8/8/2017

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

New

- 4729:5-3-04: Establishes protocol for on-site inspections of terminal distributors of dangerous drugs by the Board of Pharmacy.
- 4729:6-3-04: Establishes protocol for on-site inspections of wholesale distributors of dangerous drugs by the Board of Pharmacy.
- 4729:5-3-05: Establishes requirements for terminal distributors of dangerous drugs when releasing confidential patient records.
- 4729:5-2-02: Establishes licensing and renewal process for terminal distributors of dangerous drugs.
- 4729:5-12-01: Defines terms related to medication therapy management.
- 4729:5-12-02: Establishes licensure and regulatory requirements of licensees providing medication therapy management.

Rescinded

- 4729-9-09: Establishes protocol for on-site inspections of licensees by the Board of Pharmacy.
- 4729-5-29: Establishes requirements for licensees pertaining to confidential patient records.

Comments on the proposed rules will be accepted until close of business on August 28, 2017. Please send all comments to the following email address:
Cameron.mcnamee@pharmacy.ohio.gov

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

CSI - Ohio
The Common Sense Initiative

Business Impact Analysis

Agency Name: State of Ohio Board of Pharmacy

Regulation/Package Title: Terminal and Wholesale Distributors of Dangerous Drugs

Rule Number(s): New: 4729:5-3-04; 4729:6-3-04; 4729:5-3-05; 4729:5-2-02; 4729:5-12-01; 4729:5-12-02

Rescinded: 4729-9-09; 4729-5-29

Date: 8/8/2017

Rule Type:

New	5-Year Review
Amended	**Rescinded**

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

Regulatory Intent

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

New

- 4729:5-3-04: Establishes protocol for on-site inspections of terminal distributors of dangerous drugs by the Board of Pharmacy.
- 4729:6-3-04: Establishes protocol for on-site inspections of wholesale distributors of dangerous drugs by the Board of Pharmacy.

- 4729:5-3-05: Establishes requirements for terminal distributors of dangerous drugs when releasing confidential patient records.
- 4729:5-2-02: Establishes licensing and renewal process for terminal distributors of dangerous drugs.
- 4729:5-12-01: Defines terms related to medication therapy management.
- 4729:5-12-02: Establishes licensure and regulatory requirements of licensees providing medication therapy management.

Rescinded

- 4729-9-09: Establishes protocol for on-site inspections of licensees by the Board of Pharmacy.
- 4729-5-29: Establishes requirements for licensees pertaining to confidential patient records.

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 3719.13 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 and distribution of dangerous has traditionally been done at the state level by legislatively created state boards of pharmacy. The regulation of the pharmacy practice and distribution of dangerous drugs includes the inspection of sites with dangerous drugs, valid requirements for the release of confidential patient records, the licensure of terminal distributors of dangerous drugs, and regulations for licensees providing medication therapy management (i.e. engaged in the practice of pharmacy).

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

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

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

Section 3719.13 of the Ohio Revised Code authorizes employees Board of Pharmacy to inspect prescriptions, orders, records and stocks of dangerous drugs and controlled substances.

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

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

Development of the Regulation

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

The rules in this package were reviewed by the Board's Rules Review Committee. The Committee, composed of pharmacists from various practice settings, is responsible for reviewing and approving all rules prior to their legislatively mandated five-year review date.

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

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

For the proposed rules, the Board of Pharmacy Rules Review Committee reviewed the proposed changes. Any proposed feedback agreed to by the committee and approved by the Board was incorporated into the rule package. For these rules, the committee did not have any specific feedback that was 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.

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 inspection of sites with dangerous drugs, valid requirements for the release of confidential patient records, the licensure of terminal distributors of dangerous drugs, and oversight of licensees providing medication therapy management, 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 regulations 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 agents,

inspectors and specialists 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, quarterly staff meetings featuring a regulatory update, mandatory all-day law reviews for new employees, email updates from the Director of Policy as well as 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:

- Terminal distributors of dangerous drugs;
- Wholesale distributors of dangerous drugs; and
- Pharmacists and interns providing medication therapy management.

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 terminal distributor of dangerous drugs, wholesale distributor of dangerous drugs, pharmacist or pharmacy intern. 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

- 4729:5-3-04: Establishes protocol for on-site inspections of terminal distributors of dangerous drugs by the Board of Pharmacy. The licensee or registrant must submit either an explanation disputing violations observed by a board agent or explaining how the violation has been correct. The submission of a corrective action plan varies based upon the number of violations observed by the inspector and therefore the number of hours may vary. It should be noted that this only applies to licensees who are found in violation of Ohio laws and rules.
- 4729:6-3-04: Establishes protocol for on-site inspections of wholesale distributors of dangerous drugs by the Board of Pharmacy. The licensee or registrant must submit either an explanation disputing violations observed by a board agent or explaining how the violation has been correct. The submission of a corrective action plan varies based upon

the number of violations observed by the inspector and therefore the number of hours may vary. It should be noted that this only applies to licensees who are found in violation of Ohio laws and rules.

- 4729:5-3-05: Establishes requirements for terminal distributors of dangerous drugs when releasing confidential patient records. This does require the maintenance of the consent forms and receipts for the release of patient records to be maintained by the terminal distributor. This may result in an administrative burden to the distributor based upon the number of requests for records received by the terminal distributor.
- 4729:5-2-02: Establishes licensing and renewal process for terminal distributors of dangerous drugs. Until April 1st, 2019, fees for the initial license and annual renewal can range anywhere from $60.00 to $220.00. The renewal application can take, on average, 30 minutes to an hour to complete.
- 4729:5-12-01: Defines terms related to medication therapy management. The regulation should have no adverse impact.
- 4729:5-12-02: Establishes licensure and regulatory requirements of licensees providing medication therapy management. The fee for a limited category II terminal distributor of dangerous drugs license with a medication therapy management classification is $160.00, while the application takes about one hour to complete.

Rescinded

- 4729-9-09: Establishes protocol for on-site inspections of licensees by the Board of Pharmacy. Rule is being replaced by 4729:5-3-04. The rescission of this regulation should have no adverse impact.
- 4729-5-29: Establishes requirements for licensees when releasing confidential patient records. Rule is being replaced by 4729:5-3-05. The rescission of this regulation should have no adverse impact.

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 the following:

- Uniform licensing standards for terminal distributors (as is required by law);
- The ability to require corrective action plans to correct any identified deficiencies;
- The protection of confidential patient data; and
- The oversight of the practice of medication therapy management.

Regulatory Flexibility

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

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

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

The State of Ohio Board of Pharmacy does not fine licensees or impose penalties for first-time paperwork violations. However, any failure of a standard of care in the practice of releasing confidential patient records, providing medication therapy management or operating as a terminal or wholesaler distributor 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. Additionally, staff are trained to educate licensees on compliance with all Board of Pharmacy rules and regulations.

4729:5-3-04 - Inspections and corrective actions.

(A) Pursuant to section 3719.13 of the Revised Code, an entity licensed by the state board of pharmacy as a terminal distributor of dangerous drugs is subject to an on-site inspection by the board. An authorized board agent may, without notice, carry out an on-site inspection or investigation of an entity licensed by the board. Upon verification of the board agent's credentials, the agent shall be permitted to enter the licensed entity.

(B) Submission of an application for a license as a terminal distributor of dangerous drugs with the state board of pharmacy constitutes permission for entry and on-site inspection by an authorized board agent.

(C) If an agent of the state board of pharmacy identifies a violation specified in paragraph (D) of this rule, the agent may provide written notice, in a manner prescribed by the board, of the nature of the observed violations to the responsible person on the license or application. The licensee or applicant may also be subject to disciplinary actions pursuant to Chapter 4729. of the Revised Code.

(D) Violations may include any of the following:

(1) Violating any rule of the board;

(2) Violating any provision of Chapter 4729. of the Revised Code;

(3) Violating any provision of the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301, or Chapter 3715. of the Revised Code;

(4) Violating any provision of the federal drug abuse control laws or Chapter 2925. or 3719. of the Revised Code.

(E) The licensee or applicant shall submit to the board within thirty days, in a manner determined by the board, either of the following:

(1) The action(s) the licensee or applicant has taken to correct the violations(s) and the date of implementation of the corrective action(s); or

(2) An explanation disputing the observed violations.

RESCIND 4729-9-09: http://codes.ohio.gov/oac/4729-9-09

4729:6-3-04 Inspections and corrective actions.

(A) Pursuant to section 3719.13 of the Revised Code, an entity licensed by state board of pharmacy as a manufacturer of dangerous drugs, outsourcing facility, third-party logistics provider, repackager of dangerous drugs, or wholesale distributor of dangerous drugs is subject to an on-site inspection by the board. An authorized board agent may, without notice, carry out an on-site inspection or investigation of an entity licensed by the board. Upon verification of the board agent's credentials, the agent shall be permitted to enter the licensed or registered entity.

(B) Submission of an application for a license as a manufacturer of dangerous drugs, outsourcing facility, third-party logistics provider, repackager of dangerous drugs, or wholesale distributor of dangerous drugs with the state board of pharmacy constitutes permission for entry and on-site inspection by an authorized board agent.

(C) If an agent of the state board of pharmacy identifies a violation specified in paragraph (D) of this rule, the agent may provide written notice, in a manner prescribed by the board, of the nature of the observed violations to the responsible person on the license or application. The licensee or applicant may also be subject to disciplinary actions pursuant to Chapter 4729. of the Revised Code.

(D) Violations may include any of the following:

(1) Violating any rule of the board;

(2) Violating any provision of Chapter 4729. of the Revised Code;

(3) Violating any provision of the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301, or Chapter 3715. of the Revised Code;

(4) Violating any provision of the federal drug abuse control laws or Chapter 2925. or 3719. of the Revised Code.

(E) The licensee or applicant shall submit to the board within thirty days, in a manner prescribed by the board, either of the following:

(1) The action(s) the licensee or applicant has taken to correct the violations(s) and the date of implementation of the corrective action(s); or

(2) An explanation disputing the observed violations.

4729:5-3-05 - Confidentiality of patient records.

(A) Records relating to the practice of pharmacy, the administration of drugs, or any patient specific drug transaction are not a public record. A person having custody of, or access to, such records shall not divulge the contents thereof, or provide a copy thereof, to anyone except:

(1) The patient for whom the prescription or medication order was issued.

(2) The prescriber who issued the prescription or medication order.

(3) Licensed health care personnel who are responsible for the care of the patient.

(4) A member, inspector, agent, or investigator of the state board of pharmacy or any federal, state, county, or municipal officer whose duty is to enforce the laws of this state or the United States relating to drugs and who is engaged in a specific investigation involving a designated person or drug.

(5) An agent of an Ohio licensing agency that is responsible for the licensure or registration of a health professional authorized to prescribe drugs as defined in section 4729.01 of the Revised Code when enforcing that agency's chapter of the Revised Code.

(6) A state or federal agency charged with the responsibility of providing medical care (i.e. medicaid, medicare, workers' compensation, etc.) for the patient upon a written request by an authorized representative of the agency requesting such information.

(7) An agent of a medical insurance company who provides prescription insurance coverage to the patient upon authorization and proof of insurance by the patient or proof of payment by the insurance company for those medications whose information is requested.

(8) An agent who contracts with the terminal distributor of dangerous drugs as a "business associate" in accordance with the regulations promulgated by the secretary of the United States department of health and human services pursuant to the federal standards for privacy of individually identifiable health information.

(9) Any person, other than those listed in paragraphs (A)(1) to (A)(8) of this rule, only when the patient has given consent for such disclosure in writing, except where a patient requiring medication is unable to deliver a written consent to the necessary disclosure. Any consent must be signed by the patient and dated. Any consent for disclosure is valid until rescinded by the patient.

(a) In an emergency, the terminal distributor of dangerous drugs may disclose the information when, in the professional judgment of the pharmacist or healthcare provider, it is deemed to be in the best interest of the patient. A pharmacist or healthcare provider making an oral disclosure in

an emergency situation must prepare a written memorandum showing the patient's name, the date and time the disclosure was made, the nature of the emergency, and the names of the individuals by whom and to whom the information was disclosed.

(B) Testimonial privilege is not waived for any communication between a physician, a pharmacist, and a patient pursuant to section 2317.02 of the Revised Code.

(C) Records relating to the practice of pharmacy, the administration of drugs, or any patient specific drug transaction which may be required as evidence of a violation shall be released, upon request, to a member, inspector, agent, or investigator of the state board of pharmacy or any state, county, or municipal officer whose duty is to enforce the laws of this state or the United States relating to drugs and who is engaged in a specific investigation involving a designated person or drug. Such person shall furnish a receipt to the person having legal custody of the records. If the record is a prescription, the receipt shall list the following information:

(1) Prescription identification number; or, if an order for medication, the name of the patient;

(2) The drugs prescribed or ordered;

(3) Quantity of drugs prescribed, dispensed, administered or personally furnished;

(4) Name of the prescriber;

(5) Date, name of agency, and signature of person removing the records.

(D) All such records, including consents, memoranda of emergency disclosures, and written requests pursuant to paragraph (A)(9) of this rule, shall be kept on file at the terminal distributor of dangerous drugs for a period of three years in a readily retrievable manner.

(E) All patient records maintained by a terminal distributor of dangerous drugs shall be maintained in accordance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and all state and federal laws, rules and regulations.

RESCIND 4729-5-29: http://codes.ohio.gov/oac/4729-5-29

4729:5-2-02 – Terminal distributor of dangerous drugs licensing and renewal.

(A) Upon the effective date of this rule:

(1) All terminal distributor of dangerous drugs licenses issued pursuant to Chapter 4729. of the Revise Code shall be effective for a period of twelve months from the first day of April of each year. A license shall be renewed by the board for a like period, annually, according to the provisions of section 4729.55 of the Revised Code, and the standard renewal procedure of Chapter 4745. of the Revised Code.

(2) A person who seeks to renew a license shall submit an application for renewal and pay the required fee in accordance with section 4729.55 of the Revised Code on or before the thirty-first day of March each year.

(3) The required fees for initial licensure and annual renewal of a terminal distributor of dangerous drugs are as follows:

(a) For a category II or limited category II license: one hundred and sixty dollars;

(b) For a category III or limited category III license: two hundred and twenty dollars;

(c) A person who is required to hold a license as a terminal distributor of dangerous drugs pursuant to division (D) of section 4729.541 of the Revised Code: sixty dollars; and

(d) For a professional association, corporation, partnership, or limited liability company organized for the purpose of practicing veterinary medicine: sixty dollars.

(B) Effective April 1, 2019:

(1) All terminal distributor of dangerous drugs licenses issued pursuant to Chapter 4729. of the Revised Code shall be effective for a period of twenty-four months from the first day of April of every odd-numbered year. A license shall be renewed by the board for a like period, biennially, according to the provisions of section 4729.55 of the Revised Code, and the standard renewal procedure of Chapter 4745. of the Revised Code.

(2) A person who seeks to renew a license shall submit an application for renewal and pay the required fee in accordance with section 4729.55 of the Revised Code on or before the thirty-first day of March of every odd-numbered year.

(3) The required fees for initial licensure and biennial renewal of a terminal distributor of dangerous drugs shall be in accordance with section 4729.55 of the Revised Code.

(C) Paragraph (A) of this rule is no longer applicable effective April 1, 2019.

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4729:5-12-01 – Medication Therapy Management - Definitions

As used in in Chapter 4729:5-12 of the Administrative Code:

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

(B) “Medication therapy management” or “MTM” means:

(1) A distinct service or group of services that is intended to optimize the therapeutic outcomes of a patient. Medication therapy management can be an independent service provided by a pharmacist or pharmacy intern under the direct supervision of a pharmacist or can be in conjunction with the dispensing of a dangerous drug with the objectives of:

(a) Enhancing appropriate medication use;

(b) Improving medication adherence;

(c) Increasing detection of adverse drug events;

(d) Improving collaboration between prescriber and pharmacist; and

(e) Improving outcomes.

(2) Medication therapy management may only be performed by the following:

(a) An Ohio licensed pharmacist;

(b) An Ohio licensed pharmacy intern practicing in this state under the direct supervision of a pharmacist; and

(c) A pharmacist or pharmacy intern practicing in another state in accordance with that state’s laws and rules.

(C) “Limited category II terminal distributor of dangerous drugs license with a medication therapy management classification” means a limited category II terminal distributor license issued by the state board of pharmacy in accordance with section 4729.54 of the Revised Code to person solely engaged in the practice of medication therapy management.

(1) A limited category II terminal distributor of dangerous drugs with a medication therapy management classification does not entitle the holder to possess or sell dangerous drugs.

(D) “State” means a state of the United States, the District of Columbia, the Commonwealth of Puerto Rico or a territory or insular possession subject to the jurisdiction of the United States.

(E) "Business day" means any day that is not a Saturday or a Sunday and not a day on which governmental offices of the state of Ohio or banks in the state of Ohio are required or permitted to be closed.

4729:5-12-02 – Medication Therapy Management

(A) A pharmacist or pharmacy intern under the direct supervision of a pharmacist that provides medication therapy management services shall practice at a location that complies with one of the following:

(1) If the person or entity solely performs medication therapy management in this state or to residents of this state, the location shall be licensed as a limited category II terminal distributor of dangerous drugs license with a medication therapy management classification; or

(2) If the person or entity engages in the sale of dangerous drugs, the location is appropriately licensed as a terminal distributor of dangerous drugs.

(B) A non-resident provider of medication therapy management shall obtain an appropriate licensure as a terminal distributor of dangerous drugs.

(C) The number of interns engaged in the practice of medication therapy management at any time is limited to not more than two for each pharmacist on duty unless otherwise approved by the board.

(D) A pharmacist or pharmacy intern under the direct supervision of a pharmacist that provides medication therapy management services shall ensure that they are provided according to the individual needs of the patient and may include, but are not limited, to the following:

(1) Performing or otherwise obtaining the patient's health status assessment;

(2) Developing a medication treatment plan for monitoring and evaluating the patient's response to therapy;

(3) Monitoring the safety and effectiveness of the medication therapy;

(3) Performing a medication review to identify, prevent or resolve medication related problems;

(4) Monitoring the patient for adverse drug events;

(5) Providing education and training to the patient or the patient's agent on the use or administration of the medication;

(6) Documenting the delivery of care, communications with other involved healthcare providers and other appropriate documentation and records pursuant to paragraph (E) of this rule;

(7) Providing necessary services to enhance the patient's adherence with the therapeutic regimen;

(8) Integrating the medication therapy management services within the overall health management plan for the patient; and

(9) Providing for the safe custody and security of all records and compliance with all relevant federal and state laws, rules and regulations concerning the security and privacy of patient information.

(E) All records relating to medication therapy management service shall:

(1) Provide accountability and an audit trail; and

(2) Be uniformly maintained for a period of three years and shall be made available for inspection within three business days of a request by an agent of the state board of pharmacy.