



## 98TH GENERAL ASSEMBLY

### State of Illinois

2013 and 2014

**HB0084**

Introduced 1/9/2013, 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.

LRB098 02833 RPM 32842 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.