GT GreenbergTraurig

Behavioral Health Law Ledger | October 2023

Welcome to the Ledger

The October 2023 issue of Greenberg Traurig's quarterly Behavioral Health Law Ledger discusses the new federal fraud and abuse allowances for physician mental health and wellness programs (Stark Law and Anti-Kickback Statute exceptions) and a further extension of COVID-19 telehealth flexibilities around prescribing controlled substances.

New Fraud and Abuse Allowances for Physician Mental Health and Wellness Programs

The Consolidated Appropriations Act of 2023 (CAA) adds a new Stark (Physician Self-Referral) Law exception and federal Anti-Kickback Statute (AKS) safe harbor designed to permit certain health care facilities to offer physicians uncapped wellness programs and benefits aimed at improving or supporting their mental health.

These new provisions align with the Lorna Breen Health Care Provider Protection Act, enacted in 2022, which authorized the U.S. Department of Health and Human Services (HHS) to provide grant funding to health care facilities for evidence-based programs to improve mental health and resiliency for health care providers and professionals. This statute was named after Dr. Lorna Breen, an emergency room physician in New York City who committed suicide in April 2020 during the COVID-19 pandemic. Dr. Breen had no known mental health conditions.

Although the Stark Law and AKS already contain certain regulatory exceptions for medical staff's incidental benefits and nonmonetary compensation, those provisions have remunerative caps. These new physician wellness program exceptions have no remunerative ceiling, enabling facilities to provide a greater value benefit to its providers so long as the wellness programs meet the CAA's statutory requirements. Notably, these physician wellness program exceptions are self-effectuating via the CAA,

meaning HHS is not obligated to draft new regulatory exceptions/safe harbors to the fraud and abuse laws in order for eligible health care entities to avail themselves of this new exception/safe harbor.

Under Section 4126 of the CAA, only certain health care entities with formal medical staffs may utilize these new physician wellness exception and safe harbor provisions. This includes hospitals, ambulatory surgery centers, community health centers, rural emergency hospitals, rural health clinics, and skilled nursing facilities. The wellness programs must have a primary purpose of preventing suicide, improving mental health and resiliency, or providing training in appropriate strategies to promote mental health and resiliency, and meet other requirements for the health care entities to avail themselves of this new exception or safe harbor, including but not limited to:

- Consisting of counseling, mental health services, suicide prevention program, or substance use disorder prevention and treatment programs;
- Be set out in detail via a written policy and approved in advance of the program's operation by the entity's governing body;
- Be offered to all physicians on the same terms and conditions (and without regard to referral practices) who practice in the geographic area served by the entity offering the wellness program, including physicians who hold clinical privileges at such entity; and
- Be evidence-based and conducted by qualified health professionals.

There is industry chatter that HHS, through future agency rulemaking and comment processes, may seek to expand these provisions to enable additional provider entities (referred to in the CAA as "similar entities" as determined by the Secretary) to use these exceptions even if they lack a formal medical staff. These new physician wellness program allowances will potentially enable health care entities to provide support to physicians in a new and perhaps more robust way, as the industry is faced with provider shortages due to burnout and other factors that these programs seek to address.

UPDATE: DEA and SAMHSA Further Extend COVID-19 Telehealth Flexibilities Around Controlled Substance Prescribing

On Oct. 10, 2023, the Drug Enforcement Administration (DEA) and the Substance Abuse and Mental Health Services Administration (SAMHSA) published the "Second Temporary Extension of COVID-19 Telemedicine Flexibilities for Prescription of Controlled Medications," which extends for a second time the telehealth flexibilities originally adopted during the COVID-19 Public Health Emergency (PHE), which ended May 11, 2023 (the Second Temporary Rule). The Second Temporary Rule takes effect Nov. 11, 2023, and extends all telehealth flexibilities adopted during the PHE through Dec. 31, 2024, and enables DEA-registered providers to prescribe certain controlled medications to patients without first having an in-person evaluation as required under the Ryan Haight Online Pharmacy Consumer Protection Act of 2008 (known as the Ryan Haight Act).

For context, as reported in the June 2023 Behavioral Health Law Ledger, DEA, in concert with the U.S. Department of Health and Human Services (HHS), issued notices of proposed rulemakings (NPRMs) on March 1, 2023, to allow certain controlled medications to be prescribed via telehealth without the requisite in-person medical evaluation imposed by the Ryan Haight Act under circumstances consistent with public health, safety, and effective controls against drug diversion. Under the NPRMs, telehealth providers would no longer be able to prescribe Schedule II controlled substances such as Adderall, oxycodone, Ritalin, or Vicodin, or Schedule III-V narcotics, with the exception of buprenorphine, without first conducting an in-

person medical evaluation. Telehealth providers would be able to prescribe a 30-day supply through telemedicine without the initial in-person visit for buprenorphine and nonnarcotic Schedule III-V drugs like Ambien, Valium, Xanax, or ketamine. An in-person visit would be required for a patient to get refills beyond the initial 30-day supply.

On May 10, 2023, DEA and SAMHSA then published the "Temporary Extension of COVID-19 Telemedicine Flexibilities for Prescription of Controlled Medications," which extended the telehealth flexibilities established during the PHE and enabled enables DEA-registered providers to prescribe certain controlled medications to patients without first having an in-person evaluation (the First Temporary Rule). The First Temporary Rule also provided a one-year grace period, through Nov. 11, 2024, that extended the telehealth flexibilities to any practitioner-patient telehealth relationships formed on or before Nov. 11, 2023.

This Second Temporary Rule authorizes all DEA-registered practitioners to prescribe schedule II–V controlled medications via telemedicine through Dec. 31, 2024, regardless of when the practitioner-patient telehealth relationship was formed. In effect, the Second Temporary Rule has subsumed the grace period under the First Temporary Rule to better avoid lapses of care for patients and to ensure compliance with providers.

Many behavioral health treatment plans involve the prescription of controlled substances, and the Second Temporary Rule extends the access to tele-psychiatric services for patients who need controlled medications to address their depression, anxiety, substance-use disorders, or other psychological health conditions. Given the increasing reliance on telehealth and tele-psychiatric care across the United States, and especially in rural and tribal communities, DEA and SAMHSA are working to promulgate new standards and safeguards for telehealth by fall of 2024 and have indicated there may be another written comment period this fall.

Those needing assistance with submitting comments or otherwise maintaining compliance with the Temporary Rules should consult with experienced health-care regulatory counsel.

Let's Stay in Touch

GT's Behavioral Health Law Ledger keeps behavioral health and integrated health providers current on behavioral health legal and regulatory developments. Each quarter we highlight recent legal developments, including but not limited to audit risks, significant litigation, enforcement actions, and changes to behavioral-health-related laws or regulations such as health privacy, confidentiality, and/or security issues, consent issues, data-sharing allowances, and other cutting-edge arrangements and issues facing behavioral and integrated health care providers.

If you know someone who would appreciate receiving GT's Behavioral Health Law Ledger, please forward this newsletter to them, or they can subscribe here.

Authors

Julie A. Sullivan
Shareholder
+1 303.685.7412
Julie.Sullivan@gtlaw.com

Tyler Strobel ˇ
Law Clerk/JD
Denver
ˇ *Not admitted to the practice of law.*