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

806

2011-2012 Regular Sessions

I N  A S S E M B L Y

(PREFILED)

January 5, 2011

Introduced by M. of A. GOTTFRIED, GALEF, DINOWITZ, PAULIN, CAHILL, COOK, BRENNAN, ROSENTHAL -- Multi-Sponsored by -- M. of A. BOYLAND, BURLING, COLTON, FARRELL, GABRYSZAK, JAFFEE, LAVINE, MAISEL, McENENY, MILLMAN -- read once and referred to the Committee on Health

AN ACT to amend the public health law, in relation to reducing health risks involved with receipt, handling and distribution of samples of prescription drug products

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

Section 1. The public health law is amended by adding a new article 33-B to read as follows:

ARTICLE 33-B

THE PRESCRIPTION DRUG SAMPLE SAFETY ACT

SECTION 3398. REQUIREMENTS FOR THE SAFE HANDLING OF PRESCRIPTION DRUG SAMPLES.

S 3398. REQUIREMENTS FOR THE SAFE HANDLING OF PRESCRIPTION DRUG SAMPLES. 1. A PERSON AUTHORIZED TO DISPENSE DRUGS PURSUANT TO PARAGRAPH B OF SUBDIVISION ONE OF SECTION SIXTY-EIGHT HUNDRED SEVEN OF THE EDUCATION LAW SHALL ESTABLISH AND ADHERE TO THE FOLLOWING PROCEDURES AND REQUIREMENTS REGARDING THE HANDLING OF SUCH DRUGS:

(A) SAMPLES SHALL BE PROPERLY LOGGED IN (INCLUDING IDENTIFICATION OF THE MANUFACTURER OR ENTITY SUPPLYING OR PROVIDING SUCH SAMPLES, THE DATE, TYPE AND THE AMOUNT OF DRUG RECEIVED AND EXPIRATION DATES, IF ANY), LABELED, STORED, SECURED AND TRACKED TO PREVENT UNAUTHORIZED ACCESS AND LOSS;

(B) PRESCRIBERS SHALL MAINTAIN DOCUMENTATION OF THE DISTRIBUTION OF SAMPLES IN PATIENTS' MEDICAL RECORDS, INCLUDING THE DATE, TYPE, AND AMOUNT DISPENSED, AND OBTAIN THE INFORMED CONSENT OF PATIENTS RECEIVING SAMPLE PRODUCTS;

(C) SAMPLES SHALL BE LABELED WITH APPROPRIATE PRESCRIBING INFORMATION;

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

LBD02603-01-1

(D) PRESCRIBERS SHALL REGULARLY REVIEW SAMPLE EXPIRATION DATES AND REMOVE OUTDATED PRODUCTS;

(E) PRESCRIBERS SHALL MAINTAIN PROPER DOCUMENTATION OF RECIPIENTS OF SAMPLE PRODUCTS FOR PATIENT CONTACT IN THE EVENT OF A RECALL OR LATER-DISCOVERED INTERACTION WARNING; AND

(F) PRESCRIBERS SHALL MAINTAIN A RECORD OF THE DISPOSAL, DESTRUCTION, OR RETURN OF EXPIRED OR RECALLED SAMPLE PRODUCTS.

2. THE COMMISSIONER SHALL PROMULGATE REGULATIONS NECESSARY TO IMPLEMENT AND ENFORCE THIS SECTION.

S 2. This act shall take effect on the one hundred eightieth day after it shall have become a law.