

**12/07/2016**

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 Rules**

- 4729-9-30: Creates broker classification of the wholesale distributor of dangerous drugs license. A broker is defined as any person engaged in the marketing, offering, or contracting for wholesale distribution and sale of a dangerous drug in or into Ohio who does not take physical possession of dangerous drugs.

**Amended**

- 4729-9-14: Adds personally furnished controlled substances to records requirement and requires terminal distributors to maintain an agreement with a company possessing records at an outside location and to authorize a board agent to access those records within three business days upon notice.
- 4729-9-22: Adds personally furnished dangerous drugs to records requirement and requires terminal distributors to maintain an agreement with a company possessing records at an outside location and to authorize a board agent to access those records within three business days upon notice.

Comments on the proposed rules will be accepted until close of business on December 30, 2016. Please send all comments to the following email address:

[Cameron.mcnamee@pharmacy.ohio.gov](mailto:Cameron.mcnamee@pharmacy.ohio.gov)

In addition, please copy your comments to:

[CSIPublicComments@governor.ohio.gov](mailto:CSIPublicComments@governor.ohio.gov)

# CSI - Ohio

The Common Sense Initiative

## Business Impact Analysis

Agency Name: State of Ohio Board of Pharmacy

Regulation/Package Title: Dangerous Drugs

Rule Number(s): New: 4729-9-30

Amend: 4729-9-14; 9-22

Date: 12/07/2016

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Rescinded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 Rules

- 4729-9-30: Creates broker classification of the wholesale distributor of dangerous drugs license. A broker is defined as any person engaged in the marketing, offering, or contracting for wholesale distribution and sale of a dangerous drug in or into Ohio who does not take physical possession of dangerous drugs.

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## **Amended**

- 4729-9-14: Adds personally furnished controlled substances to records requirement and requires terminal distributors to maintain an agreement with a company possessing records at an outside location and to authorize a board agent to access those records within three business days upon notice.
- 4729-9-22: Adds personally furnished dangerous drugs to records requirement and requires terminal distributors to maintain an agreement with a company possessing records at an outside location and to authorize a board agent to access those records within three business days upon notice.

### **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. The following sections of the Ohio Revised Code are also considered authorizing statutes for this rule package: 3719.07, 4729.37, 4729.52 and 4729.53.

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

The proposed 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 dangerous drugs and records associated with prescription drugs has traditionally been done at the state level by legislatively created state boards of pharmacy, such as the State of Ohio Board 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 state 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 state board of pharmacy to adopt rules prescribing the manner of keeping and the form and content of records to be kept by persons authorized to manufacture, distribute, dispense, conduct research in, prescribe, administer, or otherwise deal with controlled substances.

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

- Ensure timely access to records maintained by licensees; and
- Properly license those involved in all aspects of wholesale distribution 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 and prescribers 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.

**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 health and safety by ensuring uniform regulations related to recordkeeping 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 regulations across Ohio. At this juncture, it was the determination of the Board and the Rules Review Committee that the rule package did not lend itself to performance-based regulations.

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

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

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

## **Adverse Impact to Business**

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

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

The rule package impacts the following:

- Terminal distributors of dangerous drugs;
- Brokers 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 or wholesale 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 Rules**

- 4729-9-30: Specifies requirements for licensure as a wholesale distributor of dangerous drugs for virtual wholesale distributors/brokers. Requires licensure as a wholesale distributor of dangerous drugs with a wholesale distributor/broker classification. Depending on whether the location will be shipping controlled or non-controlled drugs, the annual license cost ranges from \$750 to \$787.50. It also takes approximately one hour to complete the license application. Additionally, the rule imposes recordkeeping and background check requirements on licensees. The cost of a background check per officer of the company is: BCI&I - \$22, FBI - \$24, and some agencies may charge a processing fee (e.g. \$5-\$40). This rule also requires a recent state inspection report if the entity is not located in Ohio. If no inspection report is available or the state does not license this type of facility, the rule requires the entity obtain and maintain Verified-Accredited Wholesale Distributors (VAWD) accreditation from the National Association of Boards of Pharmacy. VAWD accreditation is \$5,500 in the first year and \$7,500 every three years.

## **Amended**

- 4729-9-14: Terminal distributors will incur administrative costs to ensure that an agreement is in place if they store records off-site.
- 4729-9-22: Terminal distributors will incur administrative costs to ensure that an agreement is in place if they store records off-site.

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**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 are intended to protect and promote public safety. In particular, they ensure uniform regulations that allow for:

- The confidentiality of patient records and access to authorized users, including those conducting criminal and administrative investigations;
- Validation of licensure prior to the sale of dangerous drugs to prevent illegal sales and diversion; and
- The Board to have the most up-to-date information on licensees.

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

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#### **4729-9-14 Records of controlled substances.**

(A) Each prescriber or terminal distributor of dangerous drugs shall keep a record of all controlled substances received, administered, **personally furnished**, dispensed, sold, destroyed, or used. The acts of prescribing, administering, dispensing, and destroying of a controlled substance must be documented with the positive identification of the responsible individual pursuant to paragraph (N) of rule 4729-5-01 of the Administrative Code. These records may be kept electronically if the method is approved by the state board of pharmacy and the records are backed-up each business day.

(1) Records of receipt shall contain a description of all controlled substances received, the kind and quantity of controlled substances received, the name and address of the persons from whom received, and the date of receipt.

(2) Records of administering, dispensing, or using controlled substances shall contain a description of the kind and quantity of the controlled substance administered, dispensed, or used, the date, the name and address of the person to whom or for whose use, or the owner and identification of the animal for which, the controlled substance was administered, dispensed, or used.

(3) Records of drugs administered which become a permanent part of the patient's medical record shall be deemed to meet the name and address requirements of paragraph (A)(2) of this rule.

(4) Destruction of controlled substances shall be conducted in accordance with rule 4729-9-06 of the Administrative Code.

(B) Each prescriber or terminal distributor of dangerous drugs shall maintain an inventory of all controlled substances as follows:

(1) Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date the inventory is taken.

(a) The name of the substance.

(b) The total quantity of the substance.

(i) Each finished form (e.g., ten-milligram tablet or ten-milligram concentration per milliliter).

(ii) The number of units or volume of each finished form in each commercial container (e.g., one-hundred-tablet bottle or ten-milliliter vial).

(iii) The number of commercial containers of each such finished form (e.g., three one-hundred-tablet bottles or ten one-milliliter vials).

(c) If the substance is listed in schedule I or II, the prescriber or terminal distributor of dangerous drugs shall make an exact count or measure of the contents.

(d) If the substance is listed in schedule III, IV, or V, the prescriber or terminal distributor of dangerous drugs may make an estimated count or measure of the contents, unless the container holds more than one thousand tablets or capsules in which an exact count of the contents must be made.

(2) A separate inventory shall be made for each place or establishment where controlled substances are in the possession or under the control of the prescriber or terminal distributor. Each inventory for each place or establishment shall be kept at the place or establishment.

(3) An inventory of all stocks of controlled substances on hand on the date the prescriber or terminal distributor first engages in the administering, dispensing, or use of controlled substances. In the event the prescriber or terminal distributor of dangerous drugs commences business with no controlled substances on hand, this fact shall be recorded as the initial inventory.

(4) Each prescriber or terminal distributor of dangerous drugs shall take a new inventory of all stocks of controlled substances on hand every year following the date on which the initial inventory is taken.

(5) When a substance is added to the schedule of controlled substances by the federal drug enforcement administration or the state board of pharmacy, each prescriber or terminal distributor of dangerous drugs shall take an inventory of all stock of such substance on hand at that time.

(C) All records of receipt, distribution, administering, dispensing, **personally furnishing**, inventory, destruction, or using controlled substances shall be kept for a period of three years at the place where the controlled substances are located. Any terminal distributor of dangerous drugs intending to maintain such records at a location other than this place must first send a written request to the state board of pharmacy. The request shall contain the terminal distributor of dangerous drug name and license number of the requestor and the name and address of the alternate location. The state board of pharmacy will send written notification to the terminal distributor of dangerous drugs documenting the approval or denial of the request. A copy of the board's approval shall be maintained with the other records of controlled substances. Any such alternate location shall be secured and accessible only to representatives of the terminal distributor of dangerous drugs.

**(D) A terminal distributor of dangerous drugs maintaining records at a location other than the place licensed with the state board of pharmacy or via a computerized recordkeeping system shall maintain an executed agreement with the company possessing or storing the records authorizing an agent of the Board access to the records maintained in accordance with this rule within three business days, excluding weekends and holidays.**

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## **4729-9-22 Records of dangerous drugs.**

Each prescriber or terminal distributor of dangerous drugs shall keep a record of all dangerous drugs received, administered, dispensed, **personally furnished**, distributed, sold, destroyed, or used. The acts of prescribing, administering, dispensing, and destroying of a dangerous drug must be documented with the positive identification of the responsible individual pursuant to paragraph (N) of rule 4729-5-01 of the Administrative Code. These records may be kept electronically if the method is approved by the state board of pharmacy and the records are backed-up each business day.

(A) Records of receipt shall contain a description of all dangerous drugs received, the kind and quantity of dangerous drugs received, the name and address of the persons from whom received, and the date of receipt.

(B) Records of administering, **personally furnishing**, dispensing, or using dangerous drugs shall contain a description of the kind and quantity of the dangerous drugs administered, dispensed, sold, or used, the date, the name and address of the person to whom or for whose use, or the owner and identification of the animal for which, the dangerous drug was administered, dispensed, or used.

(C) Records of dangerous drug destructions, other than controlled substances, shall contain the name, strength, dosage form, and quantity of the dangerous drug destroyed, the date destroyed, the method of destruction, the positive identification of the prescriber or responsible person that performed the destruction, and if used the positive identification of the person that witnessed the destruction.

(D) Records of dangerous drugs, other than controlled substances, administered, dispensed, **personally furnished** or used which become a permanent part of the patient's medical record shall be deemed to meet the requirements of paragraph (B) of this rule.

(E) All records of receipt, distribution, administering, dispensing, **personally furnishing**, selling, destroying, or using dangerous drugs shall be kept for a period of three years at the place where the dangerous drugs are located and upon request provided to a state board of pharmacy officer, agent, and/or inspector within three working days, excluding weekends and holidays. Any terminal distributor of dangerous drugs intending to maintain such records at a location other than this place must first send a written request to the state board of pharmacy. The request shall contain the terminal distributor of dangerous drug name and license number of the requestor and the name and address of the alternate location. The state board of pharmacy will send written notification to the terminal distributor of dangerous drugs documenting the approval or denial of the request. A copy of the board's approval shall be maintained with the other records of dangerous drugs. Any such alternate location shall be secured and accessible only to representatives of the terminal distributor of dangerous drugs.

**(F) A terminal distributor of dangerous drugs maintaining records at a location other than the place licensed with the state board of pharmacy or via a computerized recordkeeping system**

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shall maintain an executed agreement with the company possessing or storing the records authorizing an agent of the Board access to the records maintained in accordance with this rule within three business days, excluding weekends and holidays.

### **4729-9-30 Wholesale Distributor with a Broker Classification (NEW)**

(A) "Broker" means any person engaged in the marketing, offering, or contracting for wholesale distribution and sale of a dangerous drug in or into Ohio who does not take physical possession of dangerous drugs.

(B) Brokers shall be licensed by the state board of pharmacy as a wholesale distributor pursuant to section 4729.52 of the Revised Code with a broker classification.

(C) Brokers shall be registered as a business entity with the appropriate state or local authority and must operate out of a location that is zoned for commercial use and not out of a residence or personal dwelling.

(D) The following information shall be required on a form supplied by the state board of pharmacy from each person making application for a license as a wholesale distributor of dangerous drugs with a broker classification:

(1) The name, full physical business address (not a post office box), and telephone number;

(2) All trade, fictitious, or business names used by the licensee, e.g. "doing business as" or "formerly known as". Trade or business names shall not be identical to the name used by another, unrelated wholesale distributor permitted to purchase drugs in the state

(3) Addresses, telephone numbers, and the full names of contact persons for all facilities used by the licensee for the storage of records relating to the distribution of dangerous drugs;

(4) The type of ownership or operation (i.e., sole proprietorship, partnership, corporation, or government agency);

(5) The following information for the owner(s) and/or operator(s) of the wholesale distributor with a broker classification:

(a) For a partnership:

(i) the full name, business address, Social Security number, and date of birth of each partner; if the partner is not a natural person each business entity that is a partner having an ownership interest must be disclosed on the application up to and through the entity that is owned by a natural person; and

(ii) the name of the partnership; and

(iii) the partnership's federal employer identification number.

(b) For a corporation:

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(i) the full name, business address, Social Security number, date of birth, of the corporation's president, vice-president, secretary, treasurer and chief executive officer, or any equivalent position;

(ii) the name or names of the corporation;

(iii) the state of incorporation;

(iv) the corporation's federal employer identification number;

(v) the name of the parent company, if applicable; and

(vi) if a corporation is not publicly traded on a major stock exchange, the full name, business address, and Social Security number of each shareholder owning 10% or more of the voting stock of the corporation.

(c) For a sole proprietorship:

(i) the full name, business address, Social Security number, and date of birth of the sole proprietor; and

(ii) if applicable, the federal employer identification number of the business entity.

(d) For a government agency: the full name, business address, Social Security number, and date of birth of the agency director.

(6) A copy of any existing licensure the entity has from the state in which it is located or a letter from a state entity where it is located that indicates that the state does not license such entities;

(7) A copy of any applicable federal licensure or registration;

(8) If the entity making application for a wholesale distributor of dangerous drugs license with a broker classification is located outside the boundaries of the state of Ohio, part of the licensing process shall be an inquiry to the licensing authority of the state in which that entity is located. This inquiry will determine whether the entity possesses a current and valid license to broker dangerous drugs in that state and the experience the licensing authority has had with the entity. This information will be used as part of the consideration in licensing the entity by the board of pharmacy. The board will respond to inquiries of a similar nature from other states regarding Ohio licensed entities.

(9) Pursuant to section 4729.53 of the Revised Code, a new wholesale distributor of dangerous drug license with a broker classification will not be issued until the following submit fingerprints to the Ohio bureau of criminal identification and investigation (BCI&I) for a criminal records check:

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(a) The responsible person on the application for licensure of a wholesale distributor pursuant to 4729-5-11; and

(b) The following persons based upon the wholesale distributor's business type:

(i) All partners of a partnership;

(ii) The sole proprietor of a sole proprietorship;

(iii) The president, vice president, secretary, treasurer, and chief executive officer, or any equivalent position of a corporation and if a corporation is not publicly traded on a major stock exchange, each shareholder owning ten percent or more of the voting stock of the corporation;

(iv) The agency director of a government agency.

(c) The persons listed in paragraph (A)(9)(b) shall be a natural person that owns and/or operates the business entity applying for licensure. In the event the applicant is not owned by a natural person, each business entity with an ownership interest in the applicant must be disclosed on the application up to and through the entity that is owned by a natural person, who shall be subject to the criminal records check in accordance with this rule.

(10) If there is a change in any of the following persons listed in paragraph (A)(9) of this rule, the new persons shall submit to a criminal records check within thirty days of the change.

(11) All criminal records check conducted in accordance with this rule shall consist of both a BCI&I criminal records check and a federal bureau of investigations records check (FBI). The results of the criminal records check must be sent directly to the state board of pharmacy from BCI&I. To be considered valid, the criminal records check must have been performed within the past twelve months. After the board receives the results of all of the required criminal records checks the license licensing process will proceed. The persons listed in paragraph (A)(9) of this rule may submit electronic fingerprint impressions pursuant to rule 4729-5-12 of the Administrative Code, or, if located outside of Ohio, they may submit fingerprint impressions in a manner approved by the board.

(12) Any information required on the application as determined by the board.

(13) Any follow-up information as deemed necessary upon receipt of the application materials.

(E) Prior to the end of the licensing period, a renewal application requesting such information as the state board of pharmacy may require will be sent to the attention of the responsible person. Such a renewal application shall be completed and returned with the applicable fee on or before the established deadline. Failure to do so may result in a refusal by the board to renew the license.

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(F) Brokers shall establish and maintain inventories and records of all transactions regarding the transfer or other disposition of dangerous drugs.

(1) These records shall include but not be limited to the following information:

(a) The source of the drugs, including the all of the following:

(i) Name and principle address of the seller or transferor;

(ii) The address of the location from which the drugs were shipped; and

(iii) Verification that the seller and purchaser is appropriately licensed to sell or transfer dangerous drugs at wholesale.

(b) The identity and quantity of the drugs transferred and distributed.

(c) The dates of receipt and distribution of the drugs.

(d) A system shall be designed and operated to disclose distribution of controlled substances and other dangerous drugs subject to abuse. Reports, generated by the system, shall be furnished to the state board of pharmacy within three business days of receipt of a request from the board. The reports shall include the name and address of the seller and purchaser, date of purchases, product trade name, national drug code (NDC) number, size of package, and quantity purchased.

(2) Records shall be made available for inspection and copying by properly identified and authorized state board of pharmacy designated agents, federal, state, or local law enforcement agency officials for a period of three years following transfer of the drugs.

(3) Records described in this rule that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period.

(a) Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within two working days of a request by properly identified and authorized state board of pharmacy designated agents, federal, state, or local law enforcement agency officials.

(b) Brokers intending to maintain records, described in this rule, at a location other than the place licensed by the state board of pharmacy must obtain approval from the board. A broker maintaining records relating to the distribution and transfer of dangerous drugs at a location other than the place licensed with the state board of pharmacy or via a computerized recordkeeping system shall maintain an executed agreement with the company possessing or storing the records authorizing an agent of the Board access to the records maintained in accordance with this rule within three business days, excluding weekends and holidays.

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(G) Brokers shall inform the state board of pharmacy of suspicious orders or sales of controlled substances and other dangerous drugs subject to abuse, immediately upon discovery. Suspicious orders are those which, in relation to the broker's records are of unusual size, unusual frequency, or deviate substantially from established buying patterns.

(H) Brokers shall only engage in the marketing, offering, or contracting for wholesale distribution and sale of dangerous drugs that are unopened and packaged in the manufacturer's original container.

(I) Brokers shall operate in compliance with applicable federal, state, and local laws and regulations.

(1) Brokers shall permit properly identified and authorized state board of pharmacy designated agents, federal, state, and local law enforcement officials to enter and inspect their premises and delivery vehicles, and to audit their records and written operating procedures at reasonable times and in a reasonable manner, to the extent authorized by law.

(J) A broker wishing to engage in wholesale distribution pursuant to rules 4729-9-16, 4729-9-28, 4729-9-29 and 4729-16-02 of the Administrative Code shall comply with the requirements specified in those rules and shall obtain additional licensure for the operations conducted pursuant to those rules.

(K) Brokers shall verify that the seller and buyer are appropriately licensed to prevent the sale or other distribution of dangerous drugs to any person not authorized pursuant to 4729.51 of the Revised Code.

(L) Brokers shall not engage in the marketing, offering, or contracting for wholesale distribution and sale of dangerous drugs that are controlled substances.