

Office of Controlled Substances Administration (OCSA) Controlled Dangerous Substance (CDS) FAQs during COVID-19

Updated: May 15, 2020

The State of Maryland is under a <u>State of Emergency</u> as of March 5, 2020. Under Governor Hogan's direction, state agencies continue to develop comprehensive and coordinated prevention and response plans for the novel coronavirus (COVID-19). The Maryland Department of Health's Office of Provider Engagement and Regulation (OPER) will provide updates as this situation develops.

OPER endeavors to provide the most up-to-date information, but this guidance does not replace any federal, state, or local laws or regulations, or official notices issued by any regulatory agency.

For the latest information and resources about COVID-19 in Maryland, visit: coronavirus.maryland.gov/

Health care professional resources: https://coronavirus.maryland.gov/pages/provider-resources

Health care facility resources: https://coronavirus.maryland.gov/pages/hcf-resources

Drug Enforcement Administration (DEA) has issued federal guidance related to Controlled Dangerous Substances (CDS) and COVID-19: https://www.deadiversion.usdoj.gov/coronavirus.html

Please note: certain state laws and regulations are more restrictive than current federal regulations; relevant state laws should be consulted when implementing CDS-related practices during this State of Emergency.

Healthcare practitioners should consult their respective health professional licensing Board websites for profession-specific information regarding COVID-19.

Office of Controlled Substances Administration (OCSA):

Website: https://health.maryland.gov/OCSA/ Email: Maryland.gov

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Controlled Substances Prescribing/Dispensing Questions

Has anything changed about the way I can or should prescribe CDS while under a State of Emergency?

During the COVID-19 State of Emergency, it is expected that providers are complying with all current state and federal laws and regulations around the prescribing and dispensing of CDS, including opioids for pain management. At the same time, certain changes to the provision of care can be easily implemented in many situations to reduce the risk to patients and staff. The DEA has released a guidance document called Health Emergency. This guidance document is consistent with Maryland law and regulations in effect during the Maryland State of Emergency¹.

Healthcare practitioners should implement applicable provisions of <u>CDC guidance</u> to protect patients and staff from unnecessary risk, and review <u>Maryland Department of Health</u> <u>guidance</u> on social distancing in their practice. Social distancing is a way to keep people from interacting closely or frequently enough to spread an infectious disease, maintaining distance between individuals, especially in poorly ventilated spaces. Healthcare practitioners should seek to facilitate social distancing.

Possible actions to take:

- Implement telehealth or other mechanisms that do not require in-person patient visits, where such action meets applicable standards of care and in adherence with federal and state requirements. See question about telehealth below.
- Consider options to reduce patient exposure in office settings when in-person visits are warranted:
 - Post signs for patients and clinicians, such as those available on the <u>Maryland</u> <u>Coronavirus Resources for Healthcare Providers</u> page.
 - Provide access to hand sanitizer and/or hand washing stations.
 - Space out chairs at least 6 feet apart in the waiting room and limit waiting areas within the office to the capacity of the seats provided.
 - Encourage patients to transport to and attend visits alone where safe and feasible.
 - Allow patients to check in by phone and wait in their vehicles, receiving a call to come in only when the practitioner is ready for their appointment, as recommended by CDC.

Prescribers should consult their professional health licensing Board for any guidance or standards of care.

¹ Since signing of HB448 (Chapter 15, 2020) by Governor Hogan on April 3, 2020, the prescribing of Schedule II opioids for pain using telehealth is authorized during the State of Emergency only.

If you are unable to conduct a standard in-person visit for ongoing assessment of a patient on maintenance CDS medications, a prescription for the maintenance medication issuing a prescription may still be warranted.

Consider the following prior to prescribing:

- Scheduling a telehealth visit
- Talking with the patient over the phone, or communicating through any other means, to assess the ongoing treatment of the patient
- Checking the PDMP

If a Schedule II prescription cannot be issued in person to a patient, consider:

- Electronic prescribing of controlled substances (or EPCS) where technology allows.
- Emergency prescription telephonically issued to the pharmacist. See FAQ below on this topic.

Can I prescribe CDS using telehealth in Maryland?

Yes, the use of telehealth or alternative communication methods is allowed for prescribing of CDS. Please see below for additional information. According to the Governor's <u>April 1</u>, <u>2020 Executive Order</u>, "authorizing health care practitioners to use telehealth and audio-only calls or conversations under appropriate circumstances will help Marylanders continue to receive needed health care services during the catastrophic health emergency".

On Friday, April 3, 2020, Governor Hogan also signed into law <u>HB448 (Chapter 15, 2020)</u>, concerning additional provisions related to telehealth, including allowing the prescribing of opioids in Schedule II for the treatment of pain if the patient is in a health care facility or if the Governor has declared a State of Emergency.

The following are specific to prescribing CDS:

Audio Communications:

- Prior to issuing a CDS prescription for a new patient, a practitioner must complete a two-way, real-time (synchronous) telehealth medical evaluation, with the exception of prescribing buprenorphine for opioid-use disorder in line with federal guidance.²,³
- After an initial telehealth communication occurs, the practitioner may use audio-only communication for any future prescriptions.

² https://www.deadiversion.usdoi.gov/coronavirus.html

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

Telehealth Communications:

When prescribing CDS using telehealth during the COVID-19 pandemic in Maryland the following rules apply:

New Patient Evaluation:

- Practitioners are not required to conduct the first medical evaluation in person. This
 first evaluation may be conducted using synchronous telehealth, meaning the use of
 audio and video equipment that permits a two-way communication in real time.
 Telephone, fax, email, and asynchronous telehealth interactions do not meet these
 requirements.
- Exception: First time buprenorphine prescribing for opioid-use disorder audio only communication is permitted. Please see <u>guidance</u> issued by the Behavioral Health Administration (BHA) for additional information.

Ongoing Patient Treatment:

- If the practitioner has previously conducted an in-person or authorized telehealth medical evaluation, the practitioner may prescribe CDS for a legitimate medical purpose, using telehealth or by any other means including audio communication.
- When implementing telehealth practice in Maryland, practitioners should consult Maryland telehealth regulations and guidance from their professional licensing Board as the Boards may have more stringent requirements.

Reimbursement decisions for non-telehealth communication are at the discretion of the payer.

Updated: Can I prescribe CDS in Maryland without a Maryland-issued CDS Registration?

Effective May 8, 2020 the following notice has been issued by the Maryland Department of Health Secretary. This notice allows Out-of-State practitioners to apply for a waiver to prescribe and administer Controlled Dangerous Substances ("CDS") under certain circumstances without first obtaining a Maryland CDS registration from the Office of Controlled Substances Administration (OCSA). Practitioners eligible for this waiver must complete a Waiver Form (attached and posted on OCSA Website), have a CDS and DEA registration in their home state in good standing, and be practicing at a health care facility as defined in the below Executive Order.

Notice - Waiver of CDS Registration Requirement for Out-of-State Applicants for a Maryland Controlled Dangerous Substance Registration

If a practitioner will be working solely in a hospital/clinic setting, they may use the facility's DEA registration and facility's Maryland CDS Registration instead of registering independently if the hospital agrees and the situation warrants.⁴ Please note

⁴ 21 C.F.R. § 1301.22(c) https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-12)%20What%20is%20DEA's%20policy%20concerning%20Locum%20Tenens.pdf

that out-of-state practitioners prescribing and administering CDS under a facility DEA number do not need to complete this waiver form.

The Board of Physicians has also issued guidance on new rules permitting physicians and physician assistants to practice across state lines (https://www.mbp.state.md.us/forms/FAQsExecOrder.pdf)

In addition to this Notice, out-of-state practitioners must abide by the following:

- The <u>DEA waiver</u> put in place for the duration of the COVID-19 pandemic state of emergency; and
- The Maryland Governor's 3/16/2020 Executive Order Health Care Matters.

Waiver Form Required:

Prior to prescribing or administering CDS in Maryland under the conditions of this waiver, the practitioner must complete a waiver form and submit the waiver form to the Office of Controlled Substances Administration via email to sandra.yankosky@maryland.gov. If you have any questions please contact Sandy Yankosky for assistance.

This waiver is in effect for the duration of the DEA waiver or until the state of emergency in Maryland has been terminated and the proclamation of the catastrophic health emergency has been rescinded, whichever is earlier.

Can a dispenser fill an oral prescription for a Schedule II controlled substance?

In Maryland, an oral prescription for a Schedule II controlled substance may be dispensed only in an emergency as allowed under 21 CFR §1306.11(d), as allowed under COMAR 10.19.03.08. An emergency situation is defined in the Food and Drug Administration (FDA) regulation, 21CFR 290.10.

As a result of the national Public Health Emergency and to enable greater flexibility in oral prescribing, the DEA has issued a policy Exception to Regulations Emergency Oral CII Prescriptions providing two temporary exceptions to 21 CFR §1306.11(d)⁵. These exceptions are summarized below. All other requirements for issuing and filling Schedule II emergency oral prescriptions remain intact. Pharmacists continue to have a corresponding responsibility to ensure that a CDS prescription being filled has been issued for a legitimate medical purpose. Prescribers and dispensers should review the entire DEA policy to ensure compliance with all provisions.

If an oral emergency prescription is warranted and accepted by the dispenser the following changes are now in effect:

• The requirement to deliver the written prescription to the pharmacy within 7 days has been extended to allow 15 days to deliver the written prescription after issuing an emergency oral prescription

https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-021)(DEA073)%20Oral%20CII%20for%20regular%20CII%20scirpt%20(Final)%20+Esign%20a.pdf

• In place of sending the original prescription, the practitioner may send the follow-up prescription to the pharmacy electronically via: facsimile; scanning the original prescription; or by sending electronically a photograph of the original prescription.

The practitioner must ensure that for whichever method they use, the prescription contains all required information stated in COMAR 10.19.03.08 and 1306.11(d), including a statement that prescription is "Authorized for Emergency Dispensing." and the date of the oral order. Practitioners who choose to send this specific type of prescription to the pharmacy via facsimile, photograph, or scan must maintain the original paper prescription in the patient file.

Controlled Substances in Schedules III-V may always be prescribed by oral prescription under 21 U.S.C. 829(b), (c) and COMAR 10.19.03.09.

Can a Schedule II prescription be refilled?

No, refills for Schedule II prescriptions cannot be issued per federal law (21CFR 1306.12) and Maryland state law (Criminal-Law Article §5-501). However, DEA has issued DEA Policy: Registrant Guidance on Controlled Substance Prescription Refills which provides guidance including that multiple prescriptions may be written allowing the patient to receive up to a 90-day supply of a Schedule II CDS over those multiple prescriptions.⁶

Can a Schedule III-V prescription be refilled?

Yes, refills for Schedule III-V prescriptions are authorized in compliance with federal law (21CFR 1306.22), state law (Criminal-Law Article §§5-504 and 5-505).

May prescribers that routinely give short supplies of medications requiring patients to go to a pharmacy more frequently prescribe for longer periods?

Shorter duration prescriptions may continue to be unavoidable for certain situations. If appropriate, the use of longer prescription lengths should be considered. Again, this should be at the discretion of a practitioner balancing patient safety and CDS supply.

Can a pharmacy complete an early refill of a CDS medication for a patient?

Yes, early refills are allowed and may be appropriate to ensure patients have access to necessary medications.

The Maryland Insurance Administration (MIA) issued Bulletin 20-05 on March 6, 2020 stating that "carriers are required to waive any time restrictions on prescription medication refills and authorize payment to pharmacies for at least a 30-day supply of any prescription medication, regardless of the date upon which the prescription medication had most recently been filled by a pharmacist."

 $^{^6 \, \}underline{\text{https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-017)(DEA065)\%20Early\%20RX\%20Refill\%20-\%200MB\%203-20-20\%202200\%20DAA\%20approved.pdf}$

https://insurance.maryland.gov/Insurer/Documents/bulletins/Bulletin-20-05-Covid-19.pdf

Additionally, DEA has issued <u>DEA Policy: Registrant Guidance on Controlled Substance Prescription Refills</u>)⁸

Can a pharmacist fill a prescription that requires a prior authorization in an emergency if the prescriber is unavailable?

Medicaid Fee-for-Service pharmacy patients can have prescriptions requiring prior authorization filled with a 14 day emergency supply, instead of the usual 72 hour emergency supply. Consult Medicaid to complete this action in compliance with instructions. Patient insurance coverage may vary on similar policies being put in place.

May a pharmacy deliver or mail prescriptions to patients at their home?

Yes, pharmacies may deliver prescriptions, including those that contain CDS, to patients. Delivery is a convenient/safe option to help patients who are at higher risk for COVID-19 or who are in quarantine obtain refills or new prescriptions without having to visit a pharmacy location. Secure transfer of prescription in transit and upon delivery to the patient should be considered when implementing this practice. The delivery personnel should be equipped with all necessary protection to prevent spread of COVID-19.

Healthcare practitioners should recognize that patients may be switching pharmacies to protect their health and safety at this time.

Can an Opioid Treatment Program (OTP) (or Narcotic Treatment Program (NTP) order a supply of methadone early during the state of emergency?

Yes, if an OTP (or NTP) needs to place an early order for methadone due to the COVID-19 State of Emergency, the program can contact Niketa Prince, DEA Diversion Group Supervisor, Baltimore District Office, in writing at niketa.g.prince@usdoj.gov. The decision to allow an early order will be made by DEA on a case- by- case basis.

I'm a practitioner that utilizes urinalysis regularly for my patients receiving pain management medications. What should I do?

Professional judgment should be employed to determine if temporary suspension of this practice is appropriate, balancing the health and safety of the patient and the community and requirements stated under Health-Occupations Article of the Annotated Code of Maryland.

⁸ https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-017)(DEA065)%20Early%20RX%20Refill%20-%20OMB%203-20-20%202200%20DAA%20approved.pdf

Maryland CDS Practitioner Licensure Questions

I have an active CDS Individual or Establishment Registration that is due to expire soon. What should I do?

The Office of Controlled Substances Administration (OCSA) strongly encourages a registrant with a CDS Individual or Establishment Registration that is due to expire soon to go to the OCSA Online Renewal website (https://egov.maryland.gov/mdh/cds) to complete their renewal. Governor Hogan signed an Executive Order extending the expiration date of any current license or registration until 30 days after the State of Emergency for the COVID-19 pandemic influenza is ended. Although this extension is in place, OCSA will continue to process renewal applications received.

Using the OCSA Online Renewal website (https://egov.maryland.gov/mdh/cds), the registrant can renew their CDS registration online up to 60 days before or 30 days after the expiration date listed on the certificate. OCSA will process applications, but may experience delays in issuing mailed certificates during this State of Emergency; however you may always verify your CDS status, including a processed renewal, by utilizing the CDS Search tool (https://health.maryland.gov/ocsa/Pages/cdssearch) on the OCSA website. Renewed registrations will be reflected on the CDS Search tool.

If needed, a registrant can download the CDS application from the OCSA website's CDS Application page (https://health.maryland.gov/ocsa/Pages/CDS-Application.aspx) and mail the CDS application and check or money order to the Office of Controlled Substances Administration, 4201 Patterson Avenue, 5th Floor, Baltimore, MD 21215. Please note that mailed renewal applications are not the preferred method of submission at this time.

Can I still obtain a new Individual or Establishment CDS Registration?

Yes, the Office of Controlled Substances Administration (OCSA) is still accepting new Individual or Establishment Controlled Dangerous Substances (CDS) applications by mail and will continue to process these applications at this time. The new Individual or Establishment CDS application can be accessed from the Office of Controlled Substances Administration website at https://health.maryland.gov/ocsa.

A separate CDS application is required for each individual profession and the type of establishment, each principal place of business or professional practice where the controlled dangerous substances are stored, administered and dispensed. The mailing address to submit the CDS application and the registration fee is the Office of Controlled Substances Administration, 4201 Patterson Avenue, 5th Floor, Baltimore, MD 21215. OCSA will process applications, but may experience delays in issuing mailed certificates during this State of Emergency; however you may always verify your CDS status by utilizing the CDS Search tool

(https://health.maryland.gov/ocsa/Pages/cdssearch) on the OCSA website. New registrations will be reflected on the CDS Search tool.

What should I do to fast-track the processing of a CDS application for vacated hospitals to be used for COVID-19 response?

If a vacated hospital will be put in service to support the state's COVID-19 response, your application will be fast-tracked. Obtain an "Establishment - 3 Year Application" from the OCSA website: https://health.maryland.gov/ocsa/Pages/CDS-Application.aspx, where instructions for completion are also posted. Mail your completed application along with a check for \$120 and copies of appropriate Health Occupation Board, Office of Health Care Quality (OHCQ), and/or other applicable license by any carrier that does overnight delivery. Contact OCSA the next day by phone at 410-764-2890 to ensure your application arrived. Please let a staff member know that you are a vacated hospital in need of licensure quickly to aid in COVID-19 response. We will review and process your application in an expedited manner to allow the hospital to be used as needed. Mail to:

OFFICE OF CONTROLLED SUBSTANCES ADMINISTRATION (OCSA) 4201 Patterson Avenue, 5th Floor Baltimore, Maryland 21215

Patient CDS Questions

Can I get my CDS prescription now before there is a quarantine or I get sick, even though it's too early?

Pharmacists and prescribers must use their independent, professional judgment to consider early refills. You should speak with your healthcare provider.

I would like to have my CDS prescription delivered to my home. Can my pharmacy do this?

Delivery of prescriptions to a patient's home is authorized, but is subject to the discretion and policies of a pharmacy.

If you are sick or under quarantine, consider whether a trusted family member can pick up the prescription for you, or use a pharmacy that has drive-thru capabilities if a pharmacy is unable to deliver.