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Informational Bulletin from OMH Chief Medical Officer

Prescription of Controlled Substances after the Federal Public Health Emergency for COVID-19

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The Ryan Haight Act¹ requires at least one in-person medical evaluation prior to issuing a prescription for controlled substances via telehealth. During the COVID-19 public health emergency (PHE), the U.S. Department of Health and Human Services has allowed audio-visual telemedicine to be used in place of the in-person evaluation for the prescription of schedule II-V controlled substances.

In March 2023, the Drug Enforcement Administration (DEA) proposed regulatory changes to continue to allow for prescribing of scheduled medications using telemedicine and without an in-person evaluation for current patients or patients beginning treatment within 6 months after the rule was to be finalized.² However the DEA has indicated those changes will not be implemented before the end of the PHE. Instead, the DEA has enacted a temporary rule to extend the flexibilities allowed during the PHE through November 11, 2023, while it further considers permanent rules.³ Under the temporary rule, if a patient and a practitioner established a telemedicine relationship on or before November 11, 2023, the same telemedicine flexibilities that have governed the relationship to that point are permitted to be used until November 11, 2024.

According to the DEA, as of March 16, 2020, and continuing through November 11, 2024 (for patients in treatment on or before November 11, 2023), DEA-registered practitioners in all areas of the United States may issue prescriptions for all schedule II-V controlled substances to patients for whom they have not conducted an in-person medical evaluation, provided all of the following conditions are met:

- The prescription is issued for a legitimate medical purpose by a practitioner acting in the usual course of his/her professional practice;
- The telemedicine communication is conducted using an audio-visual, real-time, two-way interactive communication system; and
- The practitioner is acting in accordance with applicable Federal and State laws.

The DEA provided further flexibility during the PHE to allow authorized practitioners to prescribe buprenorphine to new and existing patients with Opioid Use Disorder by audio-only telephone communication, without requiring such practitioners to first conduct an examination of the patient in person or via telemedicine.⁴ The New York State Department of Health recently clarified that New York State laws and regulations are aligned with the DEA policy.⁵ This means that practitioners who prescribed controlled substances using telehealth under the federal flexibility issued during the PHE

¹ Ryan Haight Online Pharmacy Consumer Protection Act of 2008, 21 U.S.C. §§ 802, 829

² <https://www.federalregister.gov/documents/2023/03/01/2023-04248/telemedicine-prescribing-of-controlled-substances-when-the-practitioner-and-the-patient-have-not-had>

³ <https://www.federalregister.gov/documents/2023/05/10/2023-09936/temporary-extension-of-covid-19-telemedicine-flexibilities-for-prescription-of-controlled>

⁴ [https://www.deadiversion.usdoj.gov/GDP/\(DEA-DC-022\)\(DEA068\)%20DEA%20SAMHSA%20buprenorphine%20telemedicine%20%20\(Final\)%20+Esign.pdf](https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-022)(DEA068)%20DEA%20SAMHSA%20buprenorphine%20telemedicine%20%20(Final)%20+Esign.pdf)

⁵ See “Prescribing Controlled Substances Using Telemedicine Upon Expiration of the Federal COVID-19 Public Health Emergency Updated May 2023,” available at <https://www.health.ny.gov/professionals/narcotic/> (accessed May 17, 2023); See also https://health.ny.gov/professionals/narcotic/docs/2023-01-31_telemedicine_initial_exam.pdf

and extended through November 11, 2023 must use an audio-visual, real-time, two-way interactive communication system to conduct the evaluation. Audio-only may not be relied upon to prescribe controlled substances, except buprenorphine.

Generally, controlled substances prescribed in ambulatory mental health programs include benzodiazepines, stimulants, and buprenorphine. Under the Ryan Haight Act, in order for a prescription for controlled substances to be valid it must be issued by either a practitioner who has conducted at least one in-person medical evaluation of the patient or a covering practitioner.

For purposes of the Ryan Haight Act, a covering practitioner is a practitioner who conducts a medical evaluation (other than an in-person medical evaluation) at the request of a practitioner who is temporarily unavailable to conduct the evaluation and who has conducted at least one in-person medical evaluation of the patient or an evaluation of the patient through the practice of telemedicine within the previous 24 months.⁶

However, in certain situations,⁷ the in-person medical evaluation requirement can be waived.⁸ This includes situations where a practitioner has acquired a special registration⁹ for the practice of telemedicine¹⁰ from the U.S. Attorney General. The DEA has not issued further guidance on this process.

For practitioner-patient telemedicine relationships that have been or will be established by November 11, 2023, programs must ensure the following:

- If the practitioner has seen the patient in person prior to November 11, 2023, the practitioner may continue to prescribe the controlled medication using telehealth.
- If the practitioner has never seen the patient in person, the practitioner may continue to prescribe the controlled substance using telehealth until November 11, 2024. However, in order to renew or provide a new prescription for a controlled medication after November 11, 2024, the practitioner must see the patient at least once in person prior to November 11, 2024. **Programs are strongly encouraged to begin scheduling in-person appointments before November 11, 2024, to manage practitioner workload and mitigate risk to patients.**
- After November 11, 2024, for patients who were seen in person, but now have their medications prescribed by a covering practitioner, they must be seen in person by the prescribing practitioner within two years of the last in-person visit.

For new patients beginning treatment after November 11, 2023, new rules will likely be effective which enable practitioners to prescribe only limited quantities or types of controlled substances without an in-person evaluation, subject to possible exceptions and standards. OMH will update this guidance to reflect further changes in federal policy in this area as they are announced.

Additional information regarding compliance with the Ryan Haight Act can be found at:

- https://www.deadiversion.usdoj.gov/mtgs/pract_awareness/conf_2019/dec_2019/ikner.pdf#search=telemedicine
- https://www.deadiversion.usdoj.gov/fed_regs/rules/2020/fr0930_2.htm

Lastly, Section 1262 of the 2023 Consolidated Appropriations Act removed the federal requirement for practitioners to submit a Notice of Intent (apply for an X-waiver) to prescribe buprenorphine for the treatment of Opioid Use Disorder. All practitioners who have a current DEA registration that includes Schedule III authority, may now prescribe buprenorphine for Opioid Use Disorder in their practice. More information on the elimination of X-waiver can be found at:

- <https://www.samhsa.gov/medication-assisted-treatment/removal-data-waiver-requirement>

⁶ 21 U.S.C. § 829(e)(2)(C).

⁷ Explained in 21 C.F.R. § 1300.04(i) (<https://www.ecfr.gov/current/title-21/chapter-II/part-1300/section-1300.04>).

⁸ 21 U.S.C. § 802(54)

⁹ 21 U.S.C. § 831(h)

¹⁰ 21 C.F.R. § 1300.04(i)(5)

- https://www.health.ny.gov/professionals/narcotic/docs/2023-01-20_mat_act_commissioner_letter.pdf
- https://oasas.ny.gov/system/files/documents/2023/01/elimination_x_waiver.pdf