NOW + NEXT

HEALTH CARE ALERT | NIXON PEABODY LLP

NOVEMBER 19, 2018

New federal legislation addresses opioid crisis: Are you ready for the changes?

By Valerie Breslin Montague, Scott O'Connell, Kevin Shea, Ethan Trull, Jenna Fagerman, Jena Grady and Megha Shah

On October 24, 2018, President Trump signed into law the Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act. This comprehensive legislation tackles treatment for substance use disorders, diversion, counterfeits, international trafficking, promotion of non-opioids for pain management, prescription of controlled substances on Schedule A, data collection and telemedicine. The SUPPORT Act is a wide-ranging legislation addressing many issues intrinsic to tackling opioid use disorder—including treatment, research, funding and reporting. This alert focuses on some of the issues of particular importance to health care providers as well as pharmaceutical companies, laboratories and pharmacies.

In summary, the act increases Medicare and Medicaid coverage of various forms of treatment and services related to substance use disorders and focuses on improving treatment options for certain at-risk populations (i.e., seniors, pregnant and postpartum women, infants and children). With respect to telehealth treatment for Medicaid beneficiaries, the Centers for Medicare and Medicaid Services (CMS) will have one year to establish state guidelines to receive federal reimbursement for substance use disorder treatments, including medication-assisted treatments, counseling, medication management and medication adherence with prescribed medication regimes. The legislation also expands Medicaid coverage for services such as medication-assisted treatments (i.e., combating opioid use disorder through prescribing buprenorphine, suboxone and methadone), short-term inpatient treatment programs, bundled payment packages for care and e-health requirements. Individual states will be required to cover medication-assisted treatments, including methadone and counseling services. Prescribers will be required to check a Medicaid beneficiary's prescription history through the Prescription Drug Monitoring Program (PDMP) before prescribing a controlled substance. The act additionally expands the types of providers who may prescribe medication-assisted treatments.

The SUPPORT Act provides for changes in scheduling, wasting and disposal of controlled substances and enhanced monitoring of sales and distribution via reporting obligations.

Through a combination of new enabling language and specific directions to various agencies, new regulations on the issues above are expected in the near term.[1] Future alerts will analyze the specific changes the agencies implement.

Legislation Highlights

Impact on Medicare and Medicaid

***Medicare Provisions to Address the Opioid Crisis* (Sec. 2001 to 2008; 6011 to 6111)**

The act expands coverage of telehealth services furnished after July 1, 2019 for treatment of substance use disorders. In addition, treatment examinations and visits on or after January 1, 2020 will require comprehensive screening of seniors prescribed opioids—to include a review of risk factors for opioid use disorder, an evaluation of pain and the Medicare beneficiary's treatment plan as well as education on non-opioid treatment alternatives. As this effective date approaches, Medicare providers should work to establish processes to efficiently conduct and document such screenings.

Coverage to Medicare beneficiaries for certain opioid use disorder treatment services is extended under the act. The act also establishes a four-year "alternative payment model demonstration" project to increase access to outpatient treatment for Medicare beneficiaries.

In addition, the act requires physicians to electronically prescribe Schedule II, III, IV and V-controlled substances that are covered under either a Medicare Part D plan or a Medicare Advantage prescription drug plan, subject to limited exceptions. This requirement takes effect in January 2021.

***Medicaid Provisions to Address the Opioid Crisis* (Sec. 1001 to 1018; Sec. 5011 to 5061;)**

These sections provide explicit direction to CMS for enhancing treatment (including using telehealth technology and health homes, addressing access, removing barriers and affording flexibility), drug review and utilization, data sharing and housing-related support for the Medicaid population struggling with substance use disorders. This legislation also establishes a demonstration project designed to increase capacity for providers furnishing substance use disorder treatment or recovery services under Medicaid. States with innovative approaches, particularly those treating individuals with substance use disorders in an amount which meets or exceeds the national average, may seek participation in this demonstration project, which has $50M appropriated.

Beginning on October 1, 2019, state Medicaid plans must establish: (i) claims review limitations, including those necessary to identify when a Medicaid beneficiary is prescribed opioids in excess of a state limitation; (ii) a program to monitor and manage the use of antipsychotic medication for children who are Medicaid beneficiaries and (iii) a process to identify potential fraud and abuse of controlled substances by Medicaid beneficiaries and prescribers and pharmacies serving Medicaid beneficiaries.

Children and pregnant women under the Children's Health Insurance Program (CHIP) will have parity access to mental health and substance use disorder services.

---

[1] Under this law, the following agencies are directed to take defined action to address the impact of opioid use disorder: CDC, CMS, DEA, DOL, DOJ, FDA, HHS and the VA.

The SUPPORT Act requires covered providers, in accordance with state law, after October 1, 2021, to check the drug history of a Medicaid patient being treated through a qualified drug monitoring program before prescribing a controlled substance. Providers will need to develop appropriate practices and procedures to ensure compliance. The legislation provides for 100% federal matching rates (Federal Medical Assistance Percentages (FMAP)) to design, develop or implement a prescription drug monitoring program that is compliant with the act.

States also may elect, through a state plan amendment, to provide medical assistance for services provided to a Medicaid beneficiary with a substance use disorder who is a patient in an institution for mental diseases (IMD). Previously, it was not permissible to use federal Medicaid funds for services provided in an IMD for non-elderly adults. The act provides the option for states to cover these services for up to thirty (30) days per year from October 1, 2019 through September 30, 2023.

These services include: (i) outpatient and community-based substance use disorder treatment; (ii) evidence-based recovery and support services; (iii) clinically directed therapeutic treatment to facilitate recovery skills, relapse prevention and emotional coping strategies; (iv) outpatient medication-assisted treatment, related therapies and pharmacology; (v) counseling and clinical monitoring; (vi) outpatient withdrawal management and related treatment designed to alleviate acute emotional, behavioral, cognitive or biomedical distress resulting from, or occurring with, an individual's use of alcohol and other drugs; (vii) routine monitoring of medication adherence and (viii) other outpatient and community-based services for the treatment of substance use disorders, as designated by the Secretary of the Department of Health and Human Services (HHS). In order to secure the federal match, the state must maintain designated levels of expenditures from nonfederal funds for certain Medicaid services.

***The Eliminating Kickbacks in Recovery Act of 2018* (Sec. 8121 and 8122)**

To combat potential conflicts of interest associated with patient referrals to substance use disorder treatment facilities and laboratories, SUPPORT, subject to limited exceptions, makes it a federal crime to solicit or receive, pay or offer any remuneration for referrals of patients to a recovery home, clinical treatment facility or laboratory for services covered by any public or private health care benefit program. Violators will be subject to fines of up to $200T or imprisonment of up to ten (10) years, or both, for each occurrence.

The existing federal Anti-Kickback Statute (AKS) applies to referrals that are reimbursed by federal programs like Medicare and Medicaid. The new anti-kickback prohibitions contained in the SUPPORT extend the tenets of the AKS to include any public or private health care plan or contract in or affecting interstate or foreign commerce. In this sense, the act significantly expands the reach of existing anti-kickback prohibitions, albeit without any overlap with the AKS. At the same time, SUPPORT has a narrower scope than the AKS, because its application is specifically limited to recovery homes, clinical treatment facilities and laboratories.

Health care providers need to be aware that the anti-kickback provisions of the SUPPORT Act specifically do not supersede the AKS or preempt state laws. Moreover, while the exceptions to the act's anti-kickback provisions are similar to the statutory exemptions and safe harbors applicable to the AKS, they are not identical. Notably, SUPPORT Act authorizes the U.S. Attorney General to create additional exceptions, or to clarify exceptions by regulation, in consultation with the HHS. By contrast, HHS has exclusive authority to provide safe harbor guidance under the AKS. This asymmetric authority to create and interpret exceptions and safe harbors creates real uncertainty

whether health care providers may safely rely on existing guidance under the AKS. In particular, the narrow class of regulated providers under the act need to ensure that any arrangements whereby patients are referred to recovery homes, addiction treatment centers or to laboratories are structured to meet an exception to the act's prohibition on improper payments for referrals.

***Changes Related to Handling Controlled Substances and Synthetic Analogues* (Sec. 3001 to 3291)**

These provisions provide the FDA secretary with the authority (i) to cease distribution and to recall controlled substances because of reasonable probability of serious adverse health consequences; (ii) to deny, suspend and debar a person from improper importation of controlled substances and (iii) to require packaging changes to enhance safety and disposal. Also addressed is the safe handling and disposal of controlled substances in connection with hospice care and federal grants increase access to drug disposal facilities. To help encourage responsible prescribing, the legislation clarifies the FDA's authority to require drug manufacturers to package certain opioids to allow for a set duration (e.g., a blister pack with a three- or seven-day supply). To help prevent unused opioid diversion, the legislation clarifies the FDA's authority to require manufacturers to give patients safe options to dispose of unused opioids such as safe-disposal packaging or safe disposal systems for purposes of rendering unused drugs non-retrievable.

Significantly, these provisions require registered manufacturers or distributors of controlled substances to review, on a quarterly basis, data generated through the Automated Reports and Consolidated Ordering System (ARCOS) to identify, report and stop suspicious orders of opioids and to reduce diversion rates. Drug manufacturers and distributors who fail to consider ARCOS data when determining whether an order for opioids is suspicious are subject to civil and criminal fines. The SUPPORT Act increases the civil and criminal penalties for drug manufacturers and distributors who fail to report suspicious orders and keep accurate records.

***HHS to Provide Guidance to Pharmacists on Circumstances Under Which Pharmacists May Decline to Fill Prescriptions* (Sec. 3212)**

This provision directs the HHS, in consultation with other regulatory agencies, to develop and disseminate materials clarifying when pharmacists may decline to fill controlled substance prescriptions—including when they suspect the prescriptions are fraudulent, forged or of doubtful, questionable or suspicious origin. This provision will benefit pharmacists by providing federal guidance and training on the appropriateness of declining suspect prescriptions. In addition, assuming pharmacists follow the guidance and training issued by HHS, this provision should provide a defense to pharmacists in connection with any civil claims challenging their failure to fill.

***Fighting the Opioid Epidemic with Sunshine* (Sec. 6111)**

Currently, manufacturers of drugs, biologics and devices reimbursed by Medicare, Medicaid, or CHIP must report the provision of items of value to physicians and teaching hospitals. The SUPPORT Act expands this reporting obligation, as of January 1, 2022, to include value provided to physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists and certified nurse midwives. This expansion applies to manufacturers of all types of drugs, devices and biologicals reimbursed by Medicare, Medicaid or CHIP; it is not limited just to opioids.

***FDA* (Sec. 3001 to 3291)**

The legislation indicates a preference for the development of treatment protocols using non-opioid medications. The FDA will provide additional guidance and clarification on the qualification parameters for expedited pathways for nonaddictive medical products. Companies should take advantage of upcoming FDA clarification in addition to Breakthrough Designation and Accelerated Approval processes to novel non-opioid pain treatments in order to be first to market.

***Loan Repayment Program for Substance Use Disorder Treatment Providers* (Sec. 7071)**

The SUPPORT Act authorizes the Health Resources and Services Administration (HRSA) to implement a loan repayment program for individuals who commit to full-time employment in substance use disorder treatment in either (i) a mental health Health Professional Shortage Area (HPSA) or (ii) a county (or municipality) in which the mean drug overdose death rate per 100,000 people over the last three years is higher than the national average. HHS has the option of establishing rules and criteria for this program. This provision allows some of the areas hardest hit by the opioid epidemic to better attract social workers, therapists, physicians, nurses and other behavioral and mental health practitioners to provide services in a number of practice settings, including hospitals, treatment programs, physician practices, correctional facilities, schools and telehealth platforms.

***Emergency Department Alternatives to Opioids Demonstration Program* (Sec. 7091)**

The act permits hospitals and freestanding emergency departments to apply to HHS for grants designed to assist such facilities develop, implement, enhance or study alternatives to opioids for pain management. In particular, grant funds may be used to train providers and other personnel on best practices surrounding opioids, as well as pain management alternatives, among other purposes. Creating these programs with grant funds may serve a dual purpose for a hospital. They will (i) help to curb opioid use disorders and (ii) potentially meet other quality focused initiatives—such as potentially decreasing readmissions for pain-related issues.

Practical Implications

This legislation impacts drug manufacturers, distributors, physicians, pharmacists and a variety of other health care professionals. Health care entities will need to focus on billing for services, opioid prescription ordering and dispensing and training staff to comply with new reporting and PDMP cross-checking requirements. To avoid federal investigations or accusations of wrongdoing, health care entities may benefit from creating internal policies and procedures that require those interacting with patients and prescribing or dispensing opioids to follow the guidelines addressed above.

For more information on the content of this alert, please contact your regular Nixon Peabody attorney or:

- Valerie Breslin Montague at **vbmontague@nixonpeabody.com** or 312-977-4485
- Scott O'Connell at **soconnell@nixonpeabody.com** or 617-345-1150
- Kevin Shea at **kpshea@nixonpeabody.com** or 312-977-4860
- Ethan Trull at **etrull@nixonpeabody.com** or 312-977-4447
- Stephen Zubiago at **szubiago@nixonpeabody.com** or 401-454-1017
- Jill Gordon at **jgordon@nixonpeabody.com** or 213-629-6175