

AMENDMENTS TO HOUSE BILL NO. 2084

Sponsor: REPRESENTATIVE FRANKEL

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1 Amend Bill, page 1, line 6, by striking out the period after
2 "definitions" and inserting
3 , for license application and for storage, handling and
4 recordkeeping.

5 Amend Bill, page 1, lines 19 and 20; page 2, lines 1 through
6 3; by striking out all of said lines on said pages and inserting
7 "Virtual manufacturer." A person with a place of business
8 located in this Commonwealth in the business of manufacturing
9 and distributing a drug or medical device that:

10 (1) Holds the drug or device approval and label code or
11 is otherwise identified on the product label from the United
12 States Food and Drug Administration.

13 (2) At no time takes physical possession of any drug or
14 device in this Commonwealth.

15 Amend Bill, page 2, line 14, by striking out all of said line
16 and inserting

17 Section 2. Section 5(a) of the act is amended by adding
18 paragraphs and the section is amended by adding a subsection to
19 read:

20 Section 5. License application.

21 (a) Information on application.--An applicant for a license
22 shall provide the following information on a license application
23 form approved by the department:

24 * * *

25 (1.1) Documentation showing compliance with all Federal,
26 State and local business registration requirements.

27 * * *

28 (6.1) A surety bond in accordance with subsection (a.1).

29 * * *

30 (a.1) Bond requirement.--The applicant or owner shall submit
31 a surety bond of \$100,000 to the department with an application.
32 The department may reduce the amount of the surety bond if the
33 annual gross receipts is expected to be under \$10,000,000 at the
34 facility location. The surety bond may not be reduced to less

1 than \$25,000.

2 * * *

3 Section 3. Section 6(a) of the act is amended and the
4 section is amended by adding a subsection to read:

5 Section 6. Storage, handling and recordkeeping.

6 (a) Minimum requirements.--[Licensees] Except as provided
7 under subsection (a.1), licensees and [their] the licensees'
8 officers, agents, representatives and employees shall satisfy
9 the minimum requirements of this section for the storage and
10 handling of prescription drugs and for the establishment and
11 maintenance of prescription drug distribution records.

12 (a.1) Virtual manufacturers.--The following requirements
13 apply to virtual manufacturers:

14 (1) A virtual manufacturer shall be exempt from the
15 minimum requirements under subsections (b), (c), (d), (e),
16 (f) and (j) at the virtual manufacturer's principal place of
17 business listed on an application that was submitted to the
18 department under section 5(a)(1) where no drug or devices are
19 physically stored or handled.

20 (2) A virtual manufacturer shall ensure that the minimum
21 requirements under subsections (b), (c), (d), (e), (f) and
22 (j) are met at any locations or contract facilities where any
23 drug or medical devices are physically stored or handled on
24 the virtual manufacturer's behalf.

25 * * *

26 Section 4. This act shall take effect in 180 days.