Rules and Resolutions – November 2024

Resolutions

Indicates resolutions was authorized by the Board President in accordance with a Board resolution adopted on May 5, 2020.

1) Purchase of IV and Peritoneal Dialysis Solutions from Non-Ohio Licensed Out-of-State Facilities*

An Ohio terminal distributor of dangerous drugs that meets the requirements of this resolution may purchase IV and peritoneal dialysis solutions and related non-controlled dangerous drugs from an unlicensed pharmacy, wholesale distributor of dangerous drugs, third-party logistics provider, outsourcing facility, or manufacturer of dangerous drugs located in another state to alleviate a drug shortage if all the following apply:

1. The terminal distributor of dangerous drugs is any of the following:
   - A hospital;
   - An emergency medical service (EMS) organization; or
   - A pharmacy engaged in the compounding of IV solutions.

2. The unlicensed location (i.e., the seller) is appropriately licensed in its home state and documentation of the license verification is maintained by the Ohio terminal distributor of dangerous drugs for three years from the date of each purchase.

3. The terminal distributor is purchasing any of the following:
   - IV solutions;
   - Peritoneal dialysis solutions; or
   - Any other non-controlled drug intended to mitigate supply disruptions of IV and peritoneal dialysis solutions (ex. concentrated sodium chloride, dextrose, saline flushes, diluent vials for IV push, etc.).

4. The terminal distributor is conducting such purchases to minimize supply disruptions of IV and peritoneal dialysis solutions due to Hurricane Helene.

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5. The terminal distributor complies with all record keeping requirements for each dangerous drug received from any pharmacy, wholesale distributor, third-party logistics provider, outsourcing facility, or manufacturer not licensed in Ohio.

6. All documentation and records required above shall be maintained and readily retrievable for three years following purchase.

7. The dangerous drug was produced by an authorized FDA registered drug manufacturer or outsourcing facility.

8. The terminal distributor submits an Out-of-State Purchase Form (included with this resolution) to the Board of Pharmacy via email (compliance@pharmacy.ohio.gov) prior to purchasing any drugs from the unlicensed seller. Only one form per unlicensed location must be submitted by the terminal distributor during the effective period of this resolution. **NOTE:** If a terminal distributor purchases from multiple unlicensed sellers, the terminal distributor will need to submit a form for each facility.

9. An unlicensed pharmacy, wholesale distributor of dangerous drugs, third-party logistics provider, outsourcing facility, or manufacturer of dangerous drugs located in another state shall not be found in violation of Ohio law if they sell to a terminal distributor that meets the requirements of this resolution.

10. The dangerous drugs purchased shall be either of the following:

- FDA approved or, if imported by another country, listed on the FDA's temporary importation list; or
- A compounded drug product prepared by a pharmacy or outsourcing facility.

2) Non-Patient Specific Drug Compounding by In-State Pharmacies for Hospitals and EMS*

1. An in-state hospital pharmacy may distribute compounded drug products, as specified in this resolution, to another terminal distributor under common ownership or control of a hospital if 503B outsourcing facilities are unable to provide the compounded sterile products (CSP) in a reasonable period of time to meet patient need. The CSPs may be dispensed patient-specifically or may be provided as non-patient specific anticipatory CSPs in accordance with ORC 4729.01.

2. An in-state pharmacy may distribute compounded drug products, as specified in this resolution, to a hospital pharmacy or other entity under common ownership or control of a hospital if the hospital pharmacy is unable to compound sterile drugs to meet the demand of its own patients and 503B outsourcing facilities are unable to provide the compounded sterile products (CSP) in a reasonable period of time to meet patient need. The CSPs may be dispensed patient-specifically or may be provided as non-patient specific anticipatory CSPs in accordance with ORC 4729.01.

3. An in-state pharmacy, including a hospital pharmacy, may distribute compounded drug products, as specified in this resolution, to an emergency medical services (EMS) organization if the EMS organization is unable to obtain IV solutions to meet the demand of its own patients and 503B outsourcing facilities are unable to provide the compounded sterile products (CSP) in a reasonable period of time to meet patient need.

4. As used in this resolution, compounded drug products mean any of the following:
    - IV solutions;
    - Peritoneal dialysis solutions; or
    - Any other non-controlled drug intended to mitigate supply disruptions of IV and peritoneal dialysis solutions (ex. concentrated sodium chloride, dextrose, saline flushes, diluent vials for IV push, etc.).

5. All pharmacies shall comply with the beyond-use dating and all other requirements of USP 797 (NOTE: This is the version in effect on March 10, 2020, and not the newest version).

6. All pharmacies shall maintain all required records of the transfer or distribution of these compounded drug products in accordance with OAC 4729:5.

3) Extension of IV Fluid Hang Times Inside an ISO Class 5 PEC*

This resolution extends the time where a punctured conventionally manufactured product must be used within an Ohio hospital licensed as a terminal distributor of dangerous drugs.

1. As used in this resolution, “a conventionally manufactured pharmacy bulk package” means a container of a sterile product for parenteral use that contains many single doses. The contents are intended for use in a pharmacy admixture program that are restricted to the sterile preparation of admixtures for infusion or, through a sterile transfer device (i.e., closed system transfer device or iv spike adapters with needle-free connection) for the filling of empty sterile containers.

2. The conventionally manufactured pharmacy bulk package must be entered or punctured only in an ISO Class 5 PEC and maintained within the PEC.

3. The conventionally manufactured pharmacy bulk package may be used up to 24 hours after initial entry or puncture, unless the manufacturer’s instructions specifically permit a timeframe longer than 24 hours.

4. The hospital utilizing this resolution shall only do so to minimize supply disruptions of IV and peritoneal dialysis solutions.

Rules - ***For filing with CSI and JCARR.***

4729:3-3-06 - Immunization administration by certified and registered pharmacy technicians. (AMEND)

~~**(A) A certified or registered pharmacy technician who meets the requirements of paragraph (B) of this rule and is working under the direct supervision of a pharmacist who meets the requirements of rule 4729:1-3-02, may do any of the following:**~~

~~**(1) In the case of administer to an individual who is seven five years of age or older but not more than thirteen years of age, administer to the individual an immunization for any of the following:**~~

~~**(a) Influenza;**~~

~~**(b) COVID-19;**~~

~~**(c) Any other disease, but only pursuant to a prescription.**~~

~~**(2) In the case of an individual who is thirteen years of age or older, administer to the individual an immunization for any disease, including an immunization for influenza or COVID-19.**~~

(A) A certified or registered pharmacy technician who meets the requirements of paragraph (B) of this rule and is working under the direct supervision of a pharmacist who meets the requirements of rule 4729:1-3-02 of the Administrative Code, may:

(1) Administer to an individual who is five years of age or older an immunization for any disease, including an immunization for influenza or COVID-19.

~~**(3)**~~ **(2)** The pharmacist on duty who is supervising the technician may prohibit, limit, or restrict the type of immunizations administered, including the age of the patient, by the technician.

(B) For a certified or registered pharmacy technician to be authorized to engage in the administration of immunizations, comply with all the following requirements:

(1) Complete a practical training program that meets the requirements set forth in paragraph (C) of this rule.

(2) Administer immunizations authorized by a physician-established protocol that meets the requirements of rule 4729:1-3-02 of the Administrative Code.

(3) Be authorized by the supervising pharmacist to administer immunizations **in accordance with paragraph (A)(2) of this rule**. ~~**The supervising pharmacist may restrict the type of immunizations provided by a certified or registered technician.**~~

(4) Receive and maintain certification to perform basic life-support procedures by successfully completing a basic life-support training course certified by the American red cross, American heart association**, American safety and health institute,** or other training course approved by the board. Certification shall be obtained and maintained through courses that are conducted in- person or, at a minimum, offer an in-person or electronic hands-on training component.

(5) The pharmacist on duty who is supervising the technician shall be on-site to administer epinephrine or diphenhydramine, or both, to individuals in emergency situations resulting from adverse reactions to the immunizations administered by the registered or certified pharmacy technician.

(6) The pharmacist on duty who is supervising the technician determines if the technician is competent to administer immunizations.

(C) A course in the administration of immunizations developed pursuant **to** paragraph (B) of this rule shall meet the following requirements:

(1) The instructor shall be a licensed health care professional and have the appropriate education and experience to teach a course in the administration of immunizations.

(2) The content must meet the standards established for such courses by the centers for disease control and prevention in the public health service of the United States department of health and human services.

(3) The course shall be conducted by an accreditation council for pharmacy education (ACPE) accredited provider.

(4) The course must be a minimum of six hours in length and include, at a minimum, the following topic areas:

(a) A review of immunology that includes a discussion of the body's immune system reaction to immunizations.

(b) A review of each immunization recommended by the **advisory** committee on immunization practices of the centers for disease control and prevention in the United States department of health and human services **(6/28/2024)**~~**(8/5/2022)**~~:

(i) Disease states associated with the immunization;

(ii) Type or nature of activity of the immunization;

(iii) Administration schedules;

(iv) Routes of administration;

(v) Injection sites;

(vi) Dosages;

(vii) Monitoring and treatment of the patient for adverse reactions;

(viii) Patient populations;

(ix) Precautions and contraindications; and

(x) Proper storage requirements for the immunization.

(c) A review of sterile technique in injectable dosage preparation and administration.

(d) A minimum of one hour of instruction and physical participation in administration techniques.

(e) A review of the proper disposal procedures for contaminated needles and immunizations.

(f) A review of the proper procedures for accidental needle sticks.

(5) The course must provide a method to evaluate the successful comprehension of the content.

(6) The course must provide a method to demonstrate the participant has successfully completed the course.

(D) Courses on immunization administration may be reviewed by the state board of pharmacy. A training course that fails to comply with the requirements set forth in this rule shall be considered in violation of this rule.

(E) The pharmacy employing the technician shall ensure informed consent is obtained pursuant to rule 4729:5-5-04 of the Administrative Code prior to the administration of an immunization.

(F) The pharmacy employing the technician shall ensure the technician maintains the competency and skills necessary to safely administer immunizations. The pharmacy shall ensure the technician has initial and annual documented assessment of competency in immunization administration.

(G) Immunization records shall be maintained in accordance with rule 4729:5-5-04 of the Administrative Code.

(H) The pharmacy where a technician is administering immunizations in accordance with this rule shall comply with the vaccine information statement requirements of the National Vaccine Childhood Injury Act, 42 USC Section 300aa-26 (12/14/1993).

(I) For each immunization administered to an individual by a certified or registered pharmacy technician, other than an immunization for influenza administered to an individual eighteen years of age or older, the pharmacy employing the technician shall be responsible for ensuring the notification of the individual's primary care provider or, if the individual has no primary care provider, the board of health of the health district in which the individual resides or the authority having the duties of a board of health for that district under section 3709.05 of the Revised Code. The notice shall be given not later than thirty days after the immunization is administered. Notification shall be conducted using one of the following methods that is capable of confirming delivery of the required notification:

(1) Electronic mail;

(2) Interoperable electronic medical records system;

(3) Facsimile;

(4) Electronic prescribing system;

(5) Electronic pharmacy record system;

(6) Reporting to the state’s immunization registry;

(7) Documented verbal communication; or

(8) Any other method of notification that might reasonably be expected to allow for the confirmed transmission of the required notification.

(J) For each immunization administered by a certified pharmacy technician or registered pharmacy technician to an individual who is younger than eighteen years of age, the certified pharmacy technician or registered pharmacy technician shall inform the individual's parent or legal guardian of the importance of well child visits with a pediatrician or other primary care provider and shall refer patients when appropriate.

~~(J)~~ (K) The pharmacy employing a certified or registered technician authorized to provide immunizations in accordance with this rule, shall maintain, or have immediate access to, the following records on file at the location(s) where the pharmacy technician administers immunizations in accordance with this rule:

(1) Proof of successful completion of a training course specified in paragraph (C) of this rule;

(2) Proof of maintenance of certification to perform basic life-support procedures in accordance with paragraph (B)(4) of this rule; and

(3) Proof of competency assessments as required in paragraph (F) of this rule.

~~**(K)**~~ **(L)** A pharmacist practicing within an outpatient pharmacy shall not supervise more than three pharmacy personnel engaged in the administration of immunizations pursuant to this rule and rule 4729:2-3-03 of the Ohio Administrative Code.

~~**(L)**~~ **(M)** A pharmacist supervising an immunization clinic outside of an outpatient pharmacy shall not supervise more than six pharmacy personnel engaged in the administration of immunizations pursuant to this rule and rule 4729:2-3-03 of the Ohio Administrative Code.

4729:8-3-03 - Electronic format required for the transmission of drug sales. (RESCIND CURRENT / NEW)

(A) All prescription dispensing information or prescriber personally furnishing information required to be submitted to the board pursuant to rule 4729-8-3-02 of the Administrative Code must be transmitted in the following format specified by the "American Society for Automation in Pharmacy" (ASAP) for prescription monitoring programs:

(1) ASAP Version 5.0 Standard for Prescription Drug Monitoring Programs (1/1/2024); or

(2) Until **December** ~~**May**~~ 1, 2025, ASAP Version 4.2A Standard for Prescription Drug Monitoring Programs (3/15/2017).

(B) The board's executive director or the director's designee may authorize up to a six-month extension to the implementation of ASAP Version 5.0 beyond April 1, 2025. Such extensions may only be considered if the pharmacy or prescriber has made all reasonable and prudent attempts to meet the deadline.

(C) In the event that a pharmacy or a prescriber cannot electronically transmit the required information pursuant to paragraph (A) of this rule, the pharmacy or prescriber may request a variance from the board's executive director or the director's designee to submit drug sales information in a mutually acceptable format.

(D) All wholesale data required to be submitted to the board of pharmacy pursuant to rule 4729-8-3-02 of the Administrative Code shall be transmitted in the report format used when transmitting controlled substance data to the federal drug enforcement administration via the "Automation of Reports and Consolidated Orders System (ARCOS)" or other mutually acceptable format.

(E) In the event that a drug distributor or terminal distributor cannot electronically transmit the required information pursuant to paragraph (D) of this rule, the drug distributor or terminal distributor may request a variance from the board's executive director or the director's designee to submit drug sales information in a mutually acceptable format.

4729:1-2-01 - Criteria for licensure by examination. (AMEND)

(A) Pursuant to sections 4729.07 and 4729.13 of the Revised Code, pharmacist licensure by examination shall consist of the "North American Pharmacist Licensure Examination" (NAPLEX) and the "Multistate Pharmacy Jurisprudence Examination" (MPJE) administered by the national association of boards of pharmacy (NABP). **Pursuant to sections 4729.07 and 4729.13 of the Revised Code, pharmacist licensure by examination shall consist of:**

(1) The "North American Pharmacist Licensure Examination" (NAPLEX) administered by the national association of boards of pharmacy (NABP); and

(2) A jurisprudence examination which shall be one of the following as determined by the board:

(a) The "Multistate Pharmacy Jurisprudence Examination" (MPJE) administered by the national association of boards of pharmacy (NABP); or

(b) A jurisprudence examination administered by NABP and approved by the board.

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4729:5-5-26 - Outpatient pharmacy delivery services. (NEW)

(A) As used in this rule,

(1) **"Business day" means any day, excluding holidays, where the pharmacy is open for business.**

(2) "Common carrier" means a person holding itself out to the general public to provide transportation for compensation.

(3) "Contract carrier" means a person providing transportation for compensation under continuing agreements with one person or a limited number of persons.

(4) Pharmacy delivery agent" means the United States postal service or common carrier, contract carrier, or employee of the ~~**pharmacy**~~ **terminal distributor of dangerous drugs** who delivers dangerous drugs that have been dispensed to a patient or agent of the patient.

(**5**) "Temperature sensitive drug" means any drug that is required to be stored at temperatures outside of controlled room temperature (59 degrees Fahrenheit to 86 degrees Fahrenheit).

(B) An outpatient pharmacy licensed as a terminal distributor of dangerous drugs providing delivery services of dispensed drugs and devices in this state shall comply with the following:

(1) Contact the patient or patient's caregiver for ~~**approval**~~ **consent** prior to any billing or delivery of a drug or device, except if the patient has provided general consent for delivery services. **Consent may be provided in writing, electronically, or verbally.**

(2) **In accordance with the patient's communication preferences, make available to** ~~**Notify**~~ the patient or patient's caregiver ~~**of**~~ the date shipped, method of delivery (e.g., mail, courier, drone, etc.), and expected arrival. **This information can be provided by electronic, telephonic, or any other manner that allows the patient to access the information required pursuant to this paragraph.**

(3) Take all appropriate measures to ensure that temperature sensitive drugs, will be maintained within the temperature ranges recommended by the manufacturer until the delivery has been completed.

(4) Provide notification to the patient, if the patient's prescription is a temperature sensitive drug, of the timeliness in addressing proper storage of the medication.

(5) Arrange for any controlled substances to require proof of delivery, which may include the signature of the receiving party.

(6) Assist patients with arranging access to medication from a local pharmacy if unable to delivery medications in the expected timeframe.

(7) Provide a method by which the patient or patient's caregiver can notify the pharmacy as to any irregularity in the delivery of the drug or device, including all of the following:

(a) Timeliness of delivery.

(b) Condition of the drug or device upon delivery.

(c) Failure to receive the proper drug or device.

(8) Ensure there is a process to inform the patient or patient's caregiver within **two business days** ~~**forty-eight hours**~~ of being notified of the delay if the scheduled delivery of the patient's prescription will be interrupted or late.

(C) **Upon notification of the dispensing pharmacy by the patient or patient's caregiver, a**ny drug or device which is compromised or lost **in transit** shall be replaced ~~**by the pharmacy**~~ at no additional cost to the patient. If the timeliness of the replacement will lead to an interruption in therapy, the outpatient pharmacy shall take all available steps to mitigate patient harm.

(D) Any drug or device that has been delivered to a patient or is no longer in the possession of a pharmacy delivery agent shall not be returned to stock in accordance with rule 4729:5-5-22 of the Administrative Code.

(E) An outpatient pharmacy shall maintain the following records for all drugs and devices delivered in accordance with this rule:

(1) Patient name;

(2) Patient address;

(3) Prescription number of drug or device being delivered;

(4) Name (brand name or generic) and dosage of each drug or device being delivered;

(5) Name of the pharmacy delivery agent who performed, or attempted to perform, the **delivery as follows:**

(a) For the United State Postal Service (USPS) or a common carrier, the record shall indicate the either USPS or the name of the common carrier.

(b) For a contract carrier, the record shall indicate the name of the contract carrier and the individual conducting the delivery on behalf of the contract carrier.

(c) For an employee of the terminal distributor of dangerous drugs, the record shall include the full name of the employee.

(F) All records maintained in accordance with this rule shall be readily retrievable and uniformly maintained for a period of three years.

(G) Except for deliveries performed by the United States Postal Service or common carrier, an outpatient pharmacy that utilizes a third-party to deliver drugs and devices shall enter into a contract with the third-party to ensure the following:

(1) The required records in paragraph (E) of this rule are provided to the contracting pharmacy; and

(2) The third-party entity agrees to cooperate with all investigations regarding the theft or **significant** loss of drugs and devices and produce required records listed in paragraph (E) of this rule within three business days of a request by an agent, officer, or inspector of the board.

(H) Theft or significant loss of any dangerous drugs shall be reported to the board in accordance with rule 4729:5-3-02 of the Administrative Code.