STATE OF OHIO BOARD OF PHARMACY

Hearing Summary Report

Hearing Date: 9/20/2018

Today's Date: 10/02/2018

Rule Number(s):

4729:6-1-01 (New)
4729:6-2-01 (New)
4729:6-2-02 (New)
4729:6-2-03 (New)
4729:6-2-04 (New)
4729:6-2-05 (New)
4729:6-2-06 (New)
4729:6-3-04 (New)
4729:6-3-05 (New)
4729:6-3-06 (New)
4729:6-3-07 (New)
4729:6-3-08 (New)
4729:6-4-01 (New)
4729:6-5-01 (New)
4729:6-5-02 (New)
4729:6-6-01 (New)
4729:6-7-01 (New)
4729:6-8-01 (New)
4729:6-8-02 (New)
4729:6-9-01 (New)
4729:6-9-02 (New)
4729:6-10-01 (New)
4729:6-10-02 (New)
4729:6-11-01 (New)
4729:6-11-02 (New)
4729-9-07 (Rescind)
4729-9-08 (Rescind)
4729-9-12 (Rescind)
4729-9-13 (Rescind)
4729-9-16 (Rescind)
4729-9-18 (Rescind)
4729-9-19 (Rescind)
4729-9-24 (Rescind)
4729-9-27 (Rescind)
4729-9-28 (Rescind)
4729-9-29 (Rescind)
4729-9-30 (Rescind)
4729-16-02 (Rescind)

List organizations or individuals giving or submitting testimony before, during or after public hearing and indicate the rule number(s) in question.

- Cleveland Clinic (4729:6-3-05)
- PhRMA (4729:6-1-01; 4729:6-2-01; 4729:6-2-02; 4729:6-2-03; 4729:6-2-04; 4729:6-2-05; 4729:6-2-06; 4729:6-3-04; 4729:6-3-05; 4729:6-3-06; 4729:6-3-07; 4729:6-3-08; 4729:6-4-01; 4729:6-5-01; 4729:6-5-02; 4729:6-6-01; 4729:6-7-01; 4729:6-8-01; 4729:6-8-02; 4729:6-9-01; 4729:6-9-02; 4729:6-10-01; 4729:6-10-02; 4729:6-11-01; 4729:6-11-02)
- Healthcare Distribution Alliance (4729:6-3-04, 4729:6-3-05)
- Cardinal Health

Consolidated Summary of Comments Received

- Cleveland Clinic – Requested exemption from reporting requirements in rule if the wholesale sale is occurring within their own system.
- PhRMA – Requested delaying implementation of rules until federal regulations clarify the scope of requirements applicable to state regulatory agencies.
- Healthcare Distribution Alliance
    - Develop a system that notifies wholesalers when a terminal distributor's license has been revoked or suspended.
    - Requested that supply chain entities should be responsible for supplying complete information in response to distributors' requests.
    - Pharmacies and other terminal distributors should be disciplined for knowingly provided inaccurate information to wholesalers.
    - Suspicious order monitoring only occur after an order history has been established.
- Cardinal Health – Provided support for the rule package and the collaborative work that has taken place during the rule making process, and look forward to working with the Board.

Rule Number	Commenter	Comment Summary	Comments Incorporated or Not Incorporated in the Rule
All	PhRMA	As we have stated in previous comment letters to the Ohio Board of Pharmacy on this topic, we continue to urge you to avoid implementing state regulations that are preempted by federal law, specifically the Drug Supply Chain Security Act (DSCSA). The DSCSA explicitly preempts state law with respect to these wholesale distributor licensure requirements. FDA Commissioner Scott Gottlieb has stated that federal regulations under the DSCSA are forthcoming and will apply to all state and federal licenses for wholesale distributors and third-party logistic providers to prevent "a confusing, SO-state patchwork of requirements … [that] would frustrate Congress's	***Comment not incorporated into the rule.*** *While the Board understands that such regulations may be forthcoming, it also has a statutory mandate to regulate such entities operating in the state. The proposed rules are necessary because of recent changes adopted in HB 49 (132nd General Assembly), which created new license types to reflect the implementation of the Drug Supply Chain Security Act (DSCSA). According to the FDA's own timeline, the target date for rules*

		intent and leave vulnerabilities that ... complicate state and federal enforcement efforts." The proposed regulations introduce additional requirements on drug manufacturers and others for monitoring, reporting, facility operations and record keeping that go beyond federal requirements, are costly, and provide no added benefit to consumers.	*governing wholesalers and third-party logistics providers was 11/27/2015.*
4729:6-3-05	Cleveland Clinic	**4729:6-3-05 (F)** All drug distributors listed in paragraph (B) of this rule shall submit a zero report **unless the sales are occurring within an organization's health system then the system is exempt from reporting.** Otherwise, the report shall be submitted in a manner determined by the board, if no suspicious orders have been identified by the distributor in a calendar month. The zero report shall be submitted within fifteen days of the end of the calendar. **4729:6-3-05 (G)(1)** Except as provided in paragraph (G)(2) of this rule, a drug distributor listed in paragraph (B) of this rule shall exercise due diligence to identify customers ordering or seeking to order reported drugs to establish the normal and expected transactions conducted by those persons and to identify and prevent	***Comment not incorporated into the rule.*** *The goal is for consistency across all drug distributor types. There are a limited number of hospitals that have a wholesaler licenses with the Board (approximately 9) that would be impacted by this rule.* *To ensure consistency of the sale of controlled substances by all licensed drug distributors, the Board felt that it was important to maintain uniform standards and not carve out special exceptions.* *Hospitals are permitted to engage in wholesale sales (often referred to as drug transfers) within hospital systems without obtaining a wholesaler license by the Board. However, federal regulations require that*

		the sale of reported drugs that are likely to be diverted from legitimate channels. Such measures shall include, but are not limited to, the following which shall to be conducted prior to an initial sale and on an annual basis **unless the sales are occurring within an organization's health system, then the system shall not be subject to the conditions below:** **4729:6-3-05 (J)(2)** A system to collect the necessary information on customers in accordance with paragraph (G) of this rule, **unless exempt from the requirements of paragraph G.** **4729:6-3-05 (J)(3)(b)** The process to collect all relevant information on customers in accordance with paragraph (G) of this rule, **unless exempt from the requirements of paragraph G.**	*those entities that sell more than 5 percent of their controlled substances dispensed by the hospital/practitioner to another practitioner will have to get licensed with the Board of Pharmacy as a wholesaler. The Board will reach out to these facilities to examine if they are exceeding this threshold.*
4729:6-3-04	HDA	**4729:6-3-04 Verification of licensure prior to sale of purchase:** HDA understands that a primary goal for Ohio regulators is to address issues with downstream customers. HDA's primary wholesale distributor members have implemented robust systems to know their customers. We hope that you will help us in these efforts by	***Comments incorporated into separate rule and Board policy.*** *The Board has adopted a change to its disciplinary section for terminal distributors that prohibits a licensee from providing false statements to drug distributors. See rule amendment of 4729:5-4-01 that is included with this memo.*

		making clear, in section 4729:6-3-04, Verification of Licensure prior to sale of purchase, to all appropriate supply chain partners that they have a responsibility as wel'l to maintain valid licensure. HDA members feel that when asked, supply chain partners should be held responsible for providing complete, accurate, and valid information in response to distributors' due diligence inquiries, and **that limited terminal distributors may be subject to discipline if they knowingly provide inaccurate information.** In addition to a wholesaler's customers corresponding responsibility, HDA also requests that the Board of Pharmacy work with wholesalers to develop a system that promptly notifies wholesalers when a terminal distributor's license is revoked or suspended by the Board so that wholesalers may take prompt action to prevent distributions to that terminal distributor.	*This rule will be filed with JCARR following receipt of a recommendation memo from CSI.* *The Board will develop a notification process through its email distribution system to provide licensees with monthly updated information on administrative actions impacting the sale of dangerous drugs in the state.*
4729:6-3-05	HDA	**4729:6-3-05 Suspicious order monitoring and due diligence:** HDA members feel that supply chain partners should be responsible for providing complete, accurate, and valid information in response to distributors' due diligence inquiries, and that terminal distributors may be subject to discipline if they knowingly provide inaccurate information.	***Comments not incorporated into the rule.*** *The Board did not incorporate the comments into the rule because such a change would undermine key data items important for detecting diversion by making all customer due diligence processes optional.*

		In the same vein, wholesale distributors can only know about their customers after an order history has been established. That is, for certain types of information, ***such as the methods of payment accepted, or the proportion of out-of-state patients served compared to in-state patients, wholesalers have no means by which to independently verify the veracity of the data submitted by customer***s. HDA suggests that the Board change the language in the second sentence of 4729: 6-3-05(G)(1), to the following: ***"Such measures ~~shall~~ <u>may</u> include, but are not limited to, the following to be conducted prior to an initial sale and on an annual basis…"*** This change will account for the necessary variations in information sought, particularly when a customer – pharmacy, veterinarian, dentist, or physician – is new to the practice and has no prior ordering history for a wholesaler to consult and aptly verify.	*The Board does not expect drug distributors to examine order histories of new customers prior to an initial sale. Clearly, such a requirement will be marked as not applicable given it is a new customer. The Board will attempt to address this and other outstanding questions and scenarios in guidance documents issued prior to the rule being finalized.*

4729:5-4-01 – Disciplinary Actions (To be filed with JCARR)

(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) The furnishing of false or fraudulent information or omitting information on due diligence questionnaires and/or attestation documents regarding the purchase or receipt of dangerous drugs from manufacturers, repackagers, third-party logistics providers, outsourcing facilities, wholesale distributors or other terminal distributors;

(27) 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.