S T A T E O F N E W Y O R K

9374

I N A S S E M B L Y

February 24, 2012

Introduced by M. of A. BRENNAN, JACOBS, BARRON, CASTRO, GUNTHER, ROSENTHAL, COOK, JAFFEE, LINARES -- Multi-Sponsored by -- M. of A. BOYLAND, HIKIND, McENENY, ROBINSON, STEVENSON, WEISENBERG -- read once and referred to the Committee on Health

AN ACT to amend the public health law, in relation to enacting the "drug shortage notification act of 2012"

THE PEOPLE OF THE STATE OF NEW YORK, REPRESENTED IN SENATE AND ASSEMBLY, DO ENACT AS FOLLOWS:

Section 1. Legislative findings. In order to prevent the shortages of drugs in this state, the legislature finds that creating a system to notify the commissioner of health, pharmacies, hospitals, health care providers and the general public of the discontinuance or interruption of the manufacture of a drug is necessary and consistent with the state's duty to protect the health and welfare of its residents.

S 2. This act shall be known and may be cited as the "drug shortage notification act of 2012".

S 3. The public health law is amended by adding a new section 281 to read as follows:

S 281. DRUG SHORTAGE NOTIFICATION. 1. DEFINITIONS. FOR THE PURPOSES OF THIS SECTION:

A. "AVERAGE HISTORIC DEMAND" MEANS THE PHARMACEUTICAL MANUFACTURER'S AVERAGE MONTHLY VOLUME OF SALES OF THE DRUG DURING THE PRIOR CALENDAR YEAR.

B. "DISCONTINUANCE" MEANS THE PERMANENT TERMINATION OF THE MANUFACTURE OF A PRESCRIPTION DRUG BY A PHARMACEUTICAL MANUFACTURER.

C. "DRUG" OR "PRESCRIPTION DRUG" SHALL HAVE THE SAME MEANING AS SET FORTH IN SECTION TWO HUNDRED SEVENTY OF THIS ARTICLE.

D. "INTERRUPTION" MEANS A CHANGE THAT MAY RESULT IN THE TOTAL SUPPLY OF A DRUG MANUFACTURED BY A PHARMACEUTICAL MANUFACTURER NOT MEETING AVERAGE HISTORIC DEMAND.

E. "PHARMACEUTICAL MANUFACTURER" OR "MANUFACTURER" MEANS ANY PERSON, COMPANY OR CORPORATION THAT COMPOUNDS, MIXES, PREPARES, PRODUCES OR OTHERWISE MANUFACTURES PRESCRIPTION DRUGS.

EXPLANATION--Matter in ITALICS (underscored) is new; matter in brackets [ ] is old law to be omitted.

LBD14329-02-2

F. "PHARMACY" SHALL HAVE THE SAME MEANING AS SET FORTH IN SUBDIVISION ONE OF SECTION SIXTY-EIGHT HUNDRED TWO OF THE EDUCATION LAW.

2. A. A PHARMACEUTICAL MANUFACTURER SHALL PROVIDE NOTICE OF A DISCONTINUANCE OR INTERRUPTION IN THE MANUFACTURE OF A DRUG AT LEAST SIX MONTHS PRIOR TO THE DATE OF SUCH DISCONTINUANCE OR INTERRUPTION.

B. SUCH NOTICE SHALL BE SENT TO THE COMMISSIONER AND TO ANY PHARMACY, HOSPITAL, HEALTH CARE PROVIDER OR OTHER ENTITY AUTHORIZED TO DISPENSE THE DRUG UNDER STATE LAW TO WHICH THE MANUFACTURER SELLS OR DISTRIBUTES SUCH DRUG.

C. IN THE CASE OF AN INTERRUPTION, IF THE MANUFACTURER CANNOT PROVIDE A SIX MONTH ADVANCE NOTICE, THE NOTICE SHALL BE SENT AS SOON AS PRACTICABLE AFTER THE MANUFACTURER: (I) BECOMES AWARE OF SUCH INTERRUPTION OR ADJUSTMENT; OR (II) BECOMES AWARE THAT SUCH INTERRUPTION OR ADJUSTMENT MAY RESULT IN THE TOTAL SUPPLY OF THE DRUG NOT MEETING AVERAGE HISTORIC DEMAND.

3. A. UPON RECEIPT OF THE NOTICE REQUIRED PURSUANT TO SUBDIVISION TWO OF THIS SECTION, THE COMMISSIONER SHALL, WITHIN THREE BUSINESS DAYS, NOTIFY OR CAUSE TO BE NOTIFIED, LOCAL BOARDS OF HEALTH, STATE HOSPITALS, HOMES THAT ARE SUBJECT TO THE JURISDICTION OF THE DEPARTMENT, AND PATIENT ORGANIZATIONS, OF THE DISCONTINUANCE OR INTERRUPTION OF THE DRUG.

B. THE COMMISSIONER SHALL ALSO POST IMMEDIATELY ON THE WEBSITE OF THE DEPARTMENT COMPLETE INFORMATION ON THE DISCONTINUANCE OR INTERRUPTION OF THE DRUG, AND THE AVAILABILITY, IF ANY, OF AN ALTERNATIVE SOURCE OF THE DRUG OR OF A DRUG WITH THE SAME ACTIVE INGREDIENTS.

4. A. ANY MANUFACTURER THAT KNOWINGLY FAILS TO PROVIDE NOTICE IN VIOLATION OF SUBDIVISION TWO OF THIS SECTION SHALL BE SUBJECT TO A CIVIL PENALTY NOT TO EXCEED TEN THOUSAND DOLLARS FOR EACH DAY THAT THE VIOLATION CONTINUES, NOT TO EXCEED ONE MILLION EIGHT HUNDRED THOUSAND DOLLARS.

B. THE COMMISSIONER SHALL PROMULGATE RULES AND REGULATIONS TO IMPLEMENT THE PROVISIONS OF THIS SECTION, INCLUDING ESTABLISHING A SCHEDULE OF CIVIL MONETARY PENALTIES FOR FAILURE TO COMPLY WITH THE NOTIFICATION REQUIREMENTS PURSUANT TO SUBDIVISION TWO OF THIS SECTION.

5. NOTWITHSTANDING ANY OTHER PROVISIONS OF LAW TO THE CONTRARY, THE COMMISSIONER SHALL ENSURE THE CONFIDENTIALITY OF ANY PROPRIETARY INFORMATION SUBMITTED IN A NOTICE UNDER SUBDIVISION TWO OF THIS SECTION.

S 4. Severability. If any clause, sentence, paragraph, section or part of this act shall be adjudged by any court of competent jurisdiction to be invalid, the judgment shall not affect, impair, or invalidate the remainder thereof, but shall be confined in its operation to the clause, sentence, paragraph, section or part thereof directly involved in the controversy in which the judgement shall have been rendered.

S 5. This act shall take effect immediately, provided that section 281 of the public health law, as added by section three of this act, shall survive the repeal of article 2-A of the public health law as provided in subdivision 1 of section 79 of part C of chapter 58 of the laws of 2005, as amended.