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LEGISLATIVE ACTION

Senate	.	House
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Floor: NC/2R	.	
04/26/2019 12:09 PM	.	
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Senator Bean moved the following:

Senate Amendment to Amendment (291576)

Delete lines 316 - 365

and insert:

(c) The location, names, and titles of all principal corporate officers and the pharmacist who serves as the prescription department manager for prescription drugs exported into this state under the International Prescription Drug Importation Program.

(d) Written attestation by an owner or officer of the applicant, and by the applicant's prescription department

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manager, that:

1. The attestor has read and understands the laws and rules governing the manufacture, distribution, and dispensing of prescription drugs in this state.

2. A prescription drug shipped, mailed, or delivered into this state meets or exceeds this state's standards for safety and efficacy.

3. A prescription drug product shipped, mailed, or delivered into this state must not have been, and may not be, manufactured or distributed in violation of the laws and rules of the jurisdiction in which the applicant is located and from which the prescription drugs shall be exported.

(e) A current inspection report from an inspection conducted by the regulatory or licensing agency of the jurisdiction in which the applicant is located. The inspection report must reflect compliance with this section. An inspection report is current if the inspection was conducted within 6 months before the date of submitting the application for the initial permit or within 1 year before the date of submitting an application for permit renewal. If the applicant is unable to submit a current inspection report conducted by the regulatory or licensing agency of the jurisdiction in which the applicant is located and from which the prescription drugs will be exported, due to acceptable circumstances, as established by rule, or if an inspection has not been performed, the department must:

1. Conduct, or contract with an entity to conduct, an onsite inspection, with all related costs borne by the applicant;


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2. Accept a current and satisfactory inspection report, as determined by rule, from an entity approved by the board; or

3. Accept a current inspection report from the United States Food and Drug Administration conducted pursuant to the federal Drug Quality and Security Act, Pub. L. No. 113-54.

(5) The department shall adopt rules governing the financial responsibility of the pharmacy permittee. The rules must establish, at a minimum, financial reporting requirements, standards for financial capability to perform the functions governed by the permit, and requirements for ensuring permittees and their contractors can be held accountable for the financial consequences of any act of malfeasance or misfeasance or fraudulent or dishonest act or acts committed by the permittee or its contractors.