

7125

I N S E N A T E

April 30, 2014

Introduced by Sen. HANNON -- read twice and ordered printed, and when printed to be committed to the Committee on Health

AN ACT to amend the public health law, in relation to the use of abuse-deterrent technology for analgesic 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 ANALGESIC DRUG, BRAND OR GENERIC, OTHERWISE ELIGIBLE FOR SUCH
7 INTERCHANGE OR SUBSTITUTION UNDER SUCH SECTION FOR AN OPIOID ANALGESIC
8 DRUG INCORPORATING ABUSE-DETERRENT TECHNOLOGY WITHOUT:
9 (A) VERIFYING THAT THE DRUG TO BE SUBSTITUTED IS AN OPIOID ANALGESIC
10 DRUG INCORPORATING ABUSE-DETERRENT TECHNOLOGY WITH THE SAME DEGREE
11 (TIER) OF FEDERAL FOOD AND DRUG ADMINISTRATION APPROVED LABELING CLAIM
12 RELATED TO ABUSE DETERRENCE AS THE PRESCRIBED OPIOID ANALGESIC 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 ANAL-
16 GESIC DRUG THAT IS FORMULATED AS A NON-ABUSE DETERRENT OPIOID DRUG,
17 UNLESS AN OPIOID ANALGESIC DRUG INCORPORATING ABUSE-DETERRENT TECHNOLOGY
18 IS NOT AVAILABLE AS A SUBSTITUTE FOR THE INDICATED DRUG OR SUBSTANCE.
19 3. DEFINITIONS. AS USED IN THIS SECTION:
20 (A) "OPIOID ANALGESIC DRUG" MEANS A DRUG IN THE OPIOID ANALGESIC DRUG
21 CLASS PRESCRIBED TO TREAT MODERATE TO SEVERE PAIN OR OTHER CONDITIONS,
22 WHETHER IN IMMEDIATE RELEASE OR EXTENDED RELEASE FORM AND WHETHER OR NOT
23 COMBINED WITH OTHER DRUG SUBSTANCES TO FORM A SINGLE TABLET OR OTHER
24 DOSAGE FORM.
25 (B) "OPIOID ANALGESIC DRUG INCORPORATING ABUSE-DETERRENT TECHNOLOGY"
26 MEANS AN OPIOID ANALGESIC DRUG APPROVED AS SUCH BY THE FEDERAL FOOD AND
27 DRUG ADMINISTRATION WITH LABELING CLAIMS RELATED TO ABUSE-DETERRENCE

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

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1 BASED UPON AN APPLICATION THAT INCLUDES LABORATORY, PHARMACOKINETIC,
2 CLINICAL ABUSE POTENTIAL, AND/OR POST MARKETING STUDIES.

3 (C) "INTERCHANGE OR SUBSTITUTION OF AN OPIOID ANALGESIC DRUG" MEANS
4 THE SUBSTITUTION OF ANY OPIOID ANALGESIC DRUG, BRAND OR GENERIC, FOR THE
5 OPIOID ANALGESIC DRUG INCORPORATING AN ABUSE-DETERRENT TECHNOLOGY
6 ORIGINALLY PRESCRIBED, AS DETERMINED TO BE PHARMACEUTICALLY AND THERA-
7 PEUTICALLY EQUIVALENT BY THE FEDERAL FOOD AND DRUG ADMINISTRATION OR
8 STATE BOARD OF PHARMACY TO THE PRESCRIBED DRUG. ANY SUBSTITUTABLE OPIOID
9 ANALGESIC DRUG SHALL CONTAIN THE SAME OPIOID ACTIVE PHARMACEUTICAL
10 INGREDIENT AND THE SAME DRUG RELEASE CHARACTERISTICS WITH REGARD TO
11 IMMEDIATE RELEASE, OR EXTENDED 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 ANALGESIC DRUGS INCORPORATING
22 ABUSE-DETERRENT TECHNOLOGIES" MEANS THE FOUR GENERAL TIERS OR CLAIMS
23 AVAILABLE TO DESCRIBE THE POTENTIAL ABUSE DETERRENT PROPERTIES FOR A
24 DRUG, AS DESCRIBED BY THE FEDERAL FOOD AND DRUG ADMINISTRATION.

25 S 2. This act shall take effect immediately.