

7427--A

2015-2016 Regular Sessions

I N A S S E M B L Y

May 12, 2015

Introduced by M. of A. CUSICK, SIMANOWITZ, BRINDISI -- Multi-Sponsored
by -- M. of A. LUPARDO -- 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 and the insurance 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 ASSEM-
BLY, 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 ABUSE-DETERRENT OPIOID ANALGESIC DRUG PRODUCT, BRAND OR GENERIC, WITH AN
7 OPIOID ANALGESIC DRUG PRODUCT LACKING ABUSE-DETERRENT PROPERTIES WHEN
8 THE PRESCRIBER WRITES OR ELECTRONICALLY NOTATES "DISPENSE AS WRITTEN" OR
9 "DAW" ON THE PRESCRIPTION, WITHOUT OBTAINING A NEW PRESCRIPTION FOR A
10 NON-ABUSE DETERRENT OPIOID DRUG FROM THE PRESCRIBER. ANY SUBSTITUTABLE
11 OPIOID DRUG PRODUCT SHALL CONTAIN THE SAME OPIOID ACTIVE PHARMACEUTICAL
12 INGREDIENT AND THE SAME DRUG RELEASE CHARACTERISTICS WITH REGARD TO
13 IMMEDIATE RELEASE, OR EXTENDED RELEASE LONG ACTING PROPERTIES. A DETER-
14 MINATION OF INTERCHANGEABILITY BETWEEN TWO ABUSE-DETERRENT OPIOID ANAL-
15 GESIC DRUG PRODUCTS SHALL NOT REQUIRE THAT BOTH PRODUCTS INCORPORATE THE
16 SAME METHODS OF ABUSE-DETERRENCE, BUT THAT THE OPIOID DRUG PRODUCTS HAVE
17 THE SAME LEVEL OF FDA-APPROVED ABUSE DETERRENCE LABELING CLAIMS.
18 2. DEFINITIONS. AS USED IN THIS SECTION:
19 (A) "OPIOID ANALGESIC DRUG PRODUCT" MEANS A DRUG IN THE OPIOID ANAL-
20 GESIC DRUG CLASS PRESCRIBED TO TREAT MODERATE TO SEVERE PAIN OR OTHER
21 CONDITIONS, WHETHER IN IMMEDIATE RELEASE OR EXTENDED RELEASE LONG ACTING

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

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1 FORM AND WHETHER OR NOT COMBINED WITH OTHER DRUG SUBSTANCES TO FORM A
2 SINGLE DRUG PRODUCT OR OTHER DOSAGE FORM.

3 (B) "ABUSE-DETERRENT OPIOID ANALGESIC DRUG PRODUCT" MEANS A BRAND OR
4 GENERIC OPIOID ANALGESIC DRUG PRODUCT APPROVED BY THE FEDERAL FOOD AND
5 DRUG ADMINISTRATION WITH ABUSE-DETERRENCE LABELING CLAIMS INDICATING ITS
6 ABUSE-DETERRENT PROPERTIES ARE EXPECTED TO DETER OR REDUCE ITS ABUSE.

7 (C) "INTERCHANGE OR SUBSTITUTION OF AN OPIOID DRUG" MEANS THE SUBSTI-
8 TUTION OF ANY ABUSE-DETERRENT OPIOID DRUG PRODUCT, BRAND OR GENERIC,
9 WITH AN OPIOID ANALGESIC DRUG LACKING ABUSE-DETERRENT PROPERTIES.

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

16 S 2. The insurance law is amended by adding a new section 3216-a to
17 read as follows:

18 S 3216-A. ACCESS TO ABUSE-DETERRENT OPIOID MEDICATIONS. (A) AN INSUR-
19 ANCE CARRIER OR HEALTH PLAN SHALL PROVIDE COVERAGE ON ITS FORMULARY,
20 DRUG LIST OR OTHER LISTS OF SIMILAR CONSTRUCT FOR AT LEAST ONE
21 ABUSE-DETERRENT OPIOID ANALGESIC DRUG PRODUCT PER OPIOID ANALGESIC
22 ACTIVE INGREDIENT.

23 (1) COST-SHARING FOR BRAND NAME ABUSE-DETERRENT OPIOID ANALGESIC DRUG
24 PRODUCTS COVERED PURSUANT TO THIS SECTION SHALL NOT EXCEED THE LOWEST
25 COST-SHARING LEVEL APPLIED TO BRAND NAME NON-ABUSE DETERRENT OPIOID
26 DRUGS COVERED UNDER THE APPLICABLE HEALTH PLAN OR POLICY.

27 (2) COST-SHARING FOR GENERIC ABUSE-DETERRENT OPIOID ANALGESIC DRUG
28 PRODUCTS COVERED PURSUANT TO THIS SECTION SHALL NOT EXCEED THE LOWEST
29 COST-SHARING LEVEL APPLIED TO GENERIC NON-ABUSE DETERRENT OPIOID DRUGS
30 COVERED UNDER THE APPLICABLE HEALTH PLAN OR POLICY.

31 (3) AN INCREASE IN PATIENT COST-SHARING OR DISINCENTIVES FOR PRESCRI-
32 BERS OR DISPENSERS SHALL NOT BE ALLOWED TO ACHIEVE COMPLIANCE WITH THIS
33 SECTION.

34 (B) ANY PRIOR-AUTHORIZATION REQUIREMENTS OR OTHER UTILIZATION REVIEW
35 MEASURES FOR OPIOID ANALGESICS, AND ANY SERVICE DENIALS MADE PURSUANT
36 THERETO, SHALL NOT REQUIRE USE OF OPIOID ANALGESIC DRUG PRODUCTS WITHOUT
37 ABUSE-DETERRENT PROPERTIES IN ORDER TO ACCESS ABUSE-DETERRENT OPIOID
38 ANALGESIC DRUG PRODUCTS.

39 (C) DEFINITIONS. AS USED IN THIS SECTION:

40 (1) "OPIOID ANALGESIC DRUG PRODUCT" MEANS A DRUG IN THE OPIOID ANAL-
41 GESIC DRUG CLASS PRESCRIBED TO TREAT MODERATE TO SEVERE PAIN OR OTHER
42 CONDITIONS, WHETHER IN IMMEDIATE RELEASE OR EXTENDED LONG ACTING RELEASE
43 FORM AND WHETHER OR NOT COMBINED WITH OTHER DRUG SUBSTANCES TO FORM A
44 SINGLE DRUG PRODUCT OR OTHER DOSAGE FORM.

45 (2) "ABUSE DETERRENT OPIOID ANALGESIC DRUG PRODUCT" MEANS A BRAND OR
46 GENERIC OPIOID ANALGESIC DRUG PRODUCT APPROVED BY THE FEDERAL FOOD AND
47 DRUG ADMINISTRATION WITH ABUSE-DETERRENCE LABELING CLAIMS INDICATING ITS
48 ABUSE-DETERRENT PROPERTIES ARE EXPECTED TO DETER OR REDUCE ITS ABUSE.

49 (3) "COST-SHARING" MEANS ANY COVERAGE LIMIT, COPAYMENT, COINSURANCE,
50 DEDUCTIBLE OR OTHER OUT-OF-POCKET PATIENT EXPENSE REQUIREMENTS.

51 S 3. This act shall take effect on the one hundred twentieth day after
52 it shall have become a law, and shall apply to all policies and
53 contracts issued, renewed, modified, altered or amended on or after such
54 date.