



97TH GENERAL ASSEMBLY

State of Illinois

2011 and 2012

HB3882

Introduced 11/10/2011, by Rep. Jack D. Franks

SYNOPSIS AS INTRODUCED:

New Act

Creates the Life-Saving Drug Shortage Prevention Act. Provides that a notification to the Director of Public Health shall be required from a manufacturer of a drug concerning a discontinuance, interruption, or adjustment of the manufacture of a drug that would likely result in a shortage. Provides that the notification shall be required at least 6 months prior to the date of the discontinuance or planned interruption or adjustment, and in the case of any other interruption or adjustment a notification shall be required as soon as possible. Provides that the Director may modify the time frames. Provides that the Director shall implement evidence-based criteria for identifying drugs that may be vulnerable to a shortage, and sets forth certain criteria. Sets forth provisions concerning public notification. Effective immediately.

LRB097 14077 RPM 58737 b

1 AN ACT concerning public health.

2 **Be it enacted by the People of the State of Illinois,**
3 **represented in the General Assembly:**

4 Section 1. Short title. This Act may be cited as the
5 Life-Saving Drug Shortage Prevention Act.

6 Section 5. Purpose. In order to prevent the shortages of
7 drugs in this State, the General Assembly finds that creating a
8 system for notifying the Department of Public Health concerning
9 the discontinuance or interruption of the manufacture of a drug
10 is necessary.

11 Section 10. Definitions. In this Act.

12 "Adjustment", with respect to the notification
13 requirements of this Act, means an adjustment related to the
14 supply or raw materials and active pharmaceutical ingredients,
15 product capabilities, and business decisions that may affect
16 the manufacture of a drug. "Adjustment" includes any other
17 adjustments as determined appropriate by the Director.

18 "Department" means the Department of Public Health.

19 "Director" means the Director of Public Health.

20 "Drug" has the same meaning as defined in the Illinois
21 Food, Drug and Cosmetic Act.

22 "Drug shortage" or "shortage", when used with respect to a

1 drug, means a period of time when the total supply of all
2 versions of a drug available at the user level will not meet
3 the current demand for the drug at that user level.

4 "Notification" means the required reporting of a
5 manufacturer of a drug to the Director of a discontinuance,
6 interruption, or adjustment of the manufacture of a drug that
7 would likely result in a shortage.

8 Section 15. Notifications.

9 (a) A notification to the Director shall be required from a
10 manufacturer of a drug concerning a discontinuance,
11 interruption, or adjustment of the manufacture of a drug that
12 would likely result in a shortage.

13 (b) The notification required under subsection (a) of this
14 Section shall be required at least 6 months prior to the date
15 of the discontinuance or planned interruption or adjustment,
16 and in the case of any other interruption or adjustment a
17 notification shall be required as soon as possible.

18 (c) The Director may modify the time frames depending on
19 the type of interruption or adjustment or any other factor as
20 determined to be appropriate.

21 Section 20. Identification of potential shortages.

22 (a) The Director shall implement evidence-based criteria
23 for identifying drugs that may be vulnerable to a shortage. The
24 criteria shall be based on the following:

- 1 (1) the number of manufacturers of the drug;
- 2 (2) the sources of raw materials and active ingredients
3 for the drug;
- 4 (3) the supply chain characteristics of the drug; and
- 5 (4) the availability of therapeutic alternatives to
6 the drug.
- 7 (b) Using the criteria established in subsection (a) of
8 this Section, the Director shall determine if a drug may be
9 vulnerable to a shortage and notify the manufacturer of the
10 drug of this determination.

11 Section 25. Public notification.

12 (a) The Director shall make available to the public
13 up-to-date notifications of any shortage or adjustments
14 concerning which a notification is required.

15 (b) The information to the public regarding the
16 notifications shall be displayed on the Department's Internet
17 website.

18 (c) Notification information shall be distributed to
19 appropriate health care provider and patient organizations by
20 the Department to the maximum extent practicable.

21 (d) The Director shall honor the privacy of proprietary
22 information submitted in the notifications and exclude such
23 information from the public notification.

24 Section 99. Effective date. This Act takes effect upon
25 becoming law.