President Trump signs the SUPPORT for Patients and Communities Act (H.R. 6)

Insights 10.26.18

On October 24, 2018, President Trump signed into law the bipartisan SUPPORT for Patients and Communities Act (H.R. 6 or the "Act"), which aims to combat opioid abuse with increased attention to treatment. The wide-reaching compromise legislation combines elements from a number of opioid bills, addressing issues from access to treatment and prevention programs to expanded law enforcement efforts to curtail drug trafficking. The Act, however, does omit several items that have been part of the national dialogue on opioid abuse. For example, it does not include amendments to 42 U.S.C. § 290dd-2 and the associated regulation at 42 C.F.R. Part 2 ("Part 2") that would align the Part 2 substance use treatment privacy law with the Health Insurance Portability and Accountability Act ("HIPAA") privacy rules to better facilitate the sharing of a patient's substance use disorder information among providers. In addition, the Act does not provide for a significant increase in spending for the opioid crisis.

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This alert focuses on a number of key sections in the more than 600-page Act that are of particular relevance to providers and that illustrate the varied approach that Congress is taking to combat the opioid crisis. In particular, we have summarized below portions of the Act that address the federal Medicaid institutions for mental disease ("IMD") exclusion, Medicaid and Medicare coverage for medication assisted treatment ("MAT"), Medicaid and Medicare coverage for telehealth addiction treatment services, and the Act's new drug recovery anti-kickback provisions. We will continue to monitor the promulgation of regulations pursuant to the Act, as well as state initiatives and waivers that seek to take advantage of particular provisions of the Act.

Access to Substance Use Disorder Treatment Information (Sections 7051, 7052, and 7053)

The Act includes an iteration of "Jessie's Law," which promotes provider education and the development of best practices with regard to care coordination and privacy for patients with a substance use disorder history. Named for a Michigan woman in recovery from an opioid addiction who overdosed after a post-surgical oxycodone prescription, Jessie's Law requires HHS to develop best practices for prominently displaying substance use disorder treatment information in electronic health records when requested by patients. HHS is also required to notify providers annually regarding permitted disclosures to family members, caregivers, and health care providers during emergencies (including overdoses).

Lastly, Jessie's Law tasks HHS with identifying model programs and materials to train and educate providers, patients and families regarding the permitted uses and disclosures of patient records related to treatment for substance use disorders.

The provision does not alter existing Part 2 confidentiality requirements for records relating to the identity, diagnosis, prognosis, or treatment maintained by a federally-assisted substance use disorder program. Many providers argue that the strict confidentiality requirements under the Part 2 regulations are outdated and negatively impact patients suffering from substance use disorders by preventing providers from seeing the whole picture in a patient's medical history. Although the Part 2 requirements remain intact under the Act, the debate over patient privacy and substance use disorder records will surely continue and some will continue to advocate for alignment of Part 2 requirements with HIPAA.

Federal Medicaid IMD Exclusion (Sections 1013, 5012, 5051, and 5052)

The Act limits the federal IMD exclusion, providing a new option for state Medicaid coverage of certain services provided to IMD patients. The IMD exclusion is a federal Medicaid restriction that prohibits federal financial participation ("FFP") for individuals, between the ages of 21 and 65 years, in an IMD. An IMD is a hospital, nursing facility, or other institution of more than 16 beds, that is primarily engaged in providing diagnosis, treatment, or care of persons with mental diseases, including medical attention, nursing care, and related services. The IMD exclusion was originally intended to discourage institutionalization of people with mental illness, but many argue that it exacerbates the nationwide shortage of treatment beds.

- Medicaid Managed Care Coverage. The Act codifies in statute current Medicaid rules that permit Medicaid managed care organizations to make payments for adult enrollees in an IMD for a short stay of no more than 15 days in lieu of other services.
- New State Option for Coverage. The Act also creates a new state option to provide coverage for IMD services up to 30 days a year for individuals in need of substance use treatment centers. States that exercise this option must meet certain requirements to receive FFP, and the option is set to expire on September 30, 2023. The potential impact of this provision is unclear because many states have already secured federal waivers for Medicaid inpatient substance abuse treatment. In California, for example, the state has waiver authority to use federal Medicaid funds to pay for two 90-day stays for adults and two 30-day stays for adolescents in an IMD, for the purpose of substance use treatment services. Finally, the Act directs the Medicaid and CHIP Payment and Access Commission ("MACPAC") to submit a report on Medicaid payment to IMDs to Congress.

Medication Assisted Treatment (Sections 1006, 1014, 2005, and 3201)

The Act includes a number of provisions aimed at increasing access to and coverage of MAT, which is the treatment of a substance use disorder with FDA-approved medications in combination with counseling and behavioral therapies. And, the Act also directs MACPAC to submit a report on current utilization control policies applied to MAT for substance use treatment under state Medicaid programs. The aim of the report is to identify the limits that exist on access to MAT, such as limits on quantity or requirements for prior authorizations.

- Increase Number of MAT Providers. The Act seeks to increase access to MAT by expanding the group of health care practitioners that can prescribe or dispense controlled substances for MAT without being registered with the Drug Enforcement Administration ("MAT qualified providers"). Under current law, only physicians and, until 2021, nurse practitioners and physician assistants are potentially eligible to be MAT qualified practitioners. The Act will also permit clinical nurse specialists, certified nurse midwives, and certified RN anesthetists to be MAT qualified providers from Oct. 1, 2018 to October 1, 2023 and will make permanent the eligibility of nurse practitioners and physician assistants to be MAT qualified providers. In addition, the Act will permit MAT qualified practitioners to immediately treat 100 patients at a time if board certified in addiction medicine or addiction psychiatry or in a qualified practice setting. And, certain qualified physicians will be permitted to prescribe MAT for up to 275 patients.
- Medicaid Coverage. The Act requires state Medicaid programs to provide MAT coverage from October 1, 2020 to September 30, 2025, unless the state certifies that implementing such coverage statewide would not be feasible

because of a shortage of MAT qualified providers. MAT is defined as including all FDA-approved drugs and, with respect to providing such drugs, counseling services and behavioral therapy.

- Medicare Coverage. The Act creates a new Medicare benefit category titled "Opioid Use Disorder Treatment Services" and new type of Medicare provider "Opioid Treatment Program," or "OTP," for the purpose of furnishing MAT to Medicare beneficiaries. Payment for such services will be through a bundled payment for opioid use treatment services (including dispensing and administration of MAT medications, individual and group therapy, and counseling) furnished by OTPs during a particular episode of care.
- Incentives to Utilize MAT and Appropriate Use of Opioids in Emergency Departments. The Act also authorizes five-year grants to initiate MAT protocols, among other recovery support services, in emergency departments, and it establishes a three-year trial grant program aimed at prevention. Under the latter program, eligible hospitals and emergency departments would be able to use grant funds to target treatment approaches for painful conditions, train on protocols or best practices related to the use and prescription of opioids and alternatives to opioids for pain management in the emergency department, and develop or continue strategies to provide alternatives to opioids.

Telehealth (Sections 1009, 2001, and 3232)

The Act contains several Medicare and Medicaid provisions aimed at expanding coverage for telehealth services to treat substance use disorders.[1] However, given that these provisions, for the most part, direct federal agencies to issue guidance or regulations, the final impact of these provisions is unknown until such guidance and/or regulations are issued.

- Medicaid Substance Use Disorder Treatment via Telehealth. The Act directs CMS to issue guidance on the provision of substance use disorder treatment via telehealth to Medicaid beneficiaries. The Act also directs CMS to outline options for FFP for education directed to providers serving Medicaid beneficiaries with substance use disorders using the so-called "hub and spoke" model, under which a physician at a "hub" facility provides services to patients located at a different, "spoke" facility. Finally, CMS will issue reports assessing efforts to reduce barriers to substance use disorder treatment and other services delivered via telehealth and remote patient monitoring for pediatric populations under Medicaid.
- Medicare Substance Use Disorder Treatment via Telemedicine. Beginning July 1, 2019, the Act exempts telemedicine services treating substance use disorders from certain statutory "originating site" requirements (i.e., geographic requirements) that apply to telemedicine services generally furnished to Medicare beneficiaries. Previously, to qualify for coverage, patients were required to be located in particular geographic areas to access treatment services from a provider at a distant site. The new exemption will allow providers to receive payment when substance use disorder services are provided to Medicare beneficiaries at any originating site – including the patient's home – regardless of geographic location. Providers should note, however, that no facility fee will be paid when the originating site is the patient's home.
- Special Telemedicine Registration. Finally, the Act directs the attorney general to issue regulations establishing a process for providers to obtain a special registration permitting them to prescribe controlled substances via telemedicine in emergency situations. Currently, the Ryan Haight Online Pharmacy Consumer Protection Act of 2008 prohibits practitioners from prescribing controlled substances without conducting at least one in-person medical evaluation of the patient. As a result, some patients requiring treatment in rural areas could not access necessary care, even when such treatment was available via telemedicine, because the practitioner had not first examined the patient in-person. It is unclear whether the implementing regulations will extend the registration process to all providers or only those with behavioral health or addiction treatment backgrounds and whether all controlled substances will be covered, or just medication used in the treatment of substance use disorders. Providers should monitor the development of this special registration, which will have a significant impact on efforts to combat the opioid epidemic and the scope of services available via telemedicine to Medicare and Medicaid beneficiaries. Finally, it should be noted that state e-prescribing laws may impose more restrictive requirements that will need to be satisfied even after regulations implement the special registration procedure

Drug Recovery Anti-Kickback Provisions (Section 8122)

The Act contains an anti-kickback provision applicable to all patients receiving substance use disorder treatment, not just federal healthcare program beneficiaries, that prohibits soliciting, receiving, paying or offering any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, in return for or to induce referrals to a recovery home, clinical treatment facility, or laboratory, or "in exchange for an individual using the services of" a recovery home, clinical treatment facility, or laboratory. The new prohibition is very broad, and applies to remuneration to patients, thus potentially implicating many common industry practices, such as assisting patients with transportation to a treatment facility, or routine waivers of coinsurance or copayments.

- Definitions. A "recovery home" is defined as a shared living environment that is or purports to be drug and alcohol free, and uses peer support to promote sustained recovery from substance use. A "clinical treatment facility" is defined as a medical setting (other than a hospital) that provides "detoxification, risk reduction, outpatient treatment and care, residential treatment, or rehabilitation for substance use, pursuant to licensure or certification under State law."
- Exceptions. The new prohibition also contains a limited number of narrow exceptions that permit certain types of "remuneration" under certain circumstances, such as certain discounts, and payments to an employee or independent contractor if it is not determined by and does not vary based on the number of individuals referred or tests or procedures performed; or amounts billed or collected, for the covered substance use disorder treatment services.

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In addition to the foregoing provisions that focus on treatment, Medicare and Medicaid coverage, and fraud and abuse, the Act includes provisions that address a myriad of other issues. For example, the Act reauthorizes the 21st Century Cures Act grants through 2021, which provide up to $500 million per year in funding. It also includes provisions that aim to stop the entry of illicit drugs, specifically fentanyl, its analogues, and other synthetic opioids, by increasing coordination between federal agencies and by authorizing grants to state and local agencies for the establishment or operation of public health laboratories to improve detection and testing. Although some may criticize the Act for its omissions (particularly with regard to funding and reforms to confidentiality rules), the Act is certainly a notable legislative response to the opioid epidemic that is likely to precipitate changes in the delivery of needed substance use disorder treatment care.

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[1] "Medicare telehealth services" are a specific set of services that must satisfy statutorily proscribed reimbursement standards in order to be covered by Medicare.

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