Next Up: Uniform Licensure Standards for Wholesalers and Third-Party Logistics Providers

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Key Takeaways:

- FDA has published a proposed rule proposing national licensing standards for prescription drug wholesale distributors and third-party logistics providers as well as standards for third-party accreditation programs.
- The rule is intended to bolster the integrity of the pharmaceutical distribution supply chain while reducing the burden on wholesale distributors and logistic providers who currently have to comply with a patchwork of inconsistent state licensing regulations.
- When finalized, these licensing regulations would preempt state licensing standards or regulations that are different from the federal scheme.

In the Federal Register of February 4, 2022, the U.S. Food and Drug Administration (FDA) published a proposed rule on national standards for the licensing of prescription drug wholesale distributors (WDDs) and third-party logistics providers (3PLs).[1] By way of background, Title II of the Drug Quality and Security Act, the Drug Supply Chain Security Act (DSCSA), includes provisions designed to strengthen the integrity of the pharmaceutical distribution supply chain. Among other measures, section 204 of the DSCSA amended section 503(e) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. § 353(e)), which requires licensure of WDDs and added section 583 to the FD&C Act (21 U.S.C. § 360eee-2), which requires FDA to establish by regulation national standards for the licensure of WDDs. Section 205 of the DSCSA added section 584 to the FD&C Act (21 U.S.C. § 360eee-3), which requires licensure of 3PLs and requires FDA to establish, by regulation, national standards for the licensure of 3PLs.

The proposed regulation at hand, when finalized, will establish national standards for the licensure of WDDs and 3PLs required under sections 583 and 584 of the FD&C Act, as amended by the DSCSA. As required by statute, the standards, terms and conditions for licensure established by the regulation will apply to both Federal and State licenses (503(e)(1)(B), 583(b), and 584(a)(1)(A) of the FD&C Act). The purpose of creating a uniform national standard is to address the existing patchwork system of varying state governance over the supply chain thereby lowering the regulatory burden on WDD and 3PLs while reducing opportunities for dangerous and criminal conduct in the supply of prescription drugs in the country.

This advisory provides a high-level overview of some of the major themes presented in the proposed regulation.

A. **Preemption**

In terms of which licensure scheme to follow, section 585(b)(1) of the FD&C Act (21 U.S.C. § 360eee-4(b)(1)) expressly preempts States and localities from establishing or continuing requirements for 3PL or WDD licensure that are different from the national standards and requirements applicable under sections 584 and 503(e) of the FD&C Act. However, the statutory provisions themselves do not establish these "standards and requirements"; instead, the regulation at issue, once effective, will establish them. Accordingly, State and local licensure requirements will be preempted only once the regulation, when finalized, takes effect. But, until such time, current State licensing of WDDs and 3PLs may continue in effect. FDA believes this determination will help avoid supply chain disruption, based on licensing uncertainties, during the period between DSCSA's enactment and the effective date of the regulation. Areas within the historical police powers of the States would be unaffected by the regulation, including prohibiting employees of WDDs and 3PLs from engaging in criminal activity related to prescription drugs, provided that the State

requirements involved are not related to licensure of 3PLs or WDDs.

B. **Part 205**

Currently, the FDA requirements for state licensing of WWDs are established under 21 C.F.R. Part 205. In the rule at hand, FDA proposes to withdraw that regulation and replace Part 205 with the proposed rule to set the national standards and otherwise govern the licensure requirements that would apply to WDDs and 3PLs in any State. The DSCSA establishes FDA as the licensing authority for WWDs and 3PL licenses in States that have not established a licensing program in accordance with the regulation (sections 503(e)(1)(A)(i)(II) and 584(a)(1)(B) of the FD&C Act (21 U.S.C. §§ 353(e)(1)(A)(i)(II) and 360eee-3(a)(1)(B))).

C. **Third Party-Organizations**

When finalized, this proposed rule will also set forth the standards applicable to, and the requirements for approval of, third-party organizations involved in the licensure and inspection process ("approved organizations" or "AOs"). Sections 583(c) (21 U.S.C. § 360eee-2(c)) and 584(d)(2)(A) (21 U.S.C. § 360eee-3(d)(2)(A)) of the FD&C Act provide, respectively, that FDA may approve "third-party accreditation" or inspection services or programs to conduct inspections of facilities used by WWDs seeking licensure and to review the qualifications of 3PLs for licensure. The proposed rule addresses the standards and requirements for approving such third-party accreditation or inspection services or programs.

D. **Conforming Changes**

The regulation also proposes to amend 21 C.F.R. §§ 10.50(c) and 12.21(a)(2), which list statutory authorities that provide the opportunity for a formal evidentiary public hearing under 21 C.F.R. Part 12. Because the regulation proposes that WWDs and 3PLs could request a formal evidentiary public hearing under Part 12 for review of decisions affecting the denial, suspension, or revocation of 3PL or WWD licenses issued by the Secretary of Health and Human Services (Secretary), sections 503(e), 583, and 584 of the FD&C Act (21 U.S.C. §§ 353, 360eee-2, and 360eee-3) would be added to the list of statutory sections under which there is the opportunity for a hearing under 21 C.F.R. §§ 10.50(c) and 12.21(a)(2), regarding such decisions. FDA is also proposing a conforming change to 21 C.F.R. § 16.1(b) to describe procedures for regulatory hearings that would add actions related to approved organizations under proposed §§ 205.19 and 205.33 respectively, including revocation or suspension of approval, to the list of actions for which a regulatory hearing under 21 C.F.R. Part 16 may be held.

E. **Overview of Proposed Rule**

The proposed rule sets forth the licensure standards for 3PLs separately from the standards for WDDs. This is in keeping with the DSCSA, which prohibits States from regulating 3PLs as WDDs. A 3PL that engages in wholesale distribution in the same facility in which it engages in 3PL activities must obtain a separate WDD license. The proposed rule also sets forth the standards and processes for the associated third-party accreditation programs. To highlight some of the key provisions, the proposed rule:

- provides a set of definitions to align with existing law and regulations and current industry practices;
- sets forth the application requirements for licensure of 3PLs and WDDs and the federal licensing review process, which may involve an inspection of the facility;
- requires WDDs to furnish a surety bond;
- establishes qualifications for key personnel;
- provides procedures for licensure denial, suspension reinstatement, revocation, and termination;
- sets forth good storage practices for 3PLs and WDDs;
- imposes requirements for written policies and procedures to address the receipt, security, storage, inventory, shipment and distribution of the product;
- includes provisions for recordkeeping, document maintenance, and reporting;
- tightens the minimal quantities exemption for pharmacies to prevent diversion of products and excessive sales from pharmacies that are not licensed and registered as wholesale distributors;
- imposes training and audit requirements for AOs; and
- prohibits AOs from engaging in (or being affiliated with any entities engaged in) other prescription drug-related activities,

including manufacturing, wholesale distribution, repackaging, relabeling, dispensing, or 3PL activities.

The deadline to submit a comment regarding this proposed rule is June 6, 2022.[2]

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[1] Food & Drug Admin., Proposed Rule, National Standards for the Licensure of Wholesale Drug Distributors and Third-Party Logistics Providers, 87 Fed. Reg. 6708 (Feb. 4, 2022).

[2] Docket No. FDA–2020–N–1663.

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