Chapter 372

(Senate Bill 606)

AN ACT concerning

Health Insurance – Abuse–Deterrent Opioid Analgesic Drug Products – Coverage

FOR the purpose of requiring certain insurers, nonprofit health service plans, and health maintenance organizations to provide certain coverage for a certain minimum number of brand name abuse-deterrent opioid analgesic drug products and, if available, a certain minimum number of generic abuse-deterrent opioid analgesic drug products; prohibiting the insurers, nonprofit health service plans, and health maintenance organizations from imposing certain limits or cost-sharing requirements on coverage for abuse-deterrent opioid analgesic drug products that are less favorable to an insured or an enrollee than the limits or cost-sharing requirements that apply to coverage for any other opioid analgesic drug product; prohibiting the insurers, nonprofit health service plans, and health maintenance organizations from requiring an insured or an enrollee to first use a certain drug product before providing coverage for an a certain abuse-deterrent opioid analgesic drug product; prohibiting the insurers, nonprofit health service plans, and health maintenance organizations from increasing certain cost-sharing requirements or other out-of-pocket expenses to achieve certain compliance; authorizing the insurers, nonprofit health service plans, and health maintenance organizations to undertake utilization review for an abuse-deterrent opioid analgesic drug product under certain circumstances; defining certain terms; providing for the application of this Act; providing for a delayed effective date; and generally relating to health insurance coverage for abuse-deterrent opioid analgesic drug products.

BY adding to

Article – Insurance Section 15–848 Annotated Code of Maryland (2011 Replacement Volume and 2014 Supplement)

Preamble

WHEREAS, Prescription opioid analgesics are an important treatment option for individuals with severe pain, such as those who have experienced catastrophic or acute injuries, often allowing some to resume their daily activities; and

WHEREAS, Some individuals, however, have abused and misused opioid analgesics, creating urgent and growing public health concerns; and

WHEREAS, The U.S. Food and Drug Administration recognizes and considers the development of opioids that are formulated to deter abuse a high public health priority; and

WHEREAS, Maryland recognizes the need to eliminate barriers to abuse-deterrent formulations as an important step in reducing abuse of opiates while ensuring that these medicines remain available to those who need them for legitimate medical purposes; now, therefore,

SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND, That the Laws of Maryland read as follows:

Article – Insurance

15-848.

(A) (1) IN THIS SECTION THE FOLLOWING WORDS HAVE THE MEANINGS INDICATED.

(2) "ABUSE-DETERRENT OPIOID ANALGESIC DRUG PRODUCT" MEANS A BRAND NAME OR GENERIC OPIOID ANALGESIC DRUG PRODUCT APPROVED BY THE U.S. FOOD AND DRUG ADMINISTRATION WITH ABUSE-DETERRENT LABELING THAT INDICATES THE DRUG PRODUCT IS EXPECTED TO RESULT IN A MEANINGFUL REDUCTION IN ABUSE.

(3) "OPIOID ANALGESIC DRUG PRODUCT" MEANS A DRUG PRODUCT THAT CONTAINS AN OPIOID AGONIST AND IS INDICATED BY THE U.S. FOOD AND DRUG ADMINISTRATION FOR THE TREATMENT OF PAIN, REGARDLESS OF WHETHER THE DRUG PRODUCT:

(I) IS IN IMMEDIATE RELEASE OR EXTENDED RELEASE FORM;

OR

(II) CONTAINS OTHER DRUG SUBSTANCES.

(B) (1) THIS SECTION APPLIES TO:

(I) INSURERS AND NONPROFIT HEALTH SERVICE PLANS THAT PROVIDE COVERAGE FOR PRESCRIPTION DRUGS UNDER INDIVIDUAL, GROUP, OR BLANKET HEALTH INSURANCE POLICIES OR CONTRACTS THAT ARE ISSUED OR DELIVERED IN THE STATE; AND

(II) HEALTH MAINTENANCE ORGANIZATIONS THAT PROVIDE COVERAGE FOR PRESCRIPTION DRUGS UNDER INDIVIDUAL OR GROUP CONTRACTS THAT ARE ISSUED OR DELIVERED IN THE STATE.

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(2) AN INSURER, A NONPROFIT HEALTH SERVICE PLAN, OR A HEALTH MAINTENANCE ORGANIZATION THAT PROVIDES COVERAGE FOR PRESCRIPTION DRUGS THROUGH A PHARMACY BENEFITS MANAGER IS SUBJECT TO THE REQUIREMENTS OF THIS SECTION.

(C) (1) AN ENTITY SUBJECT TO THIS SECTION SHALL PROVIDE COVERAGE FOR ABUSE DETERRENT OPIOID ANALGESIC DRUG PRODUCTS.

(2) AN ENTITY SUBJECT TO THIS SECTION MAY NOT:

(I) IMPOSE DOLLAR LIMITS, COPAYMENTS, DEDUCTIBLES, OR COINSURANCE REQUIREMENTS ON COVERAGE FOR AN ABUSE DETERRENT OPIOID ANALGESIC DRUG PRODUCT THAT ARE LESS FAVORABLE TO AN INSURED OR AN ENROLLEE THAN THE DOLLAR LIMITS, COPAYMENTS, DEDUCTIBLES, OR COINSURANCE REQUIREMENTS THAT APPLY TO COVERAGE FOR ANY OTHER OPIOID ANALGESIC DRUG PRODUCT; OR:

(I) AT LEAST TWO BRAND NAME ABUSE–DETERRENT OPIOID ANALGESIC DRUG PRODUCTS, EACH CONTAINING DIFFERENT ANALGESIC INGREDIENTS, ON THE LOWEST COST TIER FOR BRAND NAME PRESCRIPTION DRUGS ON THE ENTITY'S FORMULARY FOR PRESCRIPTION DRUG COVERAGE; AND

(II) IF AVAILABLE, AT LEAST TWO GENERIC ABUSE-DETERRENT OPIOID ANALGESIC DRUG PRODUCTS, EACH CONTAINING DIFFERENT ANALGESIC INGREDIENTS, ON THE LOWEST COST TIER FOR GENERIC DRUGS ON THE ENTITY'S FORMULARY FOR PRESCRIPTION DRUG COVERAGE.

(11) (2) <u>AN ENTITY SUBJECT TO THIS SECTION MAY NOT</u> REQUIRE AN INSURED OR AN ENROLLEE TO FIRST USE AN OPIOID ANALGESIC DRUG PRODUCT WITHOUT ABUSE–DETERRENT LABELING BEFORE PROVIDING COVERAGE FOR AN ABUSE–DETERRENT OPIOID ANALGESIC DRUG PRODUCT <u>COVERED ON THE</u> ENTITY'S FORMULARY FOR PRESCRIPTION DRUG COVERAGE.

(3) AN ENTITY SUBJECT TO THIS SECTION MAY NOT INCREASE COPAYMENTS, DEDUCTIBLES, OR COINSURANCE REQUIREMENTS OR OTHER OUT-OF-POCKET EXPENSES IMPOSED ON OPIOID ANALGESIC DRUG PRODUCTS TO ACHIEVE COMPLIANCE WITH THIS SECTION.

(D) NOTWITHSTANDING SUBSECTION (C)(2) OF THIS SECTION, AN ENTITY SUBJECT TO THIS SECTION MAY UNDERTAKE UTILIZATION REVIEW, INCLUDING PREAUTHORIZATION, FOR AN ABUSE-DETERRENT OPIOID ANALGESIC DRUG PRODUCT <u>COVERED BY THE ENTITY</u>, IF THE SAME UTILIZATION REVIEW REQUIREMENTS ARE APPLIED TO NON-ABUSE-DETERRENT OPIOID ANALGESIC Ch. 372

DRUG PRODUCTS <u>COVERED BY THE ENTITY IN THE SAME FORMULARY TIER AS THE</u> <u>ABUSE-DETERRENT OPIOID ANALGESIC PRODUCT.</u>

SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall apply to all policies, contracts, and health benefit plans issued, delivered, or renewed in the State on or after October 1, 2015 January 1, 2016.

SECTION 3. AND BE IT FURTHER ENACTED, That this Act shall take effect October 1, 2015 January 1, 2016.

Approved by the Governor, May 12, 2015.