10/8/19

The following information is being provided pursuant to the requirements of Executive Order 2011-01K and Senate Bill 2 of the 129th General Assembly, which require state agencies, including the State of Ohio Board of Pharmacy, to draft rules in collaboration with stakeholders, assess and justify an adverse impact on the business community (as defined by S.B. 2), and provide an opportunity for the affected public to provide input on the following rules.

NEW

- 4729:5-5-19: Provides the requirements for the operation of an outpatient central fill pharmacy. A central fill pharmacy means a pharmacy licensed as a terminal distributor of dangerous drugs acting as an agent of an originating pharmacy to fill or refill a prescription or drug order.
- 4729:5-9-19: Provides the requirements for the operation of an inpatient central fill pharmacy. A central fill pharmacy means a pharmacy licensed as a terminal distributor of dangerous drugs acting as an agent of an originating pharmacy to fill or refill a prescription or drug order. [NOTE: This rule is part of a developing rule chapter on institutional pharmacies. The numbering of the rule is subject to change]
- 4729:5-3-17: Provides the standards for the operation of an automated pharmacy system. An automated pharmacy system means a mechanical system that performs operations or activities, other than administration, relative to storage, packaging, compounding, dispensing, or distribution of dangerous drugs that collects, controls, and maintains transaction information and records.
- 4729:5-3-18: Provides the procedures to be followed by a terminal distributor that dispenses or personally furnishes drugs in the event of a manufacturer recall.
- 4729:5-9-20: Permits a pharmacist to engage in remote order processing of prescriptions for an institutional pharmacy. [NOTE: This rule is part of a developing rule chapter on institutional pharmacies. The numbering of the rule is subject to change]
- 4729:5-5-20: Permits a pharmacist to engage in remote order processing of prescriptions for an outpatient pharmacy.
- 4729:5-4-02: Requires a pharmacy to report the termination or resignation of a licensed/registered employee that was based on any of the following: errors in dispensing, engaging in unprofessional conduct, being suspected of abusing alcohol or drugs, or for physical or mental impairment.

RESCIND

- 4729-5-35: Provides the current standards for automated drug delivery systems.
- 4729-5-28: Provides the current standards for central fill pharmacies.

77 SOUTH HIGH STREET | 30TH FLOOR | COLUMBUS, OHIO 43215-6117

CSIPublicComments@governor.ohio.gov

Comments on the proposed rules will be accepted until close of business on **October 25, 2019**. Please send all comments to the following email address: **RuleComments@pharmacy.ohio.gov**

In addition, please copy your comments to: **CSIPublicComments@governor.ohio.gov**

Business Impact Analysis

Agency, Board, or Commission Name: State of Ohio Board of Pharmacy

Rule Contact Name and Contact Information:

Cameron McNamee (cameron.mcnamee@pharmacy.ohio.gov)

Regulation/Package Title (a general description of the rules' substantive content):

Terminal Distributors of Dangerous Drugs

Rule Number(s): 4729:5-5-19 (NEW); 4729:5-9-19 (NEW); 4729:5-3-17 (NEW); 4729:5-3-18 (NEW); 4729:5-9-20 (NEW); 4729:5-5-20 (NEW); 4729:5-4-02 (NEW); 4729-5-35 (RESCIND); 4729-5-28 (RESCIND)

Date of Submission for CSI Review: 10/8/2019

Public Comment Period End Date: 10/25/2019

Rule Type/Number of Rules:

- ✓ New/ 7 rules
- ▪ Rescinded/ 2 rules (FYR? Y)

The Common Sense Initiative is established in R.C. 107.61 to eliminate excessive and duplicative rules and regulations that stand in the way of job creation. Under the Common Sense Initiative, agencies must balance the critical objectives of regulations that have an adverse impact on business with the costs of compliance by the regulated parties. Agencies

should promote transparency, responsiveness, predictability, and flexibility while developing regulations that are fair and easy to follow. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

Reason for Submission

1. **R.C. 106.03 and 106.031 require agencies, when reviewing a rule, to determine whether the rule has an adverse impact on businesses as defined by R.C. 107.52. If the agency determines that it does, it must complete a business impact analysis and submit the rules for CSI review.**

   Which adverse impact(s) to businesses has the agency determined the rule(s) create?

   The rule:

____ **a. Requires a license, permit, or any other prior authorization to engage in or operate a line of business.**

Yes. Rule 4279:5-3-17 requires Board approval of an automated pharmacy system.

____ **b. Imposes a criminal penalty, a civil penalty, or another sanction, or creates a cause of action for failure to comply with its terms.**

Yes. Violation of any of the rules in this package may result in administrative licensure discipline for a terminal distributor of dangerous drugs. Discipline might include reprimand, suspension of a license, monetary fine and/or revocation of a license.

____ **c. Requires specific expenditures or the report of information as a condition of compliance.**

Yes. Rule 4729:5-4-02 requires a pharmacy to report the termination or resignation of an employee that was based on any of the following: errors in dispensing, engaging in unprofessional conduct, being suspected of abusing alcohol or drugs, or for physical or mental impairment.

____ **d. Is likely to directly reduce the revenue or increase the expenses of the lines of business to which it will apply or applies.**

Yes. The rules in this package will increase administrative costs on licensees that engage in certain activities.

Regulatory Intent

2. Please briefly describe the draft regulation in plain language.
Please include the key provisions of the regulation as well as any proposed amendments.

NEW

- 4729:5-5-19: Provides the requirements for the operation of an outpatient central fill pharmacy. A central fill pharmacy means a pharmacy licensed as a terminal distributor of dangerous drugs acting as an agent of an originating pharmacy to fill or refill a prescription or drug order.
- 4729:5-9-19: Provides the requirements for the operation of an inpatient central fill pharmacy. A central fill pharmacy means a pharmacy licensed as a terminal distributor of dangerous drugs acting as an agent of an originating pharmacy to fill or refill a prescription or drug order. [NOTE: This rule is part of a developing rule chapter on institutional pharmacies. The numbering of the rule is subject to change]
- 4729:5-3-17: Provides the standards for the operation of an automated pharmacy system. An automated pharmacy system means a mechanical system that performs operations or activities, other than administration, relative to storage, packaging, compounding, dispensing, or distribution of dangerous drugs that collects, controls, and maintains transaction information and records.
- 4729:5-3-18: Provides the procedures to be followed by a terminal distributor in the event of a manufacturer recall.
- 4729:5-9-20: Permits a pharmacist to engage in remote order processing of prescriptions for an institutional pharmacy. [NOTE: This rule is part of a developing rule chapter on institutional pharmacies. The numbering of the rule is subject to change]
- 4729:5-5-20: Permits a pharmacist to engage in remote order processing of prescriptions for an outpatient pharmacy.
- 4729:5-4-02: Requires a pharmacy to report the termination or resignation of a licensed/registered employee that was based on any of the following: errors in dispensing, engaging in unprofessional conduct, being suspected of abusing alcohol or drugs, or for physical or mental impairment.

RESCIND

- 4729-5-35: Provides the current standards for automated drug delivery systems.
- 4729-5-28: Provides the current standards for central fill pharmacies.

3. **Please list the Ohio statute(s) that authorize the agency, board or commission to adopt the rule(s) and the statute(s) that amplify that authority.**

   The proposed rules are authorized by sections 4729.26 and 3719.28 of the Ohio Revised Code.

4. **Does the regulation implement a federal requirement? Is the proposed regulation being adopted or amended to enable the state to obtain or maintain approval to administer and enforce a federal law or to participate in a federal program?**
   If yes, please briefly explain the source and substance of the federal requirement.

   These rules exceed federal requirements because the regulation of the practice of pharmacy has traditionally been done at the state level. Per Ohio law, the Board regulates all aspects of pharmacy practice and the distribution of dangerous drugs.

5. **If the regulation includes provisions not specifically required by the federal government, please explain the rationale for exceeding the federal requirement.**

   Section 4729.26 of the Ohio Revised Code authorizes the Board of Pharmacy to adopt rules governing the practice of pharmacy and distribution of dangerous drugs.

   Section 3719.28 of the Ohio Revised Code authorizes the Board of pharmacy to adopt rules governing controlled substances.

   The Board is exceeding existing federal requirements because the subject areas addressed in this rule package are not addressed by federal regulations, as the practice of pharmacy and distribution of dangerous drugs in this state is, by law, the responsibility of the Board of Pharmacy.

6. **What is the public purpose for this regulation (i.e., why does the Agency feel that there needs to be any regulation in this area at all)?**

   These rules are necessary to ensure uniform standards for:

   - Central fill pharmacies engaged in outpatient and inpatient dispensing;
   - Safety and security requirements for automated pharmacy systems;
   - Drug recalls;

- Reporting of the termination/resignation of licensed/registered pharmacy employees for errors, unprofessional conduct (including sexual misconduct), being suspected of abusing alcohol or drugs, or physical or mental impairment;
- Remote order entry performed by pharmacists.

7. **How will the Agency measure the success of this regulation in terms of outputs and/or outcomes?**

   The success of the regulations will be measured by having rules written in plain language, licensee compliance with the rules, and minimal questions from licensees regarding the provisions of the rules.

8. **Are any of the proposed rules contained in this rule package being submitted pursuant to R.C. 101.352, 101.353, 106.032, 121.93, or 121.931?**
   If yes, please specify the rule number(s), the specific R.C. section requiring this submission, and a detailed explanation.

   No.

Development of the Regulation

9. **Please list the stakeholders included by the Agency in the development or initial review of the draft regulation.**
   If applicable, please include the date and medium by which the stakeholders were initially contacted.

   This rule package was reviewed by the Board's Rules Review Committee. The Committee, composed of pharmacists from a number of practice settings, is responsible for reviewing and approving all new rules and those that must be reviewed prior to their legislatively mandated five-year review date.

10. **What input was provided by the stakeholders, and how did that input affect the draft regulation being proposed by the Agency?**

    The following changes were incorporated into the rule package as a result of stakeholder feedback:

    Rule 4729:5-9-19: Members of the Committee representing institutions requested a separate central fill rule be adopted for institutional pharmacies. Therefore, this rule is being proposed.

Rule 4729:5-3-17: Committee members requested the addition of a standard form for documenting the required metrics for automated pharmacy systems. The committee members also requested that registered pharmacy technicians and technician trainees be permitted to stock automated pharmacy systems.

Rule 4729:5-3-18: Committee members requested that recall policies only apply to "drugs stocked by the terminal distributor." They also requested that the responsible person be able to have a designee be notified of a recall.

Rule 4729:5-9-20: Committee members requested the use of one training program to cover all institutional pharmacies under common ownership and control.

Rule 4729:5-5-20: Committee members requested the use of one training program to cover all outpatient pharmacies under common ownership and control.

Rule 4729:5-4-02: Committee members requested that "resignation" be added to the reporting requirements. They also recommended adding termination/resignation that was the result of a licensed/registered employee being suspected of abusing alcohol or drugs or for physical or mental impairment.

11. What scientific data was used to develop the rule or the measurable outcomes of the rule? How does this data support the regulation being proposed?

Scientific data was not used to develop or review this rule package.

12. What alternative regulations (or specific provisions within the regulation) did the Agency consider, and why did it determine that these alternatives were not appropriate? If none, why didn't the Agency consider regulatory alternatives?

As the regulations are essential to protecting the public's safety by ensuring uniform standards for the safe distribution of dangerous drugs and the responsible practice of pharmacy, the State of Ohio Board of Pharmacy did not consider any regulatory alternatives.

13. Did the Agency specifically consider a performance-based regulation? Please explain. ***Performance-based regulations define the required outcome, but don't dictate the process the regulated stakeholders must use to achieve compliance.***

The agency did not consider performance-based regulations for this rule package. It is the Board's responsibility to ensure uniform practice standards across Ohio. At this juncture, it was the determination of the Board that the rule package did not lend itself to performance-based regulations.

14. What measures did the Agency take to ensure that this regulation does not duplicate an existing Ohio regulation?

The Board of Pharmacy's Director of Policy and Communications reviewed the proposed rules to ensure that the regulations do not duplicate another State of Ohio Board of Pharmacy regulation.

15. Please describe the Agency's plan for implementation of the regulation, including any measures to ensure that the regulation is applied consistently and predictably for the regulated community.

The regulations will be included in the Board's internal electronic inspection system. This system includes guidance to all staff on how to consistently and predictably apply the rules.

Additionally, the Board will incorporate the rules into external inspection guides. These guides closely mirror the Board's internal inspection system and provide the opportunity for licensees to conduct self-inspections.

Adverse Impact to Business

16. Provide a summary of the estimated cost of compliance with the rule. Specifically, please do the following:

a. Identify the scope of the impacted business community; and

- Terminal distributors of dangerous drugs.

b. Identify the nature of all adverse impact (e.g., fees, fines, employer time for compliance,); and

Violation of these rules may result in administrative licensure discipline for a terminal distributor of dangerous drugs. Discipline might include reprimand, suspension of a license, monetary fine and/or revocation of a license. Additionally, licensees may experience and increase in employer time for compliance.

c. Quantify the expected adverse impact from the regulation.
The adverse impact can be quantified in terms of dollars, hours to comply, or other factors; and may be estimated for the entire regulated population or for a "representative business." Please include the source for your information/estimated impact.

- 4729:5-5-19: Provides the requirements for the operation of an outpatient central fill pharmacy. A central fill pharmacy means a pharmacy licensed as a terminal distributor of dangerous drugs acting as an agent of an originating pharmacy to fill or refill a prescription or drug order. This rule incorporates most of the requirements of the existing rules for central fill pharmacies. Therefore, central fill pharmacies currently licensed by the Board should not experience an overall increase in costs. Costs for new licensees may include staff time to develop policies and procedures and IT costs associated with making sure the licensee can meet the labeling and record keeping requirements.
- 4729:5-9-19: Provides the requirements for the operation of an inpatient central fill pharmacy. A central fill pharmacy means a pharmacy licensed as a terminal distributor of dangerous drugs acting as an agent of an originating pharmacy to fill or refill a prescription or drug order. This rule incorporates most of the requirements of the existing rules for central fill pharmacies. Therefore, central fill pharmacies currently licensed by the Board should not experience an overall increase in costs. Costs for new licensees may include staff time to develop policies and procedures and IT costs associated with making sure the licensee can meet the labeling and record keeping requirements.
- 4729:5-3-17: Provides the standards for the operation of an automated pharmacy system. An automated pharmacy system means a mechanical system that performs operations or activities, other than administration, relative to storage, packaging, compounding, dispensing, or distribution of dangerous drugs that collects, controls, and maintains transaction information and records. This rule incorporates most of the existing requirements for automated pharmacy systems (OAC 4729-5-35) and Board policies on the operation of automated pharmacy systems. Costs of this rule include the time/staff necessary to conduct the required 90-day review of all medications dispensed by the system to ensure the safety of the system. Additionally, this rule requires submission of a request to review and approve the system. This can be done by contacting the licensee's local inspector via phone or email.
- 4729:5-3-18: Provides the procedures to be followed by a terminal distributor in the event of a manufacturer recall. This is a new rule requiring terminal distributors that dispense or personally furnish drugs to develop and implement a policy in the event of a manufacturer recall. The cost of this rule is employer time to develop written policies addressing drug recalls and staff time to quarantine drugs subject to recall.

- 4729:5-9-20: Permits a pharmacist to engage in remote order processing of prescriptions for an institutional pharmacy. The cost of compliance is the cost of developing a contract and training on the responsibilities associated with remote medication order processing by off-site pharmacists and ensuring that remote pharmacists have access to the pharmacy's electronic patient information system.
- 4729:5-5-20: Permits a pharmacist to engage in remote order processing of prescriptions for an outpatient pharmacy. The cost of compliance is the cost of developing a contract and training on the responsibilities associated with remote medication order processing by off-site pharmacists and ensuring that remote pharmacists have access to the pharmacy's electronic patient information system.
- 4729:5-4-02: Requires a pharmacy to report the termination or resignation of a licensed/registered employee that was based on any of the following: errors in dispensing, engaging in unprofessional conduct, being suspected of abusing alcohol or drugs, or for physical or mental impairment. The cost of this rule is the employer's time to submit notification to the Board of Pharmacy. Notification will consist of a two-page form that must be submitted electronically by the employer within 10 days of termination or resignation.

17. Why did the Agency determine that the regulatory intent justifies the adverse impact to the regulated business community?

The Board determined that the regulatory intent justifies the impact on business because the regulations protect and promote public safety by ensuring uniform standards for the distribution of drugs and practice of pharmacy. Additionally, the rule package requires the reporting of the termination of employees that are licensed by the Board for actions that may endanger the public. It is in the public's interest to ensure that proper safeguards are implemented to report individuals who present a danger to the public, ensure recalled drugs are not dispensed or personally furnished to patients, and to maintain accountability for the care provided by pharmacists.

Regulatory Flexibility

18. Does the regulation provide any exemptions or alternative means of compliance for small businesses? Please explain.

The rules do not provide any exemptions or alternative means of compliance for small businesses. The law does not differentiate on the size of the business and therefore the regulation is uniform across Ohio.

19. How will the agency apply Ohio Revised Code section 119.14 (waiver of fines and penalties for paperwork violations and first-time offenders) into implementation of the regulation?

The State of Ohio Board of Pharmacy does not fine licensees or impose penalties for first-time paperwork violations. However, any failure of a standard of care in the practice of pharmacy or the distribution of dangerous drugs is not considered a paperwork error but a quality assurance issue by the licensee that is necessary for the protection of the public.

20. What resources are available to assist small businesses with compliance of the regulation?

Board of Pharmacy staff is available by telephone and e-mail to answer questions. Board staff members also provide presentations to groups and associations who seek updates on current regulations and host regional meetings to discuss changes to Ohio laws and rules. Additionally, staff are trained to educate licensees on compliance with all Board of Pharmacy rules and regulations.

Lastly, the Board will incorporate the rules into external inspection guides. These guides closely mirror the Board's internal inspection system and provide the opportunity for licensees to conduct self-inspections.

4729:5-5-19 - Central Fill Pharmacies (replaces OAC 4729-5-28)

(A) As used in this section:

(1) "Central fill pharmacy" means a pharmacy licensed as a terminal distributor of dangerous drugs acting as an agent of an originating pharmacy to fill or refill a prescription. A central fill pharmacy may also be the originating pharmacy pursuant to paragraph (D) of this rule.

(2) "Originating pharmacy" means an outpatient pharmacy licensed as a terminal distributor of dangerous drugs that uses a central fill pharmacy to fill or refill a prescription.

(B) A central fill pharmacy and originating pharmacy may process a request for the filling or refilling of a prescription received by an originating pharmacy only pursuant to the following requirements:

(1) The central fill pharmacy either has the same owner as the originating pharmacy or has a written contract with the originating pharmacy outlining the services to be provided and the responsibilities of each pharmacy in fulfilling the terms of the contract in compliance with federal and state law.

(2) The central fill pharmacy shall maintain a record of all originating pharmacies, including name, address, terminal distributor number, and drug enforcement administration registration number, for which it processes a request for the filling or refilling of a prescription received by the originating pharmacy. The record shall be made readily retrievable and maintained for a period of three years.

(3) The central fill pharmacy and originating pharmacy shall have access to common electronic files as part of a real time, online database or have appropriate technology to allow secure access to sufficient information necessary or required to dispense or process the prescription.

(4) The originating pharmacy shall comply with the minimum required information for a patient profile pursuant to rule 4729:5-5-07 of the Administration Code prior to sending a prescription to the central fill pharmacy.

(5) The originating pharmacy shall remain responsible for compliance with the dangerous drug dispensing requirements of this chapter and the compounding requirements of chapter 4729:7-2 of the Administrative Code that are not assumed in writing by the central fill pharmacy.

(6) Except as provided in paragraph (D) of this rule, the originating pharmacy shall be solely responsible to perform and comply with the patient counseling requirements of rule 4729:5-5-09 of the Administrative Code.

(7) The prescription label attached to the container shall contain the name and address of the originating pharmacy and the name of the central fill pharmacy. The date on which the prescription was dispensed shall be the date on which the central fill pharmacy filled the prescription.

(8) The originating pharmacy shall maintain the original of all prescription orders received for purposes of filing and recordkeeping as required by state and federal law, rules, and regulations.

(9) The central fill pharmacy shall maintain all original fill and refill requests received from the originating pharmacy and shall treat them as original and refill prescription orders for purposes of filing and recordkeeping as required by state and federal law, rules, and regulations.

(10) The central fill pharmacy and originating pharmacy shall each maintain records to capture the positive identification of the licensed or registered individuals responsible for performing activities in accordance with paragraph (A) of rule 4729:5-5-04 of the Administrative Code.

(11) The central fill pharmacy and originating pharmacy shall adopt a written quality assurance program for pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, resolve identified problems and ensure compliance with this rule. The quality assurance plan shall be reviewed and updated annually.

(C) No dangerous drugs shall be returned to the central fill pharmacy by the originating pharmacy. The originating pharmacy may return dangerous drugs to stock shelves in accordance with rule 4729:5-5-22 of the Administrative Code.

(D) A central fill pharmacy may dispense a prescription directly to a patient pursuant to the following requirements:

(1) A prospective drug utilization review is conducted pursuant to a written contract or agreement in accordance with rule 4729:5-5-08 of the Administrative Code;

(2) Patient counseling is provided pursuant to a written contract or agreement in accordance with rule 4729:5-5-09 of the Administrative Code;

(3) The dispensing is conducted in accordance with all other applicable state and federal laws, regulations and rules, including those specified in Federal Register Citation 68 FR 37405 (7/24/2003).

(E) All written documentation required by this rule shall be maintained for three years from the date of execution or review and shall be made readily retrievable.

4729:5-9-19 - Central Fill Pharmacies (NOTE: For Institutional Pharmacies)

(A) As used in this section:

(1) "Central fill pharmacy" means a pharmacy licensed as a terminal distributor of dangerous drugs acting as an agent of an originating pharmacy to fill or refill a prescription or drug order.

(2) "Originating pharmacy" means an institutional pharmacy licensed as a terminal distributor of dangerous drugs that uses a central fill pharmacy to fill or refill a prescription or drug order.

(B) A central fill pharmacy and originating pharmacy may process a request for the filling or refilling of a prescription or drug order received by an originating pharmacy only pursuant to the following requirements:

(1) The central fill pharmacy either has the same owner as the originating pharmacy or has a written contract with the originating pharmacy outlining the services to be provided and the responsibilities of each pharmacy in fulfilling the terms of the contract in compliance with federal and state law.

(2) The central fill pharmacy shall maintain a record of all originating pharmacies, including name, address, terminal distributor number, and drug enforcement administration registration number, for which it processes a request for the filling or refilling of a prescription received by the originating pharmacy. The record shall be made readily retrievable and maintained for a period of three years.

(3) The central fill pharmacy and originating pharmacy shall have access to common electronic files as part of a real time, online database or have appropriate technology to allow secure access to sufficient information necessary or required to dispense or process the prescription.

(4) The originating pharmacy shall comply with the minimum required information for a patient profile pursuant to rule 4729:5-9-XX of the Administration Code prior to sending a prescription to the central fill pharmacy.

(5) The originating pharmacy shall remain responsible for compliance with the dangerous drug dispensing requirements of this chapter and the compounding requirements of chapter 4729:7-2 of the Administrative Code that are not assumed in writing by the central fill pharmacy.

(6) The prescription label attached to the container shall contain the name and address of the originating pharmacy and the name of the central fill pharmacy. The date on which the prescription was dispensed shall be the date on which the central fill pharmacy filled the prescription.

(7) The originating pharmacy shall maintain the original of all prescription orders received for purposes of filing and recordkeeping as required by state and federal law, rules, and regulations.

(8) The central fill pharmacy shall maintain all original fill and refill requests received from the originating pharmacy and shall treat them as original and refill prescription orders for purposes of filing and recordkeeping as required by state and federal law, rules, and regulations.

(9) The central fill pharmacy and originating pharmacy shall each maintain records to capture the positive identification of the licensed or registered individuals responsible for performing activities in accordance with rule 4729:5-9-XX of the Administrative Code.

(10) The central fill pharmacy and originating pharmacy shall adopt a written quality assurance program for pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, resolve identified problems and ensure compliance with this rule. The quality assurance plan shall be reviewed and updated annually.

(C) No dangerous drugs shall be returned to the central fill pharmacy by the originating pharmacy. The originating pharmacy may return dangerous drugs to stock shelves in accordance with rule 4729:5-3-16 of the Administrative Code.

(D) All written documentation required by this rule shall be maintained for three years from the date of execution or review and shall be made readily retrievable.

(E) An institutional pharmacy may utilize a central fill pharmacy to dispense outpatient prescriptions in accordance with rule 4729:5-5-19.

4729:5-3-17 Automated pharmacy systems. (Replaces automated drug delivery system – 4729-5-35)

(A) As used in this rule:

(1) “Automated pharmacy system” means a mechanical system that performs operations or activities, other than administration, relative to storage, packaging, compounding, dispensing, or distribution of dangerous drugs that collects, controls, and maintains transaction information and records.

“Automated pharmacy system” does not include an “automated drug storage system” utilized by institutional facilities pursuant to Chapter 4729:5-9 of the Administrative Code or other locations licensed as terminal distributors of dangerous drugs.

[THIS IS NOT PART OF THE RULE - NOTE: “Automated drug storage system” means a mechanical system used for the secure storage of dangerous drugs used as floor stock or contingency drugs outside of an institutional pharmacy that collects, controls, and maintains transaction information and records. These are more machines for the storage of drugs (ex. Pyxis) rather than more sophisticated machines that prepare and package drugs.]

(2)

(a) "Dispense" means the final association of a drug with a particular patient pursuant to a prescription, drug order, or other lawful order of a prescriber and the professional judgment of and the responsibility for interpreting, preparing, compounding, labeling, and packaging a specific drug.

(b) In the case of an automated pharmacy system, the final association will be deemed to have occurred when the pharmacist has given final approval to the patient specific prescription in the system.

(3) “Non-hospital institutional facility” has the same meaning as in rule 4729:5-9-01 of the Administrative Code.

[THIS IS NOT PART OF THE RULE - NOTE: “Non-hospital facility” means a facility licensed as a terminal distributor of dangerous drugs where medical care is provided on site and a medical record documenting episode of care, including dangerous drugs ordered, dispensed, and administered, is maintained that includes any of the following:

(1) A freestanding inpatient rehabilitation facility or inpatient rehabilitation facility as defined in rule 3701-83-25 of the Administrative Code.

(2) An ambulatory surgical facility as defined in rule 3701-83-15 of the Administrative Code.

(3) A nursing home licensed under Chapter 3721. of the Revised Code, skilled nursing facility that meets the requirements for participation in medicare, or nursing facility that meets the requirements for participation in Medicaid.

(4) An inpatient psychiatric service provider as defined in rule 5122-14-01 of the Administrative Code.

(5) A facility that provides twenty-four-hour medically supervised detoxification services (level III) that is certified by the Ohio department of mental health and addiction services.

(6) A state or local correctional facility, as defined in section 5163.45 of the Revised Code.

(7) Any other facility as determined by the board.]

(4) "Positive identification" has the same meaning as in rule 4729:5-5-01 of the Administrative Code.

(B) An automated pharmacy system must be approved in accordance with this rule by the board prior to its implementation by the terminal distributor of dangerous drugs.

(1) Prior to the approval of an automated pharmacy system, the board shall receive a request from the responsible person on the terminal distributor of dangerous drugs license. Upon notification, the board shall conduct an inspection of the system to determine if it meets the requirements of this rule.

(2) For automated pharmacy systems that dispense dangerous drugs in accordance with paragraph (A)(2)(b) of this rule, the responsible person of the licensed terminal distributor of dangerous drugs shall be required to have a pharmacist verify for accuracy all dangerous drugs dispensed by the system for a continuous ninety-day period. The responsible person shall compile metrics, using a form developed by the board, documenting the performance of the system during this period.

(3) Approval of all automated pharmacy systems shall be site-specific.

(4) If an inspection does not result in the approval of an automated pharmacy system, the responsible person named on the terminal distributor of dangerous drugs may request an in-person meeting with the board to appeal the denial.

(C) An automated pharmacy system shall be located on the premises of a licensed terminal distributor of dangerous drugs.

(D) A terminal distributor of dangerous drugs operating an automated pharmacy system shall maintain the following documentation on-site in a readily retrievable manner:

(1) The manufacturer's name and model;

(2) A description of how the automated pharmacy system is used; and

(3) Policies and procedures for system operation, safety, security, accuracy, patient confidentiality, access, and malfunction.

(E) For automated pharmacy systems that dispense dangerous drugs in accordance with paragraph (A)(2)(b) of this rule, the terminal distributor of dangerous drugs shall implement a quality assurance program to determine continued appropriate use of the automated pharmacy system. The quality assurance program shall monitor the performance of the automated pharmacy system, ensure the system is in good working order and accurately prepares the correct strength, dosage form, and quantity of the drug prescribed. At a minimum, the quality assurance program shall consist of a review of at least ten percent of all dispensed prescriptions over the daily operational hours of the automated pharmacy system.

(F) An Ohio-licensed pharmacist shall verify using positive identification the dangerous drugs selected for stocking of the automated pharmacy system prior to the drugs being stocked or loaded in the system.

(G) A registered or certified pharmacy technician, pharmacy technician trainee or licensed nurse may stock an automated pharmacy system provided that:

(1) The container, canister, or other dangerous drug storage device being stocked by the technician or nurse is tamper evident and verified by an Ohio-licensed pharmacist and documented using positive identification;

(2) The system uses verification technology such as bar code scanning, electronic, or other technology;

(3) The positive identification of the individual stocking the system is documented;

(4) The terminal distributor's responsible person or a pharmacist delegated by the responsible person determines if the person is competent to stock any automated pharmacy system;

(5) A pharmacist is fully responsible for all activities conducted by the registered or certified pharmacy technician, pharmacy technician trainee or nurse licensed or registered in accordance with chapter 4723. of the Revised Code.

(6) A pharmacist must be immediately available to answer questions or discuss the stocking of an automated pharmacy system; and

(7) A registered pharmacy technician or pharmacy technician trainee shall be acting under the personal supervision of a pharmacist.

(H) Except for an automated pharmacy system in a non-hospital institutional facility, an Ohio-licensed pharmacist shall be physically present at the terminal distributor of dangerous drugs to provide supervision of the automated pharmacy system.

(I) The automated pharmacy system shall have security to prevent unauthorized individuals from accessing or obtaining dangerous drugs and includes safeguards to detect diversion of dangerous drugs. This shall include the use of tamper-evident containers, canisters, and other storage devices for use in non-hospital institutional facilities.

(J) The records kept by the automated pharmacy system shall comply with the applicable recordkeeping requirements of division 4729:5 of the Administrative Code and shall also capture the following information:

(1) All events involving the contents of the automated pharmacy system shall be recorded electronically.

(2) Records must be maintained by the terminal distributor for three years and shall be readily retrievable.

4729:5-3-18 – Dangerous drug recall procedures. (NEW)

(A) A terminal distributor of dangerous drugs shall develop and implement a written procedure for the management of recalls by the manufacturer for dangerous drugs stocked by the terminal distributor. Such procedures shall include, where appropriate, contacting patients to whom the recalled drug products have been dispensed or personally furnished.

(B) The written procedure shall include, but not be limited to, the following:

(1) The terminal distributor shall reasonably ensure that a recalled drug has been removed from inventory no more than twenty-four hours after receipt of the recall notice by the responsible person or the responsible person's designee, and quarantined until proper disposal, destruction, or return of the drug;

(2) If the drug that is the subject to a recall is maintained by the terminal distributor in a container without a lot number, the terminal distributor shall consider this drug included in the recall; and

(3) Maintaining records for activities taken by the terminal distributor in relation to a drug recall.

(C) The written procedures shall be updated as necessary and maintained in a readily retrievable manner. All records documenting recall activities shall be maintained for three years and shall be made readily retrievable.

4729:5-9-20 - Remote Medication Order Processing. (NEW)

(A) As used in this rule:

(1) “Remote medication order processing” means the processing of a medication order for an institutional pharmacy licensed as a terminal distributor of dangerous drugs by a remote pharmacist. Remote medication order processing does not include the dispensing of a drug, but may include receiving, interpreting, evaluating, clarifying and approval of medication orders. Additionally, remote medication order processing may include order entry, other data entry, performing prospective drug utilization review, interpreting clinical data, performing therapeutic interventions, and providing drug information services, and authorizing release of the medication for administration.

(2) “Remote medication order processing pharmacy” or “remote pharmacy” means either:

(a) A pharmacy licensed as a terminal distributor of dangerous drugs that dispenses dangerous drugs; or

(b) A pharmacy licensed as a limited category II terminal distributor of dangerous drugs which does not stock, own, or dispense any dangerous drugs, and whose sole business consists of entry, review, and/or verification of prescriber orders and consulting services under contract for institutional pharmacies in this state.

(3) “Remote pharmacist” means any Ohio licensed pharmacist, either employed or a contract employee of an institutional pharmacy or remote medication order processing pharmacy, processing the medication order from a remote site.

(B) An institutional pharmacy may outsource medication order processing to a remote medication order processing pharmacy provided the pharmacies are under common ownership or control or the institutional pharmacy has entered into a written contract or agreement with a pharmacy that outlines the services to be provided and the responsibilities and accountabilities of each party to the contract or agreement in compliance with federal and state statutes and regulations.

(C) The institutional pharmacy and remote medication order processing pharmacy must maintain a copy of the contract or agreement in a readily retrievable manner for inspection and review by an agent, inspector, or employee of the board.

(D) An institutional pharmacy utilizing a remote medication order processing pharmacy shall ensure that all pharmacists providing such services have been trained on the institutional pharmacy's policies and procedures relating to medication order processing. The training of each pharmacist shall be documented.

(1) Such training shall include, but is not limited to, policies on drug and food allergy documentation, abbreviations, administration times, automatic stop orders, substitution, and formulary compliance. The institutional pharmacy and the remote medication order processing pharmacy shall jointly develop a procedure to communicate changes in policies and procedures related to medication order processing.

(2) A terminal distributor of dangerous drugs may utilize one training program for all institutional pharmacies under the terminal distributor's common ownership and control.

(E) An institutional pharmacy utilizing a remote pharmacist shall maintain a record of the name and license number of such pharmacist, evidence of current licensure in this state, and the address of each location where the pharmacist will be providing remote order entry services.

(F) The responsible person of an institutional pharmacy shall ensure that any remote pharmacist shall have secure electronic access to the institutional pharmacy's patient information system and to other electronic systems that the on-site pharmacist has access to when the pharmacy is open.

(G) The remote pharmacist must be able to contact the prescriber issuing a medication order to discuss any concerns identified during the pharmacist's review of patient information and the order. A procedure must be in place to communicate any problems identified with the prescriber and the nursing staff providing direct patient care.

(H) Each remote entry record must comply with all recordkeeping requirements for institutional pharmacies, including capturing the positive identification of the remote pharmacist involved in the review and verification of the medication order.

(I) An institutional pharmacy utilizing remote medication order processing is responsible for maintaining records of all medication orders entered into their information system, including orders entered by a remote pharmacist. The system shall have the ability to audit the activities of the remote pharmacists.

(J) An institutional pharmacy utilizing remote medication order processing services shall maintain a policy and procedure manual. A remote pharmacy shall maintain a copy of those portions of the policy and procedure manual that relate to that pharmacy's operations. Each manual shall:

(1) Outline the responsibilities of the institutional pharmacy and the remote pharmacy;

(2) Include a list of the names, addresses, telephone numbers, and all license numbers of the pharmacies/pharmacists involved in remote medication order processing; and

(3) Include policies and procedures for:

(a) Protecting the confidentiality and integrity of patient information;

(b) Ensuring that no patient information is duplicated, downloaded, or removed from the institutional pharmacy's patient information system;

(c) Maintaining appropriate records of each pharmacist involved in order processing;

(d) Complying with federal and state statutes and regulations;

(e) Annually reviewing the written policies and procedures and documentation of the annual review; and

(f) Annually reviewing the competencies of pharmacists providing remote order entry processing services.

4729:5-5-20 - Remote Medication Order Processing. (NEW)

(A) As used in this rule:

(1) “Remote medication order processing” means the processing of a medication order (prescription) for an outpatient pharmacy licensed as a terminal distributor of dangerous drugs by a remote pharmacist. Remote medication order processing does not include the dispensing of a drug, but may include receiving, interpreting, evaluating, clarifying and approval of medication orders. Additionally, remote medication order processing may include order entry, other data entry, performing prospective drug utilization review, interpreting clinical data, performing therapeutic interventions, and providing drug information services, and authorizing release of the medication for administration.

(2) “Remote medication order processing pharmacy” or “remote pharmacy” means either:

(a) A pharmacy licensed as a terminal distributor of dangerous drugs that dispenses dangerous drugs; or

(b) A pharmacy licensed as a limited category II terminal distributor of dangerous drugs which does not stock, own, or dispense any dangerous drugs, and whose sole business consists of entry, review, and/or verification of prescriber orders and consulting services under contract for outpatient pharmacies in this state.

(3) “Remote pharmacist” means any Ohio licensed pharmacist, either employed or a contract employee of an outpatient pharmacy or remote medication order processing pharmacy, processing the medication order from a remote site.

(B) An outpatient pharmacy may outsource medication order processing to a remote medication order processing pharmacy provided the pharmacies are under common ownership or control or the outpatient pharmacy has entered into a written contract or agreement with a pharmacy that outlines the services to be provided and the responsibilities and accountabilities of each party to the contract or agreement in compliance with federal and state statutes and regulations.

(C) The outpatient pharmacy and remote medication order processing pharmacy must maintain a copy of the contract or agreement in a readily retrievable manner for inspection and review by an agent, inspector, or employee of the board.

(D) An outpatient pharmacy utilizing a remote medication order processing pharmacy shall ensure that all pharmacists providing such services have been trained on the outpatient pharmacy's policies and procedures relating to medication order processing. The training of each pharmacist shall be documented.

(1) Such training shall include, but is not limited to, policies on drug and food allergy documentation, abbreviations, substitution, and prospective drug utilization review requirements in accordance with rule 4729:5-5-08 of the Administrative Code. The outpatient pharmacy and the remote medication order processing pharmacy shall jointly develop a procedure to communicate changes in policies and procedures related to medication order processing.

(2) A terminal distributor of dangerous drugs may utilize one training program for all outpatient pharmacies under the terminal distributor's common ownership and control.

(E) An outpatient pharmacy utilizing a remote pharmacist shall maintain a record of the name and address of such pharmacist, evidence of current licensure in this state, and the address of each location where the pharmacist will be providing remote order entry services.

(F) The responsible person of an outpatient pharmacy shall ensure that any remote pharmacist shall have secure electronic access to the outpatient pharmacy's patient information system and to other electronic systems that the on-site pharmacist has access to when the pharmacy is open.

(G) The remote pharmacist must be able to contact the prescriber issuing a medication order to discuss any concerns identified during the pharmacist's review of patient information and the order. A procedure must be in place to communicate any problems identified with the prescriber and the nursing staff providing direct patient care.

(H) Each remote entry record must comply with all recordkeeping requirements for outpatient pharmacies, including capturing the positive identification of the remote pharmacist involved in the review and verification of the medication order.

(I) An outpatient pharmacy utilizing remote medication order processing is responsible for maintaining records of all medication orders entered into their information system, including orders entered by a remote pharmacist. The system shall have the ability to audit the activities of the remote pharmacists.

(J) An outpatient pharmacy utilizing remote medication order processing services shall maintain a policy and procedure manual. A remote pharmacy shall maintain a copy of those portions of the policy and procedure manual that relate to that pharmacy's operations. Each manual shall:

(1) Outline the responsibilities of the outpatient pharmacy and the remote pharmacy;

(2) Include a list of the names, addresses, telephone numbers, and all license numbers of the pharmacies/pharmacists involved in remote medication order processing; and

(3) Include policies and procedures for:

(a) Protecting the confidentiality and integrity of patient information;

(b) Ensuring that no patient information is duplicated, downloaded, or removed from the outpatient pharmacy's patient information system;

(c) Maintaining appropriate records of each pharmacist involved in order processing;

(d) Complying with federal and state statutes and regulations;

(e) Annually reviewing the written policies and procedures and documentation of the annual review; and

(f) Annually reviewing the competencies of pharmacists providing remote order entry processing services.

4729:5-4-02 - Duty to Report. (NEW)

(A) As used in this rule:

(1) "Error in dispensing" or "prescription error" means an act or omission of clinical significance relating to the dispensing of a drug. An error in dispensing may be considered a violation of division (A)(2) of section 3715.52 and section 3715.64 of the Revised Code.

(2) "Unprofessional conduct" means conduct unbecoming of a licensee, registrant or applicant, or conduct that is detrimental to the best interests of the public, including conduct that endangers the health, safety or welfare of a patient or client. Such conduct shall include, but not be limited to, the following acts: coercion, intimidation, harassment, sexual harassment, improper use of private health information, threats, degradation of character, indecent or obscene conduct, and theft.

(B) A pharmacy licensed as a terminal distributor of dangerous drugs shall be required to report the following to the board in accordance with paragraph (C) of this rule:

(1) The termination or resignation of employment of any individual licensed or registered by the board that was based, in whole or in part, on an error or errors in dispensing.

(2) The termination or resignation of employment of any individual licensed or registered by the board that was based, in whole or in part, on engaging in unprofessional conduct.

(3) The termination or resignation of employment of any individual licensed or registered by the board that was based, in whole or in part, on the individual being addicted to or suspected of abusing alcohol, drugs or other chemical substances or impaired physically or mentally to such a degree as to render the individual unfit to carry out their professional duties.

(C) Reporting required in accordance with this rule shall be made in writing, either by mail, using the board's online complaint form (available on the board's web site: www.pharmacy.ohio.gov), or by telephone and shall include the following information:

(1) The name of the employer and the employer’s terminal distributor license number;

(2) The full name and license or registration number of the licensee or registrant who was terminated from employment for a violation listed in paragraph (B) of this rule;

(3) An explanation of the circumstances that resulted in the individual’s termination from employment; and

(4) The date(s) of and place(s) of occurrence(s), if known.

(D) All required reporting shall be submitted to the board no later than ten days from the date the individual is terminated or resigns from employment.