

6062

I N S E N A T E

(PREFILED)

January 4, 2012

Introduced by Sens. MARTINS, 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 prohibiting the
substitution of opioid analgesic drugs for an opioid analgesic drug
incorporating tamper resistance technology

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

1 Section 1. The public health law is amended by adding a new section
2 3346 to read as follows:
3 S 3346. CERTAIN OPIOID SUBSTITUTIONS PROHIBITED. 1. DEFINITIONS. A.
4 "INTERCHANGE OR SUBSTITUTION OF AN OPIOID ANALGESIC DRUG" MEANS THE
5 SUBSTITUTION OF ANY OPIOID ANALGESIC DRUG, BRAND OR GENERIC, FOR THE
6 OPIOID ANALGESIC DRUG INCORPORATING A TAMPER-RESISTANCE TECHNOLOGY
7 ORIGINALLY PRESCRIBED, IRRESPECTIVE OF WHETHER THE SUBSTITUTED DRUG IS
8 RATED AS PHARMACEUTICALLY AND THERAPEUTICALLY EQUIVALENT BY THE U.S.
9 FOOD AND DRUG ADMINISTRATION OR STATE BOARD OF PHARMACY OR WHETHER THE
10 OPIOID ANALGESIC DRUG WITH TAMPER-RESISTANCE TECHNOLOGY BEARS A LABELING
11 CLAIM WITH RESPECT TO REDUCTION OF TAMPERING, ABUSE OR ABUSE POTENTIAL.
12 B. "OPIOID ANALGESIC DRUG" MEANS A DRUG IN THE OPIOID ANALGESIC DRUG
13 CLASS PRESCRIBED TO TREAT MODERATE TO SEVERE PAIN OR OTHER CONDITIONS,
14 WHETHER IN IMMEDIATE RELEASE OR EXTENDED RELEASE FORM AND WHETHER OR NOT
15 COMBINED WITH OTHER DRUG SUBSTANCES TO FORM A SINGLE TABLET OR OTHER
16 DOSAGE FORM.
17 C. "OPIOID ANALGESIC DRUG INCORPORATING A TAMPER-RESISTANCE TECHNOLO-
18 GY" MEANS AN OPIOID ANALGESIC DRUG LISTED AS SUCH BY THE STATE BOARD OF
19 PHARMACY BASED UPON A SUBMISSION OF EVIDENCE BY THE DRUG MANUFACTURER OR
20 DISTRIBUTOR THAT THE DRUG: (I) INCORPORATES A TAMPER-RESISTANCE TECHNOL-
21 OGY; AND (II) HAS BEEN APPROVED BY THE U.S. FOOD AND DRUG ADMINISTRATION
22 PURSUANT TO AN APPLICATION THAT INCLUDES AT LEAST ONE HUMAN TAMPERING OR
23 ABUSE POTENTIAL STUDY OR A LABORATORY STUDY COMPARING THE TAMPER- OR
24 ABUSE-RESISTANCE PROPERTIES OF THE DRUG TO ONE OR MORE OPIOID ANALGESIC
25 DRUGS THAT (A) HAVE BEEN APPROVED BY THE U.S. FOOD AND DRUG ADMINIS-
26 TRATION; AND (B) SERVE AS A POSITIVE CONTROL.

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

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1 D. "PHARMACIST" FOR PURPOSES OF THIS SECTION INCLUDES ANY PHARMACIST
2 DISPENSING DRUGS UNDER THE JURISDICTION OF THE STATE BOARD OF PHARMACY,
3 INCLUDING BUT NOT LIMITED TO, COMMUNITY PHARMACISTS, PHARMACISTS IN
4 HOSPITAL-BASED PHARMACIES WHEN FILLING PRESCRIPTIONS FOR INPATIENT OR
5 OUTPATIENT CARE, AND PHARMACISTS IN MAIL ORDER PHARMACIES LICENSED BY
6 THE STATE TO DISTRIBUTE IN THE STATE.

7 2. LIST OF OPIOID ANALGESIC DRUGS INCORPORATING A TAMPER-RESISTANCE
8 TECHNOLOGY. THE STATE BOARD OF PHARMACY SHALL CREATE A LIST OF OPIOID
9 ANALGESIC DRUGS FOR WHICH INFORMATION HAS BEEN SUBMITTED CONSISTENT WITH
10 PARAGRAPH C OF SUBDIVISION ONE OF THIS SECTION. INCLUSION OF A DRUG ON
11 SUCH LIST SHALL NOT REQUIRE THAT A DRUG BEAR A LABELING CLAIM WITH
12 RESPECT TO REDUCTION OF TAMPERING, ABUSE OR ABUSE POTENTIAL AT THE TIME
13 OF LISTING. SUCH LIST SHALL ALSO INCLUDE A DETERMINATION BY THE BOARD AS
14 TO WHICH LISTED OPIOID ANALGESIC DRUGS INCORPORATING TAMPER-RESISTANCE
15 TECHNOLOGIES PROVIDE SUBSTANTIALLY SIMILAR TAMPER-RESISTANCE PROPERTIES,
16 BASED SOLELY UPON STUDIES SUBMITTED BY THE DRUG MANUFACTURER CONSISTENT
17 WITH PARAGRAPH C OF SUBDIVISION ONE OF THIS SECTION.

18 3. PROHIBITION. NOTWITHSTANDING THE PROVISIONS OF SECTION SIXTY-EIGHT
19 HUNDRED SIXTEEN-A OF THE EDUCATION LAW, NO PHARMACIST SHALL INTERCHANGE
20 OR SUBSTITUTE AN OPIOID ANALGESIC DRUG, BRAND OR GENERIC, OTHERWISE
21 ELIGIBLE FOR SUCH INTERCHANGE OR SUBSTITUTION UNDER SECTION SIXTY-EIGHT
22 HUNDRED SIXTEEN-A OF THE EDUCATION LAW FOR AN OPIOID ANALGESIC DRUG
23 INCORPORATING A TAMPER-RESISTANCE TECHNOLOGY THAT IS LISTED PURSUANT TO
24 SUBDIVISION TWO OF THIS SECTION WITHOUT:

25 A. VERIFYING THAT THE OPIOID ANALGESIC DRUG HAS BEEN LISTED BY THE
26 STATE BOARD OF PHARMACY: UNDER SUBDIVISION TWO OF THIS SECTION AS
27 PROVIDING TAMPER-RESISTANCE PROPERTIES SUBSTANTIALLY SIMILAR TO THE
28 PRESCRIBED OPIOID ANALGESIC DRUG INCORPORATING A TAMPER-RESISTANCE TECH-
29 NOLOGY; OR

30 B. OBTAINING WRITTEN, SIGNED CONSENT FROM THE PRESCRIBING PHYSICIAN
31 FOR SUCH INTERCHANGE OR SUBSTITUTION.

32 S 2. This act shall take effect immediately.