



## Use of Temporary Satellite Locations for the Storage and Use of Dangerous Drugs During COVID-19

Updated 4/30/2020

In order to expand treatment capacity during the COVID-19 outbreak, the State of Ohio Board of Pharmacy has adopted the following guidance for the temporary off-site storage of dangerous drugs.

This guidance is being issued in accordance with a Board resolution adopted on March 2, 2020.

An in-state facility licensed as a terminal distributor of dangerous drugs may maintain possession, custody, or control of dangerous drugs **for the treatment of patients due to COVID-19** at a satellite location other than or in addition to its actual licensed location if the facility complies with the following:

1. The terminal distributor maintaining dangerous drugs at an off-site satellite location is responsible for the following:
  - o Implementing policies and procedures to ensure that drugs removed from the terminal distributor and stored at an off-site location are maintained under the supervision and control of licensed healthcare personnel.
    - For non-controlled substance drugs, this may be a licensed, registered, or certified healthcare provider.
    - For controlled substances, supervision is limited to prescribers, pharmacists, physician assistants, nurses (APRN, RN, LPN), and, if an EMS agency, paramedics and advanced emergency medical technicians.
  - o If supervision is not provided, the dangerous drugs shall be physically secured in a manner to prevent unauthorized access.
  - o Reasonable efforts shall be made to store the drugs at temperatures and conditions which will ensure the integrity of the drugs prior to their use as stipulated by the USP/NF and/or the manufacturer's or distributor's labeling.
  - o Maintaining required records of receipt, administration, dispensation, personally furnishing, and disposal.
2. The terminal distributor submits a COVID-19 Satellite Registration Form ([www.pharmacy.ohio.gov/SATFORM](http://www.pharmacy.ohio.gov/SATFORM)). The use of a terminal's satellite location does not require any approval from the Board, but the [Form](#) must be submitted **prior to** the off-site storage and use of dangerous drugs. **NOTE:** The Board will be reviewing submissions for completeness and forms will be subject to a review process. The licensee will receive an email indicating that the form was successfully processed by the Board.



3. If intending to maintain controlled substances at an off-site satellite location, the licensee is required to obtain a temporary registration from the Drug Enforcement Administration **and comply with any applicable guidance issued by the DEA**. For more information on this process visit: <https://www.deadiversion.usdoj.gov/coronavirus.html>. **IMPORTANT:** The satellite location may only possess controlled substances if the terminal distributor has a Category 3 terminal distributor license.
4. A wholesaler may deliver to the terminal distributor's satellite location in accordance with rule [4729:6-3-04](#) of the Administrative Code by verifying the location on the Board's website. Verification of the satellite location using the Board's website must only be conducted prior to the initial sale and is not required for subsequent sales (see FAQ starting on next page for more information).
5. Both the terminal distributor satellite location and its licensed parent location are subject to the minimum requirements to operate as set forth in section [4729.54](#) of the Revised Code.
6. Both the terminal distributor satellite location and its licensed parent location are subject to the same disciplinary measures set forth in sections [4729.57](#) and [4729.571](#) of the Revised Code, including summary suspension of either the satellite location or the licensed parent location, or both, should the Board be presented with clear and convincing evidence of a danger of immediate and serious harm to others.

This guidance is in effect until rescinded by the Board.

## **Frequently Asked Questions**

To assist licensees in complying with this process, the Board has developed the following frequently asked questions. This document will be updated as needed. If you need additional information, the most expedient way to have your questions answered is to e-mail the Board by visiting: [www.pharmacy.ohio.gov/contact](http://www.pharmacy.ohio.gov/contact).

### **1) How does a wholesaler confirm the satellite location is properly registered with the Board?**

A wholesaler (or other drug distributor) may deliver to the terminal distributor's satellite location in accordance with rule [4729:6-3-04](#) of the Administrative Code by verifying the location on the Board's website. Verification of the satellite location using the Board's website must only be conducted prior to the initial sale and is not required for subsequent sales.

To verify the satellite location is properly registered, the wholesaler must confirm the satellite location has a completed COVID-19 Satellite Registration Form. To verify, the wholesaler can view submitted forms by visiting: <https://www.pharmacy.ohio.gov/Licensing/PublicDocuments.aspx>.

From there, enter the terminal distributor license number of the parent location. The form, which includes the satellite location address, can be viewed by the wholesaler. The wholesaler should maintain a copy of the completed form obtained from the Board's website with their records to demonstrate compliance the requirements of this guidance.

**REMINDER:** [Wholesaler reporting to OARRS and suspicious order monitoring](#) should be submitted under the parent terminal distributor license information and not the satellite location.

### **2) What records do I need to maintain if transferring drugs from my licensed terminal distributor to a registered satellite location?**

A licensee may also opt to transfer drug stock to the satellite location from the terminal distributor. The terminal distributor must maintain a record of all drugs transferred to the to the satellite location, to include, at a minimum, the following: name, strength, dosage form, and quantity of the dangerous drug transferred, the address of the location where the drugs were transferred, and the date of transfer.

### **3) How long does it take the Board to process a registration form?**

Board staff are reviewing forms for completeness. Upon submission of a complete form, it may take up to 48 hours for the form to be processed and visible on the license [document view page](#). Licensees will receive an email when the form is successfully processed.

**4) Does this only apply to the treatment of COVID-19 patients at a satellite location? – UPDATED 4/3/2020**

No. The guidance has been updated to specify that satellites may be used to for the treatment of patients due to COVID-19. This allows for the use of satellite locations to treat COVID-19 patients but also allows for the use of satellites to treat patients where existing treatment capacity is limited due to COVID-19.

**IMPORTANT:** Failure to properly demonstrate this need may result in the Board refusing to process a registration form. Should the Board refuse to process a registration request, the requestor shall receive written notification from the Board.

**5) Does this apply to out-of-state locations? – UPDATED 4/3/2020**

No. This guidance only applies to satellite locations within the state of Ohio.

**6) Does this apply to EMS agencies? – UPDATED 4/3/2020**

It depends.

**Yes:** If an EMS agency needs to relocate vehicles containing drug stock (or the agency's drug stock itself) to another location where the drugs will not be consistently under the direct supervision of EMS personnel, then they must submit a registration form.

**No:** If an EMS agency is posting up, then the answer is no. An EMS is permitted to post-up at different locations pursuant to rule 4729:5-14-01 of the Administrative Code. This means locating an EMS unit containing dangerous drugs at a location other than a location licensed by the Board of Pharmacy for more than twenty-four consecutive hours pursuant to a formal agreement with the sponsors of the event and where the EMS unit is **under the direct supervision of the EMS personnel on duty.**

**REMINDER:** Posting up does not require notification to the Board during an emergency declared by the Governor.

**7) I am an opioid treatment program (OTP) and I am planning to implement the DEA policies on the use of unregistered off-site locations to provide off-site MAT services or deliveries, what do I have to do to ensure compliance with Board of Pharmacy laws and rules? – UPDATED 4/30/2020**

An OTP that registers their temporary satellite location with the Board pursuant to this guidance may use unregistered off-site locations to provide MAT services in accordance with the following DEA policies:

- **DEA Policy:** [Use of Unregistered Off-Site Locations in MAT](#) (Effective April 7, 2020)

- **DEA Policy: [Use of Unregistered Off-Site Locations in MAT \(Buprenorphine\)](#)**  
(Effective April 28, 2020)

*The Board of Pharmacy hereby adopts the DEA policies listed above. Such policies shall remain in effect from the date of approval by the DEA through the duration of this public health emergency as declared by the Secretary of HHS (unless this allowance is first modified or withdrawn by DEA).*

**REMINDER:** These policies only apply to licensed opioid treatment programs. All home delivery services must comply with the DEA and SAMHSA home delivery policies, which have been incorporated into the following Board resolution: <http://www.pharmacy.ohio.gov/OTP2020>