future spending bills will likely allocate funding towards these programs. In this way, the Act represents a first step to build systems and programs that combat and resolve the crisis.

A copy of the enrolled bill may be found here. A copy of a section-by-section summary produced by the Senate Finance Committee may be found here.

BACKGROUND

The opioid epidemic continues to be widespread, with preliminary data from the Centers for Disease Control and Prevention ("CDC") painting a picture of its devastating effects. The CDC found that of the 72,000 deaths in 2017 resulting from drug overdoses, 48,000 of those deaths were linked to opioid abuse, meaning that the epidemic led to an average of 130 deaths in the U.S. daily. Since the 1990s, more than 700,000 people in the U.S. have died of drug overdoses.

Litigation related to opioids has also seen an uptick. Several states are suing opioid manufacturers for violating state consumer protection laws by minimizing addiction risks and overstating the benefits of opioids. Several states, cities, counties and a Native American tribal council also filed suit against distributors and pharmacies for harm by not ensuring supply chains against diversion and from improperly allowing the delivery of opioids in quantities that far exceeded what could be consumed for medically necessary purposes. Several health care providers have also been under fire. Most recently on October 12, 2018, five physicians, a pharmacist and three medical assistants in New York were criminally charged with taking more than $5 million by illegally prescribing millions of oxycodone pills. Facing these realities, the action by Congress was imminent, and the Act is a step in that direction.

ANALYSIS

The Act is separated into different sections focused on Medicaid, Medicare, the Food and Drug Administration ("FDA") and controlled substance, public health and other areas such as drug trafficking. The Act is far-reaching in its subject matter from requirements for the U.S. Postal Service to screen packages from overseas for synthetic opioids, such as fentanyl, to authorization of drug courts to provide treatment to certain offenders rather than imprisonment. The sections of the legislation that are the most relevant to health care entities and providers such as hospitals, health systems, long-term care providers, mental health facilities/providers and pharmacies are listed below.

Medicaid

- **Section 1004. Medicaid drug review and utilization**. This provision builds on current state Medicaid drug utilization review activities

to help combat the opioid crisis. Under this section, state Medicaid programs are required to have safety edits in place for opioid refills, monitor concurrent prescribing of opioids and certain other drugs and monitor antipsychotic prescribing for children.

- **Section 1013. Securing flexibility to treat substance use disorders**. This provision clarifies flexibilities around Medicaid's IMD exclusion where, in some cases, managed care plans may provide or make available alternative services that are not permitted under the state plan. Stated more simply, this provision codifies 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.
- **Section 5042. Medicaid providers are required to note experiences in record systems to help in-need patients**. These provisions require Medicaid providers to check relevant prescription drug monitoring programs ("PDMPs") before prescribing a Schedule II controlled substance. The policy also encourages Medicaid providers to integrate PDMP usage into a Medicaid provider's clinical workflow and establishes standard criteria that a PDMP must meet to be counted as a qualified PDMP. Many states already require these types of PDMP checks, but this will help establish a more consistent national standard.

Medicare

- **Section 2001. Expanding the use of telehealth services for the treatment of opioid use disorder and other substance use disorders**. This provision expands the use of telehealth services by eliminating 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. It would allow payment for services furnished via telehealth at originating sites, including a beneficiary's home, regardless of geographic location. A separate facility fee would not be provided if the originating site is the beneficiary's home.
- **Section 2002. Comprehensive screenings for seniors**. This provision increases 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. It would require that the Medicare Initial Preventive Physical Examination and annual wellness visits include a review of the beneficiary's current opioid prescriptions and screening for potential substance use disorders, including a referral for treatment as appropriate.
- **Section 2003. Every prescription conveyed securely**. This provision deters prescription fraud and the diversion of opioids through the use of e-prescribing for opioids. Prescriptions for a Schedule II, III, IV or V Controlled Substance covered under a Part D prescription drug plan or Medicare Advantage Prescription Drug Plan are required to be transmitted in accordance with an electronic prescription drug program starting by January 1, 2021. The secretary may waive this requirement in certain defined cases, such as reasonable technological limitations.
- **Section 2005. Medicare coverage of certain services furnished by opioid treatment programs**. This provision expands Medicare coverage to include Opioid Treatment Programs ("OTPs") for the purposes of delivering Medication-Assisted Treatment ("MAT") to expand access to treatment options for Medicare beneficiaries. Currently, OTPs are not recognized as Medicare providers, meaning that Medicare beneficiaries receiving MAT at OTPs for their opioid use disorders must pay out of pocket.
- **Section 6111. Fighting the opioid epidemic with Sunshine**. This provision enhances the CMS-run Open Payments Program, or "the Sunshine Act," by expanding the types of professionals to 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. The bill sunsets the prohibition that prevents inclusion of the unique identification number, known as the National Provider Identifier, for all professionals and other entities displayed on the CMS Open Payments website.

DEA and Controlled Substances

- **Section 3201. Allowing for more flexibility with respect to medication-assisted treatment for opioid use disorders**. This provision will increase the number of waivered health care providers that can prescribe or dispense MAT by authorizing clinical nurse specialists, certified nurse midwives and certified registered nurse anesthetists to prescribe MAT for five years. It also makes permanent the prescribing authority for physician assistants and nurse practitioners and allows waivered practitioners to immediately treat 100 patients at a time if the practitioner is board certified in addiction medicine or addiction psychiatry or if the practitioner provides MAT in

a qualified practice setting. This provision codifies the ability for qualified physicians to prescribe MAT for up to 275 patients. This provision will of course need to be compared against and, in certain cases reconciled with, applicable state laws.

- **Section 3204. Delivery of a controlled substance by a pharmacy to be administered by injection or implantation**. This provision updates federal law to allow for implantable or injectable controlled substances for the purposes 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. Again, state law provisions should be cross-checked and considered.
- **Section 3212. Programs and materials for training on certain circumstances under which a pharmacist may decline to fill a prescription**. This provision directs the Department of Health and Human Services to help develop and disseminate materials, clarifying the circumstances of when pharmacists may decline to fill controlled substance prescriptions, such as when they suspect the prescriptions are fraudulent, forged or of doubtful, questionable or suspicious origin. This provision did not address the unilateral modification of a prescription allowing for dispensing less-than prescribed amounts.
- **Section 3222. Disposal of controlled substances of a hospice patient by employees of a qualified hospice program**. This provision will help reduce the number of unused controlled substances at risk of diversion or misuse by allowing qualified hospice employees to safely dispose of these medications on site after the death of a patient or when the controlled substance is expired or no longer needed because the hospice patient's plan of care has been modified.

Other

- **Section 8122. Criminal penalties**. This provision makes it illegal to knowingly and willfully pay or receive kickbacks in return for referring a patient to a recovery home or clinical treatment facilities. Those found guilty shall be fined up to $200,000 or 10 years in prison or both. It provides common sense exceptions for legitimate referrals, including ensuring legitimate entities can continue to refer patients to reputable treatment providers, similar to those that are applicable in Medicare and Medicaid.

PRACTICAL TAKEAWAYS

The overwhelmingly bipartisan nature of the legislation is indicative of the seriousness of the problem and commitment to action. Proponents of the Act view the statute's expansion of treatment options and services as a significant step in curbing the serious problems of opioid overdose and hope for the level of political will needed to continue working on solutions to the issue. Additionally, the Act, modeled after the congressional response to the HIV/AIDS epidemic of the 1980s, targets many different aspects of the supply chains. Supporters state that the wide variety of initiatives will provide for a multi-pronged attack.

Opponents state that it is not far-reaching enough, and they claim that little meaningful progress will be made to the long-term impacts of the opioid crisis. In part, this is because the legislation does not pay for a broad expansion of addiction treatment, nor does it actually appropriate funding for many of the programs and policies that it authorizes. Even so, the Act lays the statutory groundwork for a more robust response to the opioid epidemic.

As a result of the breadth of the Act touching upon so many aspects of health care services, health care entities will likely feel the impacts of the legislation as the federal and state governments implement its provisions. Areas of focus in particular for health care entities will include billing for services, opioid prescription ordering and dispensing, naloxone training and availability requirements.

That said, while the objectives of the Act are admirable, questions remain about the funding for many programs related to the Act and the long-term commitment of the government. Many of the treatment services may also depend upon grants or other regulations for future design or implementation. Health care entities should monitor these activities as they develop.

We will continue to actively track developments in this area.

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