**2/08/2018**

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

**New**

- 4729:5-1-01 - Definition section for the division of the OAC pertaining to terminal distributors of dangerous drugs.
- 4729:5-2-01 - Defines the responsibilities and requirements for the responsible person under each classification of terminal distributor for dangerous drugs license. Unless otherwise approved by the Board, prohibits a terminal distributor from having a responsible person criminal convictions or administrative discipline.
- 4729:5-2-03 - Defines what is considered a change in description of a terminal distributor of dangerous drugs and outlines when the board requires notification or when the board requires a new license number and application fee.
- 4729:5-2-04 - Specifies the procedure for discontinuing as a terminal distributor which requires the distributor to file a notice with the board. The terminal distributor will need to complete an inventory of all controlled substances being transferred or disposed of.
- 4729:5-3-04 - Establishes the requirements for a terminal distributor to validate licensure (or licensure exemption) within the e-licensing system prior to conducting a sale or purchase.
- 4729:5-3-07 - Establishes requirements that all category III terminal distributor licenses complete a controlled substances inventory.
- 4729:5-3-08 - Requires all persons selling dangerous drugs via the internet at retail into or out Ohio be licensed by the Board as well as maintain national accreditation.
- 4729:5-3-09 - Governs a pharmacy's ability to conduct occasional wholesale sales. Also, permits a licensed terminal distributor of dangerous drugs to transfer or deliver dangerous drugs from one licensed location to another licensed location.
- 4729:5-3-10 - Establishes the requirement that a terminal distributor of dangerous not employ individual with felony convictions if position allows for access to controlled substances as required by federal regulations.
- 4729:5-4-01- Establishes the Board of Pharmacy's authority to impose disciplinary actions on a terminal distributor of dangerous drugs.

**Rescind**

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- 4729-5-11 - Establishes the requirements for serving as a responsible person on a terminal distributor of dangerous drugs license.
- 4729-9-10 – Governs a pharmacy's ability to conduct occasional wholesale sales.

Comments on the proposed rules will be accepted until close of business on **March 1, 2018**. Please send all comments to the following email address: **Ali.Simon@pharmacy.ohio.gov**

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

CSI - Ohio
The Common Sense Initiative

**Business Impact Analysis**

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

**Regulation/Package Title: Terminal Distributors**

**Rule Number(s):**

**New:**

- **4729:5-1-01**
- **4729:5-2-01**
- **4729:5-2-03**
- **4729:5-2-04**
- **4729:5-3-04**
- **4729:5-3-07**
- **4729:5-3-08**
- **4729:5-3-09**
- **4729:5-3-10**
- **4729:5-4-01**

**Rescind:**

- **4729-5-11**

**Date: 2/8/2018**

**Rule Type:**

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

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

## Regulatory Intent

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

**New**

- 4729:5-1-01 - Definition section for the division of the OAC pertaining to terminal distributors of dangerous drugs.
- 4729:5-2-01 - Defines the responsibilities and requirements for the responsible person under each classification of terminal distributor for dangerous drugs license. Unless otherwise approved by the Board, prohibits a terminal distributor from having a responsible person criminal convictions or administrative discipline.
- 4729:5-2-03 - Defines what is considered a change in description of a terminal distributor of dangerous drugs and outlines when the board requires notification or when the board requires a new license number and application fee.
- 4729:5-2-04 - Specifies the procedure for discontinuing as a terminal distributor which requires the distributor to file a notice with the board. The terminal distributor will need to complete an inventory of all controlled substances being transferred or disposed of.
- 4729:5-3-04 - Establishes the requirements for a terminal distributor to validate licensure (or licensure exemption) within the e-licensing system prior to conducting a sale or purchase.
- 4729:5-3-07 - Establishes requirements that all category III terminal distributor licenses complete a controlled substances inventory.
- 4729:5-3-08 - Requires all persons selling dangerous drugs via the internet at retail into or out Ohio be licensed by the Board as well as maintain national accreditation.
- 4729:5-3-09 - Governs a pharmacy's ability to conduct occasional wholesale sales. Also permits a licensed terminal distributor of dangerous drugs to transfer or deliver dangerous drugs from one licensed location to another licensed location.
- 4729:5-3-10 - Establishes the requirement that a terminal distributor of dangerous not employ individual with felony convictions if position allows for access to controlled substances as required by federal regulations.
- 4729:5-4-01- Establishes the Board of Pharmacy's authority to impose disciplinary actions on a terminal distributor of dangerous drugs.

**Rescind**

- 4729-5-11 - Establishes the requirements for serving as a responsible person on a terminal distributor of dangerous drugs license.

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

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

**3. Does the regulation implement a federal requirement? Is the proposed regulation being adopted or amended to enable the state to obtain or maintain approval to administer and enforce a federal law or to participate in a federal program?**

These rules do not implement a federal requirement.

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

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

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

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

Section 3719.28 of the Ohio Revised Code authorizes the Board of Pharmacy to adopt rules prescribing the manner of keeping and the form and content of records to be kept by persons authorized to manufacture, distribute, dispense, conduct research in, prescribe, administer, or otherwise deal with controlled substances.

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

- Provide definitions to ensure uniform implementation of this division;
- Ensure proper oversight of dangerous drugs by a licensed health care provider;
- Require timely reporting for any change in licensure status by a terminal distributor;
- Provide uniform procedures for discontinuing business and the transfer or disposal of drug stock;

- Specify requirements for licensure verification by terminal distributors to in accordance with ORC 4729.60;
- Ensure regular inventories are conducted to prevent and detect the diversion of controlled substances;
- Implement standards for online pharmacies to protect the public;
- Provide standards for the occasional wholesale sale of drugs by pharmacies and clarifying how transfers may be conducted by licensees; and
- Set standards for which the Board can discipline a terminal distributor of dangerous drugs.

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

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

## Development of the Regulation

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

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

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

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

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

Specifically, the committee recommended the following changes that were adopted by the Board:

(4729:5-4-01): Removed a penalty for employing someone who had previously been disciplined by the Board of Pharmacy.

(4729:5-2-01): Specify that a responsible person can be for a pharmacy and for a hospital campus.

**9. What scientific data was used to develop the rule or the measurable outcomes of the rule? How does this data support the regulation being proposed?**

Scientific data was not used to develop or review this rule.

**10. What alternative regulations (or specific provisions within the regulation) did the Agency consider, and why did it determine that these alternatives were not appropriate? If none, why didn't the Agency consider regulatory alternatives?**

As the regulations are essential to protecting the public's safety by ensuring uniform standards for the practice of pharmacy and distribution of dangerous drugs, the State of Ohio Board of Pharmacy did not consider any regulatory alternatives.

**11. Did the Agency specifically consider a performance-based regulation? Please explain.** ***Performance-based regulations define the required outcome, but don't dictate the process the regulated stakeholders must use to achieve compliance.***

The agency did not consider a performance-based regulation for this rule package. It is the Board's responsibility to ensure uniform practice standards across Ohio. At this juncture, it was the determination of the Board that the rule package did not lend itself to performance-based regulations.

**12. What measures did the Agency take to ensure that this regulation does not duplicate an existing Ohio regulation?**

The Board of Pharmacy's Director of Policy and Communications reviewed the proposed rules to ensure that the regulations do not duplicate another State of Ohio Board of Pharmacy regulation. Corresponding rules in Chapter 4729. are being rescinded to avoid duplicate regulations but this may be occurring as part of another proposed rule package.

**13. Please describe the Agency's plan for implementation of the regulation, including any measures to ensure that the regulation is applied consistently and predictably for the regulated community.**

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

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

## Adverse Impact to Business

**14. Provide a summary of the estimated cost of compliance with the rule. Specifically, please do the following:**

**a. Identify the scope of the impacted business community;**

The rule package impacts the following:

- Employees of a terminal distributor of dangerous drugs.
- 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 terminal distributor of dangerous drugs. Discipline might include reprimand, suspension of a license, monetary fine and/or revocation of a license.

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

**New**

- 4729:5-1-01 – The rule defines an abandoned application. An applicant whose application is deemed abandoned forfeits their licensure fee ($160 or $220).
- 4729:5-2-01 – Provides the requirements for a Responsible Person under the different classifications of terminal distributors of dangerous drugs license. For pharmacies, this requires a request for approval if an individual wishes to serve as the Responsible Person at more than one location. This requires a submission of a form that takes approximately 15 minutes. Additionally, this rule will require a terminal distributor to ensure a responsible person has not violated any provision of the rule. This could result in increased costs to review the employees background (i.e. background checks, licensure searches, etc.).

- 4729:5-2-03 – Requires any change in ownership, business or trade name, category, or address of a terminal distributor of dangerous drugs requires a new application fee, required fee, and license. Licensure as a terminal distributor of dangerous drugs costs between $160 and $220 annually. The application takes between 30-60 minutes to complete.
- 4729:5-2-04 – Requires a terminal distributor of dangerous drugs to notify the board of discontinuation of business. A discontinuation of business form is two pages and takes approximately 10 minutes to complete. The licensee must also submit a complete inventory of all controlled substances being transferred or disposed of and keep records of purchase and dispensing for three years. The inventory may take several hours to complete depending on the size of the controlled substance stock. It should be noted that maintaining records pertaining to controlled substances for three years is required by the Ohio Revised Code (3719.07).
- 4729:5-3-04 – Establishes the requirements for a terminal distributor to validate licensure (or licensure exemption) within the e-licensing system prior to conducting a sale or purchase. This will add to the terminal distributor's administrative burden because the distributor will be required to validate licensure using the Board's online system for all wholesale purchases on an annual basis. The average time to confirm a licensed entity is approximately 2-3 minutes. Additionally, any terminal distributor conducting an occasional wholesale sale will be required to verify the purchaser's licensure or exemption from licensure. This will require developing an attestation process to document licensure exemptions and to maintain any records of attestations for three years.
- 4729:5-3-07 – Requires all category III terminal distributors complete a controlled substances inventory on an annual basis. Depending on the stock of controlled substances, this may take several hours to complete.
- 4729:5-3-08 – Requires all persons selling dangerous drugs via the internet at retail into or out Ohio be licensed by the Board. Licensure as a terminal distributor of dangerous drugs costs between $160 and $220 annually. The application takes between 30-60 minutes to complete. Additionally, this requires VIPPS Accreditation from the National Association of Boards of Pharmacy. The application fee for VIPPS can cost anywhere between $5,000 and $8,000.
- 4729:5-3-09 – Governs a pharmacy's ability to conduct occasional wholesale sales. Also, permits a licensed terminal distributor of dangerous drugs to transfer or deliver dangerous drugs from one licensed location to another licensed location. Pharmacies conducting a sizable amount of occasional wholesale sales will incur costs of monitoring those sales to ensure that they are not exceeding the specified limits.
- 4729:5-3-10 – Specifies that a terminal distributor of dangerous shall not employ individual with felony convictions if position allows for access to controlled substances. This is a federal requirement that all DEA registrants must comply with and will not result in any additional costs to the licensee.

- 4729:5-4-01 – Violation of this rule may result in administrative licensure discipline for a terminal distributor of dangerous drugs. Discipline might include reprimand, suspension of a license, monetary fine and/or revocation of a license.

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

The Board determined that the regulatory intent justifies the impact on business because the regulations protect and promote public safety by ensuring uniform standards for the practice of pharmacy or the preparation/distribution of dangerous drugs. In particular, they ensure uniform regulations that allow for:

- Preventing individuals convicted of crimes or who have been disciplined by a regulatory agency from having access to dangerous drugs;
- Validation of licensure prior to the sale of dangerous drugs to prevent illegal sales and diversion;
- Ensures the legitimacy of online pharmacies;
- The Board to have the most up-to-date information on licensees; and
- Regular inventories of controlled substance stocks to deter and detect diversion.

## Regulatory Flexibility

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

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

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

The State of Ohio Board of Pharmacy does not fine licensees or impose penalties for first-time paperwork violations. However, any failure of a standard of care in the practice of pharmacy or the preparation/distribution of dangerous drugs is not considered a paperwork error but a quality assurance issue by the licensee that is necessary for the protection of the public.

**18. What resources are available to assist small businesses with compliance of the regulation?**

Board of Pharmacy staff is available by telephone and e-mail to answer questions. Board staff members also provide presentations to groups and associations who seek updates on current regulations and host regional meetings to discuss changes to Ohio laws and rules. Additionally, staff are trained to educate licensees on compliance with all Board of Pharmacy rules and regulations.

**4729:5-1-01 – Definitions**

As used in this division:

(A) "Terminal distributor of dangerous drugs" or "terminal distributor" means a person who is engaged in the sale of dangerous drugs at retail, or any person, other than a manufacturer, repackager, outsourcing facility, third-party logistics provider, wholesale distributor, or pharmacist, who has possession, custody, or control of dangerous drugs for any purpose other than for that person's own use and consumption.

(1) A terminal distributor of dangerous drugs includes pharmacies, hospitals, nursing homes, and laboratories and all other persons who procure dangerous drugs for sale or other distribution by or under the supervision of a pharmacist, licensed health professional authorized to prescribe drugs or any other person authorized by the board of pharmacy.

(2) A terminal distributor shall comply with the provisions set forth in this division.

(B) "Abandoned application" means an application submitted for licensure or registration that meets the requirements in paragraphs (B)(1) and (B)(2) of this rule. An applicant forfeits all fees associated with an abandoned application. The board shall not be required to act on any abandoned application and the application may be destroyed by board staff. If the application is abandoned, the applicant shall be required to reapply for licensure or registration, submit the required fee and comply with the requirements in effect at the time of reapplication.

(1) An application shall be deemed abandoned if any of the following apply:

(a) An applicant fails to complete all application requirements within thirty days after being notified of the incomplete application by the board.

(b) An applicant for a terminal distributor of dangerous drugs that fails to demonstrate compliance with rule 4729:5-2-01 of the Administrative Code. The applicant may submit a request to the director of licensing for a one-time ninety-day extension.

(c) An applicant for a terminal distributor of dangerous drugs that fails to demonstrate compliance with appropriate security and control rules pursuant to agency 4729. of the Administrative Code. The applicant may submit a request to the director of licensing for a one-time ninety-day extension.

(2) An application shall not be deemed abandoned if the application is subject to any of the following:

(a) An administrative proceeding; or

(b) If there is discipline pending against the applicant.

(C) “Access to drug stock” includes not only physical access, but also any influence over the handling of dangerous drugs such as purchases, inventories, issuance of medical orders, etc. It does not include employees or contractors such as maintenance, janitorial, IT or other staff that may need limited supervised access to areas where dangerous drugs or D.E.A. controlled substance order forms are kept.

(D) “Act of moral turpitude” means an act or behavior that gravely violates moral sentiment or accepted moral standards of the community and is a morally culpable quality held to be present in some criminal offenses as distinguished from others.

(E) "Adulterated drug" includes a dangerous drug to which any of the following applies:

(1) A compounded dangerous drug if it exceeds the beyond use date as indicated in United States pharmacopeia chapters 795 and 797, USP 41 - NF 36, or any official supplement thereto (5/1/2018).

(2) Meets any of the requirements described in section 3715.63 of the Revised Code.

(3) Is beyond the expiration date as stated by the manufacturer, repackager, or distributor in its labeling. This does not apply to expired drugs that are donated pursuant to sections 3715.88 through 3715.92 of the Revised Code.

(4) Is not stored, dispensed or personally furnished according to the requirement of the federal act as indicated in the product labeling.

(F) "Campus", as used to describe a type of terminal distributor of dangerous drugs license issued pursuant to section 4729.51 of the Revised Code, means an establishment or place consisting of multiple buildings where dangerous drugs are stored that are located on a contiguous plot of land. All such buildings and stocks of dangerous drugs shall be under common ownership and control.

(G) "Certified diabetes educator", as used in Chapters 3719. and 4729. of the Revised Code, means a person who has been certified to conduct diabetes education by the "National Certification Board for Diabetes Educators (NCBDE)."

(H) “Distributor of Dangerous Drugs” or “Drug Distributor” means the following persons licensed in accordance with section 4729.52 of the Revised Code and division 4729:6 of the Administrative Code:

(1) Wholesale distributors of dangerous drugs, including:

(a) Brokers; and

(b) Virtual wholesalers.

(2) Manufacturers of dangerous drugs.

(3) Outsourcing facilities.

(4) Third-party logistics providers.

(5) Repackagers of dangerous drugs.

(I) "Person" has the same meaning as in division (S) of section 4729.01 of the Revised Code and also includes any individual member, regardless of the percentage of ownership, of any partnership, association, limited liability company, or corporation.

(J) "Place on probation", as used in Chapter 4729. of the Revised Code, means to take action against a license suspending some or all of the sanctions imposed by the board against that license. The terms of the probation shall state the period of time covered by the probation and may include other conditions as determined by the state board of pharmacy.

(K) “Readily retrievable”, as used in this division, means that records maintained in accordance with this division shall be kept in such a manner that they can be separated out from all other records and produced for review by an agent of the board within three business days.

(L) "Refuse to grant or renew", as used in Chapter 4729. of the Revised Code, means to deny original or continued licensure for a period of at least twenty-four months. After twenty-four months, or such period of time as the individual board order may require, a person licensed by the board or a person seeking to attain such status by licensure, and whose license the state board of pharmacy has refused to grant or renew, may make application to the board for issuance of a new license. A person that seeks to attain such status by licensure, whose license the state board of pharmacy has refused to grant or renew, must meet any requirements established by the board.

(M) "Revoke", as used in Chapters 3719. and 4729. of the Revised Code, means to take action against a license rendering such license void and such license may not be reissued. "Revoke" is an action that is permanent against the licensee.

(N) "Sale" or "sell" includes any transaction made by any person, whether as principal proprietor, agent, or employee, to do or offer to do any of the following: deliver, distribute, broker, exchange, gift or otherwise give away, or transfer, whether the transfer is by passage of title, physical movement, or both.

(O) “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.

(P) "Suspend", as used in Chapters 3719. and 4729. of the Revised Code, means to take action against a license rendering such license without force and effect for a period of time as determined by the state board of pharmacy.

(Q) "Summary suspension", as used in Chapters 3719. and 4729. of the Revised Code, means to take immediate action against a license without a prior hearing rendering such license without force and effect for a period of time as indicated in section 4729.561 or 4729.571 of the Revised Code. The board may suspend a license issued pursuant to Chapter 4729. of the Revised Code by utilizing a telephone conference call to review the allegations and take a vote.

(R) "Wholesale sale" and "sale at wholesale" mean any sale in which the purpose of the purchaser is to resell the article purchased or received by the purchaser.

**4729:5-2-01 Responsible Person – Terminal Distributor.**

(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 4729.01 of the Revised Code. A pharmacist shall be the responsible person for no more than one such pharmacy or campus unless granted permission in accordance with paragraph (E) of this rule.

(2) The responsible person shall be responsible for the practice of the profession of pharmacy, including, but not limited to, the supervision and control of dangerous drugs as required in division (B) of section 4729.55 of the Revised Code, adequate safeguards as required in division (C) of section 4729.55 of the Revised Code, security and control of dangerous drugs and maintaining all drug records otherwise required.

(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 governing 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 Revised 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 in section 4729.552 of the Revised Code. A physician shall be the responsible person for no more than one such location unless granted permission in accordance with paragraph (E) of this rule. 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 the physician will be physically present at the location for a sufficient amount of time to provide adequate 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 Revised 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.

(C) For locations licensed as a category III terminal distributor of dangerous drugs with an office-based opioid treatment classification under section 4729.553 of the Revised Code:

(1) Only a physician or certified nurse practitioner who meets the following shall may be the responsible person whose name appears on the category III terminal distributor of dangerous drugs with an office-based opioid treatment classification license as defined in section 4729.553 of the Revised Code:

(a) The physician is authorized under Chapter 4731. of the Revised Code to practice medicine and surgery or osteopathic medicine and surgery or the certified nurse practitioner is designated as a certified nurse practitioner in accordance with section 4723.42 of the Revised Code and rules adopted by the board of nursing; and

(b) The physician or certified nurse practitioner possesses a waiver to prescribe or personally furnish buprenorphine under the Drug Addiction Treatment Act of 2000 (DATA 2000) (2/20/2017).

(2) A physician or certified nurse practitioner shall not be designated the responsible person for a location licensed as a category III terminal distributor of dangerous drugs with an office-based opioid treatment classification unless the physician or certified nurse practitioner will be physically present at the location for at least fifteen hours per week. If the facility is not open more than fifteen hours per week, the minimum amount of on-site supervision shall be at least fifty per cent of the total hours the facility is open, as reported to the board by the licensee on the application. Any changes to the licensee's hours of operation shall be reported to the board, in a manner determined by the board, within three business days.

(a) The hour requirements of this paragraph do not apply if either:

(i) The responsible person is unable to meet the requirements due to a documented illness or emergency and there is another physician on-site who meets the requirements of paragraph (C)(1) of this rule who can provide on-site supervision in accordance with the requirements

described in this paragraph. The physician or certified nurse practitioner shall assume all responsibilities for compliance with this rule in the absence of the responsible person.

(ii) The location is closed for a state or federal holiday or other documented reason.

(3) The person to whom the category III terminal distributor of dangerous drugs license with an office-based opioid treatment classification has been issued, the responsible person and all licensed health professionals practicing at that location are responsible for compliance with all state and federal laws, regulations, and rules regulating the operation of an office based opioid treatment facility and prescribing of controlled substances.

(D) 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) When there is a change of responsible person, the state board of pharmacy shall be notified within ten days of the effective date of the appointment of the new responsible person in a manner determined by the board. For a limited terminal distributor of dangerous drugs license, the notification shall include a drug list required in accordance with agency 4729 of the Administrative Code.

(3) A complete inventory, pursuant to section 1304.11 of the Code of Federal Regulations (9/9/2014) and rule 4729:5-3-05 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 location licensed as a terminal distributor of dangerous drugs.

(4) The responsible person to whom the terminal distributor of dangerous drugs license has been issued and all licensed health professionals on duty are responsible for compliance with all state and federal laws, regulations, and rules governing the distribution of dangerous drugs.

(5) A responsible person must be physically present at the location for a sufficient amount of time to provide supervision and control of dangerous drugs on-site.

(6) The responsible person shall be responsible for ensuring the terminal distributor of dangerous drugs requirements are met, including, but not limited to, the supervision and control of dangerous drugs as required in division (B) of section 4729.55 of the Revised Code, adequate safeguards as required in division (C) of section 4729.55 of the Revised Code, security and control of dangerous drugs and maintaining all drug records otherwise required.

(7) The board of pharmacy shall issue a resolution providing the credential types required for the responsible person of each classification/business type of terminal distributor of dangerous drugs license. Only individuals that meet the credentials specified may be the responsible person for

that classification/business type. The resolution shall be updated as necessary and shall be made available on the board's web site, www.pharmacy.ohio.gov.

(E) Unless otherwise approved by the board, a terminal distributor shall not have a responsible person who:

(1) Has been denied the right to work in any facility by the state board of pharmacy as part of an official order of the board.

(2) Has been denied the right to work in such a facility by another professional licensing board/agency as part of an official order of that board/agency.

(3) Has committed an act that constitutes a misdemeanor theft offense, regardless of the jurisdiction in which the act was committed.

(4) Has committed an act that constitutes a misdemeanor drug offense, except for a minor misdemeanor drug offense, regardless of the jurisdiction in which the act was committed.

(5) Has committed an act that constitutes a felony, regardless of the jurisdiction in which the act was committed.

(7) Has been subject to any of the following:

(a) A finding by a court of the person's eligibility for intervention in lieu of conviction; or

(b) A finding by a court of the person's eligibility for treatment or intervention in lieu of conviction in another jurisdiction.

(8) Has been granted entry into a diversion program, deferred prosecution program, or the equivalent thereof.

(9) Cannot practice according to acceptable and prevailing standards of care by reason of mental illness or physical illness, including, but not limited to, physical deterioration that adversely affects cognitive, motor, or perceptive skills.

(10) Is addicted to or abusing alcohol or drugs;

(11) Has been excluded from participation in Medicare or a state health care program.

(12) Has been denied a license or registration by the drug enforcement administration or appropriate issuing body of any state or jurisdiction.

(13) Has been the subject of any of the following by the drug enforcement administration or licensing agency of any state or jurisdiction:

(a) A disciplinary action that resulted in the suspension, probation, surrender or revocation of the person's license or registration; or

(b) A disciplinary action that was based, in whole or in part, on the person's inappropriate prescribing, dispensing, diverting, administering, storing, securing, personally furnishing, compounding, supplying or selling a controlled substance or other dangerous drug.

(14) Has committed an act that constitutes a misdemeanor that is related to, or committed in, the employee's professional practice.

(15) Has committed an act of moral turpitude that constitutes a felony or misdemeanor, regardless of the jurisdiction in which the act was committed.

(F) Written requests for being a responsible person at more than one location pursuant to paragraphs (A) and (B) of this rule must be submitted to the state board of pharmacy in a manner determined by the board. The executive director or the director's designee shall have the authority to temporarily approve or deny a request for being a responsible person at more than one location for a period not to exceed sixty days. The full board will review requests the executive director or the director's designee has temporarily approved at the next scheduled board meeting. A terminal distributor of dangerous drugs whose request has been denied either by the executive director, the director's designee or the board will be provided with a written explanation of denial and allowed one opportunity to resubmit its request to address the identified concerns. The board may impose conditions on all approved requests, including requirements that requests be submitted for reapproval at intervals determined by the board.

**4729:5-2-03 Change in description of a terminal distributor of dangerous drugs.**

(A) Any change in the ownership, business or trade name, category, or address of a terminal distributor of dangerous drugs requires a new application, required fee, and license. The new application and required fee shall be submitted at least thirty days prior to any change in the ownership, business or trade name, category, or address.

(B) A change of ownership includes any of the following:

(1) A change of controlling interest of ten percent or more of a licensed corporation's outstanding shares of voting stock.

(2) Any business entity change from its original form, as licensed, to a sole proprietorship, partnership, limited liability company, corporation or any other business entity.

(3) An existing corporation ceases and a new corporation or other business entity is formed.

(4) An existing corporation continues and there is a one hundred per cent stock purchase by another corporation or other business entity.

(5) Two wholly-owned subsidiaries of a parent company are merged.

(6) A currently licensed terminal distributor is purchased or operated by a different business entity than what is listed on the original application, even if the location maintains the original "doing business as" (DBA) and/or responsible person.

(7) Any partnership change other than that which was originally licensed.

(a) A partnership change is deemed to have occurred when:

(i) There is an addition or removal of one or more partners in a partnership to which a license is issued.

(ii) The entity is sold and the sale becomes final.

(b) For partnerships, a transfer of a portion of ownership among existing partners is not a change of ownership, if there is no addition or removal of a partner.

(8) Any other business model change as determined by the board to be a change of ownership.

(C) For publicly traded corporations, a routine sale of stock is not a change of ownership.

A publicly traded corporation is a corporation owned by stockholders who are members of the general public and who trade shares publicly, often through a listing on a stock exchange.

(D) If any change of ownership in accordance with paragraph (B) of this rule results in a new or different DBA, or a new or different employer identification number (EIN), a new application fee and new license number are required.

(E) A change of ownership set forth in paragraphs (B)(2) and (B)(3) of this rule or as otherwise determined by the board, shall require the board to issue a new license number.

(F) A change of ownership as described in paragraph (B) of this rule of a licensee's parent or holding company shall not require a new application, required fee, and license.

(G) A change of credential class shall require notification to the board in a manner determined by the board. A change of credential class shall not require an application or full application fee but the board may charge a nominal processing fee.

**4729:5-2-04 Procedure for discontinuing business as a terminal distributor of dangerous drugs.**

(A) A terminal distributor of dangerous drugs who plans to discontinue business activities shall file a notice with the board of pharmacy. The notice shall be submitted, in a manner determined by the board, at least thirty days in advance of the proposed date of discontinuing business, unless waived by the executive director of the board. This notice shall include the following information:

(1) The name, address, and license number of the terminal distributor discontinuing business.

(2) The name, address, and license number of the terminal distributor or other authorized entity where the dangerous drugs will be transferred.

(3) The name and address of the secured location where the records of purchase and dispensing will be kept in accordance with section 4729.37 of the Revised Code and this division of the Administrative Code.

(4) The proposed date of discontinuing business.

(B) Unless the licensee is informed by the executive director before the proposed date of discontinuing business that the transfer of dangerous drugs and records may not occur, the licensee discontinuing business may transfer the dangerous drugs and records in accordance with the following:

(1) On the date of discontinuing business, a complete inventory of all controlled substances being transferred, or disposed of in accordance with rule 4729:5-3-01 of the Administrative Code, shall be made. The inventory shall list the name, strength, dosage form, and quantity of all controlled substances transferred or disposed of.

(2) This inventory shall serve as the final inventory of the licensee discontinuing business and the initial inventory of the licensee to whom the controlled substances are being transferred. A copy of the inventory shall be included in the records of each licensee involved in the transfer.

**4729:5-3-04 Verification of licensure prior to sale or purchase.**

(A) Before a terminal distributor of dangerous drugs may purchase dangerous drugs at wholesale, the terminal distributor shall query the board's online roster (available on the board's website: www.pharmacy.ohio.gov) to confirm the any of the following:

(1) The seller is licensed to engage in the sale of dangerous drugs in accordance with section 4729.52 of the Revised Code; or

(2) The seller is licensed to engage in the occasional sale or distribution of dangerous drugs at wholesale in accordance with rule 4729:5-3-09 of the Administrative Code.

(B) If no documented query is conducted before a purchase is made, it shall be presumed that the purchase of dangerous drugs by the terminal distributor is in violation of division (F) of section 4729.51 of the Revised Code.

If a licensed terminal distributor of dangerous drugs conducts a documented query at least annually and relies on the results of the query in purchasing dangerous drugs, the terminal distributor shall be deemed not to have violated division (F) of section 4729.51 of the Revised Code in making the purchase.

(C) Before a terminal distributor of dangerous drugs may make a sale of dangerous drugs pursuant to rule 4729:5-3-09 of the Administrative Code, the terminal distributor shall query the board's online roster (available on the board's website: www.pharmacy.ohio.gov) to determine if the purchaser is licensed as either:

(1) A terminal distributor of dangerous drugs.

(a) For a limited terminal distributor of dangerous drugs license, a terminal distributor shall also review a current version of the licensee's drug list to ensure the purchaser is authorized to possess the drugs ordered.

(2) A distributor of dangerous drugs in accordance with division 4729:6 of the Administrative Code.

(D) Paragraph (C) of this rule does not apply when a terminal distributor sells or distributes dangerous drugs at wholesale to any of the following:

(1) A terminal distributor, manufacturer, outsourcing facility, third-party logistics provider, repackager, or wholesale distributor that is located in another state, is not engaged in the sale of dangerous drugs within this state, and is actively licensed to engage in the sale of dangerous drugs by the state in which the distributor conducts business; or

(2) Any of the exempted persons described in section 4729.541 of the Revised Code.

(E) A terminal distributor of dangerous drugs may make a sale of a dangerous drug to any of the exempted persons described in section 4729.541 of the Revised Code in accordance with rule 4729:5-3-09 and shall ensure the purchaser meets the exemption criteria.

(1) To confirm a purchaser meets the exemption criteria, the terminal drug distributor shall comply with the all the following:

(a) Provide the purchaser, in a manner determined by the Board, the requirements in Ohio law of when a purchaser shall hold a license as a terminal distributor of dangerous drugs;

(b) If the purchaser is a prescriber, verify the prescriber is appropriately licensed in this state to prescribe drugs or dangerous drugs or drug therapy related devices in the course of the individual's professional practice;

(c) Require the purchaser who claims an exemption to the terminal distributor of dangerous drug licensing requirement to annually attest in writing, which may include an electronic signature, that the purchaser meets the licensing exemptions in section 4729.541 of the Revised Code; and

(d) Ensure that all attestations are maintained by the terminal distributor for a period of three years following the date the attestation is signed by the purchaser.

**4729:5-3-07 – Controlled Substances Inventory Requirements.**

(A) Unless otherwise stated in this division, all category III terminal distributor licenses shall complete a controlled substances inventory in accordance with section 1304.11 of the Code of Federal Regulations (9/9/2014).

(B) All controlled substance inventories performed in accordance with this rule shall be conducted on an annual basis.

(C) The terminal distributor's responsible person shall be responsible for completing and maintaining this inventory record at the location licensed as a terminal distributor of dangerous drugs.

(D) All inventory records shall be maintained for a period of three years from the completion date of the inventory and made readily retrievable.

(E) When a drug or compound is added to the schedule of controlled substances by state or federal law, rule or regulation, a terminal distributor shall complete an inventory pursuant to this rule of all stocks of such drug or compound no later than ten days of the drug or compound being added to the schedule.

(F) In the event a terminal distributor of dangerous drugs commences business with no controlled substances on hand, this fact shall be recorded as the initial inventory.

**4729:5-3-08 – Sales of dangerous drugs on-line.**

(A) All persons selling or offering to sell dangerous drugs via the internet at retail, into, out of, or within Ohio must be properly licensed with the state board of pharmacy.

(B) All terminal distributors of dangerous drugs who sell or offer to sell dangerous drugs at retail on the internet to persons located in Ohio or any other state must make such sales only in compliance with all state and federal laws, rules and regulations governing the legal distribution of dangerous drugs.

(C) All terminal distributors of dangerous drugs who sell or offer to sell dangerous drugs at retail on the internet to persons located in Ohio shall maintain accreditation as a verified internet pharmacy practice site from the national association of boards of pharmacy.

(D) Websites owned and/or maintained by a terminal distributor of dangerous drugs must provide the following information to the public:

(1) Name under which the terminal distributor is licensed to do business as in Ohio.

(2) Full address of the licensed location.

(3) Telephone number where the terminal distributor may be contacted during regular business hours.

(4) A list of the states in which the terminal distributor may legally sell dangerous drugs.

(5) The name, address and how the state licensing agency and the drug enforcement administration may be contacted in each state in which the person is authorized to do business. This may include a link to the agency's and the drug enforcement administration's website.

(E) Any Ohio licensed terminal distributor requesting personal information from the public by way of the internet (questionnaire forms or e-mail) must provide for security and confidentiality of the information. This portion of the website must also provide information regarding how the personal information will be used, pursuant to all federal and state laws, rules, and regulations, and ensure that such information is not used for purposes not disclosed without the written informed consent of the patient or person submitting personal information.

**4729:5-3-09 Occasional sale and drug transfers.**

(A) The term "occasional sale" as used in section 4729.51 of the Revised Code means a wholesale sale of a commercially manufactured dangerous drug to a person licensed in accordance with section 4729.52 of the Revised Code, terminal distributor of dangerous drugs or any entity or person exempted from licensure as a terminal distributor of dangerous drugs by either:

(1) A pharmacy licensed as a terminal distributor of dangerous drugs; or

(2) A licensed terminal distributor of dangerous drugs that is not a pharmacy, but only with respect to naloxone.

(B) The dosage units of all dangerous drugs distributed by the pharmacy pursuant to this rule shall not exceed five per cent of the total dosage units dispensed by the pharmacy during the same calendar year.

(C) The limits set forth in this rule do not apply to the following:

(1) Terminal distributors of dangerous drugs that conduct occasional sales of naloxone at wholesale; and

(2) Pharmacies that are also licensed to conduct sales of dangerous drugs in accordance with section 4729.52 of the Revised Code.

(D) The requirements of this rule do not apply to the transfer of dangerous drugs pursuant to paragraph (E) of this rule.

(E) A licensed terminal distributor of dangerous drugs having more than one licensed location may transfer or deliver dangerous drugs from one licensed location to another licensed location owned by that terminal distributor if the license issued for each location is in effect at the time of the transfer or delivery. Such transfer or delivery includes either of the following:

(1) Intracompany sales, which includes any transaction or transfer between any division, subsidiary, parent or affiliated or related company under the common ownership and control.

(2) The sale, purchase, or transfer of a drug or an offer to sell, purchase, or transfer of a drug among hospitals or other health care entities that are under common control. Common control means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, voting rights, by contract, or otherwise.

(F) Occasional sales by a licensed terminal distributor shall comply with the reporting requirements set forth in section 4729.78 of the Revised Code.

**4729:5-3-10 Employment of individuals with felony convictions.**

(A) Pursuant to 21 C.F.R. 1301.76 (9/9/2014), a terminal distributor of dangerous drugs that is a United States drug enforcement administration registrant shall not employ in a position which allows access to controlled substances any person who has been convicted of a felony relating to controlled substances, or who, at any time, has had an application for drug enforcement administration registration denied, revoked, or surrendered for cause.

"For cause" means surrendering a registration in lieu of, or as a consequence of, any federal or state administrative, civil, or criminal action resulting from an investigation of the individual's handling of controlled substances.

(B) Paragraph (A) of this rule does not apply if a waiver is obtained by a licensee pursuant to 21 C.F.R. 1307.03 (3/9/2010).

**4729:5-4-01 – Disciplinary Actions**

(A) The state board of pharmacy, in accordance with Chapter 119. of the Revised Code, may impose any one or more of the following sanctions on a person licensed as a terminal distributor of dangerous drugs for any of the causes set forth in paragraph (B) of this rule:

(1) Suspend, revoke, restrict, limit, or refuse to grant or renew a license;

(2) Reprimand or place the license holder on probation;

(3) Impose a monetary penalty or forfeiture as set forth in section 4729.57 of the Revised Code.

(B) The board may impose the sanctions set forth in paragraph (A) of this rule for any of the following:

(1) Making any false material statements in an application for a license or renewal of a license as a terminal distributor of dangerous drugs;

(2) Violating any rule of the board;

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

(4) Except as provided in section 4729.89 of the Revised Code, 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;

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

(6) Falsely or fraudulently promoting to the public a dangerous drug, except that nothing in this division prohibits a terminal distributor of dangerous drugs from furnishing information concerning a dangerous drug to a health care provider or another licensed terminal distributor;

(7) Ceasing to satisfy the qualifications of a terminal distributor of dangerous drugs set forth in section 4729.55 of the Revised Code;

(8) Except as provided in division (C) of section 4729.57 of the Revised Code:

(a) Waiving the payment of all or any part of a deductible or copayment that an individual, pursuant to a health insurance or health care policy, contract, or plan that covers the services provided by a terminal distributor of dangerous drugs, would otherwise be required to pay for the services if the waiver is used as an enticement to a patient or group of patients to receive pharmacy services from that terminal distributor;

(b) Advertising that the terminal distributor will waive the payment of all or any part of a deductible or copayment that an individual, pursuant to a health insurance or health care policy, contract, or plan that covers the pharmaceutical services, would otherwise be required to pay for the services.

(9) Conviction of a felony;

(10) Commission of an act of moral turpitude that constitutes a felony or misdemeanor, regardless of the jurisdiction in which the act was committed.

(11) Violation of any restrictions placed by the state board of pharmacy on a license or violating any terms of a board order issued against the licensee.

(12) Exclusion from participation in Medicare or a state health care program.

(13) Being denied a license or registration by the drug enforcement administration or appropriate issuing body of any state or jurisdiction.

(14) Being the subject of any of the following by the drug enforcement administration or licensing agency of any state or jurisdiction:

(a) A disciplinary action that resulted in the suspension or revocation of the person's license or registration; or

(b) A disciplinary action that was based, in whole or in part, on the person's inappropriate prescribing, dispensing, diverting, administering, storing, personally furnishing, compounding, supplying or selling a controlled substance or other dangerous drug.

(15) Commission of an act that constitutes a misdemeanor theft offense, regardless of the jurisdiction in which the act was committed.

(16) Commission of an act that constitutes a misdemeanor drug offense, except for a minor misdemeanor drug offense, regardless of the jurisdiction in which the act was committed.

(17) Has been subject to any of the following:

(a) A finding by a court of the person's eligibility for intervention in lieu of conviction; or

(b) A finding by a court of the person's eligibility for treatment or intervention in lieu of conviction in another jurisdiction.

(18) Has been granted entry into a diversion program, deferred prosecution program, or the equivalent thereof.

(19) Is addicted to or abusing alcohol or drugs.

(20) Commission of an act that constitutes a misdemeanor that is related to, or committed in, the person's professional practice.

(21) Employs a responsible person that does not meet the requirements set forth in rule 4729:5-2-01 of the Administrative Code.

(22) The ownership of such entity has been transferred from a person whose license issued in accordance with Chapter 4729. of the Revised Code has been revoked or disciplined by the state board of pharmacy or any other professional licensing agency to the spouse or other family member.

(23) The ownership of such facility has been transferred from a licensee whose license has been revoked or disciplined by the state board of pharmacy or any other professional licensing board to another who employs the former owner or who allows the former owner to be present within the physical confines of the location to be licensed.

(24) Except as provided in Chapter 3719. of the Revised Code, dispensing a sample drug as defined in rule 4729:6-3-09 of the Administrative Code.

(25) The method used by the terminal distributor to store, possess or distribute dangerous drugs poses serious harm to others;

(26) Unless otherwise approved by the board, a terminal distributor knowingly employs a person with access to drug stock who:

(a) Has been denied the right to work in any facility by the state board of pharmacy as part of an official order of the board.

(b) Has been denied the right to work in such a facility by another professional licensing agency as part of an official order of that agency.

(c) Has committed an act that constitutes a misdemeanor theft offense, regardless of the jurisdiction in which the act was committed.

(d) Has committed an act that constitutes a misdemeanor drug offense, except for a minor misdemeanor drug offense, regardless of the jurisdiction in which the act was committed.

(e) Has committed an act that constitutes a felony, regardless of the jurisdiction in which the act was committed.

(f) Has been subject to any of the following:

(i) A finding by a court of the person's eligibility for intervention in lieu of conviction; or

(ii) A finding by a court of the person's eligibility for treatment or intervention in lieu of conviction in another jurisdiction.

(g) Has been granted entry into a diversion program, deferred prosecution program, or the equivalent thereof.

(h) Is addicted to or abusing alcohol or drugs.

(i) Has been excluded from participation in Medicare or a state health care program.

(j) Has been denied a license or registration by the drug enforcement administration or appropriate issuing body of any state or jurisdiction.

(k) Has been the subject of any of the following by the drug enforcement administration or licensing agency of any state or jurisdiction:

(i) A disciplinary action that resulted in the suspension, probation, surrender or revocation of the person's license or registration; or

(ii) A disciplinary action that was based, in whole or in part, on the person's inappropriate prescribing, dispensing, diverting, administering, storing, securing, personally furnishing, compounding, supplying or selling a controlled substance or other dangerous drug.

(l) Has committed an act that constitutes a misdemeanor that is related to, or committed in, the employee’s professional practice.