FDA PROPOSES NATIONAL LICENSING STANDARDS FOR WHOLESALE DRUG DISTRIBUTORS AND THIRD-PARTY LOGISTICS PROVIDERS

Earlier this year, the Food and Drug Administration ("FDA") announced a Proposed Rule regarding national standards for the licensing of prescription drug wholesale distributors ("Wholesale Distributors") and third-party logistics providers ("3PLs"). The proposed regulation is issued pursuant to requirements for national regulatory standards under the Drug Supply Chain Security Act ("DSCSA"), which is part of the 2013 Drug Quality and Security Act and amended the Federal Food, Drug, and Cosmetic Act ("FD&C Act"). Entities that are engaged with Wholesale Distributors, or directly or indirectly with 3PLs, should consider submitting comments to FDA by June 6, 2022 at 11:59 PM EST.

BRIEF DISCUSSION

Under 21 C.F.R. part 205, pre-DSCSA guidelines establish certain minimum standards and conditions for state licensing of Wholesale Distributors. Outside of these limited federal regulatory requirements, states have generally overseen licensing requirements for Wholesale Distributors and 3PLs, creating myriad regulatory variations from state to state. This variation, in turn, has created significant inconsistency in drug distribution requirements among states. For example, some states impose licensing requirements for certain wholesale distributors and 3PLs, while other states provide certain exemptions or do not establish any standards.

With a goal of "further strengthening the supply chain and the safety of prescription drugs provided to American consumers," the Proposed Rule is intended to "provide greater assurance that [...] supply chain participants are sufficiently vetted and qualified to distribute products." Accordingly, FDA is proposing the withdrawal and replacement of the current 21 C.F.R. part 205 regulation.

If finalized, the regulation would preempt and replace the current patchwork of licensing standards across the 50 states, providing greater clarity to both states and regulated industry as to the requirements and expectations FDA has regarding licensure. State and local licensure laws identical to the federal licensure standards could continue to operate; however, per the DSCSA, FDA would become the licensing authority for states without licensing programs in accordance with the regulation. The Proposed Rule also sets forth the standards applicable to, and the requirements for approval of, 3PL organizations involved in the licensure and inspection process.

Interested stakeholders have until Monday, June 6, 2022 to submit their comments. Electronic comments may be submitted here by following the online instructions on this site for submitting comments. Paper comments may be directed to the address listed in the Proposed Rule.

PRACTICAL TAKEAWAYS

- Pursuant to the FD&C Act, FDA is proposing new standards for the licensing of prescription drug wholesale distributors and 3PLs to establish national uniformity and increased assurance in the drug supply chain.
- Interested stakeholders should submit their comments relating to Wholesale Distributor and 3PL licensing to help shape future FDA rulemaking in the drug distribution space.

If you have questions regarding FDA's Proposed Rule or would like assistance submitting a comment to FDA, please contact:

- Todd Nova at (414) 721-0464 or tnova@hallrender.com;
- Cara Tolliver at (414) 721-0459 or ctolliver@hallrender.com; or
- Your primary Hall Render contact.

Hall Render blog posts and articles are intended for informational purposes only. For ethical reasons, Hall Render attorneys cannot—outside of an attorney-client relationship—answer specific questions that would be legal advice.