S T A T E O F N E W Y O R K

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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 ASSEMBLY, DO ENACT AS FOLLOWS:

Section 1. The public health law is amended by adding a new section 3340 to read as follows:

S 3340. SUBSTITUTION OF OPIOIDS WITH ABUSE-DETERRENT TECHNOLOGY. 1. (A) NOTWITHSTANDING THE PROVISIONS OF SECTION SIXTY-EIGHT HUNDRED SIXTEEN-A OF THE EDUCATION LAW, NO PHARMACIST SHALL INTERCHANGE OR SUBSTITUTE AN ABUSE-DETERRENT OPIOID ANALGESIC DRUG PRODUCT, BRAND OR GENERIC, WITH AN OPIOID ANALGESIC DRUG PRODUCT LACKING ABUSE-DETERRENT PROPERTIES WHEN THE PRESCRIBER WRITES OR ELECTRONICALLY NOTATES "DISPENSE AS WRITTEN" OR "DAW" ON THE PRESCRIPTION, WITHOUT OBTAINING A NEW PRESCRIPTION FOR A NON-ABUSE DETERRENT OPIOID DRUG FROM THE PRESCRIBER. ANY SUBSTITUTABLE OPIOID DRUG PRODUCT SHALL CONTAIN THE SAME OPIOID ACTIVE PHARMACEUTICAL INGREDIENT AND THE SAME DRUG RELEASE CHARACTERISTICS WITH REGARD TO IMMEDIATE RELEASE, OR EXTENDED RELEASE LONG ACTING PROPERTIES. A DETERMINATION OF INTERCHANGEABILITY BETWEEN TWO ABUSE-DETERRENT OPIOID ANALGESIC DRUG PRODUCTS SHALL NOT REQUIRE THAT BOTH PRODUCTS INCORPORATE THE SAME METHODS OF ABUSE-DETERRENCE, BUT THAT THE OPIOID DRUG PRODUCTS HAVE THE SAME LEVEL OF FDA-APPROVED ABUSE DETERRENCE LABELING CLAIMS.

(B) THE REQUIREMENTS OF PARAGRAPH (A) OF THIS SECTION SHALL NOT APPLY TO A PHARMACIST DISPENSING MEDICATION IN THE INPATIENT HOSPITAL SETTING WHEN THE PRESCRIBED MEDICATION WILL BE ADMINISTERED TO THE PATIENT BY AN EMPLOYEE OF THE HOSPITAL.

2. DEFINITIONS. AS USED IN THIS SECTION:

(A) "OPIOID ANALGESIC DRUG PRODUCT" MEANS A DRUG IN THE OPIOID ANALGESIC DRUG CLASS PRESCRIBED TO TREAT MODERATE TO SEVERE PAIN OR OTHER 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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FORM AND WHETHER OR NOT COMBINED WITH OTHER DRUG SUBSTANCES TO FORM A SINGLE DRUG PRODUCT OR OTHER DOSAGE FORM.

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

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

(D) "PHARMACIST" INCLUDES ANY PHARMACIST DISPENSING DRUGS UNDER THE JURISDICTION OF THE STATE BOARD OF PHARMACY, INCLUDING BUT NOT LIMITED TO, COMMUNITY PHARMACISTS AND PHARMACISTS IN MAIL ORDER PHARMACIES LICENSED BY THE STATE TO DISTRIBUTE IN THE STATE.

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

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

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

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

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

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

(C) DEFINITIONS. AS USED IN THIS SECTION:

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

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

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

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