



PATIENTS MOVE US.



September 9, 2016

Mr. Mark A. Thierer
Chief Executive Officer
OptumRx
1600 McConnor Parkway
Schaumburg, IL 60173-6801

Via email: mark.thierer@optum.com

Dear Mr. Thierer:

It has recently come to our attention that OptumRx has instituted a new requirement for its Network Pharmacy Providers. According to communications received by pharmacies and their wholesalers, effective October 1, 2016, it is our understanding that OptumRx Network Pharmacy Providers will be required to purchase prescription drugs only from VAWD¹ - accredited wholesale distributors. The Healthcare Distribution Alliance (HDA), the Health Industry Distributors Association (HIDA), the National Association of Chain Drug Stores (NACDS), the National Association of Specialty Pharmacy (NASP) and the National Community Pharmacists Association (NCPA) are writing to express our serious concerns with this new policy. As we discuss below, imposing this requirement is not practical within the deadline imposed, does not further patient safety or supply chain security, and raises numerous concerns for the pharmaceutical supply chain. Although individual companies will decide which contracts they sign, we urge you to rescind this requirement immediately to avoid severely disrupting the supply chain and negatively impacting patient access to needed medicines.

Collectively, the members of the undersigned organizations, together with their authorized trading partners, work to safeguard the nation's supply chain and ensure that patients have safe access to medications when and where they need them, across the U.S. and its territories. Further, our organizations work diligently to preserve the integrity of the drug supply chain at every level and all are engaged in the first implementation phase of the Drug Supply Chain Security Act (DSCSA), which became effective November 27, 2013.

The constraints of this new policy requiring VAWD accreditation puts a new burden on participating pharmacies but also places a de facto requirement on the wholesale distributors from which they purchase – entities that may have no contractual or reimbursement relationship with OptumRx. VAWD-accreditation has only been required in two or three states as a condition of licensure. Consequently, while many HDA and HIDA members do have VAWD accreditation for some of their distribution centers, most do not have VAWD

¹ "VAWD" is the National Association of Boards of Pharmacy (NABP) Verified-Accredited Wholesale Distributors program.

accreditation for all of their distribution centers. In many cases, wholesale distributors decide to pursue VAWD-accreditation *only* if required for licensure in certain states and some HDA and HIDA members are not VAWD-accredited at all. This fact will pose enormous difficulties for OptumRx network pharmacies that are located, as the vast majority are, in states that never required wholesale distributors to be VAWD-accredited.

We believe that this new requirement will be problematic for many reasons, including,

- The policy could effectively limit the number of pharmacies eligible to participate in your network, potentially jeopardizing their ability to serve OptumRx covered patients;
- We are already aware of many cases where the new policy would prohibit pharmacies from continuing to work with their current distributor—in many cases, their only supplier – and would seemingly require severing longstanding business and contractual relationships which the parties do not wish to terminate;
- While the decision is not geared directly at primary distributors (which do not technically “participate” in your provider network), the effects of disqualifying reputable distributors from serving certain pharmacy customers could be detrimental to those businesses and, more importantly, to their customers’ patients.
- This policy may also have the unintended consequence of limiting patient access to prescription drug products in the near term, and will significantly impede pharmacy ability to source product from alternate trading partners in cases where products are in short supply;

Below, we bring to your attention additional concerns and issues.

I. VAWD Accreditation Has No Legal Significance.

VAWD is not sanctioned by FDA and no federal law, including the DSCSA, requires wholesale distributors to be VAWD-accredited. VAWD-accredited wholesalers range from very small secondary or tertiary wholesalers to very large publically traded primary distributors, and include independent, co-op and specialty companies. As mentioned above, VAWD-accreditation has only been required in two or three states as a condition of wholesale distributor licensure.

Additionally, with the DSCSA’s establishment of federal, uniform standards for wholesale distributor licensure, no state or political subdivision “may establish or continue any standards, requirements, or regulations with respect to” wholesale prescription drug distributors that “are inconsistent with, less stringent than, directly related to, or covered by” the DSCSA’s standards and requirements. § 585(b)(1) of the federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360eee-4(b)(1). This means, among other things, that no state can now require VAWD accreditation as a condition of wholesale distributor licensure. Even if a state could continue to mandate VAWD accreditation, the standards against which VAWD inspects and accredits could not be different than those imposed under the DSCSA.

II. Enhanced Supply Chain Protections of the DSCSA Render VAWD Accreditation Unnecessary.

It seems that OptumRx’s requirement that its participating pharmacies only purchase from VAWD-accredited distributors stems from mistaken assumptions about VAWD and current law governing wholesale distribution. While the inner workings of the supply chain are often misunderstood or overlooked by those operating outside the pharmaceutical supply chain, it is important for OptumRx to understand that the security

measures it may be seeking are already in place to ensure the proper handling and documentation of product transactions, and that questions about where product originated or what entities held it are not answered, addressed or regulated by VAWD or NABP.

Enactment of the DSCSA in 2013 established a national, uniform system of requirements to protect patients and help assure the integrity of the pharmaceutical supply chain. As of January 1, 2015, all entities in the supply chain, including OptumRx's pharmacy network participants, can only engage in transactions – that is, a change in ownership of a product – with authorized trading partners. The DSCSA defines authorized trading partner and places the burden on each trading partner to properly vet their suppliers and customers to ensure they are properly licensed and compliant with DSCSA requirements. In the DSCSA, authorized means,

“(B) in the case of a wholesale distributor, having a valid license under State law or section 583, in accordance with section 582(a)(6), and complying with the licensure reporting requirements under section 503(e), as amended by the Drug Supply Chain Security Act;” and, “(D) in the case of a dispenser, having a valid license under State law.”

§ 581(2)(B),(D), 21 U.S.C. § 360eee(2)(B),(D). Thus, wholesale distributors and pharmacies may only purchase from entities that are authorized as defined in the DSCSA.

In addition, beginning over a year ago, supply chain participants began tracing product uniformly by exchanging Transaction Information, Transaction History, and Transaction Statements with *each* transaction, that is, each purchase and sale of products as defined in the DSCSA. See § 582(b)-(d), 21 U.S.C. § 360eee-1(b)-(d). In the Transaction Statement, the entity transferring ownership of a product must attest to the buyer that it:

- Is an authorized trading partner;
- Received the product from a person that is authorized;
- Received a Transaction Statement from the prior owner of the product and Transaction Information about the product;
- Did not knowingly ship a suspect or illegitimate product;
- Has systems and processes in place to comply with the DSCSA's verification requirements (verification includes the ability to, among other things, investigate whether a product is suspect or illegitimate);
- Did not knowingly provide false Transaction Information; and
- Did not knowingly alter the product's Transaction History.

§ 581(27), 21 U.S.C. § 360eee(27). Congress carefully constructed these requirements and they are enforceable by FDA and its partner state regulatory agencies. The DSCSA was specifically enacted to enable greater transparency and security in the supply chain.

Additionally, the DSCSA establishes national, uniform standards for the licensure of wholesale distributors. “For the purpose of ensuring uniformity,” FDA must establish by regulation standards that “shall apply to all State and Federal licenses” and shall include standards for the following:

- 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 of certain persons from receiving or maintaining a wholesale distributor license.

§ 583(a),(b)(1)-(7), 21 U.S.C. § 360eee-2(a),(b)(1)-(7). FDA regulations implementing these licensure standards are expected at the end of 2016.

The DSCSA, therefore, provides protections to assure that only authorized entities buy and sell drugs, that those transactions are documented, and that wholesale distributors operate in accordance with national standards. In contrast, the VAWD program has no legal significance and VAWD has no regulatory authority to enforce these provisions over any supply chain entity.

III. The October 1, 2016 Deadline for Compliance Is Unreasonable.

OptumRx has stated that wholesalers selling to OptumRx pharmacy network participants need to be VAWD-accredited by October 1, 2016. This is extremely problematic for those entities that are not currently VAWD-accredited and, we emphasize, are not required to be VAWD-accredited under state and federal law. While your newsletters suggest that VAWD accreditation is a formality and a simple process easily accessed via a web link, this is assuredly not the case. The program is costly for wholesale distributors – over \$7,000.00 per facility plus annual fees (\$1,000) and renewal fees (\$5,000), providing little return on investment. Obtaining VAWD-accreditation is also labor intensive and time consuming for the distributor. According to our members, the process can take more than 6 months and, historically, VAWD has had issues with timely renewal inspections as well.

It is our understanding that OptumRx will permit individual companies to ship product if their VAWD application is pending. However, this presents a short-term fix that will result in a long-term undue burden. Essentially, OptumRx is forcing HDA and HIDA members to become VAWD-accredited, when they would otherwise not see any legal, patient safety, or supply chain security rationale for fully participating in this program.

Although some distributors have chosen to obtain VAWD-accreditation for certain facilities for business reasons, VAWD accreditation has no legal significance and no regulatory authority. The DSCSA's many requirements and FDA's pending licensure regulations – which states will be mandated to adopt and implement – will further secure the supply chain and help assure patient safety. Given that FDA's own licensure regulations are pending, coupled with the length of time it takes to obtain a VAWD certification, OptumRx is requiring something that is neither practically obtainable in the time allowed nor sensible.

Conclusion

The Associations representing the nation's pharmaceutical distributors and pharmacy appreciate your consideration of these issues and concerns and we urge OptumRx to rescind its decision to rely on VAWD as a benchmark and reconsider the impact this new policy will have on pharmacies, wholesale distributors and OptumRx patients. We welcome any questions you may have and invite you to engage in continued dialogue with our organizations and our members on this issue.

Sincerely,



John M. Gray
President & CEO
Healthcare Distribution Alliance



B. Douglas Hoey, RPh., MBA
Chief Executive Officer
National Community Pharmacists Association



Tom O'Donnell
Senior Vice President
Government Affairs and Public Policy
National Association of Chain Drug Stores



Burt Zweigenhaft
President
National Association of Specialty Pharmacy



Matthew J. Rowan
President and CEO
Health Industry Distributors Association

cc: Kerri Tanner
Vice President, Pharmacy Network Management
Kerri.tanner@optum.com

Thomas Irvin
Director, Pharmacy Network Compliance
thomas.irvin@optum.com

Healthcare Distribution Alliance (HDA) is the national association representing primary healthcare distributors, the vital link between the nation's pharmaceutical manufacturers and healthcare providers. Each business day, HDA member companies ensure that over 15 million prescription medicines and healthcare products are delivered safely and efficiently to more than 200,000 pharmacies, hospitals, long-term care facilities, clinics and others nationwide. HDA and its members work daily to provide value and achieve cost savings for our nation's healthcare system. HDA previously was known as the Healthcare Distribution Management Association (HDMA).

The National Community Pharmacists Association (NCPA) represents the pharmacist owners, managers, and employees of more than 22,000 independent community pharmacies across the United States. The nation's independent pharmacies, independent pharmacy franchises, and independent chains dispense nearly half of the nation's retail prescription medicines. The nation's independent

pharmacists are small business entrepreneurs and multifaceted health care providers who represent a vital part of the United States' health care delivery system. They have roots in America's communities. They are community leaders actively involved in community-oriented public health, civic, and volunteer projects. Many hold local elected offices; others serve as state legislators.

The National Association of Chain Drug Stores (NACDS) represents traditional drug stores and supermarkets and mass merchants with pharmacies. Chains operate more than 40,000 pharmacies, and NACDS' chain member companies include regional chains, with a minimum of four stores, and national companies. Chains employ more than 3.2 million individuals, including 179,000 pharmacists. They fill over 2.9 billion prescriptions yearly, and help patients use medicines correctly and safely, while offering innovative services that improve patient health and healthcare affordability. NACDS members also include more than 850 supplier partners and over 60 international members representing 22 countries. For more information, visit www.NACDS.org.

The National Association of Specialty Pharmacy (NASP) is a 501(c)(6) trade association representing all stakeholders in the specialty pharmacy industry. Our members include the nation's leading specialty pharmacies, pharmaceutical and biotechnology manufacturers, GPOs, distributors and more. With 71 corporate members and 1,200 individuals, NASP is the unified voice of specialty pharmacy in the United States. NASP is dedicated to education, national policy advocacy, and engagement of all stakeholders in the specialty pharmacy industry.

The Health Industry Distributors Association (HIDA) is the premier trade association representing medical products distribution. HIDA members primarily serve the nation's hospital, long-term care, and physician/alternative care markets. For more information, visit www.HIDA.org