**11/21/2017**

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**

- 4729:5-1-02 – Defines who is a licensed health professional authorized to prescribe drugs. (Rescinds current rule 4729-5-15)
- 4729:5-3-06 – Provides the requirements for the removal and storage of adulterated drugs by a terminal distributor of dangerous drugs. (Rescinds current rule 4729-9-17)
- 4729:5-5-01 – Definition section for outpatient pharmacy rule chapter.
- 4729:5-5-02 – Provides the minimum standards for the operation of an outpatient pharmacy. (Rescinds current rule 4729-9-02)
- 4729:5-5-03 – Provides the requirements for filing and storage of prescriptions in an outpatient pharmacy. (Rescinds current rule 4729-5-09)
- 4729:5-5-04 – Provides the record keeping requirements for outpatient pharmacies. (Rescinds current rule 4729-5-27)
- 4729:5-5-05 – Sets forth the standard format for outpatient prescriptions. (Rescinds current rule 4729-5-13)
- 4729:5-5-06 – Sets forth the labeling requirements for drugs dispensed by outpatient pharmacies. (Rescinds current rule 4729-5-16)
- 4729:5-5-07 – Provides the requirements for patient profiles maintained by outpatient pharmacies. (Rescinds current rule 4729-5-18)
- 4729:5-5-08 – Requires pharmacists dispensing prescriptions to conduct a prospective drug utilization review. (Rescinds current rule 4729-5-20)
- 4729:5-5-09 – Provides the requirements for the counseling of patients by pharmacists and pharmacy interns. (Rescinds current rule 4729-5-22)
- 4729:5-5-10 – Provides the requirements for the dispensing of a prescription in an outpatient pharmacy. (Rescinds current rule 4729-5-21)
- 4729:5-5-11 – Sets forth the requirements for when a pharmacist or pharmacy intern may transfer a prescription to another pharmacy. (Rescinds current rule 4729-5-24)
- 4729:5-5-12 – Authorizes outpatient pharmacies to partially dispense schedule II controlled substances. (Rescinds current rule 4729-5-26)
- 4729:5-5-13 – Requires outpatient prescriptions to be serially numbered. (Rescinds current rule 4729-5-19)

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- 4729:5-5-14 – Provides the requirements for entities receiving prescriptions on behalf of patients (known as prescription pick-up stations). (Rescinds current rule 4729-5-10)

Comments on the proposed rules will be accepted until close of business on **December 8, 2017**. Please send all comments to the following email address:
**Cameron.mcnamee@pharmacy.ohio.gov**

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

CSI - Ohio
The Common Sense Initiative

# Business Impact Analysis

**Agency Name:** **State of Ohio Board of Pharmacy**

**Regulation/Package Title:** **Terminal Distributors & Outpatient Pharmacies**

**Rule Number(s):**

- **4729:5-1-02 (Rescinds current rule 4729-5-15)**
- **4729:5-3-06 (Rescinds current rule 4729-9-17)**
- **4729:5-5-01**
- **4729:5-5-02 (Rescinds current rule 4729-9-02)**
- **4729:5-5-03 (Rescinds current rule 4729-5-09)**
- **4729:5-5-04 (Rescinds current rule 4729-5-27)**
- **4729:5-5-05 (Rescinds current rule 4729-5-13)**
- **4729:5-5-06 (Rescinds current rule 4729-5-16)**
- **4729:5-5-07 (Rescinds current rule 4729-5-18)**
- **4729:5-5-08 (Rescinds current rule 4729-5-20)**
- **4729:5-5-09 (Rescinds current rule 4729-5-22)**
- **4729:5-5-10 (Rescinds current rule 4729-5-21)**
- **4729:5-5-11 (Rescinds current rule 4729-5-24)**
- **4729:5-5-12 (Rescinds current rule 4729-5-26)**
- **4729:5-5-13 (Rescinds current rule 4729-5-19)**
- **4729:5-5-14 (Rescinds current rule 4729-5-10)**

**Date:** **11/21/2017**

**Rule Type:**

| | |
|---|---|
| **New** | 5-Year Review |
| Amended | **Rescinded** |

**The Common Sense Initiative was established by Executive Order 2011-01K and placed within the Office of the Lieutenant Governor. Under the CSI Initiative, agencies should balance the critical objectives of all regulations with the costs of compliance by the regulated parties. Agencies should promote transparency, consistency, predictability, and flexibility in regulatory activities. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.**

## Regulatory Intent

**1. Please briefly describe the draft regulation in plain language.**

**New**

- 4729:5-1-02 – Defines who is a licensed health professional authorized to prescribe drugs. (Rescinds current rule 4729-5-15)
- 4729:5-3-06 – Provides the requirements for the removal and storage of adulterated drugs by a terminal distributor of dangerous drugs. (Rescinds current rule 4729-9-17)
- 4729:5-5-01 – Definition section for outpatient pharmacy rule chapter.
- 4729:5-5-02 – Provides the minimum standards for the operation of an outpatient pharmacy. (Rescinds current rule 4729-9-02)
- 4729:5-5-03 – Provides the requirements for filing and storage of prescriptions in an outpatient pharmacy. (Rescinds current rule 4729-5-09)
- 4729:5-5-04 – Provides the record keeping requirements for outpatient pharmacies. (Rescinds current rule 4729-5-27)
- 4729:5-5-05 – Sets forth the standard format for outpatient prescriptions. (Rescinds current rule 4729-5-13)
- 4729:5-5-06 – Sets forth the labeling requirements for drugs dispensed by outpatient pharmacies. (Rescinds current rule 4729-5-16)
- 4729:5-5-07 – Provides the requirements for patient profiles maintained by outpatient pharmacies. (Rescinds current rule 4729-5-18)
- 4729:5-5-08 – Requires pharmacists dispensing prescriptions to conduct a prospective drug utilization review. (Rescinds current rule 4729-5-20)
- 4729:5-5-09 – Provides the requirements for the counseling of patients by pharmacists and pharmacy interns. (Rescinds current rule 4729-5-22)
- 4729:5-5-10 – Provides the requirements for the dispensing of a prescription in an outpatient pharmacy. (Rescinds current rule 4729-5-21)
- 4729:5-5-11 – Sets forth the requirements for when a pharmacist or pharmacy intern may transfer a prescription to another pharmacy. (Rescinds current rule 4729-5-24)
- 4729:5-5-12 – Authorizes outpatient pharmacies to partially dispense schedule II controlled substances. (Rescinds current rule 4729-5-26)

- 4729:5-5-13 – Requires outpatient prescriptions to be serially numbered. (Rescinds current rule 4729-5-19)
- 4729:5-5-14 – Provides the requirements for entities receiving prescriptions on behalf of patients (known as prescription pick-up stations). (Rescinds current rule 4729-5-10)

**2. Please list the Ohio statute authorizing the Agency to adopt this regulation.**

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

**3. 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?**

These rules do not implement a federal requirement.

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

This rule package exceeds federal requirements because the regulation of the practice of pharmacy, prescriber authority and the operation of pharmacies has traditionally been done at the state level by legislatively created state boards of pharmacy.

**5. 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)?**

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 prescribing the manner of keeping and the form and content of records to be kept by persons authorized to manufacture, distribute, dispense, conduct research in, prescribe, administer, or otherwise deal with controlled substances.

Without these regulations, the Board would not be able to:

- Ensure accurate recordkeeping and labeling to promote patient safety;
- Provide pharmacists with a clear understanding of who is authorized to prescribe drugs in this state;
- Allow for the electronic storage of records by a pharmacy;

- Ensure that prescriptions are formatted clearly to ensure accurate dispensing;
- Require pharmacists to conduct reviews of patient medications to look for potential drug interactions or substance abuse;
- Require pharmacists to check the Ohio Automated Rx Reporting System for possible abuse of controlled substance medications;
- Ensure that patients can receive counseling on prescription medications upon request.
- Provide consistent procedures for the transfer of prescriptions;
- Allow for the partial dispensing of schedule II controlled substances in compliance with federal laws and regulations;
- Ensure that patient-specific medications dispensed to physician offices are appropriately tracked to reduce any potential diversion and safeguard the integrity of the drug;
- Set forth minimum standards for an outpatient pharmacy, including access to internet references.
- Provide the general requirements to ensure adulterated and expired drugs are separated from existing drug stock.

**6. 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.

## Development of the Regulation

**7. Please list the stakeholders included by the Agency in the development or initial review of the draft regulation.**

The rules in this package were 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 rules prior to their legislatively mandated five-year review date.

Prior to filing with CSI, the rules were also reviewed and approved by the Board of Pharmacy.

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

For the proposed rules, the Board of Pharmacy Rules Review Committee reviewed the proposed changes. Any proposed feedback agreed to by the committee and approved by the Board was incorporated into the rule package.

The committee made the following changes that were adopted by the Board:

- 4729:5-5-03: Extended the timeframe for when an original prescription may be destroyed after scanning from 120 days to 180 days. Removed references to having to write "VOID" on a prescription that is dispensed.
- 4729:5-5-04: Delayed implementation of the positive identification requirement for one-year for data entry not conducted by a pharmacist (i.e. intern or technician).
- 4729:5-5-07: Specified that certain data must be included only if it is made known to the pharmacist or agent of the pharmacist.
- 4729:5-5-06: Allow the "doing business as" name to be included on the prescription label.
- 4729:5-5-11: Require the first and last name of the pharmacist conducting the prescription transfer. Only allow a prescription transfer upon consent of the patient or patient's caregiver. The committee did request permission to allow for the transfer of controlled substance prescriptions by pharmacy interns but that would conflict with federal regulations and was not included in the rule.

**9. 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.

**10. 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 practice of pharmacy by pharmacists and pharmacy interns, the State of Ohio Board of Pharmacy did not consider any regulatory alternatives.

**11. 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 a performance-based regulation 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.

**12. 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. Corresponding rules in Chapter 4729. are being rescinded to avoid duplicate regulations.

**13. 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 rules will be posted on the Board of Pharmacy's web site, information concerning the rules will be included in materials e-mailed to licensees, and notices will be sent to associations, individuals and groups. Board of Pharmacy staff are also available via phone or email to answer questions regarding implementation of the rules. In addition, the Board's compliance agents are trained to educate licensees on current and/or new regulations during on-site inspections.

Board of Pharmacy staff receive regular updates on rules via a monthly internal newsletter, biannual staff meetings featuring a regulatory update, mandatory all-day law reviews for new employees, email updates and quarterly webinars from the Director of Policy and feedback from the Board's legal department for every citation submitted.

## Adverse Impact to Business

**14. 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;**

The rule package impacts the following:

- Pharmacists;
- Pharmacy interns;
- Outpatient pharmacies licensed as terminal distributors of dangerous drugs.

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

Violation of these rules may result in administrative discipline for a licensee/registrant. Discipline might include reprimand, denial of a license, suspension of a license, required course work (pharmacists/interns/technicians), monetary fine and/or revocation of a license.

**c. Quantify the expected adverse impact from the regulation.**

**New**

- 4729:5-1-02 – Defines who is a licensed health professional authorized to prescribe drugs. This rule is definitional and should not have any adverse impact.
- 4729:5-3-06 – Provides the requirements for the removal and storage of adulterated drugs by a terminal distributor of dangerous drugs. This rule will require all terminal distributors to segregate adulterated and expired drugs. This is currently required by rule 4729-9-17 for all terminal distributors. Expected costs include administrative time to review drugs for expiration and adulteration as well as the cost of disposal.
- 4729:5-5-01 – Definition section for outpatient pharmacy rule chapter. This rule is a definitional section and should not have any adverse impact.
- 4729:5-5-02 – Provides the minimum standards for the operation of an outpatient pharmacy. The requirements of this rule are currently set forth in rule 4729-9-02. However, the rule does require internet access to certain pharmacy resources. Pharmacies that do not have internet access will have to permit access to specific websites listed in the rule.
- 4729:5-5-03 – Provides the requirements for filing and storage of prescriptions in an outpatient pharmacy. The requirements of this rule are set forth in rule 4729-5-09. However, this rule does allow for the scanning and disposal of prescription documents after 180 days. A pharmacy that wishes to keep paper records electronically will have to invest in scanning equipment and a system that meets the requirements set forth in the rule.
- 4729:5-5-04 – Provides the record keeping requirements for outpatient pharmacies. The requirements of this rule are set forth in rule 4729-5-27. However, this rule does require all data entry to be documented using positive identification (including technicians and interns). This will require system upgrades that vary based on the pharmacy dispensing system. In addition, the rule does allow for the scanning of paper records (end of day reports). A pharmacy that wishes to keep paper records electronically will have to invest in scanning equipment and a system that meets the requirements set forth in the rule.
- 4729:5-5-05 – Sets forth the standard format for outpatient prescriptions. These are the same standards currently in rule 4729-5-13. The cost of compliance is the time of the pharmacist to ensure the prescription is formatted correctly.

- 4729:5-5-06 – Sets forth the labeling requirements for drugs dispensed by outpatient pharmacies. Most of the requirements for this rule are currently in rule 4729-5-16. However, this rule no longer requires the actual product container to have a label, as it can be placed on the product packaging (except for compounded drug products). This may reduce the administrative burden for pharmacy staff.
- 4729:5-5-07 – Provides the requirements for patient profiles maintained by outpatient pharmacies. These are the current requirements in rule 4729-5-18 except that that certain data is only required to be included if it is made known to the pharmacist or agent of the pharmacist. The cost of this rule would be to ensure all electronic systems can collect the required patient profile information.
- 4729:5-5-08 – Requires pharmacists dispensing prescriptions to conduct a prospective drug utilization review. These are the current requirements in rule 4729-5-20. This rule includes a requirement to check OARRS for most new controlled substance prescriptions. The average time to check a patient's OARRS report is between 3-5 minutes using the web-based portal. However, the Board covers the cost of integrated access to OARRS that reduces the time to view a patient's OARRS report to 15-30 seconds.
- 4729:5-5-09 – Provides the requirements for the counseling of patients by pharmacists and pharmacy interns. These are the current requirements in rule 4729-5-22, except that there must be a verbal offer of counseling made to the patient or caregiver. The adverse impact of this rule is the time a pharmacist or intern would take to counsel a patient or caregiver only if requested by the patient or caregiver.
- 4729:5-5-10 – Provides the requirements for the dispensing of a prescription in an outpatient pharmacy. This rule requires adherence to standards based on how a prescription is transmitted to a pharmacy (as is currently required in rule 4729-5-21). Adverse costs include administrative costs of pharmacists to determine whether a prescription is valid in accordance with the rule and any necessary system upgrades to meet the standards in the rule.
- 4729:5-5-11 – Sets forth the requirements for when a pharmacist or pharmacy intern may transfer a prescription to another pharmacy. The requirements are currently listed in rule 4729-5-24. Adverse costs include the time of a pharmacist or pharmacy intern to comply with the necessary documentation requirements when receiving or transferring a prescription, including the newly added patient consent requirement.
- 4729:5-5-12 – Authorizes outpatient pharmacies to partially dispense schedule II controlled substances. These are the current requirements in rule 4729-5-26 and federal law and regulations. The adverse impact of the rule includes the administrative costs to properly document a partial dispensing and any system costs to assign a new number to the prescription if necessary.
- 4729:5-5-13 – Requires outpatient prescriptions to be serially numbered. These are the exact requirements listed in rule 4729-5-19. For a new outpatient pharmacy, the cost of implementing this rule would be the implementation of a recordkeeping system that would permit the serial numbering of prescriptions.

- 4729:5-5-14 – Provides the requirements for entities receiving prescriptions on behalf of patients (known as prescription pick-up stations). These requirements are the same as listed in rule 4729-5-10 of the Administrative Code. They include the requirement that any entity receiving a drug on the patient's behalf be appropriately licensed. Licensure as a terminal distributor of dangerous drugs costs between $160 and $220 annually. The application takes between 30-60 minutes to complete.

**15. 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 practice of pharmacy by pharmacists and pharmacy interns.

## Regulatory Flexibility

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

These 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.

**17. 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 by pharmacists and pharmacy interns is not considered a paperwork error but a quality assurance issue by the licensee that is necessary for the protection of the public.

**18. 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.

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**4729:5-5-01 Definitions – Outpatient Pharmacies**

(A) “Audit trail” means all materials and documents required for the entire processing of a prescription, which shall be sufficient to document or reconstruct the origin of the prescription order, and authorization of subsequent modifications of that order.

(B) "Business day" means any day other than Saturday, Sunday or a holiday recognized by the state of Ohio on which the offices of the board of pharmacy are not open for business.

(C) "Dispense" means the final association of a drug to a patient pursuant to the 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.

(D) "OARRS report" means a report of information related to a specific person generated by the drug database established and maintained pursuant to section 4729.75 of the Revised Code.

(E) "Original prescription" means any of the following issued in accordance with agency 4729. of the Administrative Code:

(1) A prescription issued by a prescriber in writing;

(2) An oral prescription transcribed by the pharmacist, pharmacy intern or certified pharmacy technician;

(3) An electronically transmitted prescription; or

(4) A prescription transmitted by use of a facsimile machine.

(F) "Personal supervision" or "direct supervision" means a pharmacist shall be physically present in the pharmacy, or in the area where the practice of pharmacy is occurring, and provide personal review and approval of all professional activities.

(G) "Pharmacy," except when used in a context that refers to the practice of pharmacy, means any area, room, rooms, place of business, department, or portion of any of the foregoing where the practice of pharmacy is conducted.

(H) "Pharmacist" means an individual who holds a current pharmacist license pursuant to section 4729.08, 4729.09 or 4729.12 of the Revised Code.

(I) "Positive identification" means a method of identifying an individual who prescribes, administers, dispenses a dangerous drug, or who engages in any activity requiring positive identification in accordance with this chapter.

(1) A method may not rely solely on the use of a private personal identifier such as a password, but must also include a secure means of identification such as the following:

(a) A manual signature on a hard copy record;

(b) A magnetic card reader;

(c) A bar code reader;

(d) A biometric method;

(e) A proximity badge reader;

(f) A board approved system of randomly generated personal questions;

(g) A printout of every transaction that is verified and manually signed within a reasonable period of time by the individual who prescribed, administered, or dispensed the dangerous drug. The printout must be maintained for three years and made available on request to those individuals authorized by law to review such records; or

(h) Other effective methods for identifying individuals that have been approved by the board.

(2) A method relying on a magnetic card reader, a bar code reader, a proximity badge reader, or randomly generated questions for identification must also include a private personal identifier for entry into a secure mechanical or electronic system.

(J) "Practice of pharmacy" is as defined in division (B) of section **4729.01** of the Revised Code.

(K) “Readily retrievable” means that records maintained in accordance with this division shall be kept in such a manner that they can be separated out from all other records and, upon request, produced for review no later than three business days to an agent, officer or inspector of the board.

(L) "Reportable drugs" means all the drugs listed in rules 4729-37-02 of the Administrative Code that are required to be reported to the drug database established and maintained pursuant to section 4729.75 of the Revised Code.

(M) “Responsible person” has the same meaning as defined pursuant to agency 4729. of the Administrative Code who is responsible for the practice of the profession of pharmacy, including, but not limited to, the supervision and control of dangerous drugs as required in division (B) of section 4729.55 of the Revised Code, adequate safeguards as required in division (C) of section 4729.55 of the Revised Code, security and control of dangerous drugs and maintaining all drug records otherwise required.

(N) “United States Pharmacopeia Chapter <795>” or “USP <795>” means United States Pharmacopeia Chapter <795>, USP 40-NF 35, or any official supplement thereto (6/1/2017).

(O) “United States Pharmacopeia Chapter <797>” or “USP <797>” means United States Pharmacopeia Chapter <797>, USP 40-NF 35, or any official supplement thereto (6/1/2017).

**4729:5-5-03 Filing and storage of prescriptions.**

All original outpatient prescriptions shall be filed in the following manner:

(A) Prescriptions for schedule II controlled substances shall be maintained in a separate prescription file for schedule II prescriptions.

(B) Prescriptions for schedules III, IV, and V controlled substances shall be maintained in a separate prescription file for schedules III, IV, and V prescriptions.

(C) Prescriptions for noncontrolled substances shall be maintained in a separate prescription file for noncontrolled prescriptions.

(D) Prescriptions containing multiple drug orders shall be filed in the most restrictive file.

(E) All non-controlled prescriptions maintained pursuant to this rule may be electronically maintained, provided that the system creates and maintains electronic records in accordance with the following:

(1) All paper prescriptions for non-controlled dangerous drugs may be electronically filed and then destroyed after one hundred and eighty days from the date of their creation or receipt.

(2) All paper prescriptions shall be scanned front and back in full color (i.e. retains color information and/or color graphics in the document) via technology designed to capture information in one form and reproduce it in an electronic medium presentable and usable to an end user. Prior to scanning, the front of the prescription shall be clearly notated to indicate it has been received by the pharmacy in a manner that does not destroy any of the original information contained on the prescription but prevents the unauthorized duplication of the prescription.

(3) A record or image once created shall be unalterable but may be annotated as necessary so long as the original record or image is still available for review and the individual that made the annotation is noted.

(4) Contains security features to prevent unauthorized access to the records.

(5) Contains daily back-up functionality to protect against loss of records.

(6) The electronic form shows the exact and legible image of the original paper prescription.

(F) All paper prescriptions filed electronically in accordance with this rule shall be deemed the original prescription.

(G) All prescription records stored in accordance with this rule shall be uniformly maintained for a period of three years.

(H) Prescription records shall be made available in accordance with the requirements of rule 4729:5-5-04 of the Administrative Code.

(I)

(1) Except as provided for in paragraph (I)(2) of this rule, all records maintained in accordance with this rule shall be stored at the same location of the dangerous drugs.

(2) Any terminal distributor of dangerous drugs intending to maintain records pursuant to this rule at a location other than place must first send a written request to the state board of pharmacy. The request shall contain the terminal distributor of dangerous drug name and license number of the requestor and the name and address of the alternate location. The state board of pharmacy will send written notification to the terminal distributor of dangerous drugs documenting the approval or denial of the request. A copy of the board's approval shall be maintained with the other records of dangerous drugs. Any such alternate location shall be secured and accessible only to representatives of the terminal distributor of dangerous drugs.

(J) A terminal distributor of dangerous drugs and the terminal distributor’s responsible person shall ensure that original prescriptions are properly filed in compliance with this rule.

**4729:5-5-04 Record keeping.**

The following record keeping requirements do not apply to records relating to the practice of pharmacy for an institutional facility (i.e. inpatient) as defined in agency 4729. of the Administrative Code.

(A) There shall be positive identification of the licensed or registered individuals responsible for performing the following activities authorized in Chapter 4729. of the Revised Code and agency 4729. of the Administrative Code:

(1) Prescription information entered into the record keeping system.

(a) Paragraph (A)(1) of this rule shall take effect one-year from the effective date of this rule.

(2) Verification by the pharmacist of the prescription information entered into the record keeping system.

(3) Prospective drug utilization review, which may be captured as part of either:

(a) The pharmacist verification of prescription information in paragraph (A)(2) of this rule; or

(b) The dispensing process in paragraph (A)(4) of this rule.

(4) Dispensing.

(5) Compounding.

(6) Administering immunizations pursuant to section 4729.44 of the Revised Code.

(7) Administering injectable drugs pursuant to section 4729.45 of the Revised Code.

(8) Prescription information transcribed from an order received by telephone, facsimile, or recording device.

(9) Any changes or annotations made to the prescription.

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

(C)

(1) Except as provided for in paragraph (C)(2) of this rule, all records maintained in accordance with this rule shall be stored at the same location of the dangerous drugs.

(2) Any terminal distributor of dangerous drugs intending to maintain records pursuant to this rule at a location other than place must first send a written request to the state board of pharmacy. The request shall contain the terminal distributor of dangerous drug name and license number of the requestor and the name and address of the alternate location. The state board of pharmacy will send written notification to the terminal distributor of dangerous drugs documenting the approval or denial of the request. A copy of the board's approval shall be maintained with the other records of dangerous drugs. Any such alternate location shall be secured and accessible only to representatives of the terminal distributor of dangerous drugs.

(D) Record keeping systems shall provide immediate retrieval via digital display and hard copy printout or other mutually agreeable transfer medium of information for all prescriptions dispensed within the previous twelve months and shall be made readily retrievable for all prescriptions dispensed within the previous three years. This information shall include at least, but is not limited to, the following data:

(a) The original prescription number;

(b) Date of issuance of the original prescription order by the prescriber;

(c) Full name and residential address of the patient, including the patient’s physical street address;

(d) Full name and address of the prescriber, including the physical address of the prescriber's practice location;

(e) The prescriber’s credential (MD, DDS, DVM, etc), if indicated on the prescription;

(f) Directions for use;

(g) The name, strength, dosage form, and quantity of the drug prescribed;

(h) The prescriber's Federal Drug Enforcement Administration number, if applicable;

(i) The quantity dispensed if different from the quantity prescribed;

(j) The positive identification of the persons performing specific actions pursuant to paragraph (A) of this rule;

(k) The total number of refills authorized by the prescriber;

(l) The refill history of the prescription, including all of the following:

(i) The prescription number;

(ii) The name and strength of the drug dispensed;

(iii) The date of refill; and

(iv) The quantity dispensed.

(E) A pharmacy that utilizes a computerized system to dispense dangerous drugs that is unable to electronically document positive identification in accordance with paragraph (A) of this rule shall be required to maintain hard copy documentation. Hard copy documentation shall be provided by each registered or licensed individual who makes use of such system by one of the following methods:

(1) A hard copy printout of each day's prescription data.

(a) The printout shall include, at a minimum, the following data:

(i) Date of dispensing;

(ii) Prescription number;

(iii) Patient name;

(iv) Name, strength (if applicable), and quantity of drug;

(v) Identification of pharmacy, pharmacist and pharmacy personnel responsible for any activity described in paragraph (A) of this rule;

(vi) Identification of controlled substances.

(b) The printout must be verified, dated, and signed by each individual responsible for any activity described in paragraph (A) of this rule. The printout must be verified and manually signed by the individual within a reasonable period of time.

(c) If the printout is prepared at a location other than that where the drug was dispensed, the printout must be provided to the licensed location within three working days, excluding holidays and weekends, of the date on which the drugs were dispensed. Such printouts must be verified and signed by each individual responsible for any activity described in paragraph (A) of this rule within twenty-four hours of the date the printout is received by the individual.

(d) The printout must be readily retrievable and maintained in chronological order in a separate file at the licensed location where the drug was dispensed for a period of three years from the date of dispensing.

(e) The signed printout may be stored electronically in accordance with paragraph (F) of this rule.

(2) A tamper evident log book.

(a) Each individual pharmacist involved in dispensing drugs must enter into a tamper evident log book, at a minimum, the following data for each prescription refilled:

(i) Date of dispensing;

(ii) Prescription number;

(iii) Patient name;

(iv) Name, strength (if applicable), and quantity of drug;

(v) Identification of the pharmacist and pharmacy personnel responsible for any activity described in paragraph (A) of this rule;

(vi) Identification of controlled substances.

(b) Each individual responsible for any activity described in paragraph (A) of this rule shall review this information at the end of each day and then must either:

(i) Manually sign a statement in the log book attesting to the fact that the prescription information entered into the computer that day and recorded in the log book has been reviewed by the individual and is correct as shown; or

(ii) Manually initial each entry of the log book to indicate that the prescription information entered into the computer that day and recorded in the log book has been reviewed by the individual and is correct as shown.

(F) A signed printout that is maintained in accordance with paragraph (E) of this rule may be electronically created and maintained, provided the system creates and maintains the printout in accordance with the following:

(1) All information in the printout shall be scanned in full color (i.e. retains color information and/or color graphics in the document) via technology designed to capture information in one form and reproduce it in an electronic medium presentable and usable to an end user;

(2) A record or image once created shall be unalterable but may be annotated as necessary so long as the original record or image is still available for review and the individual that made the annotation is noted;

(3) Contains security features to prevent unauthorized access to the records;

(4) Contains daily back-up functionality to protect against record loss.

(G) In addition to the immediate retrieval and production of prescription information required by paragraph (D) of this rule, a pharmacy that utilizes a computerized record keeping system shall comply with the following:

(1) Make readily retrievable the following information:

(a) An electronic record in a character-delimited or fixed-width ASCII text file or other mutually acceptable format that contains any requested data fields the pharmacy is responsible for maintaining pursuant to all federal and state laws, rules and regulations; and

(b) A hardcopy printout sorted by any requested data fields that the pharmacy is responsible for maintaining pursuant to all federal and state laws, rules, and regulations.

(2) Make readily retrievable upon request by an individual authorized by law to access such records any of the following:

(a) Printout; or

(b) Electronic record and a definition file describing the file layout and column width, if applicable.

(3) All computerized record keeping systems shall be able to capture records edited by authorized personnel and maintain an audit trail.

(H) In the event that a pharmacy which employs such computerized record keeping system experiences system down time, the pharmacy must have an auxiliary procedure which will be used for documentation of refills of prescription orders. This auxiliary procedure must ensure that refills are authorized by the original prescription order, that the maximum number of refills has not been exceeded, and that all of the appropriate data is retained for on-line service. However, nothing in this section shall preclude a pharmacist from using the pharmacist's professional judgment to benefit the health of the patient.

(I) Prescriptions entered into a computer system but not dispensed must meet all of the following conditions:

(1) The complete prescription information must be entered in the computer system;

(2) The information must appear in the patient's profile;

(3) There is positive identification, in the computer system or on the hard copy prescription, of the person who is responsible for entering the prescription information into the system and the pharmacist responsible for verifying the prescription information; and

(4) The prescription must be assigned a prescription number;

(5) The original prescription is filed according to rule 4729:5-5-03 of the Administrative Code.

(J) Records shall be maintained for three years on all immunizations administered pursuant to section 4729.41 shall include at least the following information:

(1) Full name and address of the patient;

(2) Patient's date of birth or age;

(3) Patient's gender;

(4) Patient's applicable allergy information;

(5) Date of administration;

(6) Name, strength, and dose of the immunization administered;

(7) Lot number and expiration date of the immunization;

(8) Route of administration;

(9) Location of the injection site;

(10) Positive identification of the administering pharmacist or the administering pharmacy intern and supervising pharmacist;

(11) Identification of the patient, parent, or legal guardian of the patient who gives informed consent to administer an immunization.

(K) Immunization records may be electronically created and maintained if done so in accordance with the standards set forth in paragraph (F) of this rule.

(L) A pharmacist or pharmacy intern under the direct supervision of a pharmacist who administers an immunization pursuant to section 4729.41 of the Revised Code shall maintain and immediately make available, upon the request of the state board of pharmacy, the following records:

(1) Documentation of the successful completion of a board approved course in the administration of immunizations;

(2) Documentation of current certification to perform basic life support procedures pursuant to division (B)(2) of section 4729.41 of the Revised Code.

**4729:5-5-07 Patient profiles.**

All pharmacies shall maintain a patient profile system which shall provide for immediate retrieval of information regarding those patients who have received prescriptions from that pharmacy.

(A) All patient profile systems shall maintain, at a minimum, the following data:

(1) The patient's data record, which shall consist of, but is not limited to, the following information:

(a) Full name of the patient for whom the drug is intended;

(b) Residential address, including a physical street address, and telephone number of the patient;

(c) Patient's date of birth;

(d) Patient's gender;

(e) A list of current patient specific data consisting of at least the following, if made known to the pharmacist or agent of the pharmacist:

(i) Drug related allergies;

(ii) Previous drug reactions;

(iii) History of or active chronic conditions or disease states; and

(iv) Other drugs and nutritional supplements, including nonprescription drugs used on a routine basis, or devices.

(f) The pharmacist's comments relevant to the individual patient's drug therapy, including any other necessary information unique to the specific patient or drug;

(2) The patient's drug therapy record, which shall contain at least the following information for all prescriptions dispensed by the pharmacy within the last twelve months showing:

(a) The original prescription number;

(b) Date of issuance of the original prescription order by the prescriber;

(c) Full name, address and credential of the prescriber;

(d) Directions for use;

(e) The name, strength, dosage form, and quantity of the drug prescribed;

(f) The prescriber's Federal Drug Enforcement Administration number, if applicable;

(g) The quantity dispensed if different from the quantity prescribed;

(h) The total number of refills authorized by the prescriber;

(i) The refill history of the prescription, including all of the following:

(i) The prescription number;

(ii) The name and strength of the drug dispensed;

(iii) The date of refill;

(iv) The quantity dispensed;

(B) A pharmacist or an agent of the pharmacist shall make a reasonable effort to obtain the individual's medical history,which may relate to prospective drug review.

(C) The patient profile shall be maintained for a period of not less than one year from the date of the last entry in the profile record. This record may be a hard copy or a computerized form.

**4729:5-5-05 Prescription format requirements.**

(A) Except as provided in paragraphs (E) and (F) of this rule, no pharmacist shall dispense dangerous drugs pursuant to a written outpatient prescription unless the following conditions are met:

(1) The prescription is issued in compliance with rule 4729-5-30 of the Administrative Code.

(2) If handwritten or typewritten, there are no more than three noncontrolled substance prescription orders per prescription form.

(3) If preprinted with multiple drug names or strength combinations:

(a) There are no controlled substances among the choices;

(b) There is only one prescription order selected per form.

(B) Except as provided in paragraphs (E) and (F) of this rule, no pharmacist shall dispense controlled substances pursuant to a written outpatient prescription unless the following conditions are met:

(1) The prescription has been issued in compliance with rule 4729-5-30 of the Administrative Code.

(2) The prescription contains only one prescription order per prescription form, whether handwritten, typewritten, or preprinted.

(3) The quantity has been written both numerically and alphabetically.

(4) If preprinted, there is only one drug and strength combination printed on the form.

(C) A prescription for a controlled substance issued by a medical intern, resident, or fellow in rule 4729:5-1-02 of the Administrative Code may not be dispensed unless the prescription is issued in accordance with this rule and complies with the requirements for drug enforcement administration (D.E.A.) registration numbers for hospital employed prescribers pursuant to agency 4729. of the Administrative Code.

(D) A prescription for a controlled substance issued by a staff prescriber of a hospital may not be dispensed unless the prescription is issued in accordance with this rule and complies with either:

(1) The requirements for D.E.A. registration numbers for hospital employed prescribers pursuant to agency 4729. of the Administrative Code; or

(2) Includes the prescriber's D.E.A. registration number.

(E) If a board-approved electronic prescription transmission system that converts the prescription into a computer-generated fax or scanned image is used to transmit a prescription to a pharmacy, the faxed order is exempt from paragraphs (A) and (B) of this rule. The transmission shall comply with rule 4729-5-30 of the Administrative Code.

(F) For purposes of preprinted prescription forms for hospice care program outpatients, the following conditions apply:

(1) Preprinted prescription forms may contain multiple orders on one form and the prescriber may select as many drug orders as necessary. Additional prescriptions may be manually added to this sheet.

(2) Preprinted forms may not contain prescription orders for schedule II drugs. Schedule II drugs may be manually added to the preprinted forms and signed by the prescriber.

(3) The prescriber shall indicate on each preprinted form the drug orders authorized on the form by either:

(a) Manually indicating the total drug orders authorized on the form; or

(b) Manually initialing each drug order.

(4) All written drug orders must be signed by the prescriber.

(5) All signed prescriptions may be faxed from the prescriber or the hospice location to the pharmacy.

(6) At the direction of the prescriber, verbal drug orders may be transmitted to the pharmacy by the prescriber's agent, including a hospice nurse, except for schedule II drug orders.

**4729:5-1-02 Licensed health professional authorized to prescribe drugs.**

(A) For purposes of division (Y) of section 3719.01 and division (I) of section 4729.01 of the Revised Code, the following persons, maintaining current licenses and in good standing, licensed pursuant to Chapters 4715., 4723., 4725., 4729., 4730., 4731., and 4741. of the Revised Code, are authorized by law to write prescriptions for drugs or dangerous drugs in the course of the person's professional practice:

(1) Chapter 4715. of the Revised Code: dentist.

(2) Chapter 4725. of the Revised Code: optometrist, if that person holds a current "therapeutic pharmaceutical agents certificate" as defined in division (H) of section 4725.01 of the Revised Code.

(3) Chapter 4731. of the Revised Code: doctor of medicine, doctor of osteopathic medicine and surgery, and doctor of podiatry.

(4) Chapter 4741. of the Revised Code: doctor of veterinary medicine.

(5) Chapter 4723. of the Revised Code: advanced practice nurse in accordance with paragraph (D) of this rule.

(6) Chapter 4730. of the Revised Code: physician assistant in accordance with paragraph (E) of this rule.

(7) Chapter 4729. of the Revised Code: pharmacist in accordance with paragraph (F) of this rule.

(B) Those persons pursuing an approved internship, residency, or fellowship program in this state are authorized to write prescriptions only when acting within their scope of employment in the hospital(s) or institution(s). Approved internship and residency programs are those accredited by the "Accreditation Council for Graduate Medical Education (ACGME)" or the "American Osteopathic Association (AOA)". Approved clinical fellowships are those at institutions which have a residency program in the same or a related clinical field which is accredited by the ACGME or the AOA.

(C) A nonresident prescriber whose license is current and in good standing and who is authorized to issue prescriptions for drugs in the course of their professional practice in a state, as defined in division (G) of section 1.59 of the Revised Code, other than Ohio is authorized to write prescriptions in that state for drugs to be dispensed in the state of Ohio.

(D) An advanced practice nurse approved pursuant to section 4723.48 of the Revised Code may prescribe those drugs which have been approved by the committee on prescriptive governance for advanced practice nurses and pursuant to the standard care agreement for that advanced practice nurse.

(E) A physician assistant who holds a valid prescriber number pursuant to section 4730.41 of the Revised Code issued by the state medical board is authorized to prescribe drugs and therapeutic devices in the exercise of physician-delegated prescriptive authority.

(F) A pharmacist who is authorized to manage drug therapy pursuant section 4729.39 of the Revised Code but only if specifically authorized by a consult agreement and to the extent specified in the agreement.

**4729:5-5-06 Labeling of drugs dispensed on prescription.**

(A) No drug may be dispensed on prescription unless a label is affixed to the container in which such drug is dispensed and such label includes:

(1) The name or “doing business as” (DBA) name and address of the pharmacy as it appears on the terminal distributor of dangerous drugs license;

(2) The full name of the patient for whom the drug is prescribed; or, if the patient is an animal, the full name of the owner and identification of the animal;

(3) The full name of the prescriber;

(4) Directions for use of the drug;

(5) The date of dispensing;

(6) Any cautions which may be required by federal or state law;

(7) The serial number of the prescription;

(8) The proprietary name, if any, or the generic name and the name of the distributor of the drug dispensed, and the strength, if more than one strength of the drug is marketed.

(a) The dispensing pharmacist may omit the name and strength of the drug only if the prescriber specifically requests omission and such request is documented.

(9) The quantity of drug dispensed;

(10) If the drug is compounded, the statement "Compounded Drug Product" or other similar statement shall also be displayed prominently on the label and shall comply with either of the following:

(a) Sterile compounded drugs shall comply with the labeling requirements of United States Pharmacopeia Chapter <797>.

(b) Non-sterile compounded drugs shall comply with the labeling requirements of United States Pharmacopeia Chapter <795>

(c) The inclusion of the statement "Compounded Drug Product" or other similar statement as required by paragraph (A)(10) of this rule does not apply to non-sterile compounded drugs that are reconstituted in accordance with directions contained in approved labeling provided by the product's manufacturer and other manufacturer directions consistent with that labeling.

(B) Except as provided in paragraph (B)(1) of this rule, the term "affix" means the prescription label must be attached or fastened to the container.

(1) A label meeting the requirements in paragraph (A) of this rule may be placed on the packaging of a commercially manufactured dangerous drug product.

(C) At least the prescription number and the name of the patient must be placed on all prescription containers too small to bear a complete prescription label and dispensed in a container bearing a complete prescription label. The label bearing only the prescription number and the name of the patient does not need to be applied to any product whose function would be impaired by such a label.

(D) This rule does not apply to drugs which are dispensed for use by inpatients of an institutional facility whereby the drug is not in the possession of the ultimate user prior to administration. Such drugs shall be labeled in accordance with institutional requirements in agency 4729. of the Administrative Code.

(E) Labels for a compounded drug products that are prepared in anticipation of a prescription drug order shall comply with the requirements in agency 4729. of the Administrative Code.

**4729:5-5-13 Serial numbering of prescriptions.**

All outpatient prescriptions must be serially numbered when entered into the computer system or when dispensed under a manual system.

(A) This number must appear on the original prescription.

(B) There must be a complete accounting of all numbers used in the serial numbering system.

(C) All prescriptions that cannot be refilled, either because of the dispensing of all refills or the length of time since issuance, shall be assigned a new serial number upon an authorization for additional dispensing by a prescriber.

**4729:5-5-08 Prospective drug utilization review.**

(A) Prior to dispensing any prescription, a pharmacist shall review the patient profile for the purpose of identifying:

(1) Over-utilization or under-utilization;

(2) Therapeutic duplication;

(3) Drug-disease state contraindications;

(4) Drug-drug interactions;

(5) Incorrect drug dosage;

(6) Drug-allergy interactions;

(7) Abuse/misuse;

(8) Inappropriate duration of drug treatment; and

(9) Food-nutritional supplements-drug interactions.

(B) Upon identifying any issue listed in paragraph (A) of this rule, a pharmacist, using professional judgment, shall take appropriate steps to avoid or resolve the potential problem. These steps may include requesting and reviewing an OARRS report or another state's prescription drug monitoring report, pursuant to paragraph (D) of this rule, and/or consulting with the prescriber and/or counseling the patient.

(C) Prospective drug utilization review shall be performed using predetermined standards consistent with, but not limited to, any of the following:

(1) Peer-reviewed medical literature (that is, scientific, medical, and pharmaceutical publications in which original manuscripts are rejected or published only after having been critically reviewed by unbiased independent experts);

(2) American hospital formulary service drug information; and

(3) United States pharmacopeia drug information.

(D) Prior to dispensing an outpatient prescription for a reportable drug, at a minimum, a pharmacist shall request and review an OARRS report covering at least a one year time period in any of the following circumstances:

(1) A patient adds a different or new reportable drug to their therapy that was not previously included;

(2) An OARRS report has not been reviewed for that patient during the preceding twelve months, as indicated in the patient profile;

(3) A prescriber is located outside the usual pharmacy geographic area;

(4) A patient is from outside the usual pharmacy geographic area;

(5) A pharmacist has reason to believe the patient has received prescriptions for reportable drugs from more than one prescriber in the preceding three months, unless the prescriptions are from prescribers who practice at the same physical location;

(6) Patient is exhibiting signs of potential abuse or diversion. This includes, but is not limited to, over-utilization, early refills, appears overly sedated or intoxicated upon presenting a prescription for a reportable drug, or an unfamiliar patient requesting a reportable drug by specific name, street name, color, or identifying marks.

(E) In the event an OARRS report is not immediately available, the pharmacist shall use professional judgment in determining whether it is appropriate and in the patient's best interest to dispense the prescription prior to receiving and reviewing a report.

(F) A pharmacist may use a delegate licensed or registered in accordance with Chapter 4729. to request an OARRS report.

(G) Based upon information obtained during a prospective drug utilization review, a pharmacist shall use professional judgment when making a determination about the legitimacy of a prescription. A pharmacist shall not dispense a prescription of doubtful, questionable, or suspicious origin.

**4729:5-5-09 Patient counseling.**

(A) A pharmacist or the pharmacist's designee shall verbally offer to provide the service of counseling pursuant to paragraph (B) of this rule to the patient or caregiver whenever any prescription, new or refill, is dispensed. A pharmacist or pharmacy intern under the personal supervision of a pharmacist shall not be required to counsel a patient or caregiver when the patient or caregiver refuses the offer of counseling or does not respond to the written offer to counsel. If the patient or caregiver is not physically present, the offer to counsel shall be made by telephone or in writing on a separate document accompanying the prescription or incorporated as part of documentation, in a conspicuous manner, that is included with the prescription. A written offer to counsel shall include the hours a pharmacist is available and a telephone number where a pharmacist may be reached. The telephone service must be available at no cost to the pharmacy's primary patient population.

(B) In the event a patient or caregiver accepts an offer to counsel or requests counseling, a pharmacist, or a pharmacy intern under the personal supervision of a pharmacist, shall counsel the patient or caregiver. Such counseling may include, but is not limited to, the following:

(1) The name and description of the drug;

(2) The dosage form, dose, strength, frequency, route of administration, and duration of drug therapy;

(3) The intended use of the drug and the expected action;

(4) Special directions and precautions for preparation, administration, handling, storage, disposal and use by the patient;

(5) Common adverse effects or interactions and therapeutic contraindications that may occur, including possible methods to avoid them, and the action required if they occur;

(6) Techniques for self-monitoring drug therapy;

(7) Proper storage and disposal;

(8) Prescription refill information;

(9) Action to be taken in the event of a missed dose; and

(10) The pharmacist's comments relevant to the individual's drug therapy, including other necessary information unique to the specific patient or drug.

(C) Other forms of information may be used when appropriate to supplement the counseling by the pharmacist or intern. Examples of forms that may be used include, but are not limited to, drug product information leaflets, pictogram labels, and video programs.

(D) Patient counseling shall not be required for an order for a drug to be dispensed for use in treating an inpatient of an institutional facility as defined in agency 4729. of the Administrative Code.

(E) Notwithstanding any other rule of agency 4729. of the Administrative Code, "personal supervision", as used in paragraph (B) of this rule, means that a pharmacist is on the premises at all times and is aware of all counseling activities performed by the pharmacy intern. A pharmacist who has accepted responsibility for the supervision and training of a pharmacy intern is responsible for all acts performed by the pharmacy intern working under the pharmacist's supervision.

**4729:5-5-10 Manner of processing a prescription.**

(A) A prescription, to be valid, must be issued for a legitimate medical purpose by an individual prescriber acting in the usual course of his/her professional practice. The responsibility for the proper prescribing is upon the prescriber, but a corresponding responsibility rests with the pharmacist who dispenses the prescription. An order purporting to be a prescription issued not in the usual course of bona fide treatment of a patient is not a prescription and the person knowingly dispensing such a purported prescription, as well as the person issuing it, shall be subject to the penalties of law.

(B) A pharmacist when dispensing a prescription shall:

(1) Ensure that patient information is profiled pursuant to rule 4729:5-5-07 of the Administrative Code;

(2) Perform prospective drug utilization review pursuant to rule 4729:5-5-08 of the Administrative Code;

(3) Ensure that the drug is labeled pursuant to rule 4729:5-5-06 of the Administrative Code;

(4) Ensure that a patient is provided an offer to counsel pursuant to rule 4729:5-5-09 of the Administrative Code;

(5) Ensure that a prescription is filed pursuant to rule 4729:5-5-03 of the Administrative Code.

(C) Prescriptions:

(1) When a pharmacist dispenses a drug pursuant to an original prescription, the pharmacist must record the date of such dispensing and either manually record the pharmacist's name or initials on the original prescription or using the pharmacist's positive identification in the computerized record keeping system.

(2) When a pharmacist dispenses a drug pursuant to an authorized refill of a prescription, the pharmacist must record the date of such dispensing and either manually record the pharmacist's name or initials on the original prescription or using the pharmacist's positive identification in the computerized record keeping system.

(D) Oral prescriptions:

(1) The pharmacist shall make a record of the full name of the prescriber and, if transmitted by the prescriber's agent, the full name of the agent, on the original prescription. The pharmacist is responsible for ensuring the validity of the source of the oral prescription.

(2) Upon receiving a prescription from a recording device or voicemail service, the pharmacist shall transcribe the information. The pharmacist must document on the original prescription the full name of the prescriber and, if transmitted by the prescriber's agent, the full name of the agent. The pharmacist is responsible for ensuring the validity of the prescription removed from the recorder.

(3) A licensed pharmacy intern may receive telephone prescriptions and remove prescriptions from a recording device or voicemail service if the pharmacist on duty who is supervising the activity of the intern determines that the intern is competent to perform this function.

(a) The intern shall immediately transcribe the prescription, document the full name of the prescriber and, if transmitted by the prescriber's agent, the full name of the agent, and shall review the prescription with the pharmacist on duty. Prior to dispensing, positive identification of the intern and the pharmacist on duty shall be made on the prescription to identify the responsibility for the receipt of the oral order.

(b) The pharmacist on duty is responsible for the accuracy of the prescription.

(c) The pharmacist on duty must be immediately available to answer questions or discuss the prescription with the caller.

(4) A certified pharmacy technician may receive telephone prescriptions and remove prescriptions from a recording device or voicemail service for non-controlled drugs in accordance with paragraph (B)(13) of rule 4729:3-3-04 of the Administrative Code.

(E) Facsimile prescriptions:

(1) A facsimile shall only be valid as a prescription if a system is in place that will allow the pharmacist to maintain the facsimile as a part of the prescription record including the full name of the prescriber and, if transmitted by the prescriber's agent, the full name of the agent as well as identification of the origin of the facsimile.

(2) The pharmacist must record the prescription in writing pursuant to section 4729.37 of the Revised Code or store the facsimile copy in such a manner that will allow retention of the prescription record for three years from the date of the last transaction.

(F) Electronic prescriptions:

(1) A pharmacy seeking to receive electronic prescriptions directly into its computer system must obtain approval from the state board of pharmacy. The original prescription information received from the prescriber must be saved.

(2) A pharmacy computer system meeting the following requirements shall be considered approved by the state board of pharmacy:

(a) Complies with 21 C.F.R. 1311 (04/01/13);

(b) Has the capability to receive an ICD-10-CM medical diagnosis code for all controlled substance prescriptions pursuant to agency 4729. of the Administrative Code.

(G) A pharmacist may not dispense a dangerous drug for the first time beyond six months from the date of issuance of a prescription.

(H) The quantity prescribed shall be considered the quantity dispensed, unless the quantity dispensed meets any of the following:

(1) The dispensed prescription is less than the quantity prescribed, the pharmacist shall note the quantity dispensed on the original prescription or within a computerized recordkeeping system.

(2) If the quantity dispensed on a prescription is greater than the quantity prescribed, the pharmacist shall record on the original prescription or within a computerized recordkeeping system the name of the authorizing prescriber, the full name of the agent of the prescriber if applicable, the quantity authorized to be dispensed, and the date that the authorization was obtained.

(3) A prescription dispensed in accordance with section 4729.40 of the Revised Code.

(I) Where a prescription is written using a generic name, or where the pharmacist dispenses an equivalent drug product pursuant to the provisions of sections 4729.38 and 4729.381 of the Revised Code, the brand name or drug name and name of the manufacturer or distributor of the drug or the national drug code (NDC) number of the drug dispensed must be recorded on the record of dispensing by the pharmacist.

(J) A pharmacist may document the pharmacist's own administration of an immunization, or an immunization administered by a pharmacy intern they are supervising, on a prescription form, which may be assigned a number for record keeping purposes. This documentation is in addition to the record keeping requirements noted in rule 4729:5-5-04 of the Administrative Code.

(K) A pharmacist may document the pharmacist's own administration of an injection in accordance with section 4729.45 of the Revised Code on a prescription form, which may be assigned a number for record keeping purposes. This documentation is in addition to the record keeping requirements noted in rule 4729:5-5-04 of the Administrative Code.

**4729:5-5-11 Prescription copy.**

(A) A pharmacist may transfer and may refill a copy of a prescription in accordance with the following:

(1) Copies of prescriptions shall be transferred only between pharmacists except as provided in paragraphs (G) and (H) of this rule and in accordance with rule 4729:3-3-04 of the Administrative Code.

(2) Except as provided in paragraph (2)(a) of this rule, copies of prescriptions for controlled substances shall be communicated directly between two pharmacists and shall be transferred only one time.

(a) Pharmacies electronically sharing a real time, online database may transfer a controlled substance prescription up to the maximum number of refills permitted by law and the prescriber's authorization pursuant to paragraph (A)(4) of this rule.

(3) The copy transferred shall be an exact duplicate of the original prescription except that it shall also include:

(a) Serial prescription number assigned to the prescription;

(b) Name, address and, if applicable, the "D.E.A." number for controlled substance prescriptions of the pharmacy transferring the copy;

(c) Date of issuance of the prescription;

(d) Date of last refill;

(e) Number of valid refills or quantity remaining; and

(f) The full name of the transferring pharmacist.

(4) A pharmacist transferring a copy of a controlled substance prescription shall:

(a) Write the word “VOID” on the face of the invalidated prescription in a manner that does not destroy any of the original information contained on the prescription; for electronic prescriptions, information that the prescription has been transferred must be added to the prescription record.

(b) Record on the reverse of the invalidated prescription the name, address, and, if applicable, the D.E.A. registration number of the pharmacy to which it was transferred and the first and last name of the pharmacist receiving the prescription information; for electronic prescriptions, such information must be added to the prescription record.

(c) Record the date of the transfer and the name of the pharmacist transferring the information.

(d) Copies of prescriptions may be transferred by a pharmacist if the prescription record in the system is invalidated to prevent further dispensing at the original site.

(5) A pharmacist transferring a copy of a non-controlled substance prescription shall:

(a) Utilize a manual or electronic method for invalidating the prescription to prevent further dispensing at the original site.

(b) Record the name and address of the pharmacy to which it was transferred and the first and last name of the pharmacist receiving the prescription information;

(c) Record the date of the transfer and the name of the pharmacist transferring the information.

(6) The pharmacist receiving a copy of a prescription must:

(a) Exercise reasonable diligence to determine validity of the copy;

(b) Transcribe an oral prescription by recording all of the information transferred. The oral prescription shall include all information required in paragraph (A)(3) of this rule and the pharmacist shall write the word "transfer" on the face of the prescription;

(c) Record date of transfer on the face of the prescription.

(B) A prescription copy may be transferred between two pharmacies if the two pharmacies are accessing the same prescription records in a centralized database or pharmacy computers linked in any other manner. The computerized systems must satisfy all information requirements of paragraphs (A)(3) and (A)(4)(d) of this rule. This shall include invalidation of the prescription record in the system to prevent further dispensing at the original site and, if a controlled substance prescription, the canceling of the original written prescription as required in paragraphs (A)(4)(a) and (A)(4)(b) of this rule. A system must be in place that will allow only authorized access to these computerized prescription records by a pharmacist and indicate on the prescription record when and by whom such access was made.

(C) A prescription copy may be transferred between two pharmacists by the use of a facsimile machine. This facsimile may be considered to be a copy of a prescription if all information requirements of paragraph (A) of this rule, including invalidation of the original prescription or computer records, are met. A system must be in place that will show on the facsimile positive identification of the transferring and receiving pharmacists which must become a part of the prescription record. Facsimile copies must be recorded in writing pursuant to section 4729.37 of the Revised Code, or stored in such a manner that will allow retention of the prescription record for three years from the date of the last transaction.

(D) Information on a prescription is the property of the patient and is intended to authorize the dispensing of a specific amount of medication for use by the patient.

(1) In the event that the pharmacy is not able to provide the medication when needed by the patient pursuant to an authorized refill, the pharmacist shall, upon the request of the patient or patient's caregiver, transfer the prescription information to the pharmacy designated by the patient.

(2) Unless otherwise prohibited by law, no pharmacy shall refuse to transfer information about a prescription to another pharmacy when requested by the patient or patient's caregiver. Prescription information shall be transferred in accordance with this rule as soon as possible in order to ensure that the patient's drug therapy is not interrupted.

(3) A prescription may only be transferred upon the request or consent of the patient or patient's caregiver.

(E) Prescriptions entered into a computer system but not dispensed shall be transferred to another pharmacy, at the request of the patient or patient's caregiver, if all of the following conditions are met:

(1) The complete prescription information has been entered into the computer system;

(2) The information is displayed on the patient's profile;

(3) There is positive identification of the individual responsible for entering the prescription information into the system and the pharmacist responsible for verification of the information entered into the system;

(4) The original prescription is filed in accordance with rule 4729:5-5-03 of the Administrative Code;

(5) The prescription is assigned a prescription number;

(6) All requirements of this rule are met for the transfer of the prescription;

(7) The transfer is conducted in accordance with all state and federal laws, rules and regulations;

(8) A pharmacist may transfer an unfilled electronic prescription for a controlled substance to another pharmacist in accordance regulations or policies adopted by the United States drug enforcement administration.

(F) Transfer of prescription information between two pharmacies which are accessing the same real time, online database pursuant to the operation of a board approved central filling operation shall not be considered a prescription copy and, therefore, is not subject to the requirements of this rule.

(G) A licensed pharmacy intern may send or receive copies of prescriptions pursuant to the following:

(1) The pharmacist on duty who is supervising the activity of the intern will determine if the intern is competent to send or receive a prescription copy.

(2) The pharmacist on duty who is supervising the activity of the intern is responsible for the accuracy of a prescription copy that is sent or received by an intern.

(3) The pharmacist on duty must be immediately available to answer questions or discuss the prescription copy that is sent or received by an intern.

(4) The pharmacist or intern receiving a prescription copy from an intern must document the full names of the sending intern and his/her supervising pharmacist. The receiving intern shall immediately transcribe the prescription and shall review the prescription with the pharmacist on duty. Prior to dispensing, positive identification of the intern and the pharmacist on duty shall be made on the prescription to identify who is responsible for the receipt of the copy.

(5) The pharmacist or intern sending a prescription copy to an intern must document the full names of the receiving intern and the pharmacist on duty. There must be documented positive identification of the sending intern and the pharmacist on duty who authorized the transfer of the prescription copy.

(6) The intern may not send or receive a prescription copy for a controlled substance.

(7) The intern and the pharmacist on duty shall comply with all of the requirements of this rule.

(H) A certified pharmacy technician may send or receive copies of non-controlled prescriptions in accordance with rule 4729:3-3-04 of the Administrative Code.

**4729:5-5-12 Partial dispensing of schedule II controlled substances.**

(A) A valid prescription for a schedule II controlled substance may be partially dispensed if all the following apply:

(1) For a terminally ill patient or a patient residing in a long-term care facility, in accordance with 21 C.F.R. 1306.13 (03/31/2010), the following must be observed:

(a) Prior to a partial dispensing of a schedule II controlled substance, the pharmacist must confirm that the patient is "terminally ill" or a patient residing in a "long term care facility" and note this on the prescription;

(b) The total quantity dispensed in all partial dispensings shall not exceed the total quantity prescribed; and

(c) The remaining portions of a partially dispensed schedule II controlled substance prescription shall be filled not later than sixty days after the date on which the prescription is written.

(2) For a patient who is not terminally ill or residing in a long term care facility, the following must be observed:

(a) The partial dispensing shall be requested by the patient or the prescriber that issued the prescription;

(b) The total quantity dispensed in all partial dispensings shall not exceed the total quantity prescribed; and

(c) The remaining portions of a partially dispensed schedule II controlled substance prescription shall be filled not later than thirty days after the date on which the prescription is written.

(B) The partial dispensing of a schedule II prescription can only occur at the pharmacy where the original prescription is on file.

(C) At the time of partial dispensing of a schedule II controlled substance, the following must be noted on the back of the original prescription or within a computerized record keeping system pursuant to rule 4729:5-5-04 of the Administrative Code: the date dispensed, quantity dispensed, remaining quantity authorized to be dispensed, prescription number of this partial dispensing if different, and the manual initials or other form of positive identification of the dispensing pharmacist.

(D) If a computerized record keeping system is being used and the system will not permit refills of schedule II controlled substances, a new prescription number for the partial dispensing must be assigned.

(1) A notation must also be made in the recordkeeping system that identifies this new prescription number as a partial dispensing and provides the serial number of the original prescription.

(2) A prescription bearing the new serial number must be placed in the schedule II file. The prescription for each partial filling must also show the serial number of the original prescription and all previous partial fills.

**4729:5-5-14 Prescription pick-up station.**

(A) No pharmacist shall accept prescriptions obtained from a place which offers, in any manner, its services as a "pick-up station" or intermediary for the purpose of having prescriptions filled unless such place is a pharmacy as defined in section 4729.01 of the Revised Code and all of the following apply:

(1) The site is licensed as a terminal distributor of dangerous drugs pursuant to Chapter 4729. of the Revised Code, unless exempted pursuant to section 4729.541 of the Revised Code;

(2) The receipt, storage, control, and distribution of prescriptions are in the full and actual charge of a pharmacist licensed pursuant to Chapter 4729. of the Revised Code;

(3) An appropriate recordkeeping system is in place that will provide accountability for proper receipt, delivery, disposal and return of all prescriptions;

(4) There is a documented method in place to ensure compliance with rule 4729:5-5-09 of the Administrative Code.

(B) No pharmacist shall dispense dangerous drugs to a place which offers, in any manner, its services as a "pick-up station" or intermediary for the purpose of having prescriptions filled or delivered unless such place is a pharmacy as defined in section 4729.01 of the Revised Code or, if not a pharmacy, all of the following apply:

(1) The site is licensed as a terminal distributor of dangerous drugs pursuant to Chapter 4729. of the Revised Code, unless exempted pursuant to section 4729.541 of the Revised Code or a waiver is granted by the board.

(2) There is clear and convincing evidence that delivery of a prescription medication directly to the patient would result in:

(a) Danger to public health or safety, or

(b) Danger to the patient without increased involvement by a health care professional in the patient's drug therapy.

(3) The receipt, storage, control, and distribution of prescriptions or drugs are in the full and actual charge of a health care professional licensed pursuant to Chapter 4715., 4723., 4729., 4730., 4731., or 4741. of the Revised Code.

(4) An appropriate recordkeeping system is in place that will provide accountability for proper receipt, delivery, disposal and return of all prescription medications. Unless donated to a drug

repository program pursuant to section 3715.87 of the Revised Code, a dangerous drug that is not distributed to a patient shall either:

(a) Be returned to the dispensing pharmacy for disposal; or

(b) If the pick-up station is licensed a terminal distributor of dangerous drugs, be disposed of in accordance with rule 4729:5-3-01 of the Administrative Code.

(5) There is a documented method in place to ensure compliance with rule 4729:5-5-09 of the Administrative Code.

(C) The state board of pharmacy may restrict a site from acting as a pick-up station if it has clear and convincing evidence that the activities of the pick-up station present the following:

(1) Danger to public health or safety; or

(2) Danger to the patient.

**4729:5-5-02 Minimum standards for an outpatient pharmacy.**

(A) Library

(1) All pharmacists working in a pharmacy must be able to access all current federal and state laws, regulations, and rules governing the legal distribution of drugs in Ohio, including internet access to the following:

(a) The board's website; and

(b) LAWriter® Ohio Laws and Rules (http://codes.ohio.gov/).

(c) The code of laws of the United States of America (variously abbreviated to Code of Laws of the United States, United States Code, U.S. Code, U.S.C., or USC);

(d) The code of federal regulations.

(2) The pharmacy shall have access to and utilize the references necessary to conduct a pharmacy in a manner that is in the best interest of the patients served and to comply with all state and federal laws, this shall include hardcopy or internet access to appropriate pharmacy reference materials;

(3) Telephone number of a poison control center.

(B) Equipment

The pharmacy shall carry and utilize the equipment necessary to conduct a pharmacy in a manner that is in the best interest of the patients served and to comply with all state and federal laws.

(C) Stock of drugs

The stock of drugs shall include such chemicals, drugs, and preparations sufficient to compound and prepare all types of prescriptions offered by the pharmacy.

(D) Prescription containers

The stock of prescription containers shall include such containers as are necessary to dispense drugs in accordance with federal and state laws, including the provisions of the federal Poison Prevention Act of 1970 and compendial standards, or as recommended by the manufacturer or distributor for non-compendial drug products.

(E) Space and fixtures

(1) The stock, library, and equipment shall be housed in a suitable, well-lighted and well-ventilated room or department with clean and sanitary surroundings primarily used for the compounding and preparing of prescriptions and for the manufacture of pharmaceutical preparations.

(2) All areas where drugs and devices are stored shall be dry, well-lighted, well-ventilated, and maintained in a clean and orderly condition. Storage areas shall be maintained at temperatures which will ensure the integrity of the drugs prior to their dispensing or administering as stipulated by the USP/NF and/or the manufacturer's or distributor's labeling unless otherwise indicated by the board.

(3) All storage areas shall provide adequate security for all dangerous drugs in accordance with the requirements of agency 4729. of the Administrative Code.

(a) If applicable, a pharmacy shall maintain the current contact information for the pharmacy's security system vendor.

(F) Pharmacy hours

Notice to the public of operating hours of the pharmacy department must be posted.

(G) Personnel

The pharmacy shall be appropriately staffed to operate in a safe and effective manner pursuant to section 4729.55 of the Revised Code. An employee of a pharmacy that may have contact with patients or the general public must be identified by a nametag that includes the employee's job title.

**4729:5-3-06 Storage of adulterated drugs.**

To prevent their use, adulterated drugs, as defined in agency 4729. of the Administrative Code, shall be stored in a separate and secure area apart from the storage of drugs used for dispensing, personally furnishing, compounding and administration.

(A) Adulterated drugs shall be stored no longer than one year from the date of adulteration or expiration by those holding a terminal distributor of dangerous drugs license. Adulterated drugs shall be stored in a manner that prohibits access by unauthorized persons.

(B) Dangerous drugs, other than controlled substances, may be destroyed utilizing proper methods of disposal and following the record keeping requirements noted in agency 4729. of the Administrative Code, or may be donated to a pharmacy school pursuant to sections 3715.88 to 3715.92 of the Revised Code. Methods of disposal of non-controlled dangerous drugs shall prevent the possession of the drugs by unauthorized persons.

(C) Dangerous drugs that are controlled substances shall be disposed of pursuant to rule 4729:5-3-01 of the Administrative Code.