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Welcome to the Ledger

The June 2023 issue of Greenberg Traurig's quarterly Behavioral Health Law Ledger discusses state certificate of need laws, the challenges behavioral health facilities and providers face in securing them, and how some states are addressing those challenges; as well as the expansion of COVID-19 telehealth flexibilities around controlled substance prescribing and implications for behavioral health providers who depend on remote prescribing for patients.

Certificate of Need Laws Impede Sufficient Behavioral Health Access for Patients; States Respond

In the face of America's behavioral health crisis, state certificate of need (CON) laws continue to present obstacles to behavioral health companies' expansion efforts.

CON laws are state regulatory mechanisms for approving major health care expenses. They were created to help communities and government agencies plan for more intensive health care services that are partially funded by taxpayer dollars. The laws intended to control health care costs by preventing an over-saturation of services and ensuring new health care projects meet community needs.

Patient access to, and network adequacy of, behavioral health providers has been a concern since before the COVID-19 pandemic, and some believe it has continued to worsen due in part to restrictive state CON laws. CON laws in part generally require health care organizations to seek and obtain permission from state regulatory bodies to build or expand certain health care facilities. Generally, CON applications must assert and prove a need for that service in the community and demonstrate how the proposed project or facility aligns with the state's health care development plans or interests. CON applications can be burdensome, and they also can be hotly contested by competitors rendering the same or similar services in the same or nearby communities. Where CON processes involve public comment periods, competitors may

engage in mudslinging, discouraging some organizations from opening a new behavioral health facility in certain jurisdictions due to aversion to controversy, limitation of resources, and unwillingness or inability to withstand legal challenges.

However, some states are responding to these challenges by creating exemptions from state CON laws for certain behavioral health facilities or providers. For example, North Carolina passed a law in March 2023 that not only expanded Medicaid under the Affordable Care Act but also removed the requirement for psychiatric hospitals and chemical dependency treatment facilities to obtain a CON from the North Carolina Department of Health and Human Services, noting the need for better patient access to such services and reducing the burdens imposed by CON requirements and procedures. Session Law 2023-7, House Bill 76.

Other states have also made changes to their CON laws in recent years. For instance, Montana's CON requirements now only apply to long-term care facilities; psychiatric facilities in Washington are exempt from CON laws; and Georgia has assembled a formal working group to focus on CON reform. The National Academy for State Health Policy (NASHP), which tracks state legislative efforts around CON laws, recently reported the introduction of 60 bills related to CON across 19 states. While several of the bills have died in committee, been withdrawn, or have otherwise stalled, this number indicates states' interest in improving patient access and removing certain political and legal barriers to sufficient behavioral health resources.

DEA and SAMSHA Extend COVID-19 Telehealth Flexibilities Around Controlled Substance Prescribing

On May 3, 2023, eight days before the May 11 expiration of the COVID-19 Public Health Emergency (PHE), the Drug Enforcement Administration (DEA) and the Substance Abuse and Mental Health Services Administration (SAMHSA) released the "Temporary Extension of COVID-19 Telemedicine Flexibilities for Prescription of Controlled Medications," which extends telehealth flexibilities adopted during the PHE. This temporary rule takes effect May 11 and extends all telehealth flexibilities adopted during the PHE through Nov. 11, 2023, 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, 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.

The DEA's NPRM relating to prescribing controlled substances via telehealth was criticized for omitting a telehealth-specific DEA registration classification that would have permitted such DEA registrants to continue telehealth prescribing without in-person evaluations, as had been discussed between DEA and stakeholders. As a result, DEA received more than 38,000 public comments on the NPRMs. DEA and SAMHSA will review these comments before developing a final rule.

Many behavioral health treatment plans involve the prescription of controlled substances, and the NPRMs as drafted would limit 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 public reaction to the NPRMs, DEA and HHS may revisit the telehealth DEA registration guidelines to facilitate the continued remote prescribing abilities with safeguards and controls in place to address public health and safety, as well as drug diversion concerns.

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.

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