February 23, 2018

Megan E. Marchal, Pharm.D., R.Ph.
President
State of Ohio Board of Pharmacy
77 South High Street, 17th Floor
Columbus, OH 43125

Re: Proposed Rules Governing the Licensure and Regulation of Distributors of Dangerous Drugs

Dear Dr. Marchal:

The Healthcare Distribution Alliance (HDA) is pleased to provide the following comments on the Ohio Board of Pharmacy’s February 1, 2018, proposed rules governing the licensure and regulation of distributors of dangerous drugs. Like the Board, HDA and its members are committed to maintaining the security of the pharmaceutical supply chain.

HDA represents primary pharmaceutical distributors, the vital link between the nation’s pharmaceutical manufacturers and more than 200,000 pharmacies, hospitals, long-term care facilities, clinics and others nationwide. Since 1876, HDA has helped members navigate regulations and innovations to get the right medicines to the right patients at the right time, safely and efficiently. HDA’s members include 35 national, regional and specialty primary distribution companies that are not only distributors, but also are technology innovators, information management experts, security specialists and efficiency professionals.

We sincerely appreciate the Board’s effort to restructure the regulations applicable to a wide range of entities. We believe that the proposal improves on the prior structure and format.

Additionally, in several instances, the Board proposes changes that effectively reform regulations to allow businesses to operate more efficiently while maintaining a highly secure supply chain. We do not highlight each of those changes here, but recognize and appreciate those efforts.

In these comments, we first discuss how the upcoming federal regulations on state licensure of wholesale drug distributors and third-party logistics companies (3PLs) may impact the Ohio rules. We then provide suggestions for five sections of the proposal:

4729:6-2-01 Responsible Person – Drug Distributor
4729:6-3-04 Verification of Licensure Prior to Sale or Purchase
4729:6-3-05 Suspicious Order Monitoring and Due Diligence
4729:6-4-01 Disciplinary Actions
4729:6-5-02 Wholesale Distributors – Recordkeeping

We use the term “drug distributor” as the proposed rule does, to include wholesalers, manufacturers, 3PLs, repackagers, and outsourcing facilities. To describe members of our segment of the supply chain, we use the term “wholesaler” or “wholesale distributor.”
Implications of Federal Regulations Issued Under the Drug Supply Chain Security Act (DSCSA)

To the extent that the proposed changes do not merely implement recent changes to Ohio law, we hope that the Board will carefully consider the timing of this rulemaking. Any rules that the Board finalizes now are likely to need revision in the near future, considering that the federal Food and Drug Administration (FDA) has stated that it will publish in June 2018 draft national standards for wholesale distributor and 3PL licensure as required by the federal Drug Supply Chain Security Act (DSCSA). ¹

The DSCSA mandates national uniformity in wholesale distributor licensure standards: “For the purpose of ensuring uniformity with respect to standards set forth in this section, the standards established [by FDA] . . . shall apply to all State and Federal [wholesale distributor] licenses and shall include standards for”:

- The storage and handling of prescription drugs, including facility requirements.
- The establishment and maintenance of records of the distributions of such drugs.
- The furnishing of a bond or other equivalent means of security.
- Mandatory background checks and fingerprinting of facility managers or designated representatives.
- The establishment and implementation of qualifications for key personnel.
- The mandatory physical inspection of any facility following the facility’s initial licensure application.
- Prohibitions upon certain persons receiving or maintaining a wholesale distributor license. ²

To ensure national uniformity, federal law directs that the standards promulgated by FDA preempt state “standards, requirements, or regulations with respect to wholesale prescription drug distributor or third-party logistics provider licensure.” ³

Thus, the Board could amend its regulations now, only to have to revise the same text in the near future to align with the federal standards. Regulated companies face the prospect of, within a short timeframe, (1) changing internal processes and procedures to reflect the Ohio Board’s current proposal, (2) making additional changes to reflect FDA’s national licensure standards, then (3) reconciling with the Ohio Board and FDA any discrepancies between the state and federal standards.

Compounding these issues, the federal Drug Enforcement Administration’s (DEA) revision of its suspicious order regulation also is imminent. HDA members have developed sophisticated systems to address the federal requirements. As we discuss in more detail below, however, changing these systems to conform to Ohio’s expectations as well as DEA’s forthcoming rules and evolving technological tools is likely to present challenges.

² FDCA § 583(b)(1)-(7).
³ Id. § 585(b)(1).
HDA urges the Board and the Common Sense Initiative Office to consider the complexities that multiple successive changes will create for the state of Ohio as well as industry. Ohio will have to promulgate the rules, interpret and communicate them to industry, and train staff and inspectors on their implementation. For drug distributors, each change requires revising written standard operating procedures and changing technology systems, potentially requiring capital investment. Significant staff time will be required to train employees in the new requirements, processes, and technologies. Undertaking such activities repeatedly, and over a short period, could create confusion and inconsistency, potentially undermining the very security that the federal and state requirements aim to enhance and maintain.

4729:6-2-01 Responsible Person – Drug Distributor

Recommendation: Recognize that adequate records already are available to meet the Board’s goals in section (C), allowing the Board to omit that provision.

Section 4729:6-2-01(C) would require the drug distributor to take “a complete inventory . . . of the controlled substances on site . . . on the effective date of the change of responsible person.”

Some wholesale distributors read this sentence as potentially requiring them to cease all controlled substances operations temporarily if an employee who has been deemed a Responsible Person departs for maternity leave or leave permitted under the Family and Medical Leave Act, or is injured. Such a shutdown of a distribution center’s controlled substances activities to conduct an inventory audit—including the stoppage of incoming shipments—is extremely disruptive to the entire supply chain, which operates on a “just-in-time” basis. Because medications containing controlled substances touch a wide range of patients, such stoppages are avoided unless absolutely necessary.

In general, adequate records exist to connect any future inventory concerns with the appropriate Responsible Person. Modern inventory management systems allow for detailed retrospective snapshots of inventory levels. Furthermore, for both business and compliance purposes, HDA members continually monitor their inventories, using such tools as daily activity counts and controlled substance inventories taken on a rolling daily basis or monthly. These tools build on the requirements imposed by DEA.

Thus, HDA believes that the Board can omit section (C), avoiding the disruptions and delays to patient care that could result, while still being able to access the desired information.

Recommendation: In setting the credential types or qualifications under 4729:6-2-01(F), recognize that formal educational degrees are not always the best measure.

HDA urges the Board to accept comment from regulated industry when it establishes the “credential types or qualifications required” for Responsible Persons under section 4729:6-2-01(F). A variety of credentials or qualifications may equip Responsible Persons with the tools to be effective. For these positions, a person with a high school diploma and additional experience may possess the necessary skills. HDA will offer similar comments when FDA proposes its licensure standards, including standards governing “the establishment and implementation of qualifications for key personnel,”4 to promote consistency between federal and state requirements as described above.

4 Id. § 583(b)(5).
4729:6-3-04 Verification of licensure prior to sale or purchase

Recommendation: Limit the scope of the requirement in 4729:6-3-04(D), recognizing that existing procedures and requirements provide thorough protection.

The proposal in section 4729:6-3-04(D) to require that a drug distributor query the Board’s database of licensees before every drug purchase is a significant change from current requirements that produces little incremental benefit to supply chain security but could impact patient access to medications. At present, drug distributors must manually query Ohio’s online database. Because this process is not automated, an employee would have to visit the state’s website to look up each manufacturer.

First, HDA believes that this additional verification is unnecessary because the current supplier verification requirements adequately protect the supply chain. Primary pharmaceutical wholesalers, who purchase their products directly from the manufacturer, have rigorous procedures in place to assure that they purchase only from authorized manufacturers. Federal law requires that each entity in the pharmaceutical supply chain transact only with Authorized Trading Partners, and makes trading with any unauthorized entity a violation of the Federal Food, Drug, and Cosmetic Act for both parties. “Trading Partners” include the entities from which “a manufacturer, repackager, wholesale distributor, or dispenser accepts direct ownership” or, in the case of a 3PL, direct possession of a drug. The DSCSA defines the licensure and registration requirements necessary for a trading partner to be considered “authorized.” Each time a pharmaceutical product changes ownership, the seller must attest to the buyer in a Transaction Statement that it is “authorized.”

Second, a requirement to verify the license before placing each order is likely to slow the ordering process and may disrupt wholesalers’ ability to meet healthcare delivery needs. A single primary wholesale distributor typically places more than 10,000 orders each week from hundreds of licensed drug manufacturers. Because our pharmaceutical supply chain operates on the “just-in-time” inventory management principle, these manual verifications are likely to delay order processing and ultimately may impact patient care, especially in rapidly-developing medical situations including influenza epidemics. Moreover, because some wholesalers generate orders for all of their distribution centers from a central location, this additional step for Ohio could have national impacts.

Third, primary drug wholesalers rapidly learn of a drug manufacturer’s license revocation or suspension through publicly available information, making it unnecessary to verify licensure before each order. A drug manufacturer’s activities generally have national or international implications, involve federal and state enforcement and regulatory authorities, and are highly publicized. The impact of a license suspension or revocation, even of a single facility, therefore has visible ripple effects throughout the drug supply chain. HDA shares the Board’s objective of ensuring that entities are not able to continue shipping after license suspension or revocation, but believes that a requirement to check the licensure database before every purchase is not necessary to achieve that result.

Finally, because this requirement may be preempted by the DSCSA’s limitation that “no State . . . may establish or continue in effect any requirements for tracing products through the distribution system (including . . . verification, investigation, . . . or recordkeeping relating to such systems . . . ) which are

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5 Id. § 582(c)(3).
6 Id. § 581(2)(D).
7 Id. § 581(27).
inconsistent with, more stringent than, or in addition to, any [DSCSA] requirements," supply chain members may be reluctant to make the necessary changes in processes and technology systems until these questions of preemption are resolved.

In addition to the challenges presented by the final sentence of the proposal, HDA highlights two additional concerns. First, the proposed text would appear to require verification before purchase and again before receipt. Perhaps the Board intended to require only 3PLs, which do not “purchase” drugs, to verify licensure before receipt.

Second, there appears to be an unintended conflict between the proposed definition of “manufacturer” in 4729:6-1-01(H) and the proposed requirement to verify the supplier’s licensure, such that if a manufacturer does not sell or distribute into Ohio directly, its products cannot ever reach patients in Ohio. The logic follows: The proposed definition of manufacturer includes only those that are “engaged in the sale or distribution of dangerous drugs in or into Ohio.” Under this definition, a hypothetical manufacturer in another state cannot be licensed if it does not directly distribute into Ohio, i.e., if all of its wholesalers are located outside Ohio. Under the proposal, a wholesale distributor that ships into Ohio but is physically located in Kentucky must verify its upstream supplier’s Ohio licensure. However, the hypothetical manufacturer would be unable to obtain an Ohio license because it does not itself sell or distribute into Ohio. The manufacturer’s products therefore would effectively be blocked from entering Ohio altogether.

HDA believes that the following combination of requirements would provide the necessary supply chain protections:

1. The Board’s proposal in section 4729:6-3-04(A) that all drug distributors verify their downstream customers’ licensure status;
2. The federal requirement that wholesale distributors purchase only from Authorized Trading Partners, with accompanying definitions and documentation; and
3. The Board’s current regulation, which the Board should consider incorporating in its final rule, that “Before a wholesale distributor of dangerous drugs may purchase a dangerous drug from another wholesale distributor of dangerous drugs, the purchaser must confirm the seller has a current license as a wholesale distributor of dangerous drugs.”

4729:6-3-05 Suspicious Order Monitoring and Due Diligence

Recommendation: HDA urges the Board to collaborate with DEA, to align the changes being developed at the federal and state level to meet both regulator’s objectives.

Wholesale distributors understand their critical role in the effort to stop controlled substances from reaching pharmacies and practitioners that will divert them to inappropriate uses. As logistics companies who take seriously their responsibility to be part of the solution, primary pharmaceutical distributors have invested heavily in information technology systems to help better flag suspicious ordering patterns; have enhanced overall “know your customer” due diligence efforts to further prevent

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8 Id. § 585(a).
the abuse, misuse, and potential diversion of controlled substances; and continue to support efforts
designed to improve coordination and communication with the DEA and state regulators.

HDA members invite the Board to learn more about their existing suspicious order monitoring and
“know your customer” systems to help inform the revision of this proposed rule. HDA also encourages
the Board to collaborate closely with DEA in refining the regulation’s text. Alternatively, the Board
might maintain its current requirement that “The wholesaler shall inform the state board of pharmacy
of suspicious orders . . . when discovered.”10 While HDA appreciates that the Board seeks to provide
leadership on these issues, to be effective such leadership should align with federal requirements
because the pharmaceutical supply chain is national in nature.

With DEA slated to issue a proposed revision of its suspicious orders monitoring rule in March 2018
according to the Unified Regulatory Agenda,11 HDA members anticipate that they soon may have to
make changes to their suspicious orders reporting systems and their “know your customer”
investigations to comply with the evolving federal requirements. HDA has repeatedly expressed support
for revisions that will clarify DEA’s regulations, most recently in the attached letter.

If the Board moves ahead with its proposed suspicious orders rule before knowing the revised DEA
requirements, drug distributors operating in Ohio face one or both of two challenging scenarios:

(1) Making multiple changes to procedures and systems over a short time, or

(2) Operating two entirely different systems on a parallel basis.

Both of these scenarios conflict with the objective of the Common Sense Initiative that “compliance
should be as easy and inexpensive as possible.” Compliance is made particularly difficult when, as
discussed in more detail below, the Board proposes language that resembles the federal government’s
but would have a significantly different meaning for the state’s purposes.

We described above on pages 2-3 the challenges that the state and regulated industry would face if the
Board was to adopt a regulation now, only to revise it soon thereafter. While in this case the need for
alignment between federal and state requirements stems from practical considerations rather than
federal preemption, the implications are the same, including the potential for confusion and
inconsistency.

As drafted, the Board’s proposal would require drug distributors, at least in the short term, to run two
separate but parallel systems—one federal and one state—to evaluate all Ohio orders. As described
below, the Board’s proposal could result in significantly more orders from Ohio customers being
reported and held, without providing any greater assurance that those orders indicate potential misuse
or diversion.

Additionally, while the Board’s proposal adds complexity, it may not provide greater protection to the
public. The Board of course is aware that changes in these regulations can impact patient care. The
potential consequences of inadvertent drafting errors include delay in important medications reaching
legitimate Ohio patients being treated by licensed and responsible healthcare practitioners.

11 See https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201710&RIN=1117-AB47.
In addition, as we discuss in more detail below, we strongly encourage the Board to contact DEA regarding access to DEA’s new suspicious orders database. Last week HDA asked DEA to make its new suspicious orders database into a Universal Suspicious Orders Database, accessible by all state Boards of Pharmacy, and state and local law enforcement. A Universal Suspicious Orders Database accessible to all but operated by DEA, incorporating advanced data analytics, would significantly advance Ohio’s ability to identify and act on important public health issues, including opioid overuse and abuse, while also preserving Ohio’s financial resources for other important initiatives.

**Recommendation: Revise 4729:6-3-05(B) to clarify its applicability.**

HDA asks that the Board add the underlined language to section 4729:6-3-05(B) to add clarity and avoid overbroad application of this requirement:

“(B) Drug distributors listed in paragraph (A) of this rule shall design and operate a system to identify suspicious orders of controlled substances placed by persons in this state.”

Also, while (B) requires identification of all suspicious orders regardless of the type of entity that is ordering, (B)(1) requires the computerized system only to identify orders made by a licensed terminal distributor. HDA recommends that the Board consider how its suspicious order requirements should apply when, for instance, manufacturers distribute to wholesale distributors, and allow an additional comment period on any related revisions.

**Recommendation: Revise (B)(1) to allow for greater variation among effective suspicious orders monitoring systems, including two-step suspicious order systems.**

By specifying that a “system to identify suspicious orders” “shall consist of a computer . . . system,” subsection 4729:6-3-05(B)(1) limits drug distributors’ options in creating suspicious order monitoring systems. HDA restates our comments to the Department of Justice on this topic from August 2017:

HDA recommends that, in revising its regulation, DEA allow registrants flexibility in designing multi-step systems to identify suspicious orders. While a registrant might create a one-step system in which the registrant reports every order identified by a computer algorithm as suspicious, many current suspicious orders monitoring systems evaluate orders in two steps, and future technological advancements may allow for additional steps in the evaluation, with each step increasing in analytical refinement.

HDA also recommends that DEA’s regulations acknowledge the variation within multi-step systems. The systems that wholesale distributors have developed over the past several years vary in their approaches because they were developed independently by market competitors. In some registrants’ systems, a computer algorithm may flag orders as suspicious, with a manual investigation supporting or disproving the system’s conclusion. Other registrants may have designed their algorithm to flag a broader range of orders so that staff can manually review (and maintain awareness of) more orders. In these systems, orders flagged in the first step may not be considered suspicious. The later steps of the monitoring system, involving manual review by experts within the company, may be the point at which an order is properly deemed “suspicious.”
DEA should ensure that its revised regulation accommodates the full range of different approaches that could be used to determine that an order is suspicious.12

In fact, in the short term, the Board’s proposed language may result in the reporting (and holding) of many more orders than intended. To comply with the Board’s proposed requirement, drug distributors whose suspicious order monitoring systems currently rely on human review will have to submit orders as suspicious prior to that critical second step. In reporting any order that the computer flags, those distributors may submit orders that can be plausibly explained as reasonable.

An abrupt transition to a one-step, entirely computer-based system for determining what is “suspicious” also could impact patient care. Some wholesale distributors, as a policy, do not ship any order that has been reported as suspicious. By inadvertently broadening what is reported as suspicious, the Board also would inadvertently increase the number of orders that are never shipped.

Recommendation: Omit any specific numeric threshold from the definition of suspicious order in 4729:6-3-05.

HDA recommends omitting any specific numeric threshold from the final rule, whether “5,000 unit doses” as proposed in 4729:6-3-05(B)(2)(c) or any other number, as no single number can address the full range of customers and circumstances.13 A better approach is to allow the drug distributor to determine the appropriate threshold for each situation, as a single numeric threshold will be at times both too high and too low.

For some pharmacies and practitioners and some controlled substances, 5,000 dosage units likely would vastly exceed the appropriate distribution amount for a month. By including a flat number, however, the Board may inadvertently discourage drug distributors from trusting their own judgment when a lower amount should be reported as suspicious. Some retail pharmacies dispense lower volumes of drugs than others, and some practitioners require relatively few drugs for office administration. Likewise, some controlled substances are less favored for current medical uses. For instance, only 6,200 grams of alfentanil, the ingredient in Alfenta (an analgesic administered by injection) and its generic forms, are available in all of the U.S. in of 2018. A monthly order of significantly less than 5,000 unit doses likely would be suspicious.

In other circumstances, the flat 5,000 dosage unit threshold would put an unnecessary hold on—or a stop to—appropriate medication orders, with possible repercussions for patients. A large hospital that orders all of its controlled substances under a single DEA registration may easily surpass 5,000 dosage units of several key controlled substances every month. This hospital may have to creatively order from several wholesale distributors to obtain the medications it needs. Even for smaller facilities, an arbitrary threshold could affect patient access to such important prescription drugs as Xanax (alprazolam), a schedule IV drug commonly prescribed for anxiety, and Vinpat (lacosamide), a schedule V drug that has


13 DEA has advised that, “Registrants that rely on rigid formulas to define whether an order is suspicious may be failing to detect suspicious orders.” Letter to Registrant from Joseph T. Rannazzisi, Deputy Assistant Administrator, DEA 2 (Dec. 27, 2007).
a relatively lower potential for abuse than other controlled substances and is prescribed for diabetic nerve pain.

For these reasons, HDA recommends that the Board omit 4729:6-3-05(B)(2)(c) from the final requirements.

**Recommendation:** The Board should omit the language relating to “uncommon method of payment or delivery” in (B)(2)(e) but may refer in (F) to the payments that customers accept.

The Board proposes in 4729:6-3-05(B)(2)(e) to specify that any order “having an uncommon method of payment or delivery” is suspicious. As drafted, the language will not provide the information that the Board seeks.

The concept of “uncommon method of delivery” simply does not apply to the highly automated and standardized modern pharmaceutical supply chain. The method of delivery is not variable. In addition, DEA-regulated drug distributors may deliver controlled substances only to the customer’s DEA-registered location.  

While HDA is not certain what the Board intends when it refers to an “uncommon method of payment,” HDA members seldom would have opportunity to flag such a concern for a controlled substance order. Because of the complexities of the American healthcare payment and reimbursement systems, payment is seldom received before an order is processed. Instead, wholesalers commonly allow pharmacies, hospitals, and other healthcare providers to purchase prescription drugs on credit, so that orders are shipped, prescriptions are filled, and insurance companies are billed by the provider before the wholesaler receives payment. Moreover, in companies of the size and scope of HDA members, the billing and account management operation may be entirely distinct from the regulatory oversight functions involved in suspicious orders monitoring.

The draft language derives from DEA’s regulation of listed chemicals. Due to the relatively limited oversight of listed chemical transactions, HDA does not believe that the situations are comparable. Unlike controlled substances, a wide range of customers, including retailers and laboratories, may purchase listed chemicals from chemical distributors without obtaining a DEA registration. Consumers may legally pass listed chemicals (but not lawfully-obtained controlled substances) to others. Thus, DEA’s requirement to report listed chemical transactions involving an “uncommon method of payment or delivery” appears to target the unscrupulous but relatively feasible activities of chemical wholesalers or their customers.

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14 See, e.g., 21 C.F.R. § 1305.12(c).
15 For instance, acetone, the key ingredient in nail polish remover, is a listed chemical.
16 21 C.F.R. § 1310.05(a)(1).
17 “In 1997 and 1998, the vast majority of methamphetamine labs . . . in California, obtained their precursor chemicals from domestic U.S. sources, such as chemical wholesalers, rogue chemical companies, and blackmarket sales of large quantities of ephedrine/pseudoephedrine tablets.” Statement by Joseph D. Keefe, Chief of Operations, DEA, before the House Committee on Government Reform Subcommittee on Criminal Justice, Drug Policy and Human Resources (July 12, 2001), available at https://www.dea.gov/pr/speeches-testimony/2001t/ct071201p.html.
In order to achieve the Board’s objectives, HDA recommends omitting 4729:6-3-05(B)(2)(e) and offers two potential alternatives:

- In the discussion in section (F) of factors that a drug distributor may consider in its due diligence of customers, the Board may refer to the “methods of payment the [customer] accept[s] (cash, insurance, Medicaid, and in what ratios),” as suggested by DEA.18 Wholesalers already typically obtain this information in their initial investigations of terminal distributors.

- The Board might consider prohibiting drug distributors from accepting cash as payment, if the Board considers this to indicate suspect activity.

**Recommendation: Consider that defined factors may be more relevant to “Due Diligence” than to “Suspicious Orders.”**

HDA and its members appreciate that the Board has worked to delineate “due diligence”/”know your customer” obligations from the distinct but interlinked suspicious order reporting obligations. We agree with the Board’s approach of creating a section (F) within 4729:6-3-05 for “know your customer” requirements, separate from section (B) relating to suspicious orders.

With that said, some of the factors that the Board identifies as being a part of the process for identifying or investigating a suspicious order are more appropriate for the “know your customer” section (F).

4729:6-3-05(B)(2)(g): “A purchase by any terminal distributor of dangerous goods that does not take commercial or public insurance.”

A wholesaler obtains this information in its initial “know your customer” investigation; therefore, this provision belongs in (F). This determination would impact the wholesaler’s decision to take on the pharmacy or practitioner as a customer. If the Board wishes instead to specify that no drug distributor may distribute to such a terminal distributor in any circumstance, the Board should revise its proposal accordingly.

4729:6-3-05(B)(2)(f) and (h): “Orders for a significant amount of a limited number of controlled substances together with few, if any, other non-controlled dangerous drugs” or “consisting of a disproportionate amount between controlled substance and non-controlled substance dangerous drugs.”

Rather than reviewing orders individually under these criteria, a stronger approach is for wholesale distributors to understand the customer’s ordering patterns, including ratios of drugs ordered, through “know your customer” investigations. By understanding a customer’s “normal and expected” transactions, as the Board would require in section (F), a drug distributor can make better-informed assessments of all orders. An individual order that is primarily composed of controlled substances may not appear suspicious when considered among the customer’s orders over the course of a month or relative to the customer’s 90-day drug utilization report.

Including discussion of the customer’s order ratios as part of the drug distributor’s “due diligence” investigation in section (F), rather than in the suspicious order criteria in (B), would align with DEA

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guidance. As DEA suggested in its “Suggested questions a distributor should ask prior to shipping controlled substances,” HDA members generally ask such due diligence questions as, “What is the pharmacy’s ratio of controlled vs. non-controlled orders?” and “Does the pharmacy order a full variety of controlled substances and are they fairly evenly dispersed? If not, why the disparity?”

Incorporating this inquiry into “due diligence” also allows drug distributors to account for a customer’s purchases from other suppliers.

In fact, if the Board applied the language strictly as drafted, drug distributors could be required to report and hold all orders for schedule II controlled substances, including all controlled opioids. Under DEA’s requirements, orders for schedule II controlled substances cannot include any non-controlled substances, as they must be placed separately using DEA’s Controlled Substances Ordering System (CSOS) or the triplicate DEA Form 222. 21 C.F.R. § 1305.03. Because some wholesale distributors do not ship any order that has been reported as suspicious, as noted above, the impact to legitimate patients could be significant.

4729:6-3-05(C)(a): “A review of the clinical nature of the receiving terminal distributor of dangerous drugs, including any specialty practice area.”

(C)(1)(b): “A review of the terminal distributor’s clinical business needs, location, and population served.”

HDA believes that both of these considerations should be moved to (F). As part of the “know your customer” evaluation, HDA members review such factors as the type of customer (e.g., medical practice, hospital, outpatient pharmacy, dentist), the customer’s location, and whether the customer serves long term care, hospice, and/or assisted living facilities.

However, HDA must ask the Board to remove the term “clinical” from these considerations. As distributors, HDA members have no access to patient or prescription information. Our members are not medical professionals and cannot substitute their judgment for that of the physicians who write the prescriptions or the pharmacists who fill them. The term “clinical” also should be deleted from 4729:6-3-05(B)(2)(b).

In revising this section, HDA also suggests that the Board clarify what it intends by “population served.” Is the Board referring to the broad geographic area, to the specific patient population, or some other measure?

**Recommendation: Significantly revise 4729:6-3-05(C) to align with DEA’s expectations.**

HDA urges the Board to significantly revise section 4729:6-3-05(C), which would define the review that a drug distributor must undertake before shipping an order that it has reported as suspicious.

First, the proposal requires drug distributors to investigate an order reported as suspicious even if the distributor has no interest in shipping the order. We reiterate that some wholesale distributors do not ever ship any orders that they have reported as suspicious. For those distributors, the requirement in 4729:6-3-05(C) that “all suspicious orders” be reviewed by two people serves no purpose whatever.

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19 See id.
20 See id.
Second, if a wholesale distributor does wish to consider shipping orders reported as suspicious, the distributor should not be required to have two people review the order concurrently. If a first review concludes that the order should not be shipped, there is no need for a second review.

Third, we recommend that the Board discuss with DEA its current expectations relating to the “ship/no ship” decision, as those expectations appear to be quite different from the Board’s proposed language. Certain public documents suggest that, in DEA’s view, this investigation should resolve whether the order is “likely to be diverted.” That determination would require a strikingly different review than the review necessary to determine whether the order is “reasonable” under 4729:6-3-05(C)(2). DEA also may have views regarding the factors that should be considered.

HDA notes that the considerations outlined in section (C) may more closely resemble the second step of a two-step suspicious orders reporting system, as discussed above on pages 7-8, than a “ship/no ship” decision although, as noted above, wholesalers have developed varying systems. HDA would be happy to have further conversations with the Board about the factors that might be considered in a two-step system.

Recommendation: Join HDA in urging DEA to create a Universal Suspicious Orders Database and to allow the Ohio Board, and the regulators in other states, to access that single database.

In section 4729:6-3-05(D), the Board proposes that all suspicious orders be reported electronically. Statements by the Governor suggest that the state is developing a suspicious orders database. Because HDA agrees that Ohio, like many states, would benefit from advanced data management tools, HDA recently recommended that DEA create a Universal Suspicious Orders Database, accessible to state regulators and state and local law enforcement. DEA is developing such a database for its own use, incorporating online reporting and advanced data analytical tools. DEA expects these tools to be operational within six months after the technology contract is signed. Broad access to this single data management system would allow for improved information-sharing and collaboration at all levels of government.

HDA urges the State of Ohio to press DEA for access to the suspicious orders database and tools that are under federal development. By accessing those tools, Ohio could avoid investing in a duplicative and unnecessary system, and instead could allocate those funds to such important initiatives as enforcement, training, and drug abuse prevention and treatment. Moreover, because DEA’s system is under development, Ohio has the opportunity to advocate for the inclusion of its priorities.

Recommendation: Strike the words “and fulfillment” from 4729:6-3-05(E)(3).

In subsection 4729:6-3-05(E)(3), the proposed rule would require drug distributors to provide certain training annually. HDA members have no objection to providing the described training to staff responsible for the processing of controlled substance orders. Whether to provide the same training to fulfillment staff should be a voluntary decision by drug distributors based on their specific business processes and needs.

See, e.g., Letter to Registrant from Joseph T. Rannazzisi, Deputy Assistant Administrator, DEA (Sept. 27, 2006).
HDA does not believe that providing the same training to staff responsible for fulfillment of controlled substance orders would achieve the Board’s objectives. “Fulfillment” staff likely include operations personnel involved in the picking, packing, and shipping of controlled substances, e.g., employees that work within the controlled substances vault and cage and that load drug products containing controlled substances into totes that are subsequently placed into trucks for onward distribution.

HDA is concerned that the proposed requirement to provide fulfillment staff with an overview of the “The drug distributor’s suspicious order monitoring system and suspicious order review process” under paragraph (E)(3)(a) and “The process for submission of suspicious orders to the state board of pharmacy” under paragraph (E)(3)(b) effectively could make fulfillment staff responsible for identifying and/or reporting orders as suspicious. Fulfillment staff are accustomed to seeing, picking, and packing orders of a wide variety of sizes and combinations. They do not have access to the company’s suspicious orders system, and at the time of picking and packing do not have additional information that would allow them to judge whether the order is appropriate given a customer’s volume, past order history, or population served.

While HDA urges the Board to allow drug distributors to make an individualized determination about such training, HDA would not object should the Board wish to mandate the posting of notices for distribution center staff, including fulfillment staff, regarding “Information on submitting a confidential report of a suspicious order by using the Board’s online electronic complaint form that can accessed by visiting: www.pharmacy.ohio.gov,” and that “complaints and all information submitted that identifies a complainant shall remain confidential pursuant to section 4729.23 of the Revised Code.” Such notices may be more effective than annual training if posted year-round.

**Recommendation: Revise 4729:6-3-05(F) to allow for the development of additional “know your customer” tools.**

As with suspicious orders reporting systems, HDA members’ due diligence procedures may vary to some degree, and likely will continue to evolve as drug distributors continue to obtain additional useful information. To maintain this flexibility and allow for future refinements, HDA recommends that the Board revise the second sentence of (F) to read, “Such measures may include the following:”. This change would be particularly appropriate if the Board moves considerations from sections (B) and (C) to section (F), as we discussed above on pages 10-11.

**Recommendation: Revise section 4729:6-3-05(G) to limit its applicability to Ohio.**

HDA asks the Board to revise section 4729:6-3-05(G) to include the underlined text:

> “All drug distributors listed in paragraph (A) of this rule shall submit a zero report, in a manner determined by the board, if no suspicious orders placed by any person in this state have been identified by the distributor in a calendar month.”

This language matches the language in proposed section 4729:6-3-04(A). HDA believes that this amendment will assure that the Board receives the data it is seeking. Alternatively, the Board could revise the final clause to: “. . . if the distributor has identified no suspicious orders placed by any person in this state in a calendar month.”
Recommendation: Revise the “zero report” due date in section 4729:6-3-05(G).

HDA requests that zero reports be due to the Board by the 15th day of the following month rather than the 7th. Because “zero reports” are not generated automatically, and because HDA members’ suspicious order reporting systems are national in scope, this additional time will allow drug distributors to process their data and assure accurate reporting. This is particularly useful in January and July, which generally have fewer work days at the beginning of the month because of holidays. This change also would conform the Ohio requirement with the requirement in neighboring West Virginia to provide “zero reports” within 15 days of the end of the month.

4729:6-4-01 Disciplinary Actions

In 4729:6-4-01, the Board proposes that any one of several penalties may be applied to each of 28 identified actions. While this section mirrors the statute in format,22 we hope that the Board will provide additional guidelines defining the most appropriate penalties for each the newly-added actions. While it is difficult to generalize, some appear to be grounds for license revocation while probation or reprimand may be suitable for others. In addition, if the Board issues a license despite disclosures of relevant past conduct in the initial application, the Board as a general policy should not base a future suspension, revocation, or refusal to renew solely on the same past conduct.

HDA also recommends the following in this section:

- Correcting the cross-references in subsections (B)(8) and (9);
- Revising the text of 4729:6-4-01(B)(9) and (10) to refer to “orders reported as suspicious” rather than “suspicious orders;”
- Clarifying the difference between (B)(9) and (10), with the possibility of deleting (9) altogether as (10) is more specific. If the Board retains (9), we suggest revising it to avoid reference to “due diligence.” The Board defines “due diligence” in 4729:6-3-05(F). “Due diligence” is a process separate from the investigation of whether a suspicious order is reasonable.

4729:6-5-01 Wholesale Distributors – General Operations

Recommendation: Omit 4729:6-5-01(M)(1)(a) as it conflicts with federal requirements and would not increase security.

In 4729:6-5-01(M)(1)(a), the Board would require wholesale distributors to provide specific security for controlled substances in transit, specifying in particular that they “shall be in a locked and secure storage compartment that is part of the motor vehicle, or in a locked storage container.”

HDA supports the requirement in subsection (M)(1) that wholesale distributors assure transportation “security that protects against diversion.” HDA members also agree that the vehicle used for transporting controlled substances should be lockable. This and more detailed security requirements are nearly universal in contractual relationships with common carriers.

Requiring that controlled substances be segregated from other drugs and carried in a separate part of the vehicle, however, conflicts with DEA’s requirements and could create additional security concerns.

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22 Ohio Rev. Code § 4729.56.
Because wholesale distributors comply with DEA’s requirement in 21 C.F.R. § 1301.74(e) that shipping containers not indicate that the contents are controlled substances, the carrier (and the potential thief) cannot distinguish the totes that contain controlled substances. Instead, distributors disperse controlled substances, unmarked, within the shipment. Because the driver does not know which totes contain controlled substances, she does not know which totes would need to be segregated and locked away. This lack of knowledge is, itself, a security precaution.

Furthermore, the addition of “a locked and secure storage compartment” to these vehicles is unnecessary due to the extremely low rate of robberies affecting drug transportation and delivery. The tens of millions of annual drug deliveries are made safely and securely in 99.999981% of cases using existing security procedures. HDA and its Pharmaceutical Cargo Security Coalition would be happy to discuss cargo security with the Board in more detail.

**Recommendation:** Revise 4729:6-5-01(M)(3) to require drug distributors to provide for security in their common carrier contracts.

In subsection 4729:6-5-01(M)(3), the Board would prohibit common carriers hired by wholesale distributors from using “a vehicle or mode of transportation that is primarily used for personal or nonbusiness uses” to deliver drugs.

First, HDA believes that the Board inadvertently erred in including the phrase “mode of transportation” in this provision.

Second, HDA suggests that, instead of implementing a “command and control” regulation of the type proposed, the Board implement a performance-based regulation that requires drug distributors to define security procedures and practices in their contracts with common carriers. This is consistent with current contract practice and with DEA’s regulation specifying that the distributor “is responsible for providing and requiring adequate security to guard against theft and diversion while the substances are being stored or handled by the [distributor’s] agent or agents.” 21 C.F.R. § 1301.74(f). Wholesale distributors have strong business and compliance reasons for assuring in-transit security, and the exceptionally low in-transit loss rate reflects that they are successful in doing so.

**4729:6-5-02 Wholesale Distributors – Recordkeeping**

**Recommendation:** Standardize the language used in the subsections of 4729:6-5-02(A).

The subsections of 4729:6-5-02(A) would be easier to understand and implement moving forward if the Board standardized the language. Subsection (A)(2) refers to “inventories and all records maintained in accordance with this division,” while (A)(3) refers to “records, described in this rule,” and (A)(4) refers to “records relating to the distribution, sale or transfer of dangerous drugs.” The reader does not know whether the Board intends to describe the same set of records in each of these provisions. If the Board intended to describe different sets of records, HDA asks the Board to more clearly describe each so that wholesale distributors can comply.

**Recommendation:** Omit the requirement that alternate locations be accessible only to representatives of the wholesale distributor.

Subsection 4729:6-5-02(A)(3) proposes that if records are held at an alternate location, that location “shall be secured and accessible only to representatives of the wholesale distributor.” This limitation
could present challenges for those drug distributors that maintain hardcopy records offsite with contractors such as Iron Mountain, or that use contractors to maintain digital records at an alternate physical location.

By omitting the words “and accessible only to representatives of the wholesale distributor,” the Board would not only avoid problems in such contractual situations but also would avoid unnecessary conflict relating to the DSCSA’s preemption of state law. If the Board were to finalize the language as proposed, and thus impose a state recordkeeping requirement that is inconsistent with the DSCSA’s requirements, the DSCSA preemption provision almost certainly would come into play. 23

Finally, because of the significance of the changes that drug distributors would need to make to comply with the proposed changes, as we have described here, HDA asks the Board to consider allowing regulated industry an implementation period of at least 180 days before any final regulations take effect. In the intervening time, HDA members would continue to comply with the Board’s existing requirements.

Thank you again for the opportunity to provide input into your effort to maintain pharmaceutical supply chain security. Please do not hesitate to contact Ruth Miller, Senior Director, Regulatory Affairs at rmiller@hda.org or 703-885-0266 if we can provide additional assistance.

Sincerely,

Patrick M. Kelly
Executive Vice President, Government Affairs

Enclosure: HDA Letter to Robert Patterson, Acting Administrator, DEA

23 FDCA § 585(a).
February 16, 2018

Mr. Robert Patterson
Acting Administrator
Drug Enforcement Administration
8701 Morrissette Dr.
Springfield VA 22152

Re: Need for Universal Suspicious Orders Database

Dear Administrator Patterson:

The Healthcare Distribution Alliance (HDA) applauds the Drug Enforcement Administration’s (DEA) recent decision to create sophisticated new data tools for managing and analyzing the reports of suspicious orders of controlled substances that HDA members and other DEA registrants provide in compliance with DEA’s regulations. HDA also commends your announcement this week that DEA-registered manufacturers and distributors now have access to more of DEA’s data about pharmacies and other dispensers through a new feature in DEA’s ARCOS database.

HDA supports DEA’s development of an online system through which HDA members will be able to report suspicious orders. As you know, while the reporting requirement has been in place for some time, DEA has not previously specified a reporting format. This data management system, with standardized online reporting, should help DEA identify trends that indicate that a pharmacy or other dispenser should no longer be permitted to handle controlled substances.

HDA believes that this suspicious order data management system can do more. Specifically, HDA asks DEA to allow state regulators and DEA’s state and local law enforcement partners to access DEA’s database, effectively creating a Universal Suspicious Orders Database. By creating a Universal Suspicious Orders Database, DEA would improve on today’s diverse and sometimes uneven data sharing. For instance, HDA members are required to provide their DEA suspicious order reports to some state regulatory entities, most commonly the Boards of Pharmacy. Likewise, we understand that DEA shares data with state and local law enforcement in certain circumstances. Just as DEA’s Tactical Diversion Squad program allows for improved information flow and coordination between federal, state, and local partners, so would the sharing of DEA’s suspicious orders database with state and local officials.

This Universal Suspicious Orders Database would significantly advance states’ ability to analyze and act on important public health issues, including opioid overuse and abuse. State Boards often lack...
the resources to establish the sophisticated data analytics that DEA’s database will provide. The development of duplicative tools should not be necessary. Because DEA’s database will be funded under the Diversion Control Fee Account, any additional expenses that DEA incurs in regulating access by state and local officials could be addressed by increasing the DEA registration fees that fund the Fee Account. Moreover, providing state regulators with access to DEA’s Universal Suspicious Orders Database will help prevent the inadvertent imposition of state rules for suspicious order reporting that conflict with DEA’s requirements and guidance.

We also applaud DEA’s aggressive timeline that will have this online reporting system and database operational within six months after the technology development contract is signed. Once the technological requirements are known, HDA members will work expeditiously to conform their own systems to DEA’s electronic reporting system.

Finally, we reiterate our support for DEA’s effort to revise its suspicious orders monitoring regulation to provide both clarity and flexibility. As we commented to the Department of Justice Task Force on Regulatory Reform in August of 2017, HDA hopes that DEA’s proposed regulation will broadly define the types of factors that wholesale distributors should consider in their suspicious order monitoring evaluations.

HDA and its members eagerly anticipate DEA’s publication of a proposed rule on suspicious orders in March 2018, as indicated in the Unified Regulatory Agenda. Because DEA’s expectations form the backbone for not only HDA members’ activities but also for most states’ requirements, many are interested in the content. We encourage DEA to collaborate closely with state regulatory bodies.

In the broad national effort to address prescription drug abuse, improved sharing of data is increasingly identified as a key tool. HDA anticipates additional conversations with your agency about potential data-based solutions, and HDA members look forward to continued collaboration with DEA and their state regulators to prevent legitimate controlled substances from being diverted to illegitimate uses.

Sincerely,

John M. Gray
President and Chief Executive Officer

cc: Rod Rosenstein, Deputy Attorney General
    Robert Hinchman, Senior Counsel, Office of Legal Policy