



HOUSE BILL 95: Wholesale Rx Distribution Licensee Change.

2021-2022 General Assembly

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| Committee: Senate Rules and Operations of the Senate | Date: August 18, 2021 |
| Introduced by: | Prepared by: Jennifer McGinnis |
| Analysis of: Third Edition | Staff Attorney |

OVERVIEW: *House Bill 95 would authorize the Commissioner of Agriculture (Commissioner) to review an application and issue or deny a license for wholesale distribution of prescription drugs that is conditioned upon approval of a prescription drug under federal law while the federal approval process is pending.*

CURRENT LAW/BACKGROUND: In order to comply with federal law¹, [Article 12A of Chapter 106 of the General Statutes](#) establishes a State licensing program for wholesale distributors of prescription drugs. Every wholesale distributor engaged in the wholesale distribution of prescription drugs in interstate commerce in the State must obtain a license from the Commissioner for each location from which prescription drugs are distributed and must renew each license annually. A license may cover multiple buildings and multiple operations at a single location, at the wholesale distributor's discretion.

Under the Article, the Commissioner must determine whether to issue or deny a wholesale distributor license after considering the following factors:

- Any convictions of the applicant under any federal, state, or local law relating to drug samples, wholesale or retail drug distribution, or distribution of controlled substances.
- Any felony convictions of the applicant under federal, state, or local law.
- The applicant's past experience in the manufacture or distribution of controlled substances and other prescription drugs.
- Whether the applicant has previously given any false or fraudulent information in an application made in connection with drug manufacturing or distribution.
- Suspension or revocation by the federal government or a state or local government of any license currently or previously held by the applicant for the manufacture or distribution of any controlled substances or other prescription drugs.
- Compliance with the licensing requirements under any previously granted license.
- Compliance with the requirements to maintain or make available to the Commissioner or to a federal, state, or local law enforcement official those records required under G.S. 106-145.8.
- Whether the applicant requires employees of the applicant who are involved in any prescription drug wholesale distribution activity to have education, training, experience, or any combination of these factors sufficient to enable the employee to perform assigned functions in a manner that ensures that prescription drug quality, safety, and security will be maintained at all times as required by law.

¹ The [Federal Food, Drug, and Cosmetic Act](#) requires wholesale distributors that provide services within a state, whether the wholesale distributor is located within the state or outside of the state, to be licensed or registered in good standing, or eligible to become licensed or registered, for wholesale drug distribution in the jurisdiction.

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- Any other factors or qualifications the Commissioner considers relevant to and consistent with the public health and safety.

The Commissioner must inspect the facility of an applicant at which prescription drugs will be stored, handled, or distributed before issuing the applicant a license.

BILL ANALYSIS: The bill would authorize the Commissioner to review an application and issue or deny a license for wholesale distribution of prescription drugs that is conditioned upon approval of a prescription drug under federal law while the federal approval process is pending.

EFFECTIVE DATE: The bill would be effective when it becomes law and apply to applications for licenses submitted on or after that date.