OHIO STATE BOARD OF PHARMACY

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-Equal Opportunity Employer and Service Provider-

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5/16/14

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 rule.

Proposed Rule Change

- **4729-3-01:** Authorizes the Board of Pharmacy to waive the 2:1 ratio for the operation of immunization clinics or other specific circumstances.

- **4729-5-10:** Requires electronic submission of the pick-up station waiver to avoid the unnecessary paperwork. Also, removes the requirement of pre-approval but does allow for Board inspectors to review the waiver upon inspection of the facility acting as a pick-up station and/or the pharmacy shipping to that location.

- **4729-5-11:** Requires the responsible person for a pain management clinic to be a physician that meets certain requirements (i.e. board certification). This rule ensures that there is proper oversight at each location. The requirements for the responsible person are taken from the Medical Board pain management clinic rules.

- **4729-5-17:** Clarifies that prescriber dispensing limits to not apply in the following instances, as indicated in law: (a) methadone provided to patients for the purpose of treating drug addiction, (b) buprenorphine provided to patients for the purpose of treating drug addiction, (c) controlled substances provided to research subjects by a facility conducting clinical research, (d) and a prescriber who is a veterinarian.

- **4729-5-35:** Removes the 100% accuracy requirement for automated drug delivery systems and also provides an appeal process by which a terminal distributor of dangerous drugs can appeal a decision by a Board of Pharmacy inspector.

You can view the proposed rules below.

Comments on the proposed rules will be accepted until close of business on May 30, 2014. Please send all comments to the following email address:

Cameron.mcnamee@bop.ohio.gov

In addition, please copy your comments to:

CSIPublicComments@governor.ohio.gov

CSI - Ohio
The Common Sense Initiative

Business Impact Analysis

Agency Name: Ohio State Board of Pharmacy

Regulation/Package Title: Pharmacy Interns / Pharmacists

Rule Number(s): Amended: 4729-3-01; 4729-5-10; 4729-5-11; 4729-5-17; 4729-5-35

Date: 5/16/2014

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.

Proposed Rule Change

- **4729-3-01:** Authorizes the Board of Pharmacy to waive the 2:1 ratio for the operation of immunization clinics or other specific circumstances.
- **4729-5-10:** Requires electronic submission of the pick-up station waiver to avoid the unnecessary paperwork. Also, removes the requirement of pre-approval but does allow for Board inspectors to review the waiver upon inspection of the facility acting as a pick-up station and/or the pharmacy shipping to that location.

- **4729-5-11 (5-Year Review):** Requires the responsible person for a pain management clinic to be a physician that meets certain requirements (i.e. board certification). This rule ensures that there is proper oversight at each location. The requirements for the responsible person are taken from the Medical Board pain management clinic rules.
- **4729-5-17:** Clarifies that prescriber dispensing limits to not apply in the following instances, as indicated in law: (a) methadone provided to patients for the purpose of treating drug addiction, (b) buprenorphine provided to patients for the purpose of treating drug addiction, (c) controlled substances provided to research subjects by a facility conducting clinical research, (d) and a prescriber who is a veterinarian.
- **4729-5-35:** Removes the 100% accuracy requirement for automated drug delivery systems and also provides an appeal process by which a terminal distributor of dangerous drugs can appeal a decision by a Board of Pharmacy inspector.

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 4729.552 of the Ohio Revised Code. The following sections of the Ohio Revised Code are also considered authorizing statutes for this rule package: 4729.01, 4729.08, 4729.11, 4729.27, 4729.291, 4729.28, 4729.55, 4729.60, 3719.05, 3719.07, 3719.09, 4729.37, 4729.51, 3715.64, 3719.06, 3719.08, 3719.81, 4729.29, 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 Ohio State Board of Pharmacy. The Ohio State Board of Pharmacy regulates all aspects of pharmacy practice, including admission to practice, standards of practice, dispensing and storage of drugs and the discipline of pharmacists. While the Food and Drug Administration closely regulates the manufacture and distribution of prescription drugs, the day-

to-day practice of pharmacy, including the dispensing of drugs by licensed prescribers, 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 Codes authorizes the state board of pharmacy to adopt rules governing the practice of pharmacy and the dispensing of dangerous drugs. Section 4729.552 of the Ohio Revised Code requires the state board of pharmacy to adopt rules regarding the licensure of pain management clinics. The rules proposed under this statutory authority are necessary to facilitate compliance with the provisions in Chapter 4729 of the Ohio Revised Code to promote the public's safety. Without these regulations, the Ohio State Board of Pharmacy would not be able to:

- Provide the requirements for proper oversight of pharmacy interns by their preceptors as well as provide the Board flexibility to waive the 2:1 pharmacist/pharmacy intern ratio if necessary.
- Provide an option whereby dangerous drugs that may cause patient safety issues are delivered to health care providers instead of the patient.
- Ensure that there is proper oversight of a qualified physician at every location licensed as a pain management clinic.
- Specify the requirements for machines that dispense dangerous drugs.
- Specify labeling requirements for drugs that are personally furnished by prescribers and clarify exemptions to limits on personally furnishing drugs that were established in the Ohio Revised Code (4729.291).

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 Ohio State Board of Pharmacy's Rules Review Committee. The committee is comprised of a broad array of stakeholders including:

- OhioHealth
- Trumbull Memorial Hospital
- Kroger
- Hock's Pharmacy
- Northeast Ohio Medical University
- Nationwide Children's Hospital
- Giant Eagle
- Absolute Pharmacy
- St Ann's Hospital
- Akron General
- Cedarville University

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 Ohio State Board of Pharmacy Rules Review Committee reviewed the proposed changes. Following the approval of the package by the Rules Review Committee, the Ohio State Board of Pharmacy formally approved the rules.

For 4729-5-35, the Board held an interested party meeting to discuss potential changes to the rule and the approval process of automated drug delivery systems. The rule proposed represents feedback obtained from that meeting.

For 4729-5-14, the Board received feedback from the Ohio Veterinary Medical Association asking for exemptions in ORC 4729.291 to be incorporated into 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. However, input was solicited from registered pharmacists through the Board's Rules Review Committee representing health systems, hospitals and retail practice.

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 the protecting the public's safety by ensuring uniform regulations, the Ohio State 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.

Rule 4729-5-35 is a performance based regulation in that it provides the criteria that all automated dispensing systems in Ohio must meet but does not dictate the process to achieve compliance.

The agency did not consider a performance-based regulation for the remainder of the rules in this package. It is the Board's responsibility to ensure that oversight of pharmacy interns and the regulation of pain management clinics is consistent throughout the state. It was the determination of the Board's Rule Review Committee 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 reviewed the Ohio Administrative Code to ensure that the regulation does not duplicate an existing Ohio 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 rule 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 quarterly 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:

- Pain management clinics.
- Hospitals, long-term care facilities and pharmacies that utilize automated drug delivery systems.
- Prescribers who personally furnish drugs to their patients.

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

Violation of the rules may result in administrative licensure discipline for the responsible person on the terminal distributor of dangerous drugs license (TDDD) and/or the location licensed as a TDDD. Discipline might include reprimand, suspension of the license, required course work, and/or revocation of the license.

c. Quantify the expected adverse impact from the regulation.

4729-3-01: Does not have any adverse impact on business. It might result in a cost savings to an entity wishing to utilize additional pharmacy interns, in certain circumstances (such as immunization clinics).

4729-5-10: Removes the requirements to mail the one-page pick-up station waiver to the Board and permits the form to be scanned and uploaded to the Board's web site. However, it still requires the submission of the form which takes approximately 10-15 minutes to complete.

4729-5-11: Requires the responsible person for a pain management clinic to be a physician that meets certain requirements (i.e. board certification). There will be a cost to facilities to employ a physician that meets these requirements if they do not get a waiver from the Board. There is no cost to change the responsible person on the license. However, changing of the responsible person requires a submission of a one-page form to the Board which takes approximately 5-10 minutes to complete. The Board will also grant all existing licensees an implementation period to give them time to meet the requirements of the rule or seek a waiver.

4729-5-17: This rule change will not have an adverse impact on business, as it clarifies exemptions to limits on prescribers personally furnishing drugs established in the Ohio Revised Code (4729.291).

4729-5-35: Removes the requirement for 100 percent accuracy and instead provides a performance-based outcome, which should not have an adverse impact on business. The rule also provides a formalized approval process which should assist business in getting their system approved.

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

The Ohio State Board of Pharmacy is committed to ensuring that pharmacists, pain management clinics, prescribers and systems that store and dispense drugs adhere to standards that protect the health and safety of all Ohioans.

Regulatory Flexibility

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

This rule does 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 Ohio State 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.

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 an update 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.

4729-3-01 DEFINITIONS (PROPOSED CHANGE)

As used in Chapter 4729-3 of the Administrative Code:

(A) "Pharmacy internship" means the supervised practical experience required for licensure as a registered pharmacist. The purpose of the pharmacy internship program is to provide those individuals, who intend to become registered pharmacists, with the knowledge and practical experience necessary for functioning competently and effectively upon licensure.

(B) "Preceptor" is the individual responsible for seeing that the intern is properly supervised and exposed to all aspects of an internship program.

(1) A "preceptor" is a pharmacist who holds a current identification card which is in good standing; or, is a person who is of good moral character and is qualified to direct the approved experience in the area approved by the director of internship pursuant to paragraph (C) of rule 4729-3-05 of the Administrative Code.

(2) A person may serve as the preceptor for more than one intern. The number of interns engaged in the practice of pharmacy at any time is limited to not more than two for each pharmacist on duty unless otherwise approved by the board.

(3) A preceptor must report to the board on the progress and aptitude of an intern when requested by the director of internship.

(C) "Director of internship" has the same meaning as provided in section 4729.11 of the Revised Code.

(D) "In good standing" means that the preceptor has not been denied the privilege of supervising interns by the board.

(E) "Statement of Preceptor" is a form provided by the state board of pharmacy that identifies the preceptor and internship site for a pharmacy intern.

(F) "Practical Experience Affidavit" is a form provided by the state board of pharmacy used to submit evidence of practical experience for internship credit pursuant to rule 4729-3-06 of the Administrative Code.

(G) "School of pharmacy" has the same meaning as a college of pharmacy or a department of pharmacy of a university, which has been recognized and approved by the state board of pharmacy.

4729-5-10 PRESCRIPTION PICK-UP STATION (PROPOSED CHANGE)

(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 ~~is~~ as defined in section 4729.01 of the Revised Code~~, has received board approval to function in such a manner,~~ 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~~, has received board approval to function in such a manner, and paragraphs (B)(1) to (B)(4) of this rule apply or, if not a pharmacy,~~ ~~unless~~ and all of the following apply:

(1) The site is appropriately licensed pursuant to Chapter 4729. of the Revised Code.

(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.

(~~2~~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.

(~~3~~4) An appropriate recordkeeping system is in place that will provide accountability for proper receipt, delivery, and return of all prescription medications.

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

(~~5~~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) All controlled substances shall only be shipped directly to the patient.~~

~~(D) The state board of pharmacy has approved the site for such activity due to 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.~~

(~~E~~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:

(a) Danger to public health or safety, or

(b) Danger to the patient.

4729-5-11 RESPONSIBLE PERSON (PROPOSED CHANGE AND 5-YEAR REVIEW)

(A) For a pharmacy licensed as a terminal distributor of dangerous drugs:

(1) Only a pharmacist may be the responsible person whose name appears on the terminal distributor of dangerous drugs license for a pharmacy as defined in division (A) of section 4729.01of the Revised Code. A pharmacist shall be the responsible person for no more than one such pharmacy except with written permission from the state board of pharmacy. A written request shall be submitted outlining the circumstances requiring a pharmacist to be responsible for more than one pharmacy and the period of time during which the circumstances will exist. A pharmacist shall not be designated the responsible person for a pharmacy unless he/she will be physically present in the pharmacy a sufficient amount of time to provide supervision and control.

(2) The responsible person shall be responsible for the practice of the profession of pharmacy, including but not limited to "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, and maintaining all drug records otherwise required.

(3) The person to whom the terminal distributor of dangerous drugs license has been issued and all pharmacists on duty are responsible for compliance with all state and federal laws, regulations, and rules regulating the distribution of drugs and the practice of pharmacy.

(B) For locations licensed as a category III terminal distributor of dangerous drugs with a pain management classification under section 4729.552 of the Revise Code:

(1) Only a physician authorized under Chapter 4731. of the Revised Code to practice medicine and surgery or osteopathic medicine and surgery may be the responsible person whose name appears on the category III terminal distributor of dangerous drugs with a pain management classification license as defined 4729.552 of the Revised Code. A physician shall be the responsible person for no more than one such location except with written permission from the state board of pharmacy. A written request shall be submitted outlining the circumstances requiring a physician to be responsible for more than one location and the period of time during which the circumstances will exist. A physician shall not be designated the responsible person for a location licensed as a category III terminal distributor of dangerous drugs with a pain management classification unless he/she will be physically present at the location for a sufficient amount of time to provide supervision.

(2) All employees of the facility, including the responsible person, shall submit to a criminal records check in accordance with section 4776.02 of the Revised Code.

(3) The responsible person for locations licensed as a category III terminal distributor of dangerous drugs with a pain management classification under section 4729.552 of the Revise Code must meet one of the following requirements:

(a) Hold current subspecialty certification in pain management by the American board of medical specialties, or hold a current certificate of added qualification in pain management by the American osteopathic association bureau of osteopathic specialists; or

(b) Hold current subspecialty certification in hospice and palliative medicine by the American board of medical specialties, or hold a current certificate of added qualification in hospice and palliative medicine by the American osteopathic association bureau of osteopathic specialists; or

(c) Hold current board certification by the American board of pain medicine; or

(d) Hold current board certification by the American board of interventional pain physicians; or

(e) Hold current board certification in anesthesiology, psychiatry, neurology, physical medicine and rehabilitation, occupational medicine, or rheumatology by the American board of medical specialties or hold current primary certification in anesthesiology, psychiatry, neurology, physical medicine and rehabilitation, occupational medicine, or rheumatology by the American osteopathic association bureau of osteopathic specialists.

(4) No responsible person for locations licensed as a category III terminal distributor of dangerous drugs with a pain management classification under section 4729.552 of the Revise Code shall:

(a) Have ever been denied a license to prescribe, dispense, administer, supply, or sell a controlled substance by the drug enforcement administration or appropriate issuing body of any state or jurisdiction, based, in whole or in part, on the prescriber's inappropriate prescribing, dispensing, administering, supplying or selling a controlled substance or other dangerous drug.

(b) Have held a license issued by the drug enforcement administration or a state licensing agency in any jurisdiction, under which the person may prescribe, dispense, administer, supply or sell a controlled substance, that has ever been restricted, based, in whole or in part, on the prescriber's inappropriate prescribing, dispensing, administering, supplying, or selling a controlled substance or other dangerous drug.

(c) Have been subject to disciplinary action by any licensing entity that was based, in whole or in part, on the prescribers inappropriate prescribing, dispensing, diverting, administering, supplying or selling a controlled substance or other dangerous drug.

(~~B~~ C) For all locations licensed as a terminal distributor of dangerous drugs:

(1) A location licensed as a terminal distributor of dangerous drugs must have a responsible person at all times.

(2) The responsible person whose name appears on the terminal distributor of dangerous drugs license shall sign the license and shall maintain the license in a readily available place in the principal location of the business.

(3) When there is a change of responsible person, the state board of pharmacy shall be notified by the new responsible person within thirty days on a board approved form. This notice to the state board of pharmacy shall be sent by regular mail or by verified facsimile transmission.

(4) A complete inventory, pursuant to federal regulations and rule 4729-9-14 of the Administrative Code, shall be taken of the controlled substances on hand with the new responsible person on the effective date of the change of responsible person. The new responsible person shall be responsible for completing and maintaining this inventory record at the site of the terminal distributor of dangerous drugs.

(5) The responsible person to whom the terminal distributor of dangerous drugs license has been issued is responsible for compliance with all state and federal laws, regulations, and rules regulating the distribution of drugs.

4729-5-35 AUTOMATED DRUG DELIVERY SYSTEMS (PROPOSED CHANGE)

(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:

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

(~~B~~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 ~~includes the requirement for one hundred per cent accuracy in drug and strength delivered~~;

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

(~~D~~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 division (A) of this section.

(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.

4729-5-17 LABELING BY PRESCRIBERS WHO PERSONALLY FURNISH DANGEROUS DRUGS TO THEIR PATIENTS (PROPOSED CHANGE)

(A) Whenever a prescriber personally furnishes a dangerous drug, other than a sample drug pursuant to section 3719.81 of the Revised Code, the prescriber shall affix to the container a label showing:

(1) The name and address of the prescriber.

(2) The name of the patient for whom the drug is intended. If the patient is an animal, the name of the owner and identification of the animal.

(3) Name and strength of the dangerous drug.

(4) Directions for use.

(5) Date furnished.

(B) Whenever a prescriber personally furnishes a dangerous drug, labeled as a sample pursuant to section 3719.81 of the Revised Code and where the directions for use are different from the directions on or in the sample container, the prescriber shall also provide, in written format, the following:

(1) Name of the prescriber.

(2) Name of the patient. If the patient is an animal, the name of the owner and identification of the animal.

(3) Directions for use.

(C) For controlled substances, personally furnishing quantities are limited to a seventy-two hour supply and in any thirty day period the personally furnishing quantities supplied to all patients shall not exceed two thousand five hundred dosage units pursuant to section 4729.291 of the Revised Code.

(D) None of the following shall be counted in determining whether the amounts specified in division (C) of this section have been exceeded:

(a) Methadone provided to patients for the purpose of treating drug addiction, if the prescriber meets the conditions specified in 21 C.F.R. 1306.07;

(b) Buprenorphine provided to patients for the purpose of treating drug addiction, if the prescriber is exempt from separate registration with the United States drug enforcement administration pursuant to 21 C.F.R. 1301.28;

(c) Controlled substances provided to research subjects by a facility conducting clinical research in studies approved by a hospital-based institutional review board or an institutional review board accredited by the association for the accreditation of human research protection programs.

(E) Division (C) of this section does not apply to a prescriber who is a veterinarian.