

9881--A

I N A S S E M B L Y

May 27, 2014

Introduced by M. of A. CUSICK -- read once and referred to the Committee on Higher Education -- committee discharged, bill amended, ordered reprinted as amended and recommitted to said committee

AN ACT to amend the public health law, in relation to the use of abuse-deterrent technology for opioids as a mechanism for reducing abuse and diversion of opioid drugs

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

1 Section 1. The public health law is amended by adding a new section
2 3340 to read as follows:
3 S 3340. SUBSTITUTION OF OPIOIDS WITH ABUSE-DETERRENT TECHNOLOGY. 1.
4 NOTWITHSTANDING THE PROVISIONS OF SECTION SIXTY-EIGHT HUNDRED SIXTEEN-A
5 OF THE EDUCATION LAW, NO PHARMACIST SHALL INTERCHANGE OR SUBSTITUTE AN
6 OPIOID DRUG, BRAND OR GENERIC, OTHERWISE ELIGIBLE FOR SUCH INTERCHANGE
7 OR SUBSTITUTION UNDER SUCH SECTION FOR AN OPIOID DRUG INCORPORATING
8 ABUSE-DETERRENT TECHNOLOGY WITHOUT:
9 (A) VERIFYING THAT THE DRUG TO BE SUBSTITUTED IS AN OPIOID DRUG INCOR-
10 PORATING ABUSE-DETERRENT TECHNOLOGY WITH THE SAME DEGREE (TIER) OF
11 FEDERAL FOOD AND DRUG ADMINISTRATION APPROVED LABELING CLAIM RELATED TO
12 ABUSE DETERRENCE AS THE PRESCRIBED OPIOID DRUG; OR
13 (B) OBTAINING WRITTEN, SIGNED CONSENT FROM THE PRESCRIBING PHYSICIAN
14 FOR SUCH INTERCHANGE OR SUBSTITUTION.
15 2. A PRESCRIPTION SHALL NOT BE ISSUED OR FILLED FOR ANY OPIOID DRUG
16 THAT IS FORMULATED AS A NON-ABUSE DETERRENT OPIOID DRUG, UNLESS AN
17 OPIOID DRUG INCORPORATING ABUSE-DETERRENT TECHNOLOGY IS NOT AVAILABLE AS
18 A SUBSTITUTE FOR THE INDICATED DRUG OR SUBSTANCE.
19 3. DEFINITIONS. AS USED IN THIS SECTION:
20 (A) "OPIOID DRUG" MEANS A DRUG IN THE OPIOID DRUG CLASS PRESCRIBED TO
21 TREAT MODERATE TO SEVERE PAIN OR OTHER CONDITIONS, WHETHER IN IMMEDIATE
22 RELEASE OR EXTENDED RELEASE FORM AND WHETHER OR NOT COMBINED WITH OTHER
23 DRUG SUBSTANCES TO FORM A SINGLE TABLET OR OTHER DOSAGE FORM.
24 (B) "OPIOID DRUG INCORPORATING ABUSE-DETERRENT TECHNOLOGY" MEANS AN
25 OPIOID DRUG APPROVED AS SUCH BY THE FEDERAL FOOD AND DRUG ADMINISTRATION
26 WITH LABELING CLAIMS RELATED TO ABUSE-DETERRENCE BASED UPON AN APPLICA-

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

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1 TION THAT INCLUDES LABORATORY, PHARMACOKINETIC, CLINICAL ABUSE POTEN-
2 TIAL, AND/OR POST MARKETING STUDIES.

3 (C) "INTERCHANGE OR SUBSTITUTION OF AN OPIOID DRUG" MEANS THE SUBSTI-
4 TUTION OF ANY OPIOID DRUG, BRAND OR GENERIC, FOR THE OPIOID DRUG INCOR-
5 PORATING AN ABUSE-DETERRENT TECHNOLOGY ORIGINALLY PRESCRIBED, AS DETER-
6 MINED TO BE PHARMACEUTICALLY AND THERAPEUTICALLY EQUIVALENT BY THE
7 FEDERAL FOOD AND DRUG ADMINISTRATION OR STATE BOARD OF PHARMACY TO THE
8 PRESCRIBED DRUG. ANY SUBSTITUTABLE OPIOID DRUG SHALL CONTAIN THE SAME
9 OPIOID ACTIVE PHARMACEUTICAL INGREDIENT AND THE SAME DRUG RELEASE CHAR-
10 ACTERISTICS WITH REGARD TO IMMEDIATE RELEASE, OR EXTENDED
11 RELEASE/LONG-ACTING PROPERTIES.

12 (D) "PHARMACIST" INCLUDES ANY PHARMACIST DISPENSING DRUGS UNDER THE
13 JURISDICTION OF THE STATE BOARD OF PHARMACY, INCLUDING BUT NOT LIMITED
14 TO, COMMUNITY PHARMACISTS, PHARMACISTS IN HOSPITAL-BASED PHARMACIES WHEN
15 FILLING PRESCRIPTIONS FOR INPATIENT OR OUTPATIENT CARE, AND PHARMACISTS
16 IN MAIL ORDER PHARMACIES LICENSED BY THE STATE TO DISTRIBUTE IN THE
17 STATE.

18 (E) "ABUSE-DETERRENT TECHNOLOGY OR FORMULATION" MEANS THE FRAMEWORK OF
19 ABUSE-DETERRENT PROPERTIES, AS DESCRIBED BY THE FEDERAL FOOD AND DRUG
20 ADMINISTRATION.

21 (F) "LABELING CLAIMS FOR OPIOID DRUGS INCORPORATING ABUSE-DETERRENT
22 TECHNOLOGIES" MEANS THE FOUR GENERAL TIERS OR CLAIMS AVAILABLE TO
23 DESCRIBE THE POTENTIAL ABUSE DETERRENT PROPERTIES FOR A DRUG, AS
24 DESCRIBED BY THE FEDERAL FOOD AND DRUG ADMINISTRATION.

25 S 2. This act shall take effect immediately.