

Physician Organizations

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The SUPPORT Act: Impact of Federal Opioid Legislation on Physicians and Physician Organizations

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On October 24, 2018, President Trump signed into law the “Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act” or the “SUPPORT for Patients and Communities Act” (SUPPORT Act, Public Law No: 115-271). The SUPPORT Act aims to combat the opioid crisis. More specifically, the SUPPORT Act is a major piece of legislation combining 70 different bills designed to (1) reduce the use and supply of opioids; (2) encourage recovery; (3) support caregivers and families; and (4) drive innovation and long term solutions. According to politicians promoting the legislation, the SUPPORT Act is designed to boost access to addiction treatment and many other interventions to mitigate the opioid epidemic, from law enforcement efforts against illicit drugs to combating the over prescription of opioids.

Goals and Implementation

A Press Release by the U.S. Senate Committee on Health, Education, Labor & Pensions outlines the four main goals as follows:¹

Reduce Use and Supply

The legislation includes the Stop Illicit Drug Importation Act of 2018 (STOP Act) (Section 3021 of the SUPPORT Act) which will help stop illegal drugs at the border, as well as provisions that provide flexible grants for states to better share Prescription Drug Monitoring Programs data, clarify the U.S. Food and Drug Administration (FDA) authority to require set packaging for prescription opioids, such as a three or seven day supply in a blister pack, fight opioid diversion, and enhance screening to better identify patients’ addiction potential.

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—from a declaration of the American Bar Association



Encourage Recovery

The SUPPORT Act includes provisions to support states and Native American tribes in addressing substance use disorders, establish comprehensive opioid recovery centers, expand access to medication-assisted treatment (MAT), and improve community support, access to health professionals, telehealth services and long-distance care, and recovery housing services.

Support Caregivers and Families

The SUPPORT Act includes provisions to improve plans of safe care and support for substance-exposed babies and their mothers, promote family-focused treatment and recovery, help youth with substance use disorders recover, and strengthen trauma-informed care and support in schools and early childhood education programs.

Drive Innovation and Long Term Solutions

The SUPPORT Act includes provisions to advance cutting-edge research to spur discovery and development of new non-addictive painkillers, address economic and workforce impacts of the opioid crisis, ensure parity in mental health and substance use disorder benefits, and improve pain management.

Impact on Physicians and Physician Organizations

The SUPPORT Act is a 600 plus-page law that likely has a far-reaching impact, including major changes to the health care regulatory landscape. In terms of physicians and physician organizations, the SUPPORT Act (1) creates a new anti-kickback statute applicable to both commercial and governmental payers, (2) advances telemedicine, and (3) expands Medicare coverage to include opioid treatment programs for Medicare beneficiaries.

Commercial and Governmental Payer Anti-Kickback Statute/Sunshine Act

One of the most significant provisions that may affect physicians is the creation of an anti-kickback statute applicable to both commercial and governmental payers alike. Section 8122 of the SUPPORT Act lays out the act, “Eliminating Kickbacks in Recovery Act of 2018,” or “Recovery Kickback Prohibition,” (RKP), which makes it a federal offense to pay for referrals to recovery homes, clinical treatment facilities, and laboratories. The RKP structurally mirrors the federal Anti-Kickback Statute (AKS), 42 U.S.C. 1320a-7b(b), but has some extremely important differences. Generally, the RKP aims to both (1) curtail patients’ brokering with opioid treatment centers and (2) slow the overutilization of laboratory toxicology screenings by closing a loophole remaining in the AKS. To the extent physicians have ownership in any of these facilities or otherwise receive remuneration in exchange for providing services to these entities, the physicians will need to review their arrangements to ensure they do not run afoul of the RKP.

The RKP² states:

a) OFFENSE.—Except as provided in subsection (b), [which establishes certain exceptions to the prohibition], whoever, with respect to services covered by a health care benefit program, in or affecting interstate or foreign commerce, knowingly and willfully—

(1) 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

(2) pays or offers any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—

(A) to induce a referral of an individual to a recovery home, clinical treatment facility, or laboratory; or

(B) in exchange for an individual using the services of that recovery home, clinical treatment facility, or laboratory, shall be fined not more than \$200,000, imprisoned not more than 10 years, or both, for each occurrence.

The terms “recovery home,” “clinical treatment facility,” and laboratory are defined as:

- *Recovery Home* is a shared living environment that is, or purports to be, free from alcohol and illicit drug use and centered on peer support and connection to services that promote sustained recovery from substance use disorders.
- *Clinical Treatment Facility* is 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.

- *Laboratory* is a facility for the biological, microbiological, serological, chemical, immuno-hematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings.³

The RKP operates parallel to the AKS, in that it neither amends it nor supersedes when the AKS is otherwise applicable.

The RKP is distinguishable from the AKS in that it is wider in scope because it applies to both federal health care programs *and* commercial programs. However, the RKP is narrower than the AKS in one regard because it only applies to referrals and services with respect to the three entities identified above—recovery homes, clinical treatment facilities, and laboratories. But, given the general definition of “laboratory” outlined above, the RKP may apply to *any* laboratory, not only those producing opioid-related toxicology test results.

The RKP mirrors the AKS with its enumerated exceptions, each with its own specific components that must be met. Like the AKS, the RKP contains carve outs for both (1) payments to bona fide employees and independent contractors; and (2) payments for services that meet the federal AKS safe harbor for personal services and management contracts. Importantly, however, the exception for payments to bona fide employees and contractors is much narrower than the AKS “employee” safe harbor. The AKS safe harbor simply requires a “bona fide employment relationship” to protect the compensation paid to the employee, without any restriction on the methodology utilized in determining the compensation to the employee.⁴ Under the RKP exception, compensation paid under a bona fide employment relationship can still be protected; however, the RKP now places restrictions on the compensation methodology utilized.⁵ Specifically, the RKP safe harbor requires that compensation paid to the employee may not be determined by and may not vary by: (1) the number of individuals referred to a particular recovery home, clinical treatment facility, or laboratory; (2) the number of tests or procedures performed; or (3) the amount billed to or received from, in part or in whole, the health care benefit program from the individuals referred to a particular recovery home, clinical treatment facility, or laboratory.

As a result, the RKP creates a much stricter environment for how even *bona fide* employees can be paid—perhaps eliminating the option to pay commission-based compensation for businesses subject to the RKP for both employees and contractors. However, it remains unknown how the relevant federal agencies will interpret and enforce this new law and whether they will rely on existing guidance by the Office of Inspector General under the AKS.

In an effort to continue to monitor payments made by drug and device manufacturers, Section 6111 enhances the Physician Payments Sunshine Act⁶ by expanding the types of professionals for whom a drug and device manufacturer is required to report when the manufacturer provides something of value. Now,

reporting is also required for physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, and certified midwives. As such, physicians and physician organizations will need to expand their tracking of payments beginning in calendar year 2021, as this information must be “submitted on or after January 1, 2022” (thus, likely meaning for the previous year).

Health IT and Telemedicine

Medicare currently provides coverage for telehealth services only in geographic regions that are experiencing provider shortages and requires that beneficiaries receive telehealth services in a designated originating site (physician’s office, hospital, rural health clinic, or critical access hospital). The SUPPORT Act contains multiple provisions that will allow expanded use of telemedicine to address addiction issues and that will seek to eliminate inefficiencies and barriers to the treatment of those suffering from substance abuse. For instance, the SUPPORT Act includes provisions (1) to improve Medicare reimbursement for telehealth programs, (2) to incentivize the adoption of electronic health records, (3) to streamline prior authorization of claims to improve efficiency, (4) to modernize prescribing practices (specifically, by discouraging physicians from prescribing opioids for long term use), and (5) to allow for the use of connected care platforms to expand addiction-based treatment to underserved populations.

Section 2001⁷ expands the use of telehealth services for treatment of a “substance use disorder diagnosis... [to treat] such disorder or co-occurring mental health disorder” by eliminating certain statutory originating site requirements furnished to Medicare beneficiaries beginning July 1, 2019. The new legislation will allow payment for those 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.

The SUPPORT Act also expands Medicaid coverage to enhance substance abuse treatment via telehealth services. The Centers for Medicare & Medicaid Services must develop guidance by October 2019 on reimbursement for services provided by telehealth. It also targets mothers and children and foster children who deal with opioid-addiction issues, potentially increasing Medicaid spending for those populations.⁸

Section 2003⁹ requires e-prescribing for opioids such that all prescriptions for opioids will be transmitted in accordance with an electronic prescription drug program starting in January 1, 2021. However, the Department of Health and Human Services Secretary may waive this requirement in certain defined cases, such as reasonable technological limitations. Many in the health care industry applaud this particular provision because electronic prescribing can enhance patient data to better track patients attempting to abuse the system and “doctor shop” as well reduce the risk of paper prescriptions being stolen or forged.¹⁰ Section 6001 promotes the testing of incentive payments for behavioral health providers for adoption and use of certified electronic health record technology through the Center for Medicare and Medicaid

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Innovation.¹¹ Section 6063 requires the Secretary, no later than January 1, 2021, to establish a standard, secure electronic portal to allow for “communication between the [HHS] Secretary,” insurance plans, Part D prescription drug plans, and a Medicare drug integrity contractor” to assess and catch “substantiated or suspicious” activities of a provider related to “fraud, waste, and abuse.”¹² The SUPPORT Act also requires the Attorney General to promulgate, prior to October 2019, final regulations under the Controlled Substances Act specifying the limited circumstances in which a registration may be issued to physicians, nurse practitioners, and other providers to prescribe controlled substances via telemedicine.¹³

Expanded Access and Changes to Treatment Regimens, Rules, and Reimbursement

The SUPPORT Act also makes changes to treatment of Medicare beneficiaries. For instance, Section 2002 increases screening for opioid use disorders and other substance use disorders among Medicare beneficiaries during Medicare wellness and preventative care visits to facilitate early detection and treatment. The Medicare Initial Preventative Physical Examination (Welcome to Medicare visit) and annual wellness visits will now include a review of the beneficiary’s current opioid prescriptions and screening for potential substance use disorders, including a referral for treatment as appropriate. Additionally, Section 3002 requires the FDA to develop evidence-based opioid analgesic prescribing guidelines for the indication-specific treatment of acute pain where such guidelines do not exist. The FDA Commissioner is required to publish a clear statement of intent to accompany the guidelines stating that such guidelines are intended to inform clinical decisions by prescribers and patients and are not intended to restrict, limit, delay, or deny coverage or access to a prescription issued by individual health care professionals for a legitimate purpose.

Additionally, Section 3201¹⁴ will increase the number of waived 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. In order to prescribe or dispense certain drugs typically used to combat opioid addictions, physicians had to qualify for a waiver, including completing eight hours of training.¹⁵ Upon completion of the required training, the application is submitted to the U.S. Drug Enforcement Agency which issues each physician a special identification number. Section 3201 of the SUPPORT Act loosens the waiver requirements for physicians but also makes permanent the prescribing authority for physician assistants and nurse practitioners. It also allows waived 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. Qualified physicians are also allowed to prescribe MAT for up to 275 patients. Section 3202 ensures that physicians who have recently graduated in good standing from an accredited school of allopathic or osteopathic medicine, and who meet other training requirements to prescribe MAT, to obtain a waiver to prescribe

MAT. And Section 3203 authorizes a grant to support the development of a curriculum that will help health care practitioners obtain a waiver to prescribe MAT.

Section 6042 creates a demonstration project to increase access to comprehensive, evidence-based outpatient treatment for Medicare beneficiaries with opioid use disorders, which rewards participants for performance on various quality measures.¹⁶ Additionally, Section 6065 requires the Secretary, no later than two years after the enactment of the SUPPORT Act, to annually notify prescribers that they have been identified as an outlier prescriber of opioids compared to other prescribers in their geographic area.

The SUPPORT Act acknowledges that providers need more educational resources to raise awareness regarding proper pain treatment. Sections 6021 and 6051 include such provisions, which also include an opportunity for grants and cooperative agreements to increase education and outreach to providers.

Overall, the exact impact of the SUPPORT Act, particularly as it relates to physicians, is hard to predict and assess at this point, as each agency must first publish its guidance and initial rulemaking. Regardless, the SUPPORT Act is likely to both enhance a practitioner’s tools to prevent and fight opioid addiction, but also add regulatory layers that may affect the way a physician practices and runs their business.

- 1 U.S. Senate Comm. on Health, Educ., Labor & Pensions, *Alexander: Senate Agrees to Vote Next Week on “The Opioid Crisis Response Act of 2018,”* Sept. 7, 2018, last accessed Nov. 6, 2018, <https://www.help.senate.gov/chair/newsroom/press/alexander-senate-agrees-to-vote-next-week-on-the-opioid-crisis-response-act-of-2018>.
- 2 SUPPORT Act § 8122 to be codified at 18 U.S.C. § 220(b).
- 3 The SUPPORT Act cites to the “laboratory” definition under 42 U.S.C. 263a, the Public Health Service Act, as stated here.
- 4 42 U.S.C. § 1320a-7b(b)(3)(B).
- 5 SUPPORT Act § 8122, to be codified at 18 U.S.C. § 220(b).
- 6 See, generally, “The Physician Payments Sunshine Act”, 42 U.S.C. 1320a-7h(e) (6), where this Section 6111 will be codified.
- 7 To be codified at amended 42 U.S.C. 1395m(m) Social Security Act.
- 8 SUPPORT Act § 1944(f).
- 9 To be codified and added at 42 U.S.C. § 1395w-104(e), Social Security Act.
- 10 See, for example, *Surescripts Applauds New Law to Drive Adoption of Technology to Combat the Opioid Epidemic*, Tom Skelton, Surescripts, Oct. 24, 2018; available at <https://surescripts.com/news-center/intelligence-in-action/opioids/surescripts-applauds-new-law-to-drive-adoption-of-technology-to-combat-the-opioid-epidemic/>.
- 11 To be codified and added at 42 U.S.C. 1315a(b)(2)(B), Social Security Act.
- 12 To be codified at 42 U.S.C. § 1395w-28, Social Security Act.
- 13 See SUPPORT Act § 3201, to be codified at 21 U.S.C. 823(g)(2)(G), the Controlled Substances Act.
- 14 *Id.*
- 15 Substance Abuse & Mental Health Services Admin., *Buprenorphine Waiver Management*, <https://www.samhsa.gov/programs-campaigns/medication-assisted-treatment/training-materials-resources/buprenorphine-waiver>, last accessed on Nov. 5, 2018.
- 16 To be codified at amended 42 U.S.C. § 1395cc-5, Social Security Act.