DEA TEMPORARILY EXTENDS COVID-19 FLEXIBILITIES FOR CONTROLLED SUBSTANCE PRESCRIPTIONS VIA TELEMEDICINE WHILE EVALUATING PERMANENT RULE CHANGES

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US Health Care and FDA Alert

By: Sarah Staples-Carlton

EXECUTIVE SUMMARY

- The Drug Enforcement Administration (DEA) issued a temporary rule (Temporary Rule), effective 11 May 2023, extending flexibilities regarding the prescribing of controlled substances via telemedicine that have been in place since the beginning of the COVID-19 public health emergency (PHE). These flexibilities will remain in place through 11 November 2023.
- DEA's Temporary Rule also extends PHE telemedicine flexibilities through 11 November 2024 for any practitioner-patient relationships established via telemedicine on or before 11 November 2023.
- DEA, in collaboration with the Substance Abuse and Mental Health Services Administration (SAMHSA), will continue to review comments submitted in response to DEA's proposed rules from March of 2023, which proposed to address PHE-related telemedicine flexibilities related to prescribing controlled substances via telemedicine, and intends to release final rules prior to 11

ADDITIONAL DETAIL

On 10 May 2023, DEA published its Temporary Rule that will (i) extend the full set of telemedicine flexibilities regarding controlled substance prescriptions that were in effect during the PHE through 11 November 2023 and (ii) extend such flexibilities for an additional year, through 11 November 2024, for any practitioner-patient telemedicine relationship established on or before 11 November 2023.[1] Finding good cause to justify an immediate effective date, DEA made the Temporary Rule effective 11 May 2023, concurrent with the expiration of the PHE. The Temporary Rule will expire 11 November 2024.[2]

DEA released this Temporary Rule, in concert with SAMHSA[3] after receiving over 38,000 comments to DEA's March of 2023 proposed rules (March 2023 Proposed Rules), outlined in further detail below.[4]

Public Health Emergency Telemedicine Waivers

During the PHE, DEA granted several temporary exceptions to the Ryan Haight Online Pharmacy Consumer Protection Act of 2008 (the Ryan Haight Act) and DEA's implementing regulations, which generally require an in-

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person medical evaluation prior to issuing a prescription for controlled substances.[5] The temporary exceptions allowed the prescribing through telemedicine of certain controlled substances and buprenorphine for the treatment of opioid use disorder (OUD), even where the prescribing practitioner had not previously conducted an in-person medical evaluation, provided certain conditions were met. These exceptions were intended to ensure continuity of care during the PHE.[6] In December of 2022, Congress passed a bipartisan appropriations bill that included a two-year extension for Medicare telemedicine flexibilities that had been implemented during the PHE, but that extension did not address DEA's PHE-related exceptions to the Ryan Haight Act.[7]

March 2023 Proposed Rules

With the expiration of the PHE on 11 May 2023, the March 2023 Proposed Rules sought to create permanent regulations for the prescribing of controlled substances via telemedicine, but required a face-to-face examination.[8] DEA indicated that its purpose was to "expand[] patient access to critical therapies" beyond the PHE while implementing "appropriate safeguards."[9]

Under the March 2023 Proposed Rules, telemedicine providers would have been prohibited from prescribing Schedule II and narcotic controlled substances and limited from prescribing Schedules III through V non-narcotic controlled substances and buprenorphine for the treatment of OUD for more than a 30-day period via a telemedicine encounter[10] where there was not an initial in-person evaluation. During that 30-day period, the patient would be required to obtain an in-person medical examination.[11] The 30-day limitation would not apply if the patient was referred from a medical practitioner who conducted a prior in-person medical evaluation. Additionally, telemedicine relationships established prior to the end of the PHE would have a 180-day grace period from the later of the effective date of the rule or the end of the PHE before implementation of the 30-day limitation, subject to additional record-keeping requirements.[12] DEA also sought comment on alternative supply limitations.[13]

DEA's Temporary Rule

Many of the record 38,000 comments received in response to the March 2023 Proposed Rules expressed concern that they created unnecessary barriers to care, which in some cases would put already vulnerable patients at an even greater risk of harm. Others shared concerns that the 30-day window presented an impossible time frame for patients to receive an in-person exam.[14] On 3 May 2023, DEA Administrator Anne Milgram stated that DEA recognizes "the importance of telemedicine in providing Americans with access to needed medications" and has decided to extend current telemedicine flexibilities "while we work to find a way forward to give Americans that access with appropriate safeguards."[15]

The Temporary Rule extends the PHE-related telemedicine flexibilities regarding the prescribing of controlled substances via the practice of telemedicine through 11 November 2023,[16] and further extends such flexibilities through 11 November 2024 for any practitioner-patient relationships established via telemedicine on or before 11 November 2023.[17] "In other words, as long as a practitioner and patient have established a telemedicine relationship on or before November 11, 2023, the pandemic telemedicine flexibilities will be extended through November 11, 2024, as to that established relationship."[18]

The extension of current flexibilities for controlled substances "for a narrow time period" will, according to DEA, facilitate continuity of care, prevent backlogs for in-person medical evaluations in the months shortly before and after the expiration of the PHE, and "address the urgent public health need" for access to buprenorphine to treat

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OUD during an ongoing opioid public health crisis.[19] DEA expresses concern, however, that granting an extension for practitioner-patient relationships that begin later than six months after the end of the PHE may incentivize telemedicine companies that "seek to engage in problematic prescribing practices."[20]

Future DEA Rulemaking

DEA indicates that it, along with SAMHSA, will review and respond to comments it received in response to the March 2023 Proposed Rules, "conduct a thorough evaluation of regulatory alternatives," and issue one or more final rules based on the March 2023 Proposed Rules prior to 11 November 2023. DEA advises that the additional time granted by the Temporary Rule will allow stakeholders sufficient time to prepare for the implementation of future regulations.[21]

We will continue to monitor DEA rulemaking and other health care regulatory matters related to telehealth, PHE flexibilities, and prescribing controlled substances, and are available to answer any questions you might have.

FOOTNOTES

[1] Temporary Extension of COVID-19 Telemedicine Flexibilities for Prescription of Controlled Medications, 88 Fed. Reg. 30037 (May 11, 2023).

[2] Temporary Extension of COVID-19 Telemedicine Flexibilities for Prescription of Controlled Medications, 88 Fed. Reg. at 30041. The Administrative Procedure Act generally requires a 30-day delayed effective date for final rules, which can be waived for good cause. To prevent a lapse in care for patients receiving certain controlled medications, DEA concluded that such good cause exists to justify an immediate effective date for this Temporary Rule. *Id*.

[3] SAMHSA is part of the Department of Health and Human Services (HHS).

[4] *Id*. at 30037; see also Telemedicine Prescribing of Controlled Substances When the Practitioner and the Patient Have Not Had a Prior In-Person Medical Evaluation, 88 Fed. Reg. 12879 (Mar. 1, 2023); Expansion of Induction of Buprenorphine Via Telemedicine Encounter, 88 Fed. Reg. 12890 (Mar. 1, 2023).

[5] Letter from William T. McDermott, Assistant Adm'r, Diversion Control Div., Drug Enf't Admin., to DEA Registrants, (Mar. 25, 2020), https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-018)(DEA067)%20DEA%20state%20reciprocity%20(final)(Signed).pdf; Letter from Thomas W. Prevoznik, Deputy Assistant Adm'r, Diversion Control Div., Drug Enf't Admin., to DEA Qualifying Practitioners, DEA Qualifying Other Practitioners (Mar. 31, 2020), https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-022)(DEA068)%20DEA%20SAMHSA%20buprenorphine%20telemedicine%20%20(Final)%20+Esign.pdf.

[6] *Id*.

[7] Consolidated Appropriations Act, 2023, Public L. No. 117-38.

[8] Telemedicine Prescribing of Controlled Substances When the Practitioner and the Patient Have Not Had a Prior In-Person Medical Evaluation, 88 Fed. Reg. at 12881, 12890.

[9] *DEA Announces Proposed Rules for Permanent Telemedicine Flexibilities*, DEA (Feb. 24, 2023), https://www.dea.gov/press-releases/2023/02/24/dea-announces-proposed-rules-permanent-telemedicine-

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flexibilities.

[10] As proposed, the term "telemedicine encounter" means "a communication between a practitioner and a patient using an interactive telecommunications system referred to in 42 CFR 410.78(a)(3)." Telemedicine Prescribing of Controlled Substances When the Practitioner and the Patient Have Not Had a Prior In-Person Medical Evaluation, 88 Fed. Reg. at 12880.

[11] *Id*. at 12881.

[12] *Id*. at 12888.

[13] *Id*. at 12882.

[14] *See generally Comments Submitted in Response to Docket ID DEA-2023-0029*, RIN 1117-AB40, DEA, https://www.regulations.gov/docket/DEA-2023-0029.

[15] DEA Administrator, *Statement from the DEA Administrator Anne Milgram on COVID-19 Telemedicine Flexibilities for Prescription of Controlled Medications*, DEA (May 3, 2023), https://www.dea.gov/documents/2023/2023-05/2023-05-03/statement-dea-administrator-anne-milgram-covid-19-telemedicine.

[16] Temporary Extension of COVID-19 Telemedicine Flexibilities for Prescription of Controlled Medications, 88 Fed. Reg. at 30039.

[17] *Id*.

[18] *Id*. at 30037.

[19] *Id*. at 30038.

[20] *Id*. at 30040. DEA notes that it is currently investigating "certain telemedicine companies that it believes may have engaged in problematic prescribing practices"; though, it recognizes that many telemedicine companies are engaged in "good faith, patient-centered prescribing practices," and it looks forward to working with those companies to further enhance patient access to needed medications that are issued following bona fide medical evaluations. Id.

[21] *Id*. at 30039.

KEY CONTACTS



SARAH STAPLES-CARLTON
ASSOCIATE

NASHVILLE
+1.615.780.6756
SARAH.STAPLES-CARLTON@KLGATES.COM

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