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# A First Look At The Sweeping New Opioid Law

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The newly enacted Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment, or SUPPORT, Act's wide-ranging provisions take aim at the entire health care continuum, including providers, who will be on the front lines of change as the new law takes effect. The law includes amendments to Medicare and Medicaid, and changes affecting program integrity and transparency reporting of provider payments by drug and device manufacturers and the disposal of unused medication.

President Donald Trump signed Congress' long-anticipated response to the national opioid crisis into law on Oct. 24. The SUPPORT Act, HR 6 — a product of rare broad bipartisan support in both the House of Representatives (393-8) and the Senate (98-1) — is perhaps the most significant piece of public health legislation to pass during the 115th Congress (2017–2018).

The SUPPORT Act is the product of more than 120 separate bills and the culmination of nearly two years of work across multiple committees by a number of lawmakers in the House and Senate. This achievement reflects the breadth of the opioid crisis, which claimed 72,000 lives across the country last year alone, as well as the collective resolve of Congress to address those challenges.

Broad in scope, the legislation's wide-ranging provisions take aim at the entire health care continuum, including providers, who will be on the front lines as the law reshapes the treatment and prevention of prescription drug abuse disorders. Providers should be aware of changes in the law that affect program integrity, Medicare, Medicaid, transparency reporting of provider payments by drug and device manufacturers, and the disposal of unused medication. The legislation also calls for numerous grants and countless reviews, reports and studies that are certain to result in additional health system changes.

Implementation will occur over the course of a few years and many of the new law's provisions have their own effective dates. Unless otherwise stated, the new law is effective upon enactment.

**Program Integrity**

***New Criminal Anti-Kickback Provisions for Private Health Benefit Programs Serving Recovery Homes,***

***Clinical Treatment Facilities and Labs***

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In addition to other fraud and deceptive practice prohibitions, Section 8121 of the SUPPORT Act introduces a new criminal felony referral prohibition to combat patient brokering activities and abusive payment arrangements for opioid treatment services involving laboratories, recovery homes and clinical treatment facilities. This provision, known as the Eliminating Kickbacks in Recovery Act of 2018, effectively extends federal anti-kickback–style prohibitions to the private market for these areas. Title 18 of the United States Code is amended to add Section 220, "Illegal remunerations for referrals to recovery homes, clinical treatment facilities and laboratories."

While it does not overlap with the federal anti-kickback statute that applies to federal health care programs such as Medicare and Medicaid, the SUPPORT Act anti-referral prohibition accomplishes a broad entry into regulating arrangements and relationships in the private market for conflicts of interest in referrals involving health benefit programs, defined as "any public or private plan or contract, affecting commerce, under which any medical benefit, item, or service is provided to any individual, and includes any individual or entity who is providing a medical benefit, item, or service for which payment may be made under the plan or contract."

The private referral prohibition extends to any individual or entity that:

- Solicits or receives any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, in return for referring a patient or patronage to a recovery home, clinical treatment facility or laboratory; or
- Pays or offers any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind,
- To induce a referral of an individual to a recovery home, clinical treatment facility or laboratory; or
- In exchange for an individual using the services of that recovery home, clinical treatment facility or laboratory.

Violation of the referral prohibition is punishable by a fine of not more than $200,000 and imprisonment of not more than 10 years for each occurrence. Notably, this provision does not apply in instances where the federal anti-kickback statute may apply, nor does it preempt state anti-kickback regulations. It is also clear that for now the referral prohibition only applies to recovery homes, clinical treatment facilities and laboratories, but could be amended to apply to other health industry private sector arrangements in the future.

Like the anti-kickback statute, Congress has recognized certain statutory exceptions that exempt remuneration or arrangements from the referral prohibition ambit, but notably authorizes the U.S. attorney general to create exceptions, or clarify any exceptions by regulation, in consultation with the secretary of the U.S. Department of Health and Human Services, rather than authorizing HHS, which is the agency responsible for safe harbor guidance for the federal anti-kickback statute, to do this alone. The SUPPORT Act currently includes the following exceptions to the referral prohibition:

- Properly disclosed discounts under health care benefit programs that reflect a reduction in price of the costs claimed or charges made by the provider or entity;

- Payments by employers to bona fide employees or independent contractors if the payment is not determined by or does not vary by the number of individuals referred to the provider, the number of tests or procedures performed or the amount billed to or received from individuals referred to the provider;

- Drug discounts under the Medicare coverage gap discount program;

- Payments for services under personal services and management contracts meeting the requirements of the federal anti-kickback statute's regulatory safe harbor for personal services and management contracts[1] (i.e., payment is in writing for at least one year for compensation at fair market value in a commercially reasonable transaction that does not take into account the volume or value of referrals);

- Specific coinsurance or copayment waivers and discounts;

- Federally qualified health center arrangements meeting the anti-kickback statute exceptions;

- Any payment made pursuant to an alternative payment model or payment arrangement that the secretary of HHS determines is necessary for care coordination or value-based care.

Though there are some structural similarities to the anti-kickback statute, the statutes are distinct on key issues affecting providers in this area largely aimed at prohibiting or restricting productivity compensation or any compensation related to referrals. For example, the new law provides an exception for payments by employers to bona fide employees or independent contractors, which is a narrower exception than for compensation regulated by the federal anti-kickback statute exception. The federal anti-kickback statute exception for bona fide employees protects any payments related to the furnishing of covered items or services that are reimbursed in whole or part by federal health care programs — a scope that corresponds with the anti-kickback statute. In contrast, the prohibitions in the Eliminating Kickbacks in Recovery Act of 2018 will not exempt compensation to employees or independent contractors that varies by the number of patients referred or tests performed or any benchmark to referrals. This provision would appear to prohibit productivity compensation models.

In further regulating compensation arrangements, personal services and management contracts are required to meet the requirements of the federal anti-kickback statute safe harbor for personal services and management contracts,[2] with no provision suggesting that compliance with these requirements is voluntary or may be substantially accomplished and still be legal. Under the federal anti-kickback statute, the safe harbor provisions are not mandatory nor is any noncompliance alone sufficient to render an arrangement per se illegal. In the event an arrangement does not comply with the federal anti-kickback statute safe harbor requirements, the contracting parties may not claim immunity from criminal prosecution, but they may defend the arrangement on the basis of a "facts and circumstances" test that takes into account important factors such as whether the arrangement encourages overutilization or unfair competition or distorts patient choice.

Compliance with anti-kickback statute safe harbors is generally viewed as difficult for part-time, per diem, or other nontraditional arrangements. The statutory language requiring that any personal services arrangement meet the federal anti-kickback statute safe harbor goes much further than the statute

itself by appearing to mandate full compliance with all of the anti-kickback statute safe harbor requirements under penalty of a criminal felony offense for any degree of noncompliance. The U.S. Department of Justice, the agency given interpretative authority for the Eliminating Kickbacks in Recovery Act of 2018, should issue guidance to clarify the enforcement policy approach to the imported safe harbor requirements. Adopting the HHS Office of Inspector General legal approach to safe harbor compliance would be consistent with federal anti-kickback statute enforcement.

The Eliminating Kickbacks in Recovery Act of 2018 reflects long-held public health policy concerns on how financial considerations or conflicts of interest influence medical decisionmaking. In combating abusive patient brokering activities and payment arrangements, Congress has attempted to address the difficult area of productivity compensation and has reaffirmed that providers and entities should not make more money based on the number of patients referred or procedures or tests performed. These reform provisions will challenge many existing arrangements and require a new paradigm for compensated activities in the industry sector involving recovery homes, clinical treatment facilities and laboratories.

**"Fighting the Opioid Epidemic with Sunshine" Program**

The Physician Payments Sunshine Act requires certain drug and medical device manufacturers to annually report to the Centers for Medicare and Medicaid Services payments and transfers of value made to physicians and teaching hospitals. This information is posted to and refreshed annually by CMS on the agency's open payments webpage. The SUPPORT Act expands this reporting obligation to include payments and other transfers of value made to physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists and certified nurse midwives effective for payments reported in 2022, with payment tracking beginning in 2021.

This additional requirement is intended to enhance transparency with respect to industry relationships with advanced care practitioners who are increasingly involved in furnishing primary care, including prescribing opioids and other prescription drugs. The new law may also heighten law enforcement and regulatory scrutiny of such practitioners and their affiliated institutions as a safeguard against fraud and abuse and industry conflicts of interest. Like U.S.-licensed physicians under the Sunshine Act, advanced care practitioners now will have to monitor the accuracy of their data reported to CMS by drug and device manufacturers and engage in the dispute resolution process if they believe there is an error.

***Transparency Measures Under Medicare Parts C and D***

The SUPPORT Act directs the secretary of HHS, not later than Jan. 1, 2021, to annually notify "outlier prescribers" of opioids reflected on Part D claims, based on criteria established by the secretary, and subject to various exceptions including claims for individuals receiving hospice care and those undergoing cancer treatment. The new law authorizes funding for educating outlier prescribers on best practices for prescribing opioids including nonopioid pain management therapies. "Persistent" outlier prescribers may be subject to additional education and training requirements as determined by the secretary of HHS. Aggregate information on outlier prescribers (e.g., without prescriber names) will be posted to the CMS website.

The legislation requires the secretary of HHS to set up a secure portal to facilitate communications between the secretary, Part D and Medicare Advantage plans and the Medicare drug integrity contractor regarding program integrity. It also provides that plans must submit information on actions taken with respect to overprescribers of opioids and such other data as determined by the secretary of

HHS. These provisions are effective no later than two years after enactment.

Medicare prescription drug plan sponsors may suspend payments to pharmacies pending the investigation of a credible allegation of fraud, effective Jan. 1, 2020.

**Medicare**

***Expanded Access to Screening, Prevention and Treatment Services***

The SUPPORT Act provides for a number of changes aimed at enhancing access to prescription drug abuse prevention and treatment services for Medicare beneficiaries. Starting Jan. 1, 2020, newly eligible beneficiaries will be screened for risk factors related to opioid addiction as part of the initial "Welcome to Medicare" exam. Medicare Advantage and Part D prescription drug plans will include information on the risks associated with prolonged opioid use and coverage of nonpharmacological therapies, devices and nonopioid medications to Medicare beneficiaries, either electronically or by mail, beginning for plan year 2021.

Effective Jan. 1, 2020, Medicare coverage will be expanded to include medication assisted treatment options furnished by opioid treatment programs certified and accredited by HHS. Currently, OPTs are not recognized as Medicare providers. Medicare will pay OPTs on a bundled basis for opioid use disorder treatments including dispensing and administering medications, toxicology testing, substance use counseling and individual and group therapy.

Beneficiaries at risk for prescription drug abuse will be eligible for Medication Therapy Management, effective Jan. 1, 2021. Part D plan sponsors will be required to adopt (as opposed to "voluntarily adopt" under current law) drug management programs for at-risk beneficiaries for plan years beginning in 2022. The SUPPORT Act requires CMS to identify Part D beneficiaries with a history of opioid-related overdose as potentially "at risk" for prescription drug abuse under the drug management program. At-risk beneficiaries may automatically escalate an appeal of this designation to an entity external to the plan.

A four-year demonstration project will be established by Jan. 1, 2021, to test the effectiveness of "opioid use disorder care teams" in improving the physical and mental health outcomes for drug-addicted beneficiaries and, to the extent possible, reducing program expenditures. Individuals and entities eligible to participate in the care teams include physicians, group practices and hospital outpatient departments. In implementing the demonstration project, preference will be given to entities and practitioners located in areas with higher levels of opioid use disorders than the national average.

***Hospitals: New Guidance and an Action Plan***

The SUPPORT Act directs the secretary of HHS to:

- Post all guidance on prescribing opioids published by HHS on or after Jan. 1, 2016, to the CMS website within 180 days of enactment;

- Publish a toolkit with guidance on pain management strategies and opioid use disorder prevention strategies for Part A hospitals by July 1, 2019; and

- Develop an “action plan” for addressing the opioid crisis that includes recommendations for payment and service delivery models to be tested by the Center for Medicare and Medicaid Innovation, and to report to Congress no later than Jan. 1, 2020.

The new law requires the Medicare Payment Advisory Commission to report to Congress by March 15, 2019, on how Medicare pays for opioid and nonopioid pain management treatments in inpatient and outpatient settings, including whether Medicare reimbursement provides financial incentives to prescribe opioids in place of a nonopioid alternative. To that end, the secretary of HHS is directed to review payment for outpatient surgical and pain management services and to begin making adjustments to avoid financial incentives to prescribe opioids in place of a nonopioid alternative for services furnished on or after Jan. 1, 2020.

The secretary of HHS will also convene two panels of technical experts — one to review and provide recommendations on reducing surgical-setting opioid use, and the other to review and identify quality measurement gaps relating to opioids and opioid disorder treatments and to make recommendations regarding new measures, revisions to existing measures, and inclusion of such measures in value-based programs — within six months of enactment.

***E-Prescribing and Prior Authorization Requirements***

The SUPPORT Act requires e-prescribing for Schedule II, III, IV or V controlled substances covered under a Part D or Medicare Advantage drug plan as well as secure electronic prior authorization for Part D covered drugs. Faxes or proprietary payer portals that do not meet standards defined by the secretary of HHS and electronic forms are not considered “electronic transmissions” for purposes of the prior authorization requirement. Both provisions are effective Jan. 1, 2021.

***Expanded Access to Telehealth***

Beginning July 1, 2019, the geographic requirement that restricts telehealth services to Medicare beneficiaries located in rural or shortage areas will be eliminated.

**Medicaid**

***Pregnant Women and Children***

Since so many children are covered under state Medicaid programs, it is no surprise that the SUPPORT Act focuses on pregnant women and children in the numerous amendments to Medicaid. The titles of the various provisions in the table of contents tell the story alone, from setting up “Demonstration projects to increase substance use provider capacity under the Medicaid program” to enacting “Help for moms and babies.”

The law addresses infants with neonatal abstinence syndrome, or NAS, introducing provisions that focus on incentivizing ways to decrease the incidence of NAS and clarifying that state Medicaid programs can provide care for infants with NAS in pediatric recovery centers.

The legislation requests a U.S. Government Accountability Office report that seeks best practices from the states with innovative, evidence-based payment models that focus on the prevention, screening, treatment and self-care and post-discharge plans for mothers and fathers with substance use disorders

and babies with NAS. To this end, the new law seeks guidance on suggested terminology and ICD codes to identify infants with NAS and neonatal withdrawal syndrome, which could include opioid withdrawal not requiring pharmacotherapy and withdrawal requiring pharmacotherapy.

The SUPPORT Act modifies Medicaid coverage for eligible pregnant and postpartum women receiving active treatment for substance use disorders at Medicaid Institutions for Mental Disease to provide that pregnant and postpartum women can continue to receive other Medicaid-covered care outside of the IMD, such as prenatal services.

The law requires amendments to Medicaid state plans to ensure states have programs in place that would monitor and manage the appropriate use of antipsychotic medications by children enrolled in the Medicaid program. It also aims to break down barriers that may limit access to care while being treated for substance use disorders at impatient mental health treatment facilitates with more than 16 beds, and expands eligibility under the Children's Health Insurance Program for incarcerated youth.

***Telehealth***

Telehealth is identified as an option for treating substance use disorders under Medicaid. The SUPPORT Act directs CMS, within one year of enactment, to provide guidance to states on options regarding federal reimbursement under Medicaid for services and treatment delivered via telehealth, including (1) services addressing the needs of high-risk individuals, (2) education for providers serving drug-impaired beneficiaries through a hub-and-spoke model, (3) services through contracts with managed care entities, (4) services through administrative claiming for disease management activities, (5) services through Delivery System Reform Incentive Payment programs and (6) treatment for substance use disorders for Medicaid beneficiaries in school-based health centers.

Separately, the GAO is required to report to Congress not later than one year after enactment on the results of an evaluation of children's access to services and treatment for substance use disorders under Medicaid, including increasing the number of providers using telehealth in school-based health centers. The evaluation will include an analysis of Medicaid provider reimbursement rates for treating substance use disorders. The GAO will also provide specific recommendations for administrative or legislative action necessary to improve children's access to care.

The new law directs CMS to report to Congress, no later than one year after enactment, on best practices and potential solutions for reducing barriers to using telehealth to provide substance use disorder treatment and services among pediatric populations under Medicaid.

It also requires the U.S. Drug Enforcement Administration to promulgate rules for the implementation of special registration for remote providers within one year of enactment.

**Disposal of Unused Medication**

***Safe Disposal Information for Part D Plan Enrollees***

Beginning in 2021, Medicare Advantage plans will be required to provide enrollees with information on the safe disposal of prescribed controlled substances including drug takeback programs and in-home disposal options under the in-home risk assessment or through their MTM programs.

***Disposal of Unused Patient Medications by Hospice Employees***

The SUPPORT Act permits an employee of a qualified hospice program to dispose of a patient's controlled substances onsite if the disposal occurs after the death of the patient or the controlled substance is expired. In instances where the hospice employee is a physician registered under Section 303(f) of the Controlled Substances Act, he or she may dispose of the patient's controlled substances if the patient no longer requires the controlled medication because of a change in his or her plan of care.

"Qualified hospice program" is defined as a hospice program that has written policies and procedures for assisting in the disposal of a hospice patient's controlled substances after their death, and at the time when the controlled substances are first ordered, the hospice program:

- Provides a copy of the written policies and procedures to the patient or patient representative and family;

- Discusses the policies and procedures with the patient or representative and the family in a language and manner that they understand to ensure that these parties are educated regarding the safe disposal of controlled substances; and

- Documents in the patient's clinical record that the written policies and procedures were provided and discussed.

At the time following the disposal of the controlled substances, the hospice program:

- Documents in the patient's clinical record the type of controlled substance, dosage, route of administration and quantity so disposed; and

- Documents the time, date and manner in which the disposal occurred.

The DEA may issue guidance to assist qualified hospice programs in meeting the new requirements.

The new law provides that nothing therein shall be construed to prevent a state or local government from imposing additional controls or restrictions in regulating the disposal of controlled substances in hospice care or hospice programs. It further directs the GAO to study and report back to Congress no later 18 months after enactment on legislative and administrative actions for disposing of controlled substances in a patient's home.

***Disposal Options; Access to Collections and Disposal Sites***

The SUPPORT Act directs the U.S. Food and Drug Administration to work with manufacturers in establishing safe disposal options for rendering unused drugs nonretrievable and options for dispensing opioids in unit dose packages or packages with a set treatment duration. It also requires the GAO to report to Congress within a year after the date of enactment on the effectiveness of in-home disposal products for controlled substances and packaging technologies including a description of current oversight efforts by the federal government. The U.S. attorney general may make grants to as many as five states to increase the participation of "authorized collectors" of opioids for disposal, including retail pharmacies and hospitals or clinics with onsite pharmacies.

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[1] 42 CFR 1001.952(d)

[2] 42 CFR 1001.952(d)