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Feature Article

Ohio Drug Distribution Verification

America's Key Battleground State Shakes Up the Pharmaceutical Supply Chain

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Abstract: The pharmaceutical industry faces monumental challenges in the age of globalization within the United States: state laws and regulations that are more stringent than their federal counterparts. This article provides the historical context and current overview of Ohio's laws, regulations, and sub-regulatory guidance concerning the distribution of prescription drugs, including drug samples, into and within the state, the verification requirements when distributing product to terminal distributors of dangerous drugs and prescribers, record retention responsibilities, and penalties for noncompliance. The article then examines the industry's response from a major manufacturer, a distributor/third-party logistics provider, verification vendor, and compliance advisory vendors. It concludes with a call to action to the industry to form a new coalition to address state legislative and regulatory actions that have the potential to disrupt the entire supply chain.

"[D]rug companies have demonstrated a reluctance to [distribute] . . . unless we are registered or licensed. . . . We are thus threatened with a disruption . . . throughout the state of Ohio."[2]

The pharmaceutical industry faces a major dilemma: active state legislatures, administrative agencies, and state attorney generals. There is a plethora of reasons why states have turned their attention towards the manufacturers and trading partners, such as wholesale distributors and third-party logistics providers ("3PLs"). There is an opioid crisis gripping the nation, an ever-growing increase in healthcare costs, unstoppable negative publicity aimed at the pharmaceutical industry, an emboldened citizenry demanding their legislatures to do something, hospital and insurance lobbies joining the fight. As a result, state politicians are using all of this to their advantage to pass laws aimed at the industry.

This article discusses a law that has been on the books for over forty years, and amended numerous times, including a 2017 revision that lead to Ohio becoming pharma's "key battleground state."

PDMA's Verification Requirements: Back to the Basics

The Prescription Drug Marketing Act of 1987 ("PDMA"),[3] as amended by the Prescription Drug Amendments of 1992 (PDA),[4] requires, among other things, that drug sample requests must contain "[t]he practitioner's State license or authorization number or, where a scheduled drug product is requested, the practitioner's Drug Enforcement Administration number."[5] In

1 *Views expressed in this article are that of the authors and do not necessarily reflect the opinions, position, or policy of G&M Health, LLC, Porzio Life Sciences, LLC, Porzio, Bromberg & Newman PC, J. Knipper and Company, Inc., or MedPro Systems LLC. either company's other employees, or its clients. Further, the information presented within this article is not legal advice or a legal opinion and should not be interpreted or relied upon as such.*

2 *See 1962 Op. Att'y No. 2781, infra note 11 (alteration added).*

3 *Pub. L. No. 100-293, 102 Stat. 95 (1988).*

4 *Pub. L. No. 102-353, 106 Stat. 941 (1992).*

5 *21 C.F.R. §§ 203.30(b)(ii), 203.31(b)(ii) (alteration added).*

addition, the manufacturer or authorized distributor of record ("ADR") is required to "verif[y] with the appropriate State authority that the practitioner requesting the drug sample is licensed or authorized under State law to prescribe the drug product."[6] In the preamble to the final rule, FDA actually stated it had considered removing the verification requirements, but decided to keep them in response to the comments.[7]

Therefore, under the PDMA, only "practitioners authorized by State law to prescribe drugs may request and receive drug samples."[8] However, because the regulations lack express preemption provisions, the States are free to impose additional requirements on practitioners and manufacturers. For example, many states require practitioners obtain prescriptive authority licenses/registrations or separate controlled substance registrations. States may also impose their own verification requirements upon manufacturers and their agents before any drugs, trade or samples, may be distributed to licensed practitioners.

Historical Rewind: Compliance with Ohio's Verifications Laws Began When?!

Ohio's laws and regulations must be placed within proper historical context to understand how the law and regulation imposes more stringent requirements than federal law. The state's laws and regulations existed well before the PDMA, as amended, and its implementing regulations.

In fact, Ohio signed into law the Dangerous Drug Act in 1961.[9] While the law has been amended since then, the verification law (Ohio Rev. Code § 4729.60) and terminal distributor of dangerous drug ("TDDD") licenses have always existed.

In 1962, the Ohio Department of Health requested the state Attorney General issue an advisory opinion asking whether, among other things, a licensed manufacturer, wholesaler, or distributor would be subject to prosecution and fine under the sections noted above if they were to sell "dangerous drugs" to the Board of Health or another similar state/district operated entity, which were unlicensed.[10] It seems that the industry recognized the difficulty of "verifying" a license and therefore expressed a "reluctance" to distribute within the state.[11]

Ten years later, the Board of Pharmacy ("BOP") enacted Ohio Admin. Code 4729-9-12 (i.e., the verification rule), which also has been amended.[12] While the laws and regulations have existed for over four decades, the industry only realized the full scope and application of the verification rule with 2016 legislation requiring all prescribers to obtain a Category III TDDD license in order to possess, have custody or control of, and distribute controlled substances.[13] The BOP promulgated regulations, such as amending the verification rule to allow companies to utilize an online registry to confirm a TDDD license, and issued a handful of guidance documents on TDDD licensure.[14] It was initially through a BOP guidance document that the agency stated drug samples were included in the BOP's definition of "dangerous drugs."[15]

Thus, the lesson we take from the story above: don't ignore the states.

Ohio's "New" Drug Law: It's Like a Giant Puzzle

A. Key Definitions

The following are essential definitions to understanding Ohio's drug distribution laws:

5 *21 C.F.R. §§ 203.30(b)(ii), 203.31(b)(ii) (alteration added).*
6 *21 C.F.R. §§ 203.30(a)(2), 203.31(a)(2) (alteration added).*
7 *Prescription Drug Marketing Act of 1987; Prescription Drug Amendments of 1992; Policies, Requirements, and Administrative Procedures, 64 Fed. Reg. 67,720, 67,754 (Dec. 3, 1999) [hereinafter PDMA Final Rule].*
8 *Id. at 67,736.*
9 *1961 Ohio Laws 1376 (Am. Sub. H.B. 416, eff. Jan. 1, 1962). According to Debbie Tavenner, Library Administrator for the Ohio Legislative Service Commission, Section 4729.60 was amended in 1962, 1982, 1998-99, and 2014-17. It should be noted that the Lawriter Ohio Laws and Rules (a free resource provided by the state) nor the Thomson should be noted that the Lawriter Ohio Laws and Rules (a free resource provided by the state) nor the Thomson Reuters WESTLAW (subscription required) Baldwin's Ohio Revised Code Annotated do not provide the full legislative history for section 4729.60 of the Revised Code.*
10 *1962 Op. Att'y No. 2781, p. 70-79, available at http://www.ohioattorneygeneral.gov/getattachment/e8198770-ac14-40da-9bc6-e10f56f9e243/1962-2781.aspx.*
11 *Id. at 72.*
12 *See Ohio Admin. Code 4729-9-12, available at http://codes.ohio.gov/oac/4729-9-12 (providing the "prior effective dates"). The regulation has been in effect since at least October 1, 1971 with revisions in 1987, 1991, 1995, 1996, 1999, 2009, 2015, and 2017. Id. The rule's statutory authority stems from Ohio Rev. Code §§ 3719.28 (concerns BOP's authority to adopt rules for administration and enforcement relating to controlled substances) and 4729.26 (concerns BOP's authority to adopt administrative rules relating to the practice of pharmacy and dangerous drugs); the rule amplifies sections 3719.04 (sale of controlled substances by manufacturer or wholesaler), 4729.51 (selling, purchasing, distributing, or delivering dangerous or investigational drugs), 4729.54 (terminal distributor licenses), 4729.541 (exemption from licensure as terminal distributor of dangerous drugs), 4729.60 (obtaining certificates prior to transactions) of the Revised Code. Id.*
13 *See Sub. S.B. 319, 131st Gen. Assemb. (Ohio 2016); see also Ohio Rev. Code § 4729.541(D)(2).*
14 *See Terminal Distributor Licensure Requirements for the Possession of Controlled Substances, ST. OHIO BOARD OF PHARMACY (April 4, 2017), available at https://www.pharmacy.ohio.gov/Documents/Licensing/TDDD/General/Terminal%20Distributor%20Licensure%20Requirements%20for%20the%20Possession%20of%20Controlled%20Substances.pdf [hereinafter TDDD Controlled Substance Guidance]; see also Terminal Distributor Licensing of Prescriber Practices, ST. OHIO BOARD OF PHARMACY (June 21, 2017), available at https://www.pharmacy.ohio.gov/Documents/Licensing/TDDD/General/Terminal Distributor Licensing of Prescriber Practices.pdf [hereinafter "TDDD Prescriber Practices Guidance"].*
15 *See TDDD Prescriber Practices Guidance, supra note 14.*

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- **"Dangerous drug"** . . . means any drug or drug product whose commercial package bears a label containing the symbol "Rx only", the legend "Caution: Federal Law Prohibits Dispensing Without Prescription" or "Caution: Federal Law Restricts This Drug To Use By Or On The Order Of A Licensed Veterinarian," or any similar restrictive statement.[16]
- **"Sample"** means a dangerous drug or pharmaceutical preparation that would be hazardous to health or safety if used without the supervision of a licensed health professional authorized to prescribe drugs, or a drug of abuse, and that, at one time, had been placed in a container plainly marked as a sample by a manufacturer.[17]
- **"Complimentary supply" also known as "starter packs," "initial dose packs," "starter stocks," "replacement programs," or any other similar supply** means a drug or pharmaceutical preparation that is distributed without charge by licensed wholesale distributors or manufacturers to pharmacies licensed as terminal distributors or prescribers to assist patients in the initiation of drug therapy. A complimentary supply shall not contain the markings or labeling of a sample drug.[18]
- **"Sale" and "sell"** include delivery, transfer, barter, exchange, or gift, or offer therefor, and each such transaction made by any person, whether as principal proprietor, agent, or employee.[19]
- **"Wholesale sale" and "sale at wholesale"** mean any sale in which the purpose of the purchaser is to resell the article purchased or received by the purchaser.[20]
- **"Terminal distributor of dangerous drugs"** means a person who is engaged in the sale of dangerous drugs at retail, or any person, other than a wholesale distributor or a pharmacist, who has possession, custody, or control of dangerous drugs for any purpose other than for that person's own use and consumption, and includes pharmacies, hospitals, nursing homes, and laboratories and all other persons who procure dangerous drugs for sale or other distribution by or under the supervision of a pharmacist or licensed health professional authorized to prescribe drugs.[21]
- **"Licensed health professional authorized to prescribe drugs" or "prescriber"** means an individual who is authorized by law to prescribe drugs or dangerous drugs or drug therapy related devices in the course of the individual's professional practice.[22]

B. Are You a Wholesale Distributor of Dangerous Drugs?

The answer for most pharmaceutical companies is most likely "yes." The Ohio Board of Pharmacy licenses nearly every type of in-state and out-of-state entity, from manufacturers that distribute drug samples and complimentary supplies (hand-carry and direct-to-practitioner),[23] brokers,[24] wholesale distributors (known as a "wholesale distributor of dangerous drugs"),[25]

15 See TDDD Prescriber Practices Guidance, supra note 14.

16 Ohio Rev. Code. § 4729.01(A) (alteration added) (emphasis added).

17 Verification of Licensure Prior to the Sale or Distribution of Drug Samples or Complimentary Supplies, ST. OHIO BOARD OF PHARMACY (July 14, 2017), available at https://www.pharmacy.ohio.gov/Documents/Licensing/WDDD/General/Verification%20of%20Licensure%20Prior%20to%20the%20Sale%20or%20Distribution%20of%20Drug%20Samples%20or%20Complimentary%20Supplies.pdf (providing the BOP's adoption of the term "sample" which was in the process of being incorporated in Ohio Admin. Code 4729-9-13) (emphasis added) [hereinafter Sample Verification Guidance]. The rule will become effective September 15, 2017. See Ohio Admin. Code 4729-9-13(A)(1), available at http://codes.ohio.gov/oac/4729-9-13v2.

18 Id. (emphasis added). The definition for "complementary supply" was also in the process of being incorporated into the same section and will similarly become effective September 15, 2017. See Ohio Admin. Code 4729-9-13(A)(2).

19 Ohio Rev. Code. § 4729.01(J) (emphasis added).

20 Ohio Rev. Code. § 4729.01(K) (emphasis added).

21 Ohio Rev. Code § 4729.01(Q) (emphasis added). TDDDs include, but are not limited to, the following: (1) Prescriber practices that possess non-controlled prescription drugs, unless exempt (i.e., dentists, sole shareholders, and sole proprietors); (2) Prescriber practices that possess controlled substances within Schedules II-V (NO EXEMPTIONS); (3) Pharmacies; (4) Hospitals; (5) Nursing homes; (6) Laboratories; and (7) Clinics & facilities (e.g., Ambulatory Surgery Center, Infusion/Oncology Clinic, Dialysis Clinics, Imaging/Diagnostic Clinic, Convenience Care Clinic, Free Standing Emergency Department, Behavioral Health, Chemical Treatment Facilities, Opioid Treatment Program, Specialty Clinic). See Application for Facility or Practitioner, ST. OHIO BOARD OF PHARMACY (Aug. 23, 2017), available at https://pharmacy.ohio.gov/Documents/Licensing/TDDD/Apps/Facility%20or%20Practitioner%20Application.pdf (describing the types of clinics, facilities, and prescriber practices subject to licensure) ; see also supra note 17 and accompanying text.

22 Ohio Rev. Code § 4729.01(I) (emphasis added). The term "prescriber" includes: (1) A dentist; (2) A clinical nurse specialist, certified nurse-midwife, or certified nurse practitioner who holds a current, valid license to practice nursing as an advanced practice registered nurse; (3) An optometrist to practice optometry under a therapeutic pharmaceutical agents certificate; (4) A physician authorized to practice medicine and surgery, osteopathic medicine and surgery, or podiatric medicine and surgery; (5) A physician assistant who holds a valid prescriber number issued by the state medical board, and has been granted physician-delegated prescriptive authority; and (6) A veterinarian. Id.

23 See Ohio Admin. Code 4729-9-13; see also Ohio Rev. Code § 4729.01(P) (defining "manufacturer of dangerous drugs").

24 See Ohio Admin. Code 4729-9-30(A) (defining "wholesale distributor with a broker classification" 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").

25 Ohio Rev. Code § 4729.01(O) (defining "wholesale distributor of dangerous drugs" as "a person engaged in the sale of dangerous drugs

(cont. on page 4)

3PLs,[26] and even virtual wholesale distributors.[27] The BOP considers all othese entities as wholesale distributors of danger drugs ("WDDD").[28] Companies engaged in the distribution or manufacturer of controlled substances are also required to maintain a controlled substance license.[29]

C. T...D...What?

Both the official name, terminal distributor of dangerous drugs, and acronym "TDDD," are a mouthful. There are some in the industry using the term "T-Triple D" and according to some reports received back from a major manufacturer's sales force, prescribers and their office staff refer to it as "TDL." In 2017, the Ohio legislature reduced the types of TDDD licenses from six (6) to four (4): Category II; Limited Category II; Category III; and Limited Category III.[30] A Category II license allows the licensee to "possess, have custody or control of, and distribute prescription drugs . . . that are not controlled substances,"[31] whereas a Category III license permits the licensee to possess, have custody or control of, and distribute all dangerous drugs.[32] A Limited Category II and Limited Category III are defined the same, except that the licensee is "limited" to those dangerous drugs listed in their application for licensure.[33] For context, Figure 1, left, provides the current active TDDD licenses by category.[34]

Figure 1: Active TDDD Licenses as of August 26, 2017

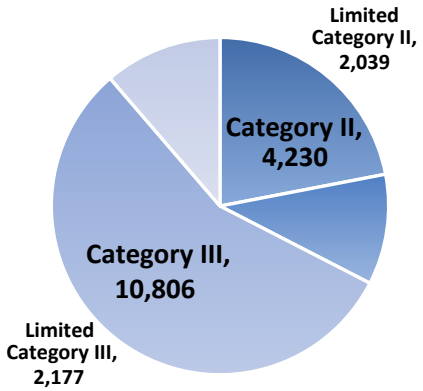
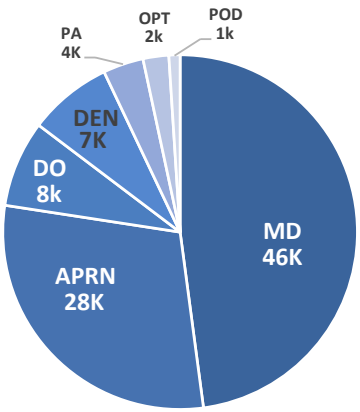


Figure 2: 96k Active Ohio HCPs



In terms of the actual health care providers ("HCP") numbers involved, as of August 2017, there are 96,000 HCPs with an active state license number in Ohio. Figure 2, on the left, provides the breakdown of state licenses numbers by professional designation.[35]

There are also roughly 19,000 active TDDD licenses in the state of Ohio with the top two license types being clinics. For additional context, see Figure 3 on the next page, which provides the top ten TDDD license types.[36] Early indications are that mid to large size pharma companies on average provide samples to between 8,000 and 15,000 practitioners across these organizations.

D. Verification Simplified

1. Non-Controlled Prescription Drugs (Samples & Complimentary Supplies): The "Alternative Method"[37]

Prior to the distribution[38] of non-controlled samples and complimentary supplies the following requirements apply:

(cont. from page 3) at wholesale and includes any agent or employee of such a person authorized by the person to engage in the sale of dangerous drugs at wholesale").

26 See Ohio Admin. Code 4729-9-29(A) (defining "third party logistics provider" as "any person who contracts with a manufacturer or wholesale distributor of dangerous drugs to provide or coordinate warehousing, distribution, or other services on behalf of a manufacturer or wholesaler, but does not take title of the dangerous drug or have general responsibility to direct the dangerous drug's sale or disposition").

27 See Ohio Admin. Code 4729-9-28(A) (defining "virtual wholesale distributor" as "any person engaged in wholesale distribution of dangerous drugs in or into Ohio which has title but does not take physical possession of dangerous drugs").

28 See Ohio Admin. Code 4729-9-13 (stating that "[n]o manufacturer, manufacturer's representative, or wholesale dealer in pharmaceuticals may furnish a sample of a drug of abuse [includes dangerous drugs] . . . to a prescriber unless requested by the prescriber and unless the company is registered as a wholesale distributor of dangerous drugs and maintains a record of such distribution which will be available to the state board of pharmacy"). It should be noted that a revised version of rule will become effective September 15, 2017; the word "furnish" is now replaced with "sell or distribution." See Ohio Admin. Code 4729-9-13(B); see also Sample Verification Guidance, supra note 17 (providing additional context).

29 Ohio Admin. Code 4729-9-16(L)(2).

30 See H.B. 319, 132nd Gen. Assemb. (Ohio 2017). The BOP has also already adopted these terms, by resolution. See Sample Verification Guidance, supra note 17; see also License Verification for Wholesale Distributors, ST. OHIO BOARD OF PHARMACY (July 14, 2017), available at [hereinafter License Verification Guidance].

31 See License Verification Guidance, supra note 30.

32 Id.

33 Id.; see also Ohio License Document View, ST. OHIO BOARD OF PHARMACY, available at http://www.pharmacy.ohio.gov/Licensing/PublicDocuments.aspx (last accessed August 25, 2017) (providing the mechanism for companies to view a limited licensee's drug list).

34 See License Roster Requests, ST. OHIO BOARD OF PHARMACY, available at http://www.pharmacy.ohio.gov/Licensing/RosterRequests.aspx (last accessed August 25, 2017); see also Licensing List – Guidance Document, ST. OHIO BOARD OF PHARMACY (JULY 14, 2017), available at http://www.pharmacy.ohio.gov/Documents/Licensing%20Information.pdf (providing additional information about the list and explaining, among other things, the TDDD category types).

35 See License Roster Requests, supra note 34.

36 See eLicense Ohio, OHIO DEP'T OF ADMIN. SERV., available at https://elicense.ohio.gov/OH_HomePage (last accessed August 25, 2017) (providing a way to perform individual or business lookups. Licenses were processed through MedPro Systems® Healthcare Provider Database.

37 See License Roster Requests, supra note 34.

38 It should be noted the BOP also uses the word "sale," which is highly

(cont. on page 5)

Top Ten TDDD License Types	Count
Clinic - Category Three	3,984
Clinic - Category Two	3,479
Pharmacy - Category Three	2,681
Facility - Limited Category Three	2,097
Facility - Category Three	1,657
Pharmacy Supplied Contingency Stock - Category Three	1,469
Other Categories	1,271
Medical Gas - Limited Category Two	1,138
Nonresident Pharmacy - Category Three	808
Facility - Limited Category Two	637

1. Verify that the prescriber's license is in good standing and that there are no restrictions on the prescriber's license to practice and utilize prescription drugs.
2. If a TDDD number is provided by the prescriber, verify using Ohio's online licensing registry that the license is active and in good standing.
3. Update the company's sample/complimentary supply request form to: (a) State, in a conspicuous manner, the requirements in Ohio law (Ohio Rev. Code § 4729.51) of when a prescriber must hold TDDD and instructions on where to access the Board's guidance document on prescriber licensure requirements; (b) Require the prescriber who claims an exemption to the TDDD licensing requirement to attest that they meet one of the licensing exemptions; and (c) Ensure that all sample/complimentary request forms are maintained for a period of three-years in accordance with the recordkeeping requirements of Chapter 4729-9 of the Ohio Administrative Code.

Companies expressing a reluctance to comply with the above must realize that these requirements are **in lieu of** performing the "verification exemption" requirements explained in the next section.

2. Non-Controlled Prescription Drugs (Wholesale Sales)

If the prescriber is exempt (i.e., sole proprietors, sole shareholders, and dentists),[39] companies are required, prior to distribution, to obtain:

1. A copy of the licensee's current license to practice and authorization to use the drugs requested (use of an online registry not discussed);[40]
2. A prescriber doing business as a sole shareholder of a corporation or a limited liability company must also provide **official documentation** that states he/she is the sole shareholder;[41]
3. The address of all sites of practice where the drugs will be delivered to and stored;[42]
4. Verification from the licensing board that the prescriber's license is in good standing and that there are no restrictions on his/her license to practice and use drugs in his/her practice;[43] and
5. If the license has been restricted by the licensing board, a copy of the official documents restricting the license to practice and use drugs in the course of professional practice must be furnished to the company.[44]

3. Controlled Substances (Trade, Samples, Complimentary Supplies)

Prior to the sale or distribution of controlled substances, including samples and complimentary supplies, the following requirements apply:

1. Obtain a copy of the TDDD's license or utilize Ohio's online licensing registry to confirm the TDDD.[45]
2. Verify that the prescriber's license is in good standing and that there are no restrictions on the prescriber's license to practice and utilize dangerous drugs.[46]
3. Verify the prescriber's registration with the DEA and verify that the DEA registration and authority to use controlled substances in the course of professional practice has not been restricted by the appropriate professional licensing board or the DEA.[47]

(cont. from page 4) *highly confusing and brings great angst to industry professionals considering prescription drug samples cannot, by law, be sold. See 21 U.S.C. § 353(c)(1) (stating that "[n]o person may sell, purchase, or trade or offer to sell, purchase, or trade any drug sample").*

39 *See TDDD Prescriber Practices Guidance, supra note 14.*
40 *See Ohio Admin. Code 4729-9-12(C)(2)(a).*
41 *See id.*
42 *See Ohio Admin. Code 4729-9-12(C)(2)(b).*
43 *See Ohio Admin. Code 4729-9-12(C)(2)(c).*
44 *See id.*
45 *See Ohio Admin. Code 4729-9-12(C)(1).*
46 *See Ohio Admin. Code 4729-9-12(C)(2)(c).*
47 *See Ohio Admin. Code 4729-9-12(C)(2)(d); see also Ohio Admin. Code 4729-9-12(D) (stating "[c]ontrolled substances may only be shipped to those addresses registered with the federal drug enforcement administration for the purpose of storing controlled substances").*

There are several nuances that should not be overlooked, such as the prohibition against certain mid-level professionals (i.e., clinical nurse specialist, certified nurse mid-wife, or certified nurse practitioner, physician assistant) "personally furnishing" controlled substance samples.[48]

4. Requirements/Considerations Applicable to All Verification Methods

There are several additional requirements that are applicable to all methods discussed above:

1. Verification must occur every time.[49]
2. Licenses are location specific.[50]
3. For limited licenses, companies must also confirm that the TDDD's drug list permits the possession of the specific drug requested.[51]
4. When utilizing the online registry, the Sample Verification Guidance states "[a] wholesale or terminal distributor of dangerous drugs may utilize this licensing information to verify licensure status prior to sale or purchase. The spreadsheet must be accessed on a weekly basis to ensure the most up-to-date licensure status."[52]

Third-party logistics providers are in a difficult position. On one hand, the BOP states a 3PL does not have to do its own verification provided it can produce documentation that the manufacturer/wholesaler verified the TDDD license.[53] If not, 3PLs must perform verification separately (it is a condition of maintaining licensure).[54]

E. Record Retention

Use of the board's online registry must be documented and maintained for a period of three (3) years for TDDD verification, as well as all documents establishing the fact that a prescriber is exempt from holding a TDDD.[55] According to Cameron McNamee, Director of Policy and Communications for the Ohio BOP, "[companies] are not required to obtain an actual copy of the license. [Companies] just need to verify online or using the spreadsheet. [Companies] can keep a screen shot or even maintain the spreadsheets in a central location for 3-years."

In addition, companies licensed as a TDDD must also adhere to, among things, the record retention, inventory, and BOP reporting requirements under Ohio Admin. Code 4729-9-16 (Minimum requirements for wholesalers). This includes, but is not limited to, the following: (1) maintaining a system to prevent anyone who is not authorized to possess any dangerous drug (e.g., a prescriber who is required to hold a TDDD, but who currently does not possess a license);[56] (2) informing the BOP of suspicious orders for any type of drug (i.e., unusual size, unusual frequency, or deviates substantially from established buying patterns);[57] and (3) notifying the BOP that the company is storing its records at a place other than the place licensed by the BOP.[58] Similar to the verification records, these records must be maintained for three (3) years,[59] and the BOP has the authority to inspect licensees at any time.[60]

F. Are there penalties?

When asked about penalties, Director McNamee stated that "[i]n general, the State of Ohio Board of Pharmacy may take administrative action against a wholesaler that fails to comply with Ohio laws and the rules adopted thereunder. Such action may include a fine ($2,500 per violation) and/or suspension or revocation of a license."[61] Historically and depending on the severity of the violation, the BOP has typically issued cease and desist letters. These letters strongly inform the recipient of the alleged violative conduct at issue, the specific laws and regulations that must be adhered to, and the penalties for violating those laws and regulations.

48 *See Ohio Admin. Code 4723-9-08(B)(3) (providing the prohibition on certain nursing professionals); see also Ohio Rev. Code § 4730.43(A)(3) (prohibiting a physician assistant from "personally furnishing" a controlled substance).*
49 *See Ohio Admin. Code 4729-9-12(A), (C)(1); see also Sample Verification Guidance, supra note 17.*
50 *See Ohio Rev. Code § 4729.54(H)(2).*
51 *See Ohio Admin. Code 4729-9-(A)(1), (C)(1); see also Ohio License Document View, supra note 33.*
52 *See Sample Verification Guidance, supra note 17.*
53 *See id.*
54 *Id.*
55 *See Ohio Admin. Code 4729-9-12(E), (K); see also Sample Verification Guidance, supra note 17.*
56 *Ohio Admin. Code 4729-9-16(H)(1)(d).*
57 *Ohio Admin. Code 4729-9-16(H)(1)(e)(i).*
58 *Ohio Admin. Code 4729-9-16(H)(3)(b).*
59 *Ohio Admin. Code 4729-9-16(H)(2).*
60 *Id. It should be noted that the BOP is currently in the process of drafting a new rule, 4729:6-3-04, which establish a protocol for on-site inspections of wholesale distributors of dangerous drug. See CSI Business Impact Analysis - Terminal and Wholesale Distributors of Dangerous Drugs, ST. OHIO BOARD OF PHARMACY (Aug. 8, 2017), available at https://pharmacy.ohio.gov/Documents/LawsRules/ProposedRules/CommonSense/CSI%20Business%20Impact%20Analysis%20-%20Terminal%20and%20Wholesale%20Distributors%20(Comm....pdf. The rule grants broad authority to the BOP to allow an "authorized board agent" to enter any licensed entity, without notice. Id.*
61 *See, e.g., Minutes of the Meeting, ST. OHIO BOARD OF PHARMACY (Mar. 7, 2005), available at https://www.pharmacy.ohio.gov/Documents/Pubs/Minutes/2005/200503%20-%20Minutes%20(Mar%202005)-3.pdf (discussing how the BOP issued a cease and desist letter to ASD Specialty Healthcare, Inc., a licensed WDDD, for violating Ohio Rev. Code § 4729.60(A) and informing the licensee of the potential actions the BOP may take under Section 4729.51(B) of the Ohio Revised Code).*

The BOP has issued administrative fines too.[62] Because controlled substance samples must be disclosed under Ohio's prescription drug monitoring program, those distributing controlled substances will likely come under greater scrutiny. A query should be able to identify non-compliance easily. Thus, although companies have seemed to think PDMA compliance was a thing of the past, active state legislatures and administrative bodies are causing companies to rethink.

Need for Solutions

Past the regulatory issues discussed above, pharmaceutical companies are searching for solutions to address the new Ohio regulations. Controlled Dangerous Substance ("CDS") licenses are issued by 26 states enabling HCPs to handle controlled drugs. Ohio TDDD licenses are similar to CDS state issued licenses in that they are both issued specific to an address. However, TDDD licenses differ in two important ways. The first is that instead of explicitly issuing TDDD licenses to an HCP, TDDD licenses are issued to an organization. The second difference is that TDDD licenses apply to dangerous drugs which include both non-controlled drugs and samples, broadening the scope of these licenses.

The result is that depending on the type of drug involved and the ownership model of the physicians practice, both the practitioner state license and the organizations license must be considered before samples are dropped or shipped. Essentially, for HCPs covered by the regulations, verification of the HCP's ability to receive drug samples is now at the address level in Ohio.[63]

The Industry Responds

A Major Pharmaceutical Manufacturer Takes Swift Action

To ensure sampleability compliance, the manufacturer has its own business unit devoted to prescription drug sampling and complimentary supplies. The sampling division is fully staffed, but relies on outside vendors for compliance, field support, and distribution for its direct-to-practitioner program. Sales representatives also deliver samples and complimentary supplies. Volume varies and numbers range from approximately 1,200 units per quarter (direct-to-practitioner) and approximately 650 units per week (hand-carry). When the sampleability division first became aware of the regulation, it relied on an outside compliance vendor to understand the regulation to enable them to adequately inform upper management.

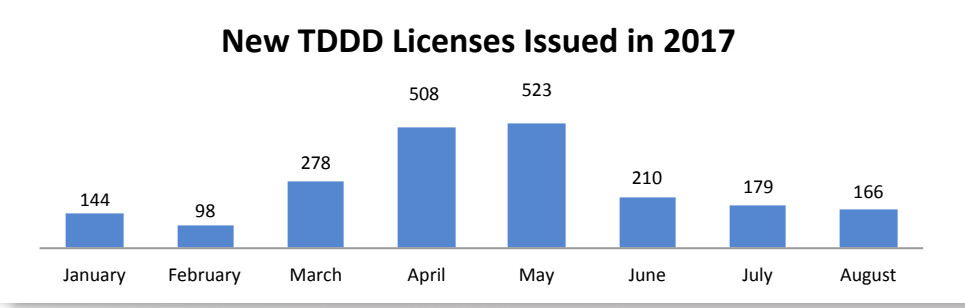
A decision was made to fully comply with the regulation, while also being creative in how it could use current systems without halting operations completely. Because the company's sample request form ("SRF") was electronic, it decided to implement a process where its sales force would provide a one-page SRF addendum to comply with Ohio's "alternative method" described above. Next, the division began creating and testing a process before implementing it across the sales force. Initially, the sales representatives were limited in how they could sample with a strict policy of no distributions unless the prescriber held a TDDD license. Sales representatives, including managers, were required to attend one of four training sessions. It was simple and to the point: (1) reps were required, as part of their pre-call activity, to identify if the prescriber or the practice held a TDDD license (completed by either calling the office or utilizing the BOP's website); (2) verify the TDDD license each time; and (3) always provide the addendum when providing samples. Following a fifteen-minute presentation, an FAQ was held. The most common questions were related to sole proprietors/shareholders and how often must verification checks occur.

The manufacturer is still working on streamlining the process from an IT perspective. Additionally, because a different business unit handles promotion via product website, SRFs found on the product sites will take longer to implement; language will also be broadened for the possibility of other jurisdictions implementing similar requirements. While this manufacturer has taken the necessary steps to comply, other companies must find a solution that can be tailored uniquely to meet both compliance and business demands. Some companies may interpret the *Sample Verification Guidance*, laws, and regulations differently. For example, some in the industry may recall efforts to collect mid-level practitioner collaborative agreements and how internal policies were created to require their collection. Sampling became difficult for these companies, as compliance with policies became the focus instead of finding compliant work-arounds. Likewise, there are other methods companies could explore, such as splitting its non-controlled prescription drug

62 *See, e.g., Minutes of the Feb. 1-3, 2016 Meeting, ST. OHIO BOARD OF PHARMACY (Feb. 1, 2016), available at https://www.pharmacy.ohio.gov/Documents/Pubs/Minutes/2016/201602%20-%20Minutes%20(Feb%202016).pdf (discussing how Midwest Veterinary Supply, Inc., a licensed WDDD, violated, among other provisions, Ohio Rev. Code § 4729.60(A) and Ohio Admin. Code 4729-9-12(A)(2), for failing to verify a TDDD and subsequently was fined $5,000).drafting a new rule, 4729:6-3-04, which establish a protocol for on-site inspections of wholesale distributors of dangerous drug. See CSI Business Impact Analysis - Terminal and Wholesale Distributors of Dangerous Drugs, ST. OHIO BOARD OF PHARMACY (Aug. 8, 2017), available at https://pharmacy.ohio.gov/Documents/LawsRules/ProposedRules/CommonSense/CSI%20Business%20Impact%20Analysis%20-%20Terminal%20and%20Wholesale%20Distributors%20(Comm....pdf. The rule grants broad authority to the BOP to allow an "authorized board agent" to enter any licensed entity, without notice. Id.*

63 *See Ohio Rev. Code § 4729.54(H)(2); see also Sample Verification Guidance, supra note 17 (stating in Q7 that while "[t]erminal Distributor licenses are location-based. . . . [t]he only instance where the address may not be an exact match is if the prescriber is practicing at a hospital. In this instance, the Board typically issues a campus license.")*

sampling program into a hand-carry for exempt prescribers (i.e., sole proprietors, sole shareholders, and dentists) and direct-to-practitioner for those that require TDDD licenses. Another option for companies is to create an enrollment (renewed annually) form that complies with the alternative method; subsequent sample requests would rely on the prescriber's attestation that the information remains the same or has since changed.[64]



Pharmaceutical manufacturers must keep in mind the company needs a license as a WDDD to distribute into and within Ohio; this means that the verification responsibilities ultimately rest upon them. Manufacturers that rely heavily upon outside vendors must be sure to carefully review current contracts and establish business rules to comply with Ohio's verification and record retention requirements.

At the heart of the needed solution is a solid cross-reference between the HCPs in Ohio and the organizations where they practice. While the datasets needed are available (i.e., the HCP licensing data from the State Medical Board and the TDDD organizational licensing data from the State Board of Pharmacy), the difficulty is a common identifier between the datasets. **More specifically, the difficulty is a lack of clean identifiers between the datasets.** Common identifiers such as State License number, National Provider Identifier ("NPI") number or even the Drug Enforcement Administration ("DEA") number are not present, leaving only the address in common. Making the needed link between the HCP and the HCO can be difficult to navigate due to common address nuances and anomalies. Complex matching algorithms are needed along with many practitioner addresses from authoritative sources to maximize creation of the cross-reference.

While some pharmaceutical organizations initial reaction was to halt all sampling in Ohio, many are now moving to solutions based on the cross-reference described above to allow sampling to continue. Though not all required Ohio practitioners possess the needed TDDD licenses as of today (see the "New TDDD Licenses Issued in 2017" chart on this page),[65] or are not aware they need one for each address where they intend to receive or handle dangerous drugs, **it is important for solutions to have a defined exception process to maximize usage of existing licenses.** This process might include manual stewardship and/or contacting the HCP for information on their available/preferred TDDD locations.

Conclusion: Where to go from here?

Challenging Ohio's distribution laws via the legislature could potentially cause the industry to face more negative publicity, especially in the midst of an ever-growing chorus of politicians, journalists, and engaged citizens calling for increased regulation of the industry. Bringing the matter to the courts would likely fail. It can be summed up from a 1996 U.S. Court of Appeals case originating from the Northern District Court for the Northern District of Ohio: **The "burden imposed upon interstate commerce by § 4729 [is likely] incidental and minimal while the benefit to the State of Ohio [would likely be found to be] substantial."**[66] That interest here is largely ensuring that only those who are lawfully able to possess "dangerous drugs" have access to them. Ohio is also a key battleground for the opioid epidemic and state legislatures and administrative agencies will continue to take the necessary steps to inhibit the unauthorized possession of prescription drugs.

State issues are going to continue to plague the industry. Manufacturers, big and small, are strained by added legal and regulatory requirements. Their vendors (e.g., compliance, distributors, verification) are ready to meet their demands and needs. A collective voice is needed to work and educate the state legislatures and administrative bodies on how the industry works and the impact laws and regulations have on the supply chain.

64 *It should be noted that the alternative method described in the Sample Verification Guidance places the responsibility on the prescriber to provide the TDDD license number. See Sample Verification Guidance, supra note 17 (stating "[i]f a TDDD number is provided by the prescriber, verify using Ohio's online licensing registry that the license is active and in good standing").*

65 *See Terminal Distributor (TDDD) Licenses, ST. OHIO BOARD OF PHARMACY, available at https://pharmacy.ohio.gov/Licensing/TDDD.aspx (last accessed Aug. 25, 2017) (providing general information on TDDD licenses). TDDD license statistics were provided by MedPro Systems® Healthcare Provider Database.*

66 *See Ferndale Laboratories, Inc. v. Cavendish, 79 F.3d 488, 496 (1996) (footnotes omitted) (alteration added).*