5/4/2018

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

- 4729:5-3-11: Provides the requirements for the transmission of a prescription by a prescriber or an agent of the prescriber.
- 4729:5-5-15 Provides the requirements for manner of issuance of a prescription, including requirements for refilling. (Rescinds 4729-5-30 and 4729-5-30.1)
- 4729:5-5-16 Provides the requirements allowing a pharmacist to make modifications to a prescription.
- 4729:5-5-17 Provides the labeling and recordkeeping requirements for drugs that are repackaged or relabeled by a pharmacy. (Rescinds 4729-9-20)
- 4729:5-5-18 Permits the packaging of multiple drugs in the same container under certain conditions. (Rescinds 4729-9-23)

Rescinded:

- 4729-5-30: Defines the manner of issuance of a prescription. Content of the rule is moving to a new division (4729:5-5) of the Administrative Code.
- 4729-5-30.1: Establishes the standards that all pharmacy computer systems receiving electronic controlled substance prescriptions have the capacity to receive diagnosis or procedure codes. Content of the rule is moving to a new division (4729:5-5) of the Administrative Code.
- 4729-9-20: Provides the labeling and recordkeeping requirements for drugs that are repackaged or relabeled by a pharmacy. Content of the rule is moving to a new division (4729:5-5) of the Administrative Code.
- 4729-9-23: Permits the packaging of multiple drugs in the same container under certain conditions. Content of the rule is moving to a new division (4729:5-5) of the Administrative Code.

Comments on the proposed rules will be accepted until close of business on **May 21, 2018**. Please send all comments to the following email address: **Ali.Simon@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: Outpatient Pharmacies

Rule Number(s):

New:

- **4729:5-3-11**
- **4729:5-5-15**
- **4729:5-5-16**
- **4729:5-5-17**
- **4729:5-5-18**

Rescind:

- **4729-5-30**
- **4729-5-30.1**
- **4729-9-20**
- **4729-9-23**

Date: 5/4/2018

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

- 4729:5-3-11: Provides the requirements for the transmission of a prescription by a prescriber or an agent of the prescriber.
- 4729:5-5-15 Provides the requirements for manner of issuance of a prescription, including requirements for refilling. (Rescinds 4729-5-30 and 4729-5-30.1)
- 4729:5-5-16 Provides the requirements allowing a pharmacist to make modifications to a prescription.
- 4729:5-5-17 Provides the labeling and recordkeeping requirements for drugs that are repackaged or relabeled by a pharmacy. (Rescinds 4729-9-20)
- 4729:5-5-18 Permits the packaging of multiple drugs in the same container under certain conditions. (Rescinds 4729-9-23)

Rescinded:

- 4729-5-30: Defines the manner of issuance of a prescription. Content of the rule is moving to a new division (4729:5-5) of the Administrative Code.
- 4729-5-30.1: Establishes the standards that all pharmacy computer systems receiving electronic controlled substance prescriptions have the capacity to receive diagnosis or procedure codes. Content of the rule is moving to a new division (4729:5-5) of the Administrative Code.
- 4729-9-20: Provides the labeling and recordkeeping requirements for drugs that are repackaged or relabeled by a pharmacy. Content of the rule is moving to a new division (4729:5-5) of the Administrative Code.
- 4729-9-23: Permits the packaging of multiple drugs in the same container under certain conditions. Content of the rule is moving to a new division (4729:5-5) of the Administrative Code.

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

The proposed rule is 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 has traditionally been done at the state level by legislatively created state boards of pharmacy. The regulation of the pharmacy practice includes valid requirements for issuing or modifying prescriptions and packaging of pharmaceuticals.

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 the legal distribution of prescription drugs.

Section 3719.28 of the Ohio Revised Code authorizes the Board of Pharmacy to adopt rules regarding 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.

The rules proposed under the statutory authority listed above are necessary to support efforts to ensure patient safety and consistency of practice across the state.

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 rule.

Development of the Regulation

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

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 rules prior to their legislatively mandated five-year date.

Prior to filing with CSI, the rules were 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.

Such modifications recommended by the Committee and included in the rule package are as follows:

- 4729:5-5-15: Acceptance of refill PRN authorizations.
- 4729:5-5-16: Allowing the pharmacist to modify the name of the patient on a prescription upon consultation with the prescriber or prescriber's agent.
- 4729:5-5-17: Clarification to allow the national drug code or universal product code (UPC) to be embedded in a bar code. Addition of the requirement to include the code on the package labeling, if applicable.
- 4729:5-5-18: Addition of special handling instructions for hazardous drugs. Permitting the inclusion of drugs in a single dose container if stability information can be provided by the manufacturer.

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 these rules.

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 and distribution of dangerous drugs, 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.

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 staff 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; and
- 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 this rule may result in administrative licensure discipline for a pharmacist, prescriber or terminal distributor of dangerous drugs. Discipline might include reprimand, suspension of a license, monetary fine and/or revocation of a license.

c. Quantify the expected adverse impact from the regulation.

New

- 4729:5-5-15 Establishes the requirements for manner of issuance of a prescription, including requirements for refilling. Currently, these requirements are set forth in 4729-5-30. The rule does allow for prescriptions for non-controlled substances bearing "PRN", "ad lib" or similar to be refilled. As this has not been previously permitted, any pharmacy accepting a script may have to update system software to accommodate a PRN refill.
- 4729:5-5-16 Establishes the requirements allowing a pharmacist to make modifications to a prescription. Currently, these requirements are set forth in 4729-5-30. The provision may impose an administrative burden to properly document the consultations between a pharmacist and the prescriber or agent of the prescriber. Additionally, there is a requirement to consult an FDA publication. However, this publication is available at no-cost on the FDA's website.
- 4729:5-3-11 Provides the requirements for the transmission of a prescription by a prescriber or an agent of the prescriber. Currently, these exact requirements are set forth in 4729-5-30 and 4729-5-30.1. Any electronic system that is out-of-compliance will have to comply with the requirements, which may require time and costs to modify prescription transmission software.
- 4729:5-5-17 Provides the labeling and recordkeeping requirements for drugs that are repackaged or relabeled by a pharmacy. Currently, these requirements are set forth in 4729-9-20. There may be increased administrative costs to ensure compliance with recordkeeping and labeling requirements for pharmacies that relabel/repackage drugs, including the additional requirements of the NDC or UPC codes.
- 4729:5-5-18 Permits the packaging of multiple drugs in the same container under certain conditions. Currently, these requirements are set forth in 4729-9-23. Pharmacies that dispense hazardous drugs may experience an increase in administrative costs because the rule requires any hazardous drug to be appropriately labeled and include proper handling instructions.

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 following:

- The information required on all prescriptions;
- The transmission of prescriptions;
- The labeling and repackaging of drugs by pharmacies; and
- Modifications to prescriptions made by a pharmacist.

Regulatory Flexibility

16. 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 regulations are 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 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.

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.

NOTE: All rule text listed are new rules. The yellow highlights in the rule text serve to indicate the major changes from the rule language that current exists in the OAC.

4729:5-5-15 - Manner of issuance of a prescription. (Rescind 4729-5-30 and 4729-5-30.1)

(A) A prescription, to be valid, must be issued for a legitimate medical purpose by an individual prescriber acting in the usual course of the prescriber's 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) All prescriptions issued by a prescriber shall:

(1) Be dated as of and on the day when issued.

(2) Contain the manually printed, typewritten, or preprinted full name, professional title, and address of the prescriber. The prescriber's address shall include the physical address of the prescriber's practice location.

(3) Indicate a telephone number where the prescriber can be contacted during normal business hours.

(4) Indicate the full name and residential address of the patient. The patient's residential address shall include the patient's physical street address.

(5) Indicate the drug name and strength.

(6) Indicate the quantity to dispense.

(7) Indicate the appropriate and explicit directions for use.

(8) Specify the number of times or the period of time for which the prescription may be refilled. If no such authorization is given, the prescription may not be refilled except in accordance with section 4729.281 of the Revised Code. ~~A prescription marked "Refill P.R.N." or some similar designation is not considered a valid refill authorization.~~

(a) Prescriptions for non-controlled substance dangerous drugs bearing “PRN”, “Ad lib”, or other similar prescription refill designation permitting the pharmacist to refill the prescription as needed by the patient, shall be refilled only in keeping with the number of doses ordered and according to the directions for use, and, in no instance, shall such prescription be refilled beyond one year from the date of issue. The prescription shall not be refilled out of context with the

dosage schedule indicated in the directions for use unless specifically authorized by the prescriber.

(b) Prescriptions for controlled substance dangerous drugs bearing “PRN”, “Ad lib”, or other similar prescription refill designation are not considered a valid refill authorization.

(9) Not authorize any refills for schedule II controlled substances.

(10) Authorize refills for schedules III and IV controlled substances only as permitted by section 3719.05 of the Revised Code.

(11) Not authorize a refill beyond one year from the date of issuance for schedule V controlled substances and for dangerous drugs that are not controlled substances.

(12) Identify the trade name or generic name of the drug(s) in a compounded prescription.

(13) Not be coded in such a manner that it cannot be dispensed by any pharmacy of the patient's choice.

(14) For a controlled substance:

(a) Indicate the drug enforcement administration registration number of the prescriber pursuant to Title 21 CFR 1306.05 (3/31/2010).

(b) Except for veterinarians licensed pursuant to Chapter 4741. of the Revised Code, indicate either:

(i) The ICD-10-CM medical diagnosis code of the primary disease or condition that the controlled substance is being used to treat. The code shall, at a minimum, include the first four alphanumeric characters of the ICD-10-CM medical diagnosis code, sometimes referred to as the category and the etiology (ex. M 16.5).

(ii) For dentists licensed pursuant to Chapter 4715. of the Revised Code, the Code on Dental Procedures and Nomenclature (CDT Code), as published by the American dental association, of the dental treatment requiring the controlled substance prescription.

(15) Except for veterinarians licensed under Chapter 4741. of the Revised Code, for all controlled substances and products containing gabapentin:

(a) Indicate the prescriber’s intended days' supply of the prescription.

(16) For a managing pharmacist acting as an agent of a physician pursuant to section 4729.38 of the Revised Code and rules adopted thereunder, the prescription shall include the full name of the managing pharmacist.

(17) Be issued in compliance with all applicable federal and Ohio laws, rules, and regulations.

(C) Failure of a prescription to contain the requirements set forth in paragraphs (B)(14)(b) and (B)(15) of this rule or of the pharmacist to obtain the information set forth in paragraphs (B)(14)(b) and (B)(15) of this rule shall not render the prescription, if dispensed in good faith, to be invalid.

(D) All prescriptions issued on paper to a patient by a prescriber shall be:

(1) Manually signed on the day issued by the prescriber in the same manner as the prescriber would sign a check or legal document.

(2) Issued in compliance with rule 4729:5-5-05 Administrative Code.

(E) When forms are used that create multiple copies of a prescription issued to a patient by a prescriber, the original prescription that includes the actual signature of the prescriber must be issued to the patient for dispensing by a pharmacist.

(F) Pursuant to section 4729.38 of the Revised Code, a pharmacist shall not select a generically equivalent drug or interchangeable biological product if either of the following applies:

(1) In the case of a written or electronic prescription, including a computer- generated prescription, the prescriber handwrites or actively causes to display on the prescription "dispense as written," "D.A.W," "do not substitute." "brand medically necessary." or any other statement or numerical code that indicates the prescriber's intent to prevent substitution. Such a designation shall not be preprinted or stamped on the prescription, but a reminder to the prescriber of the designation procedure may be preprinted or displayed on the prescription form or electronic system the prescriber uses to issue the prescription.

(2) In the case of an oral prescription, the prescriber or the prescriber's agent specifies that the drug as prescribed is medically necessary or otherwise indicates the prescriber's intent to prevent substitution.

(G) Pursuant to section 4729.40 of the Revised Code, a pharmacist shall not dispense a quantity or amount of a drug that ~~varies from the quantity~~ exceeds the quantity or amount of the drug that otherwise would be dispensed pursuant to the prescription if the following applies:

The prescriber included "dispense as written" or another phrase having a similar meaning on the prescription, or, when issuing a prescription electronically or orally, the prescriber did not specify that the quantity or amount of the drug to be dispensed may not vary from the quantity or amount specified in the prescription.

4729:5-5-16 – Pharmacist modifications to a prescription.

A pharmacist may make the following modifications to a prescription:

(A) Add or change the patient's address upon verification with the patient or patient's caregiver.

(B) For a schedule II controlled substance prescription, a pharmacist may add or change the dosage form, drug strength, drug quantity, directions, patient name, issue date or do not fill until date only after consultation with and agreement of the prescriber.

(C) For a schedule III-V controlled substance prescription, a pharmacist may add or change the dosage form, drug strength, drug quantity, directions, patient name, issue date or do not fill until date only after consultation with and agreement of the prescriber or agent of the prescriber.

(D) Except as provided for in paragraph (G) of this rule, for a non-controlled substance prescription, a pharmacist may add or change the dosage form, drug strength, drug quantity, directions, patient name, issue date or do not fill until date only after consultation with and agreement of the prescriber or agent of the prescriber.

(E)

(1) For all controlled substance prescriptions or prescriptions for drugs containing gabapentin, a pharmacist may add or change the days' supply only after consultation with and agreement of the prescriber or agent of the prescriber.

(2) For all controlled substance prescriptions, a pharmacist may add or change the ICD-10- CM medical diagnosis code or code on dental procedures and nomenclature only after consultation with and agreement of the prescriber or agent of the prescriber.

(F) A pharmacist may modify a prescription to specify if "dispense as written" or another phrase or indicator having a similar meaning applies to the following only after consultation with and agreement of the prescriber or agent of the prescriber.

(G) For a non-controlled substance prescription, a pharmacist may change the dosage form, drug strength, drug quantity and directions for use without consultation with and agreement of the prescriber or agent of the prescriber in accordance with the following:

(1) The drug selected must be therapeutically equivalent as indicated in the approved drug products with therapeutic equivalence evaluations (commonly known as the orange book), 38th edition or any official supplement thereto, published by the United States food and drug administration;

(2) The drug selected must have the same frequency and duration of therapy as the prescribed drug;

(3) The prescription is for a human patient;

(4) No modifications shall be made pursuant to this paragraph if "dispense as written" or another phrase or indicator having a similar meaning is indicated on the prescription pursuant to paragraphs (I) and (J) of this rule;

(5) The pharmacist who selects the drug to be dispensed pursuant to this paragraph shall assume the same responsibility for selecting the dispensed drug as would be incurred in filling a prescription for a drug using the prescribed form; and

(6) The pharmacist shall not permit substitution between long-acting and short- acting forms of a drug with the same chemical ingredients or between one drug product and two or more drug products with the same chemical ingredients.

(H) All consultations and corresponding changes performed in accordance with this paragraph shall be noted by the pharmacist on the prescription or in the patient's profile and shall be communicated to the patient or patient's caregiver.

(I) A pharmacist shall not make changes to the dangerous drug prescribed, except for generic substitution permitted by law, or the prescriber's signature.

4729:5-3-11 – Transmission of a prescription.

(A) Oral transmission by a prescriber or a prescriber's agent of original prescriptions and refills authorized by a prescriber shall comply with rule 4729:5-5-10 of the Administrative Code. For any oral prescription transmitted by an agent of a prescriber, the prescriber's agent must provide the agent's first and last name when transmitting the prescription. An oral prescription may be transmitted by a prescriber or prescriber's agent to a recording device or voice mail service.

(B) Original written prescriptions authorized and signed by a prescriber, in the same manner as the prescriber would sign a check or legal document, may be transmitted by the prescriber or the prescriber's agent by facsimile machine to a pharmacy.

(1) The facsimile of the prescription must include the full name of the prescriber and, if applicable, the full name of the prescriber's agent transmitting the prescription to the pharmacy.

(2) The prescription must comply with the requirements of rule 4729:5-3-16 of the Administrative Code.

(3) The original prescription signed by the prescriber from which the facsimile is produced shall not be issued to the patient. The original prescription signed by the prescriber must remain with the patient's records at the prescriber's office or the institutional facility where it was issued for three years from the date of issuance. Following the successful transmission of the prescription, the word "VOID" is written or stamped on the face of the original prescription in a manner that does not destroy any of the original information contained on the prescription.

(4) Prescriptions for schedule II controlled substances may be transmitted by facsimile in accordance with 21 C.F.R. 1306.11 (3/31/2010) and must also meet the facsimile requirements of this rule.

(C) If a prescription is transmitted from an institutional facility where it was not originally issued, an individual licensed pursuant to Chapter 4723., 4729., 4730. or 4731. of the Revised Code may transmit the prescription by facsimile machine to a pharmacy as an agent of the prescriber if all the following applies:

(1) Following the successful transmission of the prescription, the original prescription shall be marked as follows:

(a) The word "VOID" is written or stamped on the face of the original prescription in a manner that does not destroy any of the original information contained on the prescription;

(b) The name of the individual who transmitted the prescription and the date of transmission shall be indicated on the back of the original prescription.

(2) The prescription shall be maintained in the patient's record for three years from the date of transmission.

(3) The prescription transmitted is for a non-controlled dangerous drug. The transmission of a controlled substance prescription in accordance with this paragraph is prohibited.

(D) Outpatient prescriptions may be transmitted by means of an electronic prescription transmission system that complies with the prescription requirements in rule 4729:5-3-16 of the Administrative Code.

(1) An outpatient prescription transmitted by means of an electronic prescription transmission system shall include the full name of the prescriber's agent transmitting the prescription.

(2) A controlled substance outpatient prescription shall only be transmitted by means of an electronic prescription transmission system if the system complies with 21 CFR 1311 (3/31/2010).

(3) An institutional facility, as defined in agency 4729 of the Administrative Code, may only transmit inpatient prescriptions by means of a board approved electronic prescription transmission system provided that:

(a) The system requires positive identification of the prescriber and the full name of any authorized agent of the prescriber who transmits the prescription.

(b) The prescription data is retained for a period of three years from the date of transmittal.

(c) The approved system complies with the rules governing institutional facilities in agency 4729 of the Administrative Code.

(4) Except as provided in paragraphs (D)(5) and (D)(6) of this rule, no prescriptions may be transmitted by means of an electronic prescription transmission system that converts the prescription into a computer-generated fax or scanned image.

(5) A non-controlled prescription may be transmitted by means of an electronic prescription transmission system that converts the prescription into a computer-generated fax or scanned image if all the following apply:

(a) The transmission is conducted by means of a board approved system that meets the prescription requirements of rule 4729:5-3-16 of the Administrative Code.

(b) The prescription transmission system operates within a closed-system. A closed system includes a system whereby prescription information is transmitted directly between:

(i) Any division, subsidiary, parent or affiliated or related company under the common ownership and control.

(ii) One or more contracted entities. Contracted means having a written agreement (to include business associate agreements) between one or more prescribers and a pharmacy and shall not include a third-party intermediary unless otherwise approved by the board.

(6) A non-controlled prescription may be converted into a computer-generated fax by a board approved third-party intermediary only if the conversion is necessitated by a temporary telecommunication outage of the third-party intermediary or receiving pharmacy.

4729:5-5-17 – Drugs repackaged or relabeled by a pharmacy. (Rescind 4729-9-20)

(A) Labels of drugs repackaged by and stored within a pharmacy prior to being dispensed shall contain, but not be limited to, the following:

(1) Name of drug, strength, and dosage form;

(2) National drug code or universal product code, if applicable.

(3) The identification of the repackager by name or by the final seven digits of their terminal distributor of dangerous drugs license number;

(4) Pharmacy control number;

(4) Pharmacy's expiration date or beyond-use date, which shall be within the proven period of stability of the drug. This expiration or beyond-use date shall be no later than the manufacturer's expiration date of a not previously opened manufacturer's container.

(B) A record of all drugs repackaged and stored within a pharmacy prior to being dispensed shall be kept for at least three years or one year past manufacturer's expiration date, whichever is greater. This record shall include at least the following:

(1) Name of drug, strength, dosage form, and quantity;

(2) National drug code or universal product code, if applicable, which may be embedded in a barcode or quick response (QR) code on the label;

(3) Manufacturer's or distributor's control number;

(4) Manufacturer's or distributor's name, if a generic drug is used;

(5) Pharmacy control number;

(6) Manufacturer's or distributor's expiration date;

(7) The pharmacy's expiration date or beyond-use date;

(8) Positive identification of the pharmacist responsible for the repackaging of the drug.

(C) Supplemental labels created by a pharmacy that contain a barcode for the purpose of identifying a drug shall contain a means of identifying the positive identification of the pharmacist responsible for:

(1) The creation of the barcode; and

(2) Affixing the barcode label to the drug product.

4729:5-5-18 – Dispensing of multiple drugs in single-dose containers. (Rescind 4729-9-23)

Multiple drugs may be packaged in the same container such that the different drugs are in contact with each other only under the following conditions:

(A) The number of drugs placed in one package cannot exceed the capability of the receptacle to prevent damage to the dosage forms.

(B) Any package containing a drug on the national institute for occupational safety and health's list of antineoplastic and other hazardous drugs in healthcare settings, publication number 2016-161 or any official supplement thereto, shall be appropriately labeled as hazardous and shall include appropriate handling instructions.

(C) The quantity dispensed may not be more than a thirty-one-day supply.

(D) The labels must be of sufficient size to properly and clearly label a thirty-one-day or less supply with all information required by state and federal law including accessory labels.

(E) Each individual package must include a beyond-use date of not more than sixty days from the date the drugs were placed in the package.

(F) Medications which have been packaged in multi-dose packaging are considered adulterated if returned to the pharmacy for any reason and may not be returned to stock or re-dispensed.

(G) The packaging is tamper-evident.

(H) Any pharmacist or pharmacy using multi-dose packaging must implement policies and procedures which will exclude drugs having the following characteristics from such packaging:

(1) The U.S.P. monograph or official labeling requires dispensing in the original container, unless there is documented stability testing from the manufacturer;

(2) The drugs or dosage forms are incompatible with packaging components or each other;

(3) The drugs are therapeutically incompatible when administered simultaneously;

(4) The drug products require special packaging.