

9487

I N A S S E M B L Y

March 10, 2016

Introduced by M. of A. CUSICK, SIMANOWITZ, BRINDISI, PEOPLES-STOKES --
Multi-Sponsored by -- M. of A. LUPARDO -- read once and referred to
the Committee on Health

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 (A) NOTWITHSTANDING THE PROVISIONS OF SECTION SIXTY-EIGHT HUNDRED
5 SIXTEEN-A OF THE EDUCATION LAW, NO PHARMACIST SHALL INTERCHANGE OR
6 SUBSTITUTE AN ABUSE-DETERRENT OPIOID ANALGESIC DRUG PRODUCT, BRAND OR
7 GENERIC, WITH AN OPIOID ANALGESIC DRUG PRODUCT LACKING ABUSE-DETERRENT
8 PROPERTIES WHEN THE PRESCRIBER WRITES OR ELECTRONICALLY NOTATES
9 "DISPENSE AS WRITTEN" OR "DAW" ON THE PRESCRIPTION, WITHOUT OBTAINING A
10 NEW PRESCRIPTION FOR A NON-ABUSE DETERRENT OPIOID DRUG FROM THE PRESCRI-
11 BER. ANY SUBSTITUTABLE OPIOID DRUG PRODUCT SHALL CONTAIN THE SAME OPIOID
12 ACTIVE PHARMACEUTICAL INGREDIENT AND THE SAME DRUG RELEASE CHARACTER-
13 ISTICS WITH REGARD TO IMMEDIATE RELEASE, OR EXTENDED RELEASE LONG ACTING
14 PROPERTIES. A DETERMINATION OF INTERCHANGEABILITY BETWEEN TWO ABUSE-DET-
15 ERRENT OPIOID ANALGESIC DRUG PRODUCTS SHALL NOT REQUIRE THAT BOTH
16 PRODUCTS INCORPORATE THE SAME METHODS OF ABUSE-DETERRENCE, BUT THAT THE
17 OPIOID DRUG PRODUCTS HAVE THE SAME LEVEL OF FDA-APPROVED ABUSE DETER-
18 RENCE LABELING CLAIMS.
19 (B) THE REQUIREMENTS OF PARAGRAPH (A) OF THIS SECTION SHALL NOT APPLY
20 TO A PHARMACIST DISPENSING MEDICATION IN THE INPATIENT HOSPITAL SETTING
21 WHEN THE PRESCRIBED MEDICATION WILL BE ADMINISTERED TO THE PATIENT BY AN
22 EMPLOYEE OF THE HOSPITAL.
23 2. DEFINITIONS. AS USED IN THIS SECTION:
24 (A) "OPIOID ANALGESIC DRUG PRODUCT" MEANS A DRUG IN THE OPIOID ANAL-
25 GESIC DRUG CLASS PRESCRIBED TO TREAT MODERATE TO SEVERE PAIN OR OTHER
26 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 AND PHARMACISTS IN MAIL ORDER PHARMACIES
13 LICENSED BY THE STATE TO DISTRIBUTE IN THE STATE.

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

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

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

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

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

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

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

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

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

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

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