Vaccine Storage and Administration in Institutional Facilities and Other Settings

Updated 3/17/2021

The following guidance applies to institutional facilities (nursing homes, jails, etc.) and other settings (congregate, EMS) that are developing vaccine distribution and administration plans. This document is intended only to provide guidance on compliance with Board of Pharmacy requirements. Licensees and other facilities are reminded to consult with other regulating entities, including the Ohio Department of Health, to ensure full compliance with all federal and state laws, rules, and policies.

This guidance features three sections:

- **Long-Term Care and Other Institutional Facilities**
- **Other Congregate Care Settings**
- **Emergency Medical Services**

For questions regarding this guidance, please e-mail the Board office by visiting: http://www.pharmacy.ohio.gov/contact.aspx

REMINDER: *The State of Ohio Board of Pharmacy is committed to safely addressing any operational issues licensees may experience during COVID-19. Licensees may submit requests for waivers to Ohio laws and regulations governing the practice of pharmacy or distribution of dangerous drugs to: compliance@pharmacy.ohio.gov. Please include a detailed justification for the waiver request and the expected time period.*

Long-Term Care and Institutional Facilities

This section applies to long-term care and other institutional facilities holding licensure as a terminal distributor of dangerous drugs. As a reminder, an institutional facility means any of the following:

> *A hospital as defined in section 3727.01 of the Revised Code, or a facility licensed by the state board of pharmacy and the Ohio Department of Health, the Ohio Department of Rehabilitation and Correction, the Ohio Department of Developmental Disabilities, or the Ohio Department of Mental Health and Addiction Services at which medical care is provided on site and a medical record documenting episodes of care, including medications ordered and administered, is maintained, including, the following:*
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> *(1) Convalescent homes;*
> *(2) Developmental facilities;*
> *(3) Long term care facilities;*
> *(4) Nursing homes;*
> *(5) Psychiatric facilities;*
> *(6) Rehabilitation facilities;*
> *(7) Developmental disability facilities;*
> *(8) Level III sub-acute detoxification facilities certified by the Ohio Department of Mental Health and Addiction Services;*
> *(9) State or local correctional facilities, as defined in section 5163.45 of the Revised Code;*
> *(10) Any other facility as determined by the board.*

Q1) I am a long-term care facility or other institutional facility where a pharmacy maintains a terminal distributor of dangerous drugs license for contingency stock drugs, am I required to obtain another terminal distributor license to store vaccines at my facility?

No. Per Board resolution (see below), the facility does not need another license by the Board to possess and administer vaccines and emergency medications to treat adverse reactions to vaccine administration (e.g., epinephrine). However, if the facility is not being serviced by a pharmacy then it would have to obtain its own license as a terminal distributor of dangerous drugs to maintain vaccines and any other drugs on-site.

Resolution (Adopted 11.2.2020) – Updated 3.16.2021

To promote improved access to vaccinations during the COVID-19 pandemic, the State of Ohio Board of Pharmacy hereby authorizes a long-term care facility or other institutional facility, as defined under agency 4729 of the Ohio Administrative Code, to possess and administer COVID-19 or other vaccines to patients and staff under the terminal distributor of dangerous drugs license issued to the facility's servicing pharmacy (e.g., contingency stock license). This resolution shall also permit the use of the servicing pharmacy's contingency stock license to maintain dangerous drugs used to treat adverse reactions to vaccines stored at the facility.

Q2) Who is responsible for maintaining the appropriate records of drug administration for vaccines maintained at an institutional facility?

The responsibility for maintaining appropriate records of drug administration in accordance with rule 4729-17-04 of the Ohio Administrative Code is on the license holder and the licensee's responsible person. The pharmacy servicing a nursing home should ensure that proper records of drug administration are being maintained by the institutional facility.

Q3) Can vaccines be administered within an institutional facility pursuant to a protocol?

Yes. As applicable, rule 4729:5-3-12 of the Ohio Administrative Code authorizes the following to be administered via protocol:

- Biologicals or vaccines to individuals for the purpose of preventing diseases; and
- The administration of influenza antiviral treatment and chemoprophylaxis to residents and health care personnel at an institutional facility, according to current guidance issued by the United States Centers for Disease Control and Prevention.

As a reminder, a valid vaccine protocol must include all the following:

- Include a description of the intended recipients to whom the drugs are to be administered; drug name and strength; instructions of how to administer the drug, dosage, and frequency; signature of a prescriber or some other form of positive identification of the prescriber; and date of signature;
- Be administered by an individual authorized by law to administer the drugs;
- Be reviewed as necessary to ensure patient safety and practice in accordance with acceptable and prevailing standards of care; and
- Be maintained by the terminal distributor of dangerous drugs for a period of three years from the date of authorization or reauthorization following any modification or amendment.

IMPORTANT: The U.S. Department of Health and Human Services (HHS), through the Assistant Secretary for Health, issued guidance under the Public Readiness and Emergency Preparedness Act (PREP Act) authorizing pharmacy personnel to administer vaccines. For more information on these changes, the Board has developed the following guidance documents:

- Administration of Childhood Vaccines during the COVID-19 Pandemic (Pharmacists and Interns)
- Administration of COVID-19 Vaccines during the COVID-19 Pandemic (Pharmacists and Interns)
- Pharmacy Technician Administration of Vaccines during the COVID-19 Pandemic (Registered/Certified Technicians)

Q4) Is there a way for vaccination services to be provided by third parties at a long-term care facility or other institutional facility?

Yes. Paragraph (C) of rule 4729:5-3-13 of the Ohio Administrative Code permits a licensed healthcare professional employed by an existing terminal distributor of dangerous drugs to remove vaccines and other non-controlled drugs to administer off-site in accordance with a valid prescriber order or protocol. In general, this provision permits a licensed terminal distributor to operate off-site vaccination clinics.

IMPORTANT: The protocol must comply with the requirements listed in Q3 of this document.

Specifically, paragraph (C) states:

> *A licensed health care professional, in accordance with their applicable scope of practice, who provides immunizations or any other non-controlled substance dangerous drugs that may be administered in accordance with a protocol or valid prescriber's order may temporarily remove dangerous drugs from a licensed terminal distributor of dangerous drugs in order to treat current or prospective patients. The dangerous drugs shall be returned to the licensed terminal distributor of dangerous drugs within twenty-four hours, unless otherwise approved by the board. The licensed health professional shall maintain direct supervision and control over the dangerous drugs and any hypodermics removed from the terminal distributor. If direct supervision is not provided, the dangerous drugs and any hypodermics shall be physically secured in a manner to prevent unauthorized access and shall be stored 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. The responsible person on the terminal distributor of dangerous drugs license shall be responsible for compliance with the requirements of this paragraph.*

Q5) What are the security and control requirements for vaccines maintained at an institutional facility?

Institutional facilities must comply with rule 4729-17-03 of the Administrative Code for securing vaccines and other drugs at the facility.

Other Congregate Care Settings

This section applies to congregate settings (e.g. assisted living, etc.) that are not institutional facilities and do not currently hold a license as a terminal distributor of dangerous drugs.

Q6) Can other congregate care settings possess and administer vaccines?

Yes. Such settings may apply for a terminal distributor of dangerous drugs license if the facility has a prescriber or pharmacist who is able to serve as the licensee's responsible person. Unless advised otherwise, locations should apply for a "FIRST AID DEPARTMENT" license. More information on applying for a license can be accessed here.

For more information on the requirements for maintaining a first aid department terminal distributor license, visit: www.pharmacy.ohio.gov/FAinspect

The following are links to the applicable First Aid Department rules:

- 4729:5-13-01 First aid departments - definitions.
- 4729:5-13-02 Licensure and drug list.
- 4729:5-13-03 Security, control and storage of dangerous drugs.
- 4729:5-13-04 Record keeping.

Q7) Can vaccines be administered within a congregate care setting pursuant to a protocol?

Yes. As applicable, rule 4729:5-3-12 of the Ohio Administrative Code authorizes the use of a protocol for the administration of biologicals or vaccines to individuals for the purpose of preventing diseases.

As a reminder, a valid vaccine protocol must include all the following:

- Include a description of the intended recipients to whom the drugs are to be administered; drug name and strength; instructions of how to administer the drug, dosage, and frequency; signature of a prescriber or some other form of positive identification of the prescriber; and date of signature;
- Be administered by an individual authorized by law to administer the drugs;
- Be reviewed as necessary to ensure patient safety and practice in accordance with acceptable and prevailing standards of care; and
- Be maintained by the terminal distributor of dangerous drugs for a period of three years from the date of authorization or reauthorization following any modification or amendment.

IMPORTANT: The U.S. Department of Health and Human Services (HHS), through the Assistant Secretary for Health, issued guidance under the Public Readiness and Emergency Preparedness Act

(PREP Act) authorizing pharmacy personnel to administer vaccines. For more information on these changes, the Board has developed the following guidance documents:

- Administration of Childhood Vaccines during the COVID-19 Pandemic (Pharmacists and Interns)
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- Pharmacy Technician Administration of Vaccines during the COVID-19 Pandemic (Registered/Certified Technicians)

Q8) Is there a way to provide vaccines in congregate care or other settings without needing a terminal distributor of dangerous drugs license?

Yes. Paragraph (C) of rule 4729:5-3-13 of the Ohio Administrative Code permits a licensed healthcare professional employed by an existing terminal distributor of dangerous drugs to remove vaccines and other non-controlled drugs to administer off-site in accordance with a valid prescriber order or protocol. In general, this provision permits a licensed terminal distributor to operate off-site vaccination clinics.

IMPORTANT: The protocol must comply with the requirements listed in Q7 of this document.

Specifically, paragraph (C) states:

> *A licensed health care professional, in accordance with their applicable scope of practice, who provides immunizations or any other non-controlled substance dangerous drugs that may be administered in accordance with a protocol or valid prescriber's order may temporarily remove dangerous drugs from a licensed terminal distributor of dangerous drugs in order to treat current or prospective patients. The dangerous drugs shall be returned to the licensed terminal distributor of dangerous drugs within twenty-four hours, unless otherwise approved by the board. The licensed health professional shall maintain direct supervision and control over the dangerous drugs and any hypodermics removed from the terminal distributor. If direct supervision is not provided, the dangerous drugs and any hypodermics shall be physically secured in a manner to prevent unauthorized access and shall be stored 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. The responsible person on the terminal distributor of dangerous drugs license shall be responsible for compliance with the requirements of this paragraph.*

Emergency Medical Services

This section applies to EMS agencies licensed by the Board of Pharmacy as a terminal distributor of dangerous drugs pursuant to chapter 4729:5-14 of the Administrative Code.

Q9) Are EMS certificate holders permitted to administer vaccines?

On September 3, 2020, the Ohio EMS Board issued the following guidance:

> *The Board recognizes that EMS certificate holders are permitted to administer vaccinations so long as the route of administration is within the scope of practice and the certificate holder administers the vaccine pursuant to medical direction and training on the specific vaccine, which includes adherence to the recommendations and instructions of the Food and Drug Administration.*

For specific questions regarding scope of practice and the guidance, please contact to the Ohio EMS Board.

Q10) Do I need to make any adjustments to my drug list or protocols if my EMS agency begins providing vaccinations in accordance with the guidance issued by the Ohio EMS Board?

Yes. Per rule 4729:5-14-02 of the Administrative Code, any changes to the drugs stored by the EMS agency must be updated on the agency's drug list. The licensee must then upload the entire drug list (not just updates), signed by the agency's medical director, in .PDF format by visiting: www.pharmacy.ohio.gov/upload. A sample drug list can be downloaded here.

IMPORTANT: If uploading a new drug list, please be advised that this will replace the current drug list on file. The list being uploaded should include all drugs (not just updates) that may be purchased and possessed by the licensee.

EMS agencies should also note that any modification to the drug list requires an update to the EMS organization's protocols. Unlike the drug list, updated protocols **ARE NOT** to be submitted to the Board but must be available for inspection by an agent or inspector of the Board.