Federal Opioid Legislation to Address Addiction

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Amidst the current partisan gridlock and political infighting in Washington, lawmakers of all stripes have nevertheless joined together in an overwhelmingly bipartisan effort to address the issue of opioid addiction. The Support for Patients and Communities Act, signed into law on Oct. 24, 2018, provides the first comprehensive, nation-wide approach for dealing with the issue.

The new law tackles abuse and addiction from a public health and safety angle, focusing on expanding addiction prevention and treatment programs, strengthening labeling and screening requirements to deter counterfeit and illegal importation of opioids, and providing grants and other incentives to improve provider and patient education. Doctors will undoubtedly feel the effects of this legislation, and among the law's 250 pages, the following components stand to have the greatest impact on physician practices.

Perhaps foremost among the changes affecting doctors is a push to improve prescribing and treatment practices. Congress has ordered the FDA to issue evidence-based opioid analgesic prescribing guidelines by this time next year. Between now and then, the FDA is instructed to seek robust input from the public, specifically including medical professional societies, medical boards, pharmacists, academics, and researchers, as well as patient groups. Additional changes are coming with respect to Medicare beneficiaries: beginning January 1, 2020, new entrants to Medicare must receive a screening for substance abuse disorders at their first-time wellness visits, and going forward, providers must also perform an annual assessment for use disorders on Medicare patients who are receiving prescriptions for opioid medications.

Technology will play a prominent role in the years to come. By January 1, 2021, all prescriptions written for Schedule II, III, IV, and V drugs covered under either Medicare Part D or Medicare Advantage must be transmitted electronically. This mandate is expected not only to act as a deterrent to diversion and fraud, but also to provide the government

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with ample data with which to assess prescribing patterns. Also beginning in 2021, the U.S. Department of Health and Human Services will start tracking prescriber data gleaned from the aforementioned e-prescribing to determine which prescribers are statistical outliers, based on their specialty and geographic location. These outliers will then be notified of their status as such, and "persistent outliers" will be required to enroll in remedial training. Finally, the legislation requires the federal Drug Enforcement Administration, by October 2019, to issue regulations allowing prescribers to obtain a special registration to prescribe controlled substances via telemedicine, and to set forth procedures and prerequisites on how prescribers can qualify.

Expanding the availability of substance abuse treatment is another priority, particularly for vulnerable populations. The Support Act includes a significant expansion of coverage of addiction treatment under Medicaid for mothers and infants, for at-risk youth, and for inpatient treatment generally. The Act further broadens treatment options by allowing a wider scope of medical professionals to prescribe medication-assisted treatment (MAT), *i.e.* methadone, buprenorphine, and naltrexone. Presently, physicians must either hold one of several board certifications or undergo certain special training to be MAT providers, and are typically limited to treating no more than 30 MAT patients at one time, with a maximum of 100 at a time in certain instances. The new law expands this limit to 275 patients, and also extends MAT prescribing capabilities to recent medical school graduates; this means that residents who undergo the requisite training will now be permitted to prescribe MAT as well. The law also broadens the ability of nurse practitioners and physician assistants to prescribe MAT, and extends this option to clinical nurse specialists, certified registered nurse anesthetists, and certified nurse midwives (provided that state medical and nursing boards permit it, which is generally the case in Ohio for buprenorphine and naltrexone). Finally, as an incentive to clinicians, the Act offers student loan forgiveness of up to $250,000 for providers working full time in the field of substance use disorder treatment either in rural areas or in counties where the mean drug overdose death rate is higher than the national average.

A last-minute addition to the bill involves new anti-kickback rules. Section 8122 of the Act prohibits any payment or remuneration (including kickbacks, bribes, or rebates) to or from any individual to incentivize referrals to or usage of "recovery homes, clinical treatment facilities, and laboratories." Although this language generally mirrors that of the existing Anti-Kickback Statute, and carries with it similar exceptions, these new prohibitions are not limited to services paid for by Medicare or Medicaid. Rather, the Act amends the federal bribery statute, and these new restrictions apply to any services provided by recovery homes, treatment facilities, and labs, regardless of who is paying for the bill. Physicians who practice in this area should carefully review any existing referral relationships they have to ensure compliance with the new statute.

Although the law was passed by overwhelming margins in both chambers of Congress (393-8 in the House and 98-1 in the Senate), the debate was not completely devoid of controversy. One criticism has been that the funding level for an issue of this magnitude ($8 billion over five years) is insufficient. A second relates to patient privacy, namely the "Part 2" restrictions that require treatment records for drug and alcohol addiction to be kept separate from the rest of a patient's chart. A proposal discussed during the House-Senate conference would have removed this requirement, and instead required that addiction treatment charts be maintained in accordance with HIPAA along with a patient's other medical records. Proponents of the change, including the American Hospital Association, argued that practitioners needed to know if their patients had a history of addiction in order to take appropriate precautions when prescribing pain killers and other medications. However, opponents of the amendment, including the American Medical Association, warned that including patients' addiction treatment history in their standard medical charts would likely deter many from seeking the help they need for their addiction. Ultimately the amendment was not adopted, meaning the status quo will continue as to addiction treatment confidentiality, although it is likely the debate on this point will continue.

While the ink is still fresh on the Support Act, its full impact will continue to evolve over the next several years, as the effects of the law take hold and new regulations are rolled out. While not a silver bullet, the Support Act figures to play a prominent role in addressing issues surrounding opioid abuse and addiction in the years to come. ■

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