April 27, 2020

Dr. Leigh Verbois, Ph.D.
Director, Office of Drug, Security, Integrity and Response
Center for Drug Evaluation and Research
Food and Drug Administration
WO51; Room 4268
10903 New Hampshire Ave
Silver Spring, MD 20993

Re: Drug Supply Chain Security Act Licensing Standards

Dear Dr. Verbois:

We, PDSA, write to you regarding the implementation of licensing standards for third-party logistics providers (3PLs) pursuant to the Drug Supply Chain Security Act (DSCSA). While we appreciate the Agency's October 2014 draft guidance titled "The Effect of Section 585 of the FD&C Act on Drug Product Tracing and Wholesale Drug Distributor and Third-Party Logistics Provider Licensing Standards and Requirements: Questions and Answers"[1] language around preemption, the content does not clearly convey to States the effect of the DSCSA's deeming provision. Specifically, we request formal clarification of 3PL licensure status, as stated in the DSCSA, in written form through guidance, press statements, letters or other methods. Transparent written clarification that reiterates the statutory language for states and other relevant stakeholders will allow for broad communication and education and protect trade within the pharmaceutical supply chain.

PDSA is a multi-stakeholder coalition with membership that spans the entire spectrum of the U.S. pharmaceutical distribution system, including manufacturers, repackagers, wholesale distributors, third-party logistics providers, and pharmacies. More than 25 companies are formal members of PDSA, while many other external stakeholders provide additional policy and technical support through industry trade associations. Our primary goal is ensuring patients have uninterrupted access to safe, authentic, FDA-approved medicine.

The Importance of Third-Party Logistics Provider Standards

The clear and primary intent of the DSCSA was to establish uniformity among States regarding both traceability (Section 582 of the Federal Food, Drug, and Cosmetic Act) and licensure (Section 583 and 584 of the Federal Food, Drug, and Cosmetic Act). Throughout the legislative process, Congress emphasized the need to replace the current patchwork of State laws with

[1] Subject to the intended updates announced by Former Commissioner Gottlieb on February 28, 2018 in his Remarks on Enhancing Drug Distribution Security.

uniform national standards that improve safety, eliminate duplicative regulation, and create certainty and predictability. State actions that differ in any way from, or add to, the DSCSA's approach to traceability and 3PL licensure, undermine the policy objectives of the DSCSA.[2]

Despite the DSCSA's demand for uniformity several States have taken divergent approaches to licensure, while others are expressly waiting for final FDA action. The resulting landscape has produced significant confusion and gaps and has impeded the ability of organizations to conduct business in certain states.

The development of state licensure requirements prior to release of the federal standards has created confusion. The DSCSA statutory text itself also clearly contemplates that states will not establish 3PL licensure requirements until federal standards are developed and released. Section 582(a)(7) provides that "until the effective date of the third-party logistics provider licensing regulations under section 584, a third-party logistics provider shall be considered 'licensed' under section 581(9)(B)." Specifically, unlike wholesale distributors, a 3PL is *deemed to be licensed* for purposes of the DSCSA until the relevant state properly establishes 3PL licensure requirements. Furthermore, until the federal standards are effective, Section 582(a)(7) grants the Agency adequate authority to protect the supply chain from unqualified and unscrupulous 3PLs by revoking their deemed licensed status and requiring compliance with the reporting requirements under section 584(b). There is good reason for this distinction. Prior to enactment of the DSCSA, every state had active licensure requirements for wholesale distributors. Those requirements have remained in place, pending update and revision based on the forthcoming standards from FDA. Conversely, 3PL licensure requirements were, and remain, a complex patchwork of requirements, ranging from state 3PL-specific licensure requirements, states that force 3PLs to be licensed as wholesalers (in contradiction to the DSCSA), and states that do not require licensure of 3PLs pending the forthcoming standards. This patchwork, 6.5 years after DSCSA became law, is still creating significant confusion. For example, Missouri requires a nonresident 3PL to be licensed in the home state and requires a home state inspection. However, if the home state does not license a 3PL, it also is also unlikely to conduct an inspection the 3PL. Indiana also requires a nonresident 3PL to either be licensed in the home state or "licensed by the federal Food and Drug Administration."

DSCSA Clearly Establishes 3PL Standard Requirements

One component of DSCSA established a national requirement for the licensure of third-party logistics providers. The law was intended to establish a single, uniform set of national standards for the licensure of third-party logistics providers, thus avoiding conflicting state standards that complicate the flow of pharmaceuticals through the supply chain. The statute sets forth those general standards and directs FDA to further define the standards through regulation not later than two years after enactment of the law.

[2] Commissioner Scott Gottlieb, Remarks on Enhancing Drug Distribution Security, February 28, 2018. https://www.fda.gov/news-events/speeches-fda-officials/remarks-enhancing-drug-distribution-security-02282018.

> *"(1) In general.--Not later than 2 years after the date of enactment of the Drug Supply Chain Security Act, the Secretary shall issue regulations regarding the standards for licensing under subsection (a), including the revocation and reissuance of such license, to third-party logistics providers under this section.*
> *(2) Content. --Such regulations shall—*
> *(A) establish a process by which a third-party accreditation program approved by the Secretary shall, upon request by a third-party logistics provider, issue a license to each third-party logistics provider that meets the requirements set forth in this section."*[3]

In lieu of these standards, which have not been published at the time of this writing, we request more specific and public announcement that 3PLs are considered licensed based on Sec 582(a)(7):

> *"(7) Third-party logistics provider licenses.--Until the effective date of the third-party logistics provider licensing regulations under section 584, a third-party logistics provider shall be considered 'licensed' under section 581(9)(B) unless the Secretary has made a finding that the third-party logistics provider does not utilize good handling and distribution practices and publishes notice thereof."*[4]

Until such regulations are promulgated, it should be made clear that States must follow the statutory standards in the DSCSA including 3PL's being deemed licensed provided they are in compliance with the reporting requirements under section 584(b), unless FDA affirmatively finds a 3PL is not utilizing good handling and distribution practices. Current state practice is focused on establishing independent, and often contradictory, standards. Lacking the public clarification states will continue to act independently to establish disruptive standards and further impede commerce and patient access to critical pharmaceuticals.

Conclusion

We request clear, written clarification of 3PL licensure status, allowing broad communication and education to all relevant stakeholders. States regulators and the patients they oversee are waiting for the clarity.

We thank you for your efforts to secure the pharmaceutical supply chain. FDA plays a critical role in the implementation of DSCSA, and we welcome questions, comments, and feedback as you implement this complicated and vital law.

[3] Title II of the Drug Quality and Security Act, Sec 584(d)(2), https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/title-ii-drug-quality-and-security-act.
[4] Title II of the Drug Quality and Security Act, Sec 582(a)(7), https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/title-ii-drug-quality-and-security-act.

Sincerely,

The Pharmaceutical Distribution Security Alliance (PDSA):[5]

Manufacturers:
Association for Accessible Medicines (AAM)
Pharmaceutical Research and Manufacturers of America (PhRMA)
abbvie
Allergan
Apotex
AstraZeneca
Bayer
Bristol-Meyers Squibb
Fresenius Kabi
Genentech
GlaxoSmithKline
Johnson & Johnson
Merck
Mylan
Novartis
Pfizer
Upsher-Smith Laboratories

Wholesale Distributors:
Healthcare Distribution Alliance (HDA)
AmerisourceBergen
CardinalHealth
Medline Industries

Third-Party Logistics Providers:
International Warehouse Logistics Association (IWLA)
Inmar
UPS

Dispensers:
American Pharmacists Association (APhA)
American Society of Health-System Pharmacists (ASHP)
National Association of Chain Drug Stores (NACDS)
CVSHealth

[5] Members are listed according to their primary supply chain sector, but many operate business units across multiple sectors.