

7427

2015-2016 Regular Sessions

I N A S S E M B L Y

May 12, 2015

Introduced by M. of A. CUSICK -- read once and referred to the Committee
on Higher Education

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 WITHOUT
8 OBTAINING A NEW PRESCRIPTION FOR A NON-ABUSE DETERRENT OPIOID DRUG FROM
9 THE PRESCRIBER. ANY SUBSTITUTABLE OPIOID DRUG PRODUCT SHALL CONTAIN THE
10 SAME OPIOID ACTIVE PHARMACEUTICAL INGREDIENT AND THE SAME DRUG RELEASE
11 CHARACTERISTICS WITH REGARD TO IMMEDIATE RELEASE, OR EXTENDED RELEASE
12 LONG ACTING PROPERTIES. A DETERMINATION OF INTERCHANGEABILITY BETWEEN
13 TWO ABUSE-DETERRENT OPIOID ANALGESIC DRUG PRODUCTS SHALL NOT REQUIRE
14 THAT BOTH PRODUCTS INCORPORATE THE SAME METHODS OF ABUSE-DETERRENCE, BUT
15 THAT THE OPIOID DRUG PRODUCTS HAVE THE SAME LEVEL OF FDA-APPROVED ABUSE
16 DETERRENCE LABELING CLAIMS.
17 2. DEFINITIONS. AS USED IN THIS SECTION:
18 (A) "OPIOID ANALGESIC DRUG PRODUCT" MEANS A DRUG IN THE OPIOID ANAL-
19 GESIC DRUG CLASS PRESCRIBED TO TREAT MODERATE TO SEVERE PAIN OR OTHER
20 CONDITIONS, WHETHER IN IMMEDIATE RELEASE OR EXTENDED RELEASE LONG ACTING
21 FORM AND WHETHER OR NOT COMBINED WITH OTHER DRUG SUBSTANCES TO FORM A
22 SINGLE DRUG PRODUCT OR OTHER DOSAGE FORM.
23 (B) "ABUSE-DETERRENT OPIOID ANALGESIC DRUG PRODUCT" MEANS A BRAND OR
24 GENERIC OPIOID ANALGESIC DRUG PRODUCT APPROVED BY THE FEDERAL FOOD AND

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

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1 DRUG ADMINISTRATION WITH ABUSE-DETERRENCE LABELING CLAIMS INDICATING ITS
2 ABUSE-DETERRENT PROPERTIES ARE EXPECTED TO DETER OR REDUCE ITS ABUSE.

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

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

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

14 S 3216-A. ACCESS TO ABUSE-DETERRENT OPIOID MEDICATIONS. (A) AN INSUR-
15 ANCE CARRIER OR HEALTH PLAN SHALL PROVIDE COVERAGE FOR ALL ABUSE-DETER-
16 RENT OPIOID ANALGESIC DRUG PRODUCTS AS PREFERRED DRUGS ON THEIR FORMU-
17 LARY, PREFERRED DRUG LIST OR OTHER LISTS OF SIMILAR CONSTRUCT.

18 (1) COST-SHARING FOR ABUSE-DETERRENT OPIOID ANALGESIC DRUG PRODUCTS
19 SHALL NOT EXCEED THE LOWEST COST-SHARING LEVEL APPLIED TO PRESCRIPTION
20 DRUGS.

21 (2) AN INCREASE IN PATIENT COST-SHARING OR DISINCENTIVES FOR PRESCRI-
22 BERS OR DISPENSERS SHALL NOT BE ALLOWED TO ACHIEVE COMPLIANCE WITH THIS
23 SECTION.

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

29 (C) THIS SECTION SHALL NOT BE CONSTRUED TO PREVENT AN INSURER OR
30 HEALTH PLAN FROM APPLYING PRIOR-AUTHORIZATION REQUIREMENTS TO ABUSE-DET-
31 ERRENT OPIOID ANALGESIC DRUG PRODUCTS, PROVIDED THAT SUCH REQUIREMENTS
32 ARE APPLIED TO NON-ABUSE-DETERRENT VERSIONS OF THAT OPIOID.

33 (D) DEFINITIONS. AS USED IN THIS SECTION:

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

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

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

45 S 3. This act shall take effect immediately, and shall apply to all
46 policies and contracts issued, renewed, modified, altered or amended on
47 or after such date.