



738486

LEGISLATIVE ACTION

Senate

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House

Senator Bean moved the following:

Senate Amendment to Amendment (368506)

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



738486

12 manager, that:

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

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

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

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

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



738486

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

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

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