7/27/15

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 Ohio State 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.

Amended Rules

- **4729-5-24:** Removes requirement that prescription copies transferred for nonrefillable prescriptions be marked on the face of the prescription or orally noted.
- **4729-5-38:** Expands the list of vaccinations/immunizations that may be provided by pharmacists and pharmacy interns to include all recommended vaccinations/immunizations recommended by the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention (CDC).
- **4729-5-14:** Authorizes a prescriber's agent to transmit verbal orders in an outpatient hospice.
- **4729-5-35:** Corrects a spelling error.
- **4729-7-01:** Defines pharmacy jurisprudence and patient medication safety related continuing education. Removes the requirement that jurisprudence continuing education be approved by the State of Ohio Board of Pharmacy.
- **4729-7-02:** Requires pharmacists to obtain 0.2 continuing education units (CEUs) of patient or medication safety continuing education.
- **4729-7-08:** Requires pharmacists who have pharmacy practice specific specialty certification to obtain 0.2 continuing education units (CEUs) of patient or medication safety continuing education
- **4729-5-10:** Permits a site that is not licensed by the Board to act as a pick-up station if granted a waiver by the Board.

No Change (5-Year Review)

- **4729-5-16:** Includes the labeling requirements for drugs dispensed by a pharmacy pursuant to a prescription.
- **4729-5-13:** Provides the requirements for a valid prescription for pharmacist dispensing.

Comments on the proposed rules will be accepted until close of business on August 11, 2015. 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

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CSI - Ohio
The Common Sense Initiative

Business Impact Analysis

Agency Name: State of Ohio Board of Pharmacy

Regulation/Package Title: Pharmacists – Administrative Provisions / Pharmacists – Continuing Education

Rule Number(s): Amended: 4729-5-24; 4729-5-38; 4729-5-14; 4729-5-35; 4729-7-01; 4729-7-02; 4729-7-08; 4729-5-10

No Change: 4729-5-16; 4729-5-13

Date: 07/27/2015

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.

Amended Rules

- **4729-5-24:** Specifies the requirements for the transfer of prescriptions in a pharmacy. Removes the requirement that prescription copies transferred for nonrefillable prescriptions be marked on the face of the prescription or orally noted.

- **4729-5-38:** Authorizes pharmacists to administer vaccinations/immunizations beyond those listed in ORC 4729.41. Expands the list of vaccinations/immunizations that may be provided by pharmacists and pharmacy interns to include all recommended vaccinations/immunizations recommended by the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention (CDC). Please note the current rule will be rescinded.
- **4729-5-14:** Specifies requirements of prescriptions for hospice patients. Authorizes a prescriber's agent to transmit verbal orders in an outpatient hospice.
- **4729-5-35:** Provides the requirements for approval of automated drug delivery systems. Corrects a spelling error.
- **4729-7-01:** Definitional rule for pharmacist continuing education chapter. Defines pharmacy jurisprudence and patient medication safety related continuing education. Removes the requirement that jurisprudence continuing education be approved by the State of Ohio Board of Pharmacy.
- **4729-7-02:** Provides the requirements for renewal of a pharmacist license. Requires pharmacists to obtain 0.2 continuing education units (CEUs) of patient or medication safety continuing education.
- **4729-7-08:** Provides alternative methods for proving continuing competency as a pharmacist. Requires pharmacists who have pharmacy practice specific specialty certification to obtain 0.2 continuing education units (CEUs) of patient or medication safety continuing education
- **4729-5-10:** Requires electronic submission of a pick-up station notification in order to ship patient specific drugs to a location other than the patient's home. Permits a site that is not licensed by the Board to act as a pick-up station if granted a waiver by the Board.

No Change (5-Year Review)

- **4729-5-16:** Includes the labeling requirements for drugs dispensed by a pharmacy pursuant to a prescription.
- **4729-5-13:** Provides the requirements for a valid prescription for pharmacist dispensing.

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

The proposed rules are authorized by sections 4729.26, 3719.28 and 4729.41 of the Ohio Revised Code. The following sections of the Ohio Revised Code are also considered authorizing statutes for this rule package: 3719.05, 4729.37, 3719.06, 4729.01, 4729.12, 4729.13, 4729.15, 3719.07, 3719.09, 4729.28, 4729.37 and 4729.51

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?**

The rule does 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 pharmacy profession has traditionally been done at the state level by legislatively created state boards of pharmacy, such as the State of Ohio Board of Pharmacy. The State of Ohio Board of Pharmacy regulates all aspects of pharmacy practice. While the Food and Drug Administration closely regulates the manufacture and distribution of prescription drugs, the day-to-day practice of pharmacy traditionally has been left to state boards.

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 state board of pharmacy to adopt rules governing the practice of pharmacy, which includes a pharmacist's scope of practice and the regulation of entities that store dangerous drugs.

Section 4729.41 of the Ohio Revised Code authorizes the state board of pharmacy to adopt rules pertaining to the administration of immunizations by pharmacy professionals, including the types of immunizations that can be provided.

Section 3719.28 of the Ohio Revised Code authorizes the state 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.

The rules proposed under this statutory authority are necessary to facilitate compliance with the provisions in the above mentioned chapters of the Ohio Revised Code to promote the public's safety and uniformity of care throughout Ohio. Without these regulations, the Ohio State Board of Pharmacy would not be able to:

- Provide uniform requirements for prescription transfers between pharmacies.
- Provide uniform requirements for prescriptions dispensed by pharmacies.

- Ensure the competency of pharmacists practicing in Ohio.
- Ensure that pharmacists/pharmacy interns are able to provide the most up-to-date CDC ACIP recommended immunizations.
- Ensure uniform standards for the approval of automated drug delivery systems.

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 and prescribers of dangerous drugs 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 were reviewed and approved by the State of Ohio Board of Pharmacy's Rules Review Committee. The committee is comprised of a broad array of stakeholders including:

- Select Specialty Hospital – Akron
- Berger Health System
- The Kroger Company
- Meijer
- Nationwide Children's Hospital
- Fort Hamilton Hospital
- Central Ohio Compounding Pharmacy
- Healthspan Physicians and Integrated Care
- Cedarville University School of Pharmacy
- Fairview Hospital – Cleveland Clinic
- OhioHealth
- Wal-Mart
- Pharmacy Systems, Inc.

All rules are subject to final approval by the state board of pharmacy prior to filing with the Joint Committee on Agency Rule Review.

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.

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 the 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 rules for prescription processing, continuing education, automated drug systems, immunization administration, and labeling of prescriptions, 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 Board did not consider a performance-based regulation for the rules in this package. It is the Board's responsibility to ensure that regulations are consistent throughout the state. 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 Legal Affairs and Pharmacist Compliance Supervisor 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 Pharmacy Board's web site, information concerning the rule will be included in materials e-mailed to licensees, and notices will be sent to associations, individuals and groups. Pharmacy Board staff are also available via phone or email to answer questions regarding implementation of the rule. In addition, the Board's compliance agents are trained to educate licensees on current and/or new regulations during on-site inspections.

Pharmacy Board 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, monthly email updates from the legislative affairs liaison and feedback from the Board's legal director 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:

- Ohio licensed Pharmacists and Pharmacy Interns;
- 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 licensure discipline for a pharmacist, pharmacy intern or terminal distributor of dangerous drugs. Discipline might include reprimand, suspension of a license, required course work (pharmacists/interns), monetary fine and/or revocation of a license.

c. Quantify the expected adverse impact from the regulation.

- **4729-5-24:** Specifies the requirements for the transfer of prescriptions in a pharmacy. Removes the requirement that prescription copies transferred for nonrefillable prescriptions be marked on the face of the prescription or orally noted. While the proposed change will not result in an expected adverse impact, the overall regulation will result in administrative costs for prescribers/pharmacists to comply with the rule.
- **4729-5-38:** Authorizes pharmacists to administer vaccinations/immunizations beyond those listed in ORC 4729.41. Expands the list of vaccinations/immunizations that may be provided by pharmacists and pharmacy interns to include all recommended vaccinations/immunizations recommended by the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention (CDC). Compliance with this rule may result in administrative and record keeping costs to pharmacies that provide immunizations to patients.

- **4729-5-14:** Specifies requirements of prescriptions for hospice patients. Authorizes a prescriber's agent to transmit verbal orders in an outpatient hospice. While the proposed change will not result in an expected adverse impact, the overall regulation will result in administrative costs for prescribers/pharmacists to comply with the rule.
- **4729-5-35:** Provides the requirements for approval of automated drug delivery systems. Corrects a spelling error. While the proposed change will not result in an expected adverse impact, the overall regulation does require automated systems to meet certain standards. If a system does not meet the required standards, upgrades to that system may be required which will result in increased costs.
- **4729-7-01:** Definitional rule for pharmacist continuing education chapter. Defines pharmacy jurisprudence and patient medication safety related continuing education. Removes the requirement that jurisprudence continuing education be approved by the State of Ohio Board of Pharmacy. This is a definitional section and should have no adverse impact.
- **4729-7-02:** Provides the requirements for renewal of a pharmacist license. Requires pharmacists to obtain 0.2 continuing education units (CEUs) of patient or medication safety continuing education. The rule itself imposes a cost to pharmacists to obtain 60 hours of continuing education over the course of 3 years. Costs associated with this rule include the cost of the continuing education (although there are free courses available) and the time to complete this requirement. This requires pharmacists to obtain 2 hours of continuing education in patient safety out of their total 60 hours. It may require a pharmacist who has already completed the 60 hour requirement to obtain 2 additional hours. While low cost and no-cost CEUs are available, one source cites $30 as the average cost per continuing education credit.
- **4729-7-08:** Allows a pharmacist to demonstrate the completion of continuing education requirements by presenting evidence of pharmacy practice specialty certification. This is a continuation of an existing rule. This allows a pharmacist the flexibility to obtain specialty certification (for example, Board Certified Pharmacotherapy Specialist) to meet their continuing education requirements. The cost of a BCPS certification is $600 for an initial exam and $100 for annual recertification.[1] Requires pharmacists who have pharmacy practice specific specialty certification to obtain 0.2 continuing education units (CEUs) of patient or medication safety continuing education. This will require a pharmacist that obtains this certification to obtain 2 hours of continuing education. While low cost and no-cost CEUs are available, one source cites $30 as the average cost per continuing education credit.
- **4729-5-10:** Requires electronic submission of a pick-up station notification in order to ship patient specific drugs to a location other than the patient's home. Permits a site that is not licensed by the Board to act as a pick-up station if granted a waiver by the Board.

[1] https://www.bpsweb.org/apply/fees.cfm

This requires the submission of a notification form which takes approximately 10-15 minutes to complete.

- **4729-5-16:** Includes the labeling requirements for drugs dispensed by a pharmacy pursuant to a prescription. This will result in administrative costs for pharmacists to ensure compliance with the rule.
- **4729-5-13:** Provides the requirements for a valid prescription for pharmacist dispensing. This will result in administrative costs for pharmacists to ensure compliance with the rule.

Regulatory Flexibility

15. 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.

16. 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 is not considered a paperwork error but a quality assurance issue by the licensee that is necessary for the protection of the public.

17. 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. Additionally, field staff (i.e. compliance officers) is trained to educate licensees on compliance with all Board of Pharmacy rules and regulations.

4729-5-24 Prescription copy.

(A) A pharmacist may transfer a copy of a prescription; a pharmacist may refill a copy of a prescription; such actions must be in accordance with the following unless otherwise approved by the state board of pharmacy:

(1) Copies of prescriptions shall be transferred only between pharmacists except as provided in paragraph (G) of this rule; copies of prescriptions for controlled substances pursuant to sections 3719.41, 3719.43, and 3719.44 of the Revised Code shall be communicated directly between two pharmacists and shall be transferred only one time. However, 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)(3) of this rule.

(2) 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 and address (and "D.E.A." number for controlled substance prescriptions) of the pharmacy transferring the copy;

(c) Date of issuance of the prescription;

(d) Date of original dispensing of the prescription;

(e) Original number of refills;

(f) Date of last refill;

(g) Number of valid refills remaining; and

(h) The full name of the transferring pharmacist.

~~(3) Copies transferred for nonrefillable prescriptions shall be marked on the face of the prescription or orally noted by the transferring pharmacist "For Information Purposes Only" and are not valid prescriptions for the dispensing of drugs.~~

(3) The pharmacist transferring a copy of a prescription must:

(a) Cancel the original prescription by writing the word "void" on the face of the prescription in such a way as to avoid destroying any of the original information contained on the prescription;

(b) Record on the reverse side of the original written prescription:

(i) The date of transfer;

(ii) His/her signature; and

(iii) The name and address (and "D.E.A." number for controlled substance prescriptions) of the pharmacy receiving the prescription and the full name of the pharmacist receiving the prescription.

(c) Except, if an alternate record keeping system is being used pursuant to rule 4729-5-27 of the Administrative Code, 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. The prescription record in the system must contain the date of transfer, full name of pharmacist making transfer, full name of pharmacist receiving the prescription, and the name and address of the pharmacy receiving the copy. Also, original written prescriptions for controlled substances must be canceled as required in paragraphs (A)(3)(a) and (A)(3)(b) of this rule.

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

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

(b) Reduce an oral prescription to writing by recording all of the information transferred (must include all information required in paragraph (A)(2) of this rule) and 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)(2) and (A)(3)(c) 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)(3)(a) and (A)(3)(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. Original copies of prescriptions shall be maintained by pharmacies for the purpose of documenting the dispensing of drugs to a particular 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, transfer the prescription information to the pharmacy designated by the patient.

(2) No pharmacy shall refuse to transfer information about a previously dispensed prescription to another pharmacy when requested by the patient. Prescription information shall be transferred in accordance with this rule as soon as possible in order to assure that the patient's drug therapy is not interrupted.

(E) Prescriptions entered into a computer system but not dispensed may be transferred to another pharmacy 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, either in the computer system or on the hard copy prescription, of the pharmacist who is responsible for entering the prescription information into the system;

(4) The original prescription is filed in accordance with rule 4729-5-09 of the Administrative Code;

(5) All requirements of this rule are met for the transfer of the prescription.

(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 supervising pharmacist must be immediately available to answer questions or discuss the prescription copy that is sent or received by an intern.

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

(5) 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 reduce the prescription copy to writing and shall review the prescription with the supervising pharmacist. Prior to dispensing, positive identification of the intern and the supervising pharmacist shall be made on the prescription to identify the responsibility for the receipt of the copy.

(6) The pharmacist or intern sending a prescription copy to an intern must document the full names of the receiving intern and his/her supervising pharmacist. There must be documented positive identification of the sending intern and his/her supervising pharmacist who authorized the transfer of the prescription copy.

(7) The approved intern and the supervising pharmacist must meet all the requirements of this rule.

4729-5-38 Immunization & Vaccine administration.

Rescind current rule and replace with the following:

(A) A pharmacist or pharmacy intern acting under the direct supervision of a pharmacist may administer in accordance with section 4729.41 of the Revised Code the following:

(1) Any immunization or vaccine that is included in either of the following schedules and is administered according to those schedules:

(a) The immunization schedule for persons aged zero through eighteen years recommended by the advisory committee on immunization practices of the centers for disease control and prevention in the United States department of health and human services (5/28/2015):

(b) Except as listed in paragraph (A)(2) of this rule, the adult immunization schedule recommended by the advisory committee on immunization practices of the centers for disease control and prevention in the United States department of health and human services (5/28/2015).

(2) The zoster vaccine according to the age criteria specified in the F.D.A. approved labeling.

(3) Except as provided in paragraph (A)(4) and (A)(5) of this rule, any other immunization or vaccine recommended by the advisory committee on immunization practices of the centers for disease control and prevention in the United States department of health and human services if administered in accordance with the recommendations adopted by the committee.

(4) The rabies vaccine for post exposure if all the following are met:

(a) A pharmacist or pharmacy intern does not provide the initial dose of the rabies post expsoure vaccine;

(b) Follow-up doses are administered pursuant to a prescription issued by a prescriber;

(c) The follow-up doses are administered in accordance with recommendations adopted by the advisory committee on immunization practices of the centers for disease control and prevention in the United States department of health and human services (5/28/2015); and

(5) The requirements listed in paragraph (A)(4) of this rule do not apply to the rabies vaccine for preexposure if administered in accordance with recommendations adopted by the advisory committee on immunization practices of the centers for disease control and prevention in the United States department of health and human services (5/28/2015).

(B) A pharmacist or pharmacy intern shall obtain informed consent to administer an immunization or vaccination pursuant to paragraph (O) of rule 4729-5-27 of the Administrative Code.

(C) A pharmacist or pharmacy intern shall comply with the vaccine information statement requirements of the National Vaccine Childhood Injury Act, 42 U.S.C. § 300aa-26 (5/28/2015).

(D) A pharmacist or pharmacy intern who engages in the administration of an immunization or vaccination shall do so in accordance with rules 4729-5-36 and 4729-5-37 of the Administrative Code.

(E) An immunization or vaccine specified in this rule shall not be administered to any individual who is less than thirteen years of age, except in the following situations:

(1) The immunization for influenza is administered to individuals who are seven years of age or older; or

(2) Pursuant to a prescription from a licensed prescriber, an immunization or vaccine is administered to individuals who are seven years of age or older but not more than thirteen years of age.

(F) For each immunization administered to an individual by a pharmacist or pharmacy intern, other than an immunization for influenza administered to an individual eighteen years of age or older, the pharmacist or pharmacy intern shall notify the individual's family physician or, if the individual has no family physician, the board of health of the health district in which the individual resides or the authority having the duties of a board of health for that district under section 3709.05 of the Revised Code. The notice shall be given not later than thirty days after the immunization is administered.

4729-5-13 Prescription format.

Except as provided in rule 4729-5-14 of the Administrative Code:

(A) 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) No prescriber shall write and 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 as defined in paragraph (B) of rule 4729-5-15 of the Administrative Code may not be dispensed unless the prescription is issued in compliance with this rule and rule 4729-17-13 of the Administrative Code and unless it bears the identification number issued by the employing hospital or institution pursuant to rule 4729-17-13 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 compliance with this rule and rule 4729-17-13 of the Administrative Code and unless it bears the identification number issued by the employing hospital or institution pursuant to rule 4729-17-13 of the Administrative Code.

(E) If a board approved electronic prescription transmission system is used to fax a prescription to a pharmacy, the faxed order is exempt from paragraphs (A) and (B) of this rule. The faxed order must comply with rule 4729-5-30 of the Administrative Code and must be filed in the most restrictive file according to rule 4729-5-09 of the Administrative Code.

4729-5-14 Prescription format for a hospice outpatient.

For purposes of preprinted prescription forms for hospice outpatients, the following conditions apply:

(A) 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.

(B) 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.

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

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

(2) Manually initialing each drug order.

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

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

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

4729-5-16 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 and address of the pharmacy as it appears on the terminal distributor of dangerous drugs license unless it is filled pursuant to a board-approved central filling operation, in which case the label shall bear the name and address of the originating 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. The dispensing pharmacist may omit the name and strength of the drug only if the prescriber specifically requests omission in writing in the case of a written prescription, or verbally in the case of an orally transmitted prescription;

(9) The quantity of drug dispensed;

(10) If filled as part of a board-approved central filling operation, an identification of the pharmacy providing the drugs for the dispensing operation.

(B) The term "affix" means the prescription label must be attached or fastened to the container.

(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. In all cases, a complete prescription label meeting the requirements of paragraph (A) of this rule must be applied to the container in which such product is dispensed.

(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 rule 4729-17-10 of the Administrative Code.

4729-5-35 Automated drug delivery systems.

(A) All automated drug delivery systems intended for use by a terminal distributor of dangerous drugs to assist in the dispensing of a drug pursuant to rules 4729-5-01 and 4729-17-01 of the Administrative Code must meet the following requirements:

(1) Each automated drug delivery system must be approved via the procedure established in paragraph (B) of this rule by the board of pharmacy prior to its implementation by the terminal distributor of dangerous drugs;

(2) The automated drug delivery system shall have a documented and ongoing quality assurance program that monitors total system performance and includes security measures to ensure the safe and effective distribution of drugs;

(3) The automated drug delivery system shall have adequate security to prevent unauthorized individuals from accessing or obtaining dangerous drugs and includes ~~safegaurds~~ safeguards to detect diversion of dangerous drugs;

(4) The records kept by the automated drug delivery system shall comply with all board requirements.

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

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

4729-7-08 Alternative methods of proving continuing competency.

(A) As an alternative to providing evidence of all of the required C.E.U.S of approved continuing education as required by rule 4729-7-02 of the Administrative Code except for the 0.3 C.E.U.S of ~~Ohio state board of~~ pharmacy ~~approved~~ jurisprudence and 0.2 C.E.U.S of patient or medication safety, a pharmacist may satisfy the continuing pharmacy education requirements by providing evidence at the time of renewal that he/she has met the requirements of and is currently certified by a board approved pharmacy practice specific specialty certification program. At a minimum, such pharmacy practice specific specialty certification programs shall consist of:

(1) Periodic recertification examinations;

(2) Documentation by the certification program that the pharmacist is currently certified by the program;

(3) Other requirements as determined by the board.

(B) Pharmacists who choose to meet their continuing pharmacy education requirements in the manner described in paragraph (A) of this rule are still required to provide evidence of having completed at least 0.3 C.E.U.S of ~~Ohio state board of pharmacy approved~~ pharmacy jurisprudence and 0.2 C.E.U.S of patient or medication safety related continuing education.

4729-7-01 Definitions.

As used in Chapter 4729-7 of the Administrative Code.

(A) "Approved continuing education" is defined as participation in an organized and structured continuing pharmacy education experience that has been presented by an approved provider or the state board of pharmacy and that presents information directly related to the practice of pharmacy.

(B) "Approved provider" is defined as an individual, institution, organization, association, corporation, or agency that has been approved by the state board of pharmacy and/or accredited by the "Accreditation Council for Pharmacy Education" (A.C.P.E.).

(C) "Continuing education unit (C.E.U.)" is defined as ten contact hours of participation in an organized continuing pharmacy education experience presented by an approved provider.

(D) "Continuing pharmacy education", as required in section 4729.12 of the Revised Code, is defined as post-registration pharmacy education of approved quality undertaken to maintain professional competency to practice pharmacy, improve professional skills, and preserve uniform qualifications for continuing the practice of the profession for the purpose of protecting public health and welfare.

(E) "Pharmacy jurisprudence" related continuing education shall include any A.C.P.E. law program as identified by A.C.P.E numbering convention "03" or, if an in-state provider of continuing education, an Ohio state board of pharmacy approved continuing pharmacy education experiences that deal with current laws, rules, and regulations dealing with the practice of pharmacy and the recent changes that have occurred to those laws, rules and regulations.

(F) "Patient or medication safety" related continuing education shall include any A.C.P.E. program as identified by A.C.P.E. numbering convention "05" that deals with the prevention of healthcare errors and the elimination or mitigation of patient injury caused by healthcare errors.

4729-7-02 Requirements for renewal of a pharmacist identification card.

(A) Except as provided in rule 4729-7-08 of the Administrative Code, evidence of six C.E.U.s of approved continuing education shall be submitted to the board no later than September fifteenth of the year in which evidence of the continuing pharmacy education is required for identification card renewal. At least 0.3 C.E.U.s of the total required C.E.U.s must be obtained ~~from Ohio state board of~~ in pharmacy ~~approved programs in~~ jurisprudence and 0.2 C.E.U.S of patient or medication safety.

(B) The C.E.U.s must be obtained within a period of time that is no more than three years prior to September fifteenth of the year in which evidence of the continuing pharmacy education is required for identification card renewal. A pharmacist shall be subject to further action of the board if the continuing pharmacy education is not submitted to the board by September fifteenth of the year in which evidence of the continuing pharmacy education is required for identification card renewal. If reporting continuing education is required after a pharmacist's license has lapsed or where the license is being renewed after board action, continuing education must be obtained during the three year period immediately preceding the date the renewal application is filed with the board office.

(C) C.E.U.s obtained in excess of the required C.E.U.s at the time the continuing education is required for identification card renewal, may not be transferred and applied to future requirements.

(D) For the first four C.E.U. reporting years following the adoption of this rule (2014, 2015, 2016 and 2017), the board may accept C.E.U.s within a period of time from March first, three years prior to September fifteenth of the year in which evidence of the continuing pharmacy education is required for identification card renewal.

(E) A pharmacist whose identification card has lapsed or has been suspended may renew his/her identification card, if he/she qualifies for renewal pursuant to section 4729.12 or section 4729.13 of the Revised Code, by paying the required fee, completing the application for renewal, and, if he/she would have been required to report continuing pharmacy education during the period of lapse or suspension, by providing evidence of having obtained the number of C.E.U.s required at the time of renewal by submitting the certificates of participation obtained during the three-year period immediately preceding the date of applying for renewal.

(F) Ohio-registered pharmacists who hold a current license in states where continuing education is mandatory, have met the continuing pharmacy education requirements of that state, and who do not practice pharmacy in Ohio, may renew their identification card by paying the required fee, completing the application for renewal, and submitting the following signed statement on their continuing pharmacy education report form:

"I declare under penalties of falsification that I hold a current and valid pharmacist license, number (insert license number), in the state of (insert name of state), that I have met the continuing pharmacy education requirements of this state and I do not presently practice pharmacy in the state of Ohio. I hereby agree to immediately notify the Ohio state board of pharmacy if I return and commence the practice of pharmacy in the state of Ohio."

(G) The state board of pharmacy may grant extension periods and waivers for the completion of license renewal and continuing education requirements for active military service members and their spouses. If a current pharmacist or their spouse is called to active duty for military service, the time period allowed for

completion of any continuing education requirements will be extended by the amount of time that the pharmacist or the pharmacist's spouse was on active duty. A pharmacist seeking an extension period or waiver must provide documentation to the board demonstrating active-duty service.

(H) If a pharmacist is a member of the armed forces, reserves, the Ohio national guard, the Ohio military reserve, or the Ohio naval militia, the state board of pharmacy shall consider relevant military education, training or service that has been completed by the license holder when determining the fulfillment of any continuing education requirements.

4729-5-10 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 appropriately licensed pursuant to Chapter 4729. 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, and return of all prescriptions;

(4) There is a documented method in place to ensure compliance with rule 4729-5-22 of the Administrative Code.

(5) The following documentation is submitted in a manner prescribed by the board:

(a) If the pharmacy shipper and receiver are not within the same corporation, then the pick-up station must complete the "pick-up station ~~request~~ form 1-1" available on www.pharmacy.ohio.gov; or

(b) If the shipper and receiver are within the same corporation, then the pick-up station must complete the "pick-up station ~~request~~ form 1-many" available on www.pharmacy.ohio.gov.

(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 appropriately licensed pursuant to Chapter 4729. of the Revised Code, unless 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, and return of all prescription medications.

(5) There is a documented method in place to ensure compliance with rule 4729-5-22 of the Administrative Code.

(6) The following documentation is submitted in a manner prescribed by the board:

(a) If the pharmacy shipper and receiver are not within the same corporation, then the pick-up station must complete the "pick-up station ~~request~~ form 1-1" available on www.pharmacy.ohio.gov; or

(b) If the shipper and receiver are within the same corporation, then the pick-up station must complete the "pick-up station ~~request~~ form 1-many" available on www.pharmacy.ohio.gov.

(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.