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There is Hope

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Potential Pitfalls of Telehealth Prescribing

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While Congress has acted to extend certain COVID-era telehealth flexibilities (mostly related to Medicare coverage) beyond the Public Health Emergency (PHE), the future of prescribing controlled substances via telehealth is uncertain. Although the American Telemedicine Association and other industry groups continue to advocate for changes to allow telehealth providers to prescribe controlled substances in certain circumstances, without further action by Congress or the Drug Enforcement Administration (DEA), telehealth providers who prescribe controlled substances will need to conduct an in-person examination of the patient once the PHE ends.

Despite recent investigations into certain telehealth prescribing practices involving controlled substances, signs point to the DEA eventually making permanent changes to allow some controlled substances to be prescribed via telehealth. For example, in 2018, Congress directed the DEA to create a telemedicine special registration program as part of the SUPPORT for Patients and Communities Act, and in recent months, several states have loosened their requirements for telehealth prescribing. However, the PHE flexibility and anticipated changes do not fully address the risks involved for telehealth prescribers, which should be mitigated given the heightened scrutiny around prescribing controlled substances. Below are two key areas that telehealth prescribers should evaluate and address by implementing appropriate safeguards as necessary.

State Requirements for Prescribing and Standard of Care

As any multi-state provider knows, getting a handle on different states' regulatory requirements is a constant challenge. The federal Controlled Substances Act and DEA regulations set the requirement of an in-person examination prior to issuing a prescription except in limited situations (including the current PHE) as a baseline for prescribing controlled substances via telehealth. However, several states have more stringent requirements. For example, several states require in-person ex-

aminations prior to prescribing a controlled substance without any exceptions or with exceptions that are narrower than the DEA's exceptions. State laws around renewing and reissuing prescriptions also vary, and telehealth providers need to navigate how often an in-person or audio-visual visit needs to occur in order to renew a prescription.

Telehealth providers operating in multiple states should carefully consider all relevant state laws when developing protocols around prescribing controlled substances. Providers can either adopt specific protocols for each individual state or, alternatively, adopt protocols that comply with the most stringent state requirements. Regardless of the approach, protocols should allow individual clinicians to exercise their professional judgment while complying with all relevant state law.

In addition, telehealth providers should, to the best of their ability, monitor changes in law and regulation and update relevant protocols as necessary.

In California, an appropriate prior examination and a medical indication is required for all prescription drugs, but the examination may be performed using telehealth provided it meets the standard of care and the prescriber obtains and documents the patient's consent (may be verbal or written) to the use of telehealth.¹ As of October 1, 2021, California providers are required to obtain consent to telehealth (the COVID-19 waiver is no longer in effect).

Telehealth providers must also use their clinical judgment to ensure that the telehealth encounter is adequate to meet the standard of care for prescribing the controlled substance indicated. In many circumstances, an audio-visual visit will enable the provider to gather adequate information to make a diagnosis and determine that a controlled substance is the appropriate treatment, but this may not always be the case. Once a controlled substance is prescribed, the prescriber should also ensure that mechanisms for clinically appropriate follow-up are also in place.

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For telehealth providers focused on only one aspect of the patient's care, it can be difficult to obtain a full picture of the patient's health. Telehealth providers and their pharmacy partners should adopt systems to ensure that systems are in place to combat over-prescribing and screen for medications that could have adverse effects when taken together. Providers should also implement policies and procedures to ensure that clinicians can verify telehealth patients' identities and confirm that patients have the capacity to consent to treatment.

Demonstrating Compliance

For individual providers who are licensed and providing telehealth services to patients in multiple states with different regulatory schemes, it is very challenging to stay on top of the various requirements. Strong, clinically supported policies, procedures and protocols are key, but they should not be so prescriptive as to interfere with the providers' individual clinical judgment. Telehealth providers should adopt strong compliance programs to support clinical best practices, and any marketing materials should be developed by, or in close collaboration with, the clinical teams.

As mentioned above, in California, telehealth may only be used by prescribers of controlled substances if medically indicated and the standard of care can be met. The same standard of care applies to in-person and telehealth examinations, and the Medical Board of California (MBC) has made it clear in guidance that in-person examinations enhance the opportunity to confirm if a patient needs the identified medication or to rule out other medical conditions.² For safety reasons an in-person examination will likely be preferred by the MBC for controlled substances, and as a result evidence-based written treatment protocols developed by clinicians designed to confirm the need for medication and rule out other medical conditions should be followed. Further, a detailed medical record documenting all steps of the patient encounter including the details of the patient examination should be maintained supporting a health care provider's decision to prescribe a controlled substance. Additionally, health care practitioners must consult the California Controlled Substance Utilization Review and Evaluation System (CURES) before prescribing a schedule II, III, or IV controlled substance for the first time and at least once every 4 months thereafter if the patient is still using the substance (unless an exemption applies)³ and thus maintaining documentation in the medical record that this step has been taken (or which exemption applies) is recommended. Providers should also be aware that a report to CURES is required when controlled substances are dispensed, and that various agencies including the California Department of Justice and provider licensing boards use CURES data as an investigation tool and have the capability to identify and investigate providers who prescribe controlled substances in a manner that is concerning to the agencies.⁵



In California, it is a provider's responsibility to review and approve all telehealth marketing materials to ensure compliance with advertising requirements for professional medical services. Among other things, such advertising may not create false or unjustified expectations of favorable results and price advertising must be exact.⁶ Furthermore, if providers utilize a management services organization or other unlicensed service provider for marketing services, physicians must remain in control of advertising and marketing activities to avoid potential corporate practice of medicine issues.⁷ In these situations, physician review and approval should be documented.

While the use of telehealth has become more widely accepted in the wake of the COVID-19 pandemic and continues to play a huge role in increasing access to care, prescribing of controlled substances using telehealth is heavily regulated and will continue to be scrutinized by state and federal agencies. As telehealth's prevalence has increased, so too will enforcement efforts targeting telehealth providers, especially when controlled substances are involved. Providers should stay up to date on the status of the PHE, telehealth waivers on the state and federal levels, and enforcement activities focusing on telehealth providers.

¹Cal. Bus & Prof Code 2242; 2290.5; 4022

²Medical Board of California, "Internet Prescribing - Information for Physicians" available at <https://www.mbc.ca.gov/Resources/Medical-Resources/Internet-Prescribing.aspx#>

³Cal. Health & Safety Code 11165.4

⁴Medical Board of California, "Controlled Substance Utilization Review and Evaluation System (CURES) Mandatory Consultation - Frequently Asked Questions" available at <https://www.mbc.ca.gov/Download/Documents/CURES-FAQ.pdf>

⁵Cal. Health & Safety Code 11165

⁶Cal. Bus. & Prof Code 651

⁷Cal. Bus. & Prof Code 2052