HOUSE BILL 1359

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CF SB 952

By: **Delegates P. Young, Bhandari, Carr, Gilchrist, Kipke, R. Lewis, and Saab**
Introduced and read first time: February 7, 2020
Assigned to: Health and Government Operations

A BILL ENTITLED

AN ACT concerning

Health Insurance – Requirements for Establishing Step Therapy Protocol and Requesting Exceptions

FOR the purpose of repealing the prohibition on certain insurers, nonprofit health service plans, and health maintenance organizations imposing a step therapy or fail–first protocol on an insured or an enrollee under certain circumstances; repealing the prohibition on certain insurers, nonprofit health service plans, and health maintenance organizations imposing a step therapy or fail–first protocol on an insurer or an enrollee for a certain prescription drug under certain circumstances; requiring a step therapy protocol to be established by using certain criteria based on certain guidelines; establishing certain requirements for certain guidelines; authorizing the substitution of certain publications in the absence of certain guidelines; requiring certain insurers, nonprofit health service plans, or health maintenance organizations to establish a certain process for requesting an exception step therapy protocol; authorizing certain entities to use an existing medical exceptions process to satisfy a certain requirement; requiring that a step therapy exception request be granted in a certain manner under certain circumstances; requiring a certain entity to authorize coverage for a certain prescription drug under certain circumstances; requiring certain entities to grant or deny certain requests and appeals within a certain period of time; providing that certain requests or appeals be treated as granted under certain circumstances; requiring that certain requests that are denied under certain circumstances be eligible for certain appeal; requiring the Maryland Insurance Commissioner to adopt certain regulations; making conforming changes; defining certain terms; providing for the application of this Act; providing for a delayed effective date; and generally relating to step therapy protocols and health insurance.

BY repealing and reenacting, without amendments,
Article – Health – General
Section 19–108.2(a)(1)
Annotated Code of Maryland

EXPLANATION: **CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.**
[Brackets**]** indicate matter deleted from existing law.

(2019 Replacement Volume)

BY repealing and reenacting, with amendments,
Article – Health – General
Section 19–108.2(a)(5), (b), and (c)(4)
Annotated Code of Maryland
(2019 Replacement Volume)

BY repealing
Article – Insurance
Section 15–142
Annotated Code of Maryland
(2017 Replacement Volume and 2019 Supplement)

BY adding to
Article – Insurance
Section 15–142
Annotated Code of Maryland
(2017 Replacement Volume and 2019 Supplement)

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

Article – Health – General

19–108.2.

(a) (1) In this section the following words have the meanings indicated.

(5) "Step therapy **[**or fail–first**]** protocol" has the meaning stated in § 15–142 of the Insurance Article.

(b) In addition to the duties stated elsewhere in this subtitle, the Commission shall work with payors and providers to attain benchmarks for:

(1) Standardizing and automating the process required by payors for preauthorizing health care services; and

(2) Overriding a payor's step therapy **[**or fail–first**]** protocol.

(c) The benchmarks described in subsection (b) of this section shall include:

(4) On or before July 1, 2015, establishment, by each payor that requires a step therapy **[**or fail–first**]** protocol, of a process for a provider to override the step therapy **[**or fail–first**]** protocol of the payor; and

Article – Insurance

[15–142.

(a) (1) In this section the following words have the meanings indicated.

(2) "Step therapy drug" means a prescription drug or sequence of prescription drugs required to be used under a step therapy or fail–first protocol.

(3) "Step therapy or fail–first protocol" means a protocol established by an insurer, a nonprofit health service plan, or a health maintenance organization that requires a prescription drug or sequence of prescription drugs to be used by an insured or an enrollee before a prescription drug ordered by a prescriber for the insured or the enrollee is covered.

(4) "Supporting medical information" means:

(i) a paid claim from an entity subject to this section for an insured or an enrollee;

(ii) a pharmacy record that documents that a prescription has been filled and delivered to an insured or an enrollee, or a representative of an insured or an enrollee; or

(iii) other information mutually agreed on by an entity subject to this section and the prescriber of an insured or an enrollee.

(b) (1) This section applies to:

(i) insurers and nonprofit health service plans that provide hospital, medical, or surgical benefits to individuals or groups on an expense–incurred basis under health insurance policies or contracts that are issued or delivered in the State; and

(ii) health maintenance organizations that provide hospital, medical, or surgical benefits to individuals or groups under contracts that are issued or delivered in the State.

(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) An entity subject to this section may not impose a step therapy or fail–first protocol on an insured or an enrollee if:

(1) the step therapy drug has not been approved by the U.S. Food and Drug Administration for the medical condition being treated; or

(2) a prescriber provides supporting medical information to the entity that a prescription drug covered by the entity:

(i) was ordered by a prescriber for the insured or enrollee within the past 180 days; and

(ii) based on the professional judgment of the prescriber, was effective in treating the insured's or enrollee's disease or medical condition.

(d) Subsection (c) of this section may not be construed to require coverage for a prescription drug that is not:

(1) covered by the policy or contract of an entity subject to this section; or

(2) otherwise required by law to be covered.

(e) An entity subject to this section may not impose a step therapy or fail–first protocol on an insured or an enrollee for a prescription drug approved by the U.S. Food and Drug Administration if:

(1) the prescription drug is used to treat the insured's or enrollee's stage four advanced metastatic cancer; and

(2) use of the prescription drug is:

(i) consistent with the U.S. Food and Drug Administration–approved indication or the National Comprehensive Cancer Network Drugs & Biologics Compendium indication for the treatment of stage four advanced metastatic cancer; and

(ii) supported by peer–reviewed medical literature.**]**

15–142.

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

(2) "CLINICAL PRACTICE GUIDELINES" MEANS STATEMENTS SYSTEMATICALLY DEVELOPED TO ASSIST DECISION MAKING BY HEALTH CARE PROVIDERS AND PATIENTS ABOUT APPROPRIATE HEALTH CARE FOR SPECIFIC CLINICAL CIRCUMSTANCES AND CONDITIONS.

(3) "CLINICAL REVIEW CRITERIA" MEANS THE WRITTEN SCREENING PROCEDURES, DECISION ABSTRACTS, CLINICAL PROTOCOLS, AND PRACTICE GUIDELINES USED BY AN INSURER, NONPROFIT HEALTH SERVICE PLAN, HEALTH MAINTENANCE ORGANIZATION, OR UTILIZATION REVIEW ORGANIZATION TO DETERMINE WHETHER A HEALTH CARE SERVICE IS A MEDICAL NECESSITY.

(4) "MEDICAL NECESSITY" MEANS A HEALTH SERVICE OR SUPPLY THAT UNDER AN APPLICABLE STANDARD OF CARE IS APPROPRIATE:

(I) TO IMPROVE OR PRESERVE HEALTH, LIFE, OR FUNCTION;

(II) TO SLOW THE DETERIORATION OF HEALTH, LIFE, OR FUNCTION; OR

(III) FOR THE EARLY SCREENING, PREVENTION, EVALUATION, DIAGNOSIS, OR TREATMENT OF A DISEASE, CONDITION, ILLNESS, OR INJURY.

(4) "STEP THERAPY PROTOCOL" MEANS A PROTOCOL, POLICY, OR PROGRAM THAT ESTABLISHES A SPECIFIC SEQUENCE IN WHICH PRESCRIPTION DRUGS MUST BE USED OR TRIED FOR A SPECIFIED MEDICAL CONDITION AND, AS MEDICALLY APPROPRIATE FOR A PARTICULAR PATIENT, TO BE COVERED BY AN INSURER, NONPROFIT HEALTH SERVICE PLAN, OR A HEALTH MAINTENANCE ORGANIZATION.

(5) "STEP THERAPY EXCEPTION REQUEST" MEANS A REQUEST TO OVERRIDE A STEP THERAPY PROTOCOL IN FAVOR OF IMMEDIATE COVERAGE OF A HEALTH CARE PROVIDER'S SELECTED PRESCRIPTION DRUG.

(6) "UTILIZATION REVIEW ORGANIZATION" MEANS AN ENTITY THAT CONDUCTS UTILIZATION REVIEW, OTHER THAN AN INSURER, NONPROFIT HEALTH SERVICE PLAN, OR A HEALTH MAINTENANCE ORGANIZATION PERFORMING UTILIZATION REVIEW FOR ITS OWN HEALTH BENEFIT PLANS.

(B) (1) THIS SECTION APPLIES TO:

(I) INSURERS AND NONPROFIT HEALTH SERVICE PLANS THAT PROVIDE PRESCRIPTION DRUG BENEFITS TO INDIVIDUALS OR GROUPS UNDER HEALTH INSURANCE POLICIES OR CONTRACTS THAT ARE ISSUED OR DELIVERED IN THE STATE; AND

(II) HEALTH MAINTENANCE ORGANIZATIONS THAT PROVIDE PRESCRIPTION DRUG BENEFITS TO INDIVIDUALS OR GROUPS UNDER CONTRACTS THAT ARE ISSUED OR DELIVERED IN THE STATE.

(2) (I) AN INSURER, NONPROFIT HEALTH SERVICE PLAN, OR HEALTH MAINTENANCE ORGANIZATION THAT PROVIDES COVERAGE FOR PRESCRIPTION DRUGS BY IMPOSING A STEP THERAPY PROTOCOL IS SUBJECT TO THE REQUIREMENTS OF THIS SECTION.

(II) A UTILIZATION REVIEW ORGANIZATION CONDUCTING A UTILIZATION REVIEW ON BEHALF OF AN INSURER, NONPROFIT HEALTH SERVICE PLAN, OR HEALTH MAINTENANCE ORGANIZATION DESCRIBED IN SUBPARAGRAPH (I) OF THIS PARAGRAPH IS SUBJECT TO THE REQUIREMENTS OF THIS SECTION.

(III) A POLICY OR CONTRACT IS NOT REQUIRED TO INCLUDE THE SPECIFIC TERM STEP THERAPY PROTOCOL IN ORDER FOR THE INSURER, NONPROFIT HEALTH SERVICE PLAN, OR HEALTH MAINTENANCE ORGANIZATION PROVIDING COVERAGE UNDER THE POLICY OR CONTRACT TO BE SUBJECT TO THIS SECTION IF THE COVERAGE REQUIRED UNDER THE POLICY OR CONTRACT MEETS THE DEFINITION OF STEP THERAPY PROTOCOL ESTABLISHED IN SUBSECTION (A) OF THIS SECTION.

(C) (1) SUBJECT TO PARAGRAPH (2) OF THIS SUBSECTION, A STEP THERAPY PROTOCOL SHALL BE ESTABLISHED BY USING CLINICAL REVIEW CRITERIA BASED ON CLINICAL PRACTICE GUIDELINES THAT:

(I) RECOMMEND THAT SPECIFIED PRESCRIPTION DRUGS BE TAKEN IN THE SPECIFIC SEQUENCE REQUIRED BY THE STEP THERAPY PROTOCOL;

(II) ARE DEVELOPED AND ENDORSED BY A MULTIDISCIPLINARY PANEL OF EXPERTS THAT:

1. REQUIRES MEMBERS TO DISCLOSE ANY POTENTIAL CONFLICTS OF INTEREST WITH ENTITIES, INCLUDING INSURERS, NONPROFIT HEALTH SERVICE PLANS, HEALTH MAINTENANCE ORGANIZATIONS, OR PHARMACEUTICAL MANUFACTURERS, AND RECUSE THEMSELVES FROM VOTING ON AN ISSUE IF THE MEMBER HAS A CONFLICT OF INTEREST;

2. USES A METHODOLOGIST TO PROVIDE OBJECTIVITY IN DATA ANALYSIS AND RANKING OF EVIDENCE THROUGH THE PREPARATION OF EVIDENCE TABLES AND FACILITATING CONSENSUS; AND

3. OFFERS OPPORTUNITIES FOR PUBLIC REVIEW AND COMMENT;

(III) ARE BASED ON HIGH–QUALITY STUDIES, RESEARCH, AND MEDICAL PRACTICE;

(IV) ARE CREATED BY AN EXPLICIT AND TRANSPARENT PROCESS THAT:

1. MINIMIZES BIASES AND CONFLICTS OF INTEREST;

2. EXPLAINS THE RELATIONSHIP BETWEEN TREATMENT OPTIONS AND OUTCOMES;

3. RATES THE QUALITY OF THE EVIDENCE SUPPORTING RECOMMENDATIONS; AND

4. CONSIDERS RELEVANT PATIENT SUBGROUPS AND PREFERENCES;

(V) TAKE INTO ACCOUNT THE NEEDS OF ATYPICAL PATIENT POPULATIONS AND DIAGNOSES; AND

(VI) ARE CONTINUALLY UPDATED THROUGH A REVIEW OF NEW EVIDENCE, RESEARCH, AND NEWLY DEVELOPED TREATMENTS.

(2) IN THE ABSENCE OF CLINICAL GUIDELINES THAT MEET THE REQUIREMENTS IN PARAGRAPH (1) OF THIS SUBSECTION, PEER–REVIEWED PUBLICATIONS MAY BE SUBSTITUTED.

(3) THIS SUBSECTION MAY NOT BE CONSTRUED TO REQUIRE AN ENTITY SUBJECT TO THIS SECTION OR THE STATE TO SET UP A NEW ENTITY TO DEVELOP CLINICAL REVIEW CRITERIA USED FOR ESTABLISHING STEP THERAPY PROTOCOLS.

(D) (1) AN ENTITY SUBJECT TO THIS SECTION SHALL ESTABLISH A PROCESS FOR REQUESTING AN EXCEPTION TO A STEP THERAPY PROTOCOL THAT IS:

(I) CLEARLY DESCRIBED;

(II) EASILY ACCESSIBLE BY A PATIENT AND PRESCRIBING PROVIDER; AND

(III) POSTED ON THE ENTITY'S WEBSITE.

(2) AN ENTITY SUBJECT TO THIS SECTION MAY USE AN EXISTING MEDICAL EXCEPTIONS PROCESS TO SATISFY THE REQUIREMENT UNDER PARAGRAPH (1) OF THIS SUBSECTION.

(3) A STEP THERAPY EXCEPTION REQUEST SHALL BE EXPEDITIOUSLY GRANTED IF:

(I) THE REQUIRED PRESCRIPTION DRUG IS CONTRAINDICATED OR WILL LIKELY CAUSE AN ADVERSE REACTION BY OR PHYSICAL OR MENTAL HARM TO THE PATIENT;

(II) THE REQUIRED PRESCRIPTION DRUG IS EXPECTED TO BE INEFFECTIVE BASED ON THE KNOWN CLINICAL CHARACTERISTICS OF THE PATIENT AND THE KNOWN CHARACTERISTICS OF THE PRESCRIPTION DRUG REGIMEN;

(III) WHILE COVERED BY A CURRENT OR PREVIOUS HEALTH BENEFIT PLAN OR CONTRACT WITH A CURRENT OR PREVIOUS INSURER, THE PATIENT HAS TRIED:

1. THE REQUIRED PRESCRIPTION DRUG; OR

2. ANOTHER PRESCRIPTION DRUG THAT:

A. IS IN THE SAME PHARMACOLOGIC CLASS OR HAS THE SAME MECHANISM OF ACTION AS THE REQUIRED PRESCRIPTION DRUG; AND

B. WAS DISCONTINUED DUE TO LACK OF EFFICACY OR EFFECTIVENESS, DIMINISHED EFFECT, OR AN ADVERSE EVENT;

(IV) THE REQUIRED PRESCRIPTION DRUG IS NOT IN THE BEST INTEREST OF THE PATIENT, BASED ON MEDICAL NECESSITY; OR

(V) THE PATIENT IS STABLE ON A PRESCRIPTION DRUG SELECTED BY THE PATIENT'S HEALTH CARE PROVIDER FOR THE MEDICAL CONDITION UNDER CONSIDERATION WHILE THE PATIENT WAS COVERED BY A CURRENT OR PREVIOUS HEALTH BENEFIT PLAN WITH A CURRENT OR PREVIOUS INSURER.

(4) IF A STEP THERAPY EXCEPTION REQUEST IS GRANTED, AN ENTITY SUBJECT TO THIS SECTION SHALL AUTHORIZE COVERAGE FOR THE PRESCRIPTION DRUG PRESCRIBED BY THE PATIENT'S TREATING HEALTH CARE PROVIDER.

(5) (I) AN ENTITY SUBJECT TO THIS SECTION SHALL GRANT OR DENY A STEP THERAPY EXCEPTION REQUEST OR AN APPEAL:

1. WITHIN 72 HOURS AFTER RECEIVING THE REQUEST OR APPEAL; OR

2. IN CASES WHERE EXIGENT CIRCUMSTANCES EXIST, WITHIN 24 HOURS AFTER RECEIVING THE REQUEST OR APPEAL.

(II) IF AN ENTITY SUBJECT TO THIS SECTION DOES NOT GRANT OR DENY A STEP THERAPY EXCEPTION REQUEST OR AN APPEAL WITHIN THE TIME PERIOD REQUIRED UNDER SUBPARAGRAPH (I) OF THIS PARAGRAPH, THE REQUEST OR APPEAL SHALL BE TREATED AS GRANTED.

(6) ANY STEP THERAPY EXCEPTION REQUEST DENIED UNDER THIS SECTION SHALL BE ELIGIBLE FOR APPEAL BY AN INSURED.

(7) THIS SECTION MAY NOT BE CONSTRUED TO PREVENT:

(I) AN ENTITY SUBJECT TO THIS SECTION FROM REQUIRING A PATIENT TO TRY AN AB–RATED GENERIC EQUIVALENT OR INTERCHANGEABLE BIOLOGICAL PRODUCT BEFORE PROVIDING COVERAGE FOR THE EQUIVALENT BRANDED PRESCRIPTION DRUG;

(II) AN ENTITY SUBJECT TO THIS SECTION FROM REQUIRING A PHARMACIST TO MAKE SUBSTITUTIONS OF PRESCRIPTION DRUGS CONSISTENT WITH THE REQUIREMENTS OF THIS ARTICLE; OR

(III) A HEALTH CARE PROVIDER FROM PRESCRIBING A PRESCRIPTION DRUG THAT IS DETERMINED TO BE MEDICALLY APPROPRIATE.

(E) THE COMMISSIONER SHALL ADOPT REGULATIONS TO CARRY OUT THIS SECTION.

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 January 1, 2021.

SECTION 3. AND BE IT FURTHER ENACTED, That this Act shall take effect January 1, 2021.