

**Drug Enforcement Administration
Diversion Control Division
Guidance Document**

Title: COVID-19 Flexibility Updates

Summary: The Drug Enforcement Administration (DEA) granted certain flexibilities during the COVID-19 Public Health Emergency (PHE). DEA has determined that some of those flexibilities should remain in place under the ongoing Opioid PHE, to help respond to the opioid crisis after the COVID-19 PHE expires at the end of the day on May 11, 2023. This document describes which flexibilities will automatically terminate at the end of the day on May 11, 2023, and which flexibilities will remain in effect under the Opioid PHE. DEA also is withdrawing three guidance documents that mention the COVID-19 PHE.

Activity: Continuing Application of Certain COVID-19 PHE Related Flexibilities during the Opioid PHE

To Whom it Applies: DEA Registrants and Others Impacted by PHE Related Flexibilities to DEA Regulations

The Department of Health and Human Services (HHS) has [announced](#) that, based on current COVID-19 trends, the federal [COVID-19 Public Health Emergency \(PHE\)](#), declared under Section 319 of the Public Health Service (PHS) Act on January 31, 2020, will expire at the end of the day on May 11, 2023.

The former Secretary of HHS determined on Oct. 26, 2017, that a separate public health emergency exists nationwide as a result of the consequences of the opioid crisis affecting our nation. This [Opioid PHE](#) was most recently renewed effective April 1, 2023.

During the COVID-19 PHE, the Drug Enforcement Administration (DEA) responded to the needs of registrants for increased flexibilities both by exercising its authority under [21 CFR 1307.03](#) to issue temporary exceptions to DEA regulations and by indicating the circumstances in which DEA will exercise its discretion in enforcing certain statutory requirements. This document summarizes the status of the flexibilities following the expiration of the COVID-19 PHE on May 11, 2023. This document does not describe the status of telemedicine prescribing flexibilities such as the guidance's on state reciprocity ([DEA-DC-018 EO-DEA067](#)) and medications for opioid use disorder prescribed by telephone ([DEA-DC-022 EO-DEA068](#)), which DEA and the Substance Abuse and Mental Health Services Administration addressed in the temporary rule titled "Temporary Extension of COVID-19 Telemedicine Flexibilities for Prescription of Controlled Medications" which publish in the federal register on May 10, 2023, [Temporary Extension](#).

During the COVID-19 Public Health Emergency, DEA extended the following flexibilities under the Administrator's enforcement discretion, authority to interpret DEA's regulations, and authority granted under 21 CFR 1307.03. DEA is further extending these flexibilities to respond to the Opioid Public Health Emergency. They will remain in effect until the expiration of the Opioid PHE unless first modified or withdrawn by DEA.

- Off-Site Delivery Methods for NTPs (methadone). An announcement of DEA’s exercise of authority to allow NTPs to repeatedly deliver take-home doses of methadone to the same off-site location without becoming registered at that location, subject to certain limitations. [DEA-DC-025 EO-DEA078](#)
- NTP Exception for Home Delivery. An exception to 21 CFR 1301.74(h) to allow NTPs to make a “doorstep” delivery of take-home medication to a patient in the event a patient is quarantined due to coronavirus. The guidance allows NTP staff, law enforcement, or National Guard to deliver take-home doses of methadone or buprenorphine to a patient in these circumstances. [DEA-DC-015 EO-DEA064](#)
- Off-Site Delivery Methods for NTPs (buprenorphine). An announcement of DEA’s exercise of authority to permit NTPs to repeatedly deliver take-home doses of buprenorphine to the same off-site location without obtaining a separate registration for that location, subject to certain limitations. [DEA-DC-030 EO-DEA087](#)
- Administering Certain Controlled Substances in the Parking Lot of a Healthcare Provider’s DEA-Registered Location. A clarification that DEA considers it permissible to provide medically supervised treatment using controlled substances in a provider parking lot, so long as the parking lot is located immediately adjacent to the provider’s DEA-registered facility and in compliance with all other applicable federal, state, local and tribal laws and regulations. [DEA-DC-043 EO-DEA213](#)
- DEA Form 222: Scanning and Fax/Email to Supplier. An exception to the requirements set forth under [21 CFR 1305.13](#) to allow DEA registrants who order controlled substances to fax or scan/email a DEA Form 222 instead of submitting the original to the supplier by mail. Upon the expiration of the emergency, purchasers will be required to send suppliers hard copies of the executed DEA Form 222 that were transmitted to the supplier via email or fax during the PHE. [DEA-DC-019 EO-DEA066](#)

The following exceptions will expire on May 11, 2023, at which time they will automatically be rescinded and removed from the DEA and DOJ Guidance Document Portal. If registrants seek the continued flexibility of any of these expiring exceptions, DEA would encourage registrants to apply for an exception under 21 CFR 1307.03 by filing a written request stating the reasons for such exception. Requests may be emailed to odlp@dea.gov or sent by mail to Drug Enforcement Administration, Attn: Policy Section, 8701 Morrisette Dr., Springfield, VA 22152.

- Narcotic Treatment Program (NTP) Exception to Signing Invoices at Delivery. An exception to [21 CFR 1301.74\(h\)](#) that normally requires a licensed practitioner or other authorized individual to sign an invoice at the time of delivery of controlled substances to an NTP. DEA-DC-027, issued April 11, 2020.
- Hospital/Clinic Registration (Campus) Exception. An exception to [21 CFR 1301.12\(a\)](#) to provide DEA-registered hospital/clinics with the flexibility to utilize satellite hospital/clinic locations under their current registrations under certain conditions. In

addition, DEA granted distributors an exception to the requirements of [21 CFR 1305.13\(c\)](#) and [1305.22\(f\)](#) to allow them to ship controlled substances directly to these satellite hospitals/clinics, even though they are non-registered locations. DEA-DC-028, issued April 11, 2020.

- Distributors Questions and Answers. DEA granted an exception to 21 CFR 1305.13(c) and 1305.22(f) to allow deliveries to ‘safe zones’ adjacent to the purchaser’s registered location, provided that the delivery is still made in a person-to-person manner, with an agent or employee of the purchasing registrant taking possession of the delivery within sight of the delivery driver. DEA also referenced other COVID-19 PHE guidance documents. DEA further indicated that due diligence and site inspections via teleconferencing may be acceptable alternatives during the COVID-19 PHE. DEA-DC-032, issued April 10, 2020.
- 5% Rule: Practitioner Exception. An exception to [21 CFR 1307.11](#) allowing a registered practitioner to distribute controlled substances ‘beyond’ five percent of the total number of dosage units of controlled substances distributed and dispensed during the same calendar year without being required to register as a distributor. DEA-DC-029, issued April 13, 2020.
- 65% Bulk Manufacturing Exception. An exception to [21 CFR 1303.24\(b\)](#) that normally requires the inventory for individual manufacturers to remain at 65 percent of estimated net disposals or less. DEA-DC-020, issued March 25, 2020.
- Emergency Schedule II Call in Exception. While practitioners must determine on a case-by-case basis whether an ‘emergency’ exists under the requirements of 21 CFR 290.10, this guidance granted an exception to the requirements set forth under [21 CFR 1306.11\(d\)\(4\)](#) to allow practitioners fifteen (15) days to provide a follow-up paper prescription to the pharmacy after issuing an emergency oral prescription. It also granted an exception allowing the practitioner to send the follow-up written prescription to the pharmacy via facsimile, or to send a photograph or scan of the written prescription to the pharmacy. DEA-DC-21, issued March 27, 2020.
- Prescription Chart. This decision tree summarized policies for quick reference but has become out of date due to its reference to the DATA-waiver requirements that were repealed by Congress in December 2022. DEA-DC-23, issued March 31, 2020.

To avoid confusion, DEA also is withdrawing the following guidances that mention the COVID-19 PHE.

- Prescription Refills. Guidance concerning the refill of prescriptions for controlled substances during the COVID-19 PHE. DEA-DC-17, issued March 21, 2020.
- Mail Order Methadone. Guidance concerning the delivery of methadone to NTP patients by mail, mentioning other flexibilities granted during the COVID-19 PHE. DEA-DC-24, issued March 25, 2020.

- EPCS Hospitals & Remote ID Proofing. Guidance relating to remote identity proofing of individual practitioners when issuing authentication credentials to eligible practitioners engaged in electronic prescribing of controlled substances during the COVID-19 PHE. DEA-DC-26, issued April 8, 2020.

The contents of this document do not have the force and effect of law and are not meant to bind the public in any way. This document is intended only to provide clarity to the public regarding existing requirements under the law or Department of Justice policies.

For further information regarding DEA's Diversion Control Division, please visit www.DEAdiversion.usdoj.gov. If you have additional questions, please contact the Diversion Control Division Policy Section by email at odlp@dea.gov or by phone at (571) 362-3260.

Sincerely,

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Diversion Control Division

EO-DEA277, DEA-DC-072, May 10, 2023