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HOUSE BILL NO. 2329

Offered January 13, 2025

Prefiled January 8, 2025

A BILL to amend and reenact § 38.2-3407.9:01 of the Code of Virginia, relating to health insurance; prescription drug formularies.

Patron—Sickles

Referred to Committee on Labor and Commerce

Be it enacted by the General Assembly of Virginia:

1. That § 38.2-3407.9:01 of the Code of Virginia is amended and reenacted as follows:

§ 38.2-3407.9:01. Prescription drug formularies.

A. *As used in this section:*

"Biosimilar" means any biological product that is licensed under 42 U.S.C. § 262(k) and has been listed in the U.S. Food and Drug Administration's Database of Licensed Biological Products as biosimilar to or interchangeable with a reference biological product.

"Brand drug" means a drug for which an application has been approved under 21 U.S.C. § 355(c) or a biological product, other than a biosimilar, that is licensed under 42 U.S.C. § 262(a).

"Formulary" means a list of prescription drugs that is developed by the pharmacy and therapeutics committee or other clinical and pharmacy experts and represents the prescription drugs approved for use by any insurer, corporation, or health maintenance organization.

"Generic drug" means a drug for which an application has been approved under 21 U.S.C. § 355(j) and t hat has been listed in the U.S. Food and Drug Administration's Approved Drug Products with Therapeutic Equivalence Evaluations as therapeutically equivalent to a reference drug, even if the manufacturer of such drug applies a trade name to the drug.

"Reference listed drug" is the listed drug identified by the U.S. Food and Drug Administration as the drug product upon which an applicant relies in seeking approval of its application submitted under 21 U.S.C. § 355(j).

"Reference product" is a single biological product, licensed by the U.S. Food and Drug Administration under 42 U.S.C. § 262(a), against which a proposed biosimilar or interchangeable product is compared, and listed as a reference product in the FDA's Database of Licensed Biological Products.

"Wholesale acquisition cost" has the same meaning as provided in 42 U.S.C. § 1395w-3a(c)(6)(B).

B. Each (i) insurer proposing to issue individual or group accident and sickness insurance policies providing hospital, medical and surgical or major medical coverage on an expense-incurred basis, (ii) corporation providing individual or group accident and sickness subscription contracts, and (iii) health maintenance organization providing a health care plan for health care services, whose policy, contract or plan, including any certificate or evidence of coverage issued in connection with such policy, contract or plan, includes coverage for prescription drugs on an outpatient basis may apply a formulary to the prescription drug benefits provided by the insurer, corporation, or health maintenance organization if the formulary is developed, reviewed at least annually, and updated as necessary in consultation with and with the approval of a pharmacy and therapeutics committee, a majority of whose members are actively practicing licensed pharmacists, physicians and other licensed health care providers.

~~B.~~ *C.* If an insurer, corporation, or health maintenance organization maintains one or more closed drug formularies, each insurer, corporation, or health maintenance organization shall:

1. Make available to participating providers and pharmacists and to any nonpreferred or nonparticipating pharmacists as described in §§ 38.2-3407.7 and 38.2-4312.1, the complete, current drug formulary or formularies, or any updates thereto, maintained by the insurer, corporation, or health maintenance organization, including a list of the prescription drugs on the formulary by major therapeutic category that specifies whether a particular prescription drug is preferred over other drugs;

2. Establish a process to allow an enrollee to obtain, without additional cost-sharing beyond that provided for formulary prescription drugs in the enrollee's covered benefits, a specific, medically necessary nonformulary prescription drug if the formulary drug is determined by the insurer, corporation, or health maintenance organization, after reasonable investigation and consultation with the prescribing physician, to be an inappropriate therapy for the medical condition of the enrollee. The insurer, corporation or health maintenance organization shall act on such requests within one business day of receipt of the request; ~~and~~

3. Establish a process to allow an enrollee to obtain, without additional cost-sharing beyond that provided for formulary prescription drugs in the enrollee's covered benefits, a specific, medically necessary nonformulary prescription drug when the enrollee has been receiving the specific nonformulary prescription

drug for at least six months previous to the development or revision of the formulary and the prescribing physician has determined that the formulary drug is an inappropriate therapy for the specific patient or that changing drug therapy presents a significant health risk to the specific patient. After reasonable investigation and consultation with the prescribing physician, the insurer, corporation or health maintenance organization shall act on such requests within one business day of receipt of the request. For purposes of this subsection, substituting the generic equivalent drug, which has been approved by the U.S. Food and Drug Administration, for a branded version of such drug shall not constitute a change in drug therapy*; and*

4. Publish an up-to-date, accurate, and complete list of all covered drugs on each formulary, including any tiering structure that it has adopted and any restrictions on the manner in which a drug can be obtained, in a manner that is easily accessible to plan enrollees, prospective enrollees, and the general public. For the purposes of this subdivision, a formulary is easily identifiable when (i) it can be viewed on the plan's public website through a clearly identifiable link or tab without requiring an individual to create or access an account or enter a policy number and (ii) if the insurer, organization, or health maintenance organization offers more than one plan, an individual can easily discern which formulary drug list applies to which plan.

~~C.~~ *D.* Each insurer, corporation, or health maintenance organization that applies a formulary to the prescription drug benefits provided as set forth in subsection ~~A~~ *B* shall *(i)* provide to each affected group health benefit plan policyholder or contract holder or each affected individual health benefit plan policyholder or contract holder not less than 30 days' prior written notice of a modification to a formulary that results in the movement of a prescription drug to a tier with higher cost-sharing requirements *and (ii) for any change to the formulary, update the easily accessible formulary published pursuant to subdivision A 4 and shall make the change easily identifiable and include the date of such change in bold within 30 days of the change*. This ~~section~~ *subsection* does not apply to modifications that occur at the time of coverage renewal.

E. If a generic drug or biosimilar is approved or licensed by the U.S. Food and Drug Administration, is marketed pursuant to such approval or licensure, and has a wholesale acquisition cost that is less than the wholesale acquisition cost of the reference listed drug or reference product of such generic drug or biosimilar on the generic drugs or biosimilar initial date of marketing, then any insurer, corporation, or health maintenance organization that applies a formulary to the prescription drug benefits provided as set forth in subsection B and includes coverage for the reference listed drug or reference product, (i) shall immediately provide coverage for the generic drug or at least one biosimilar with more favorable cost-sharing, including actual out-of-pocket costs, relative to the reference listed drug or reference product and (ii) shall not impose any prior authorization, step therapy, or other limitation on coverage of the generic drug or biosimilar or any restriction on a pharmacy through which an enrollee may obtain the generic drug or biosimilar, that makes it more difficult for an enrolled to obtain coverage or access to the generic drug or biosimilar than to the reference listed drug or reference product. The provisions of this subsection shall apply for so long as the wholesale acquisition cost of the generic drug or biosimilar is lower than the reference listed drug or reference product. Nothing in this subsection shall require (i) continued coverage of the brand drug after a generic drug or biosimilar is approved or licensed, as applicable, or marketed or (ii) coverage of the generic drug or biosimilar if the pharmacy and therapeutics committee determines that such generic drug or biosimilar is no longer medically appropriate or cost-effective.

2. That the provisions this act shall apply to formularies, as defined in § 38.2-3407.9:01 of the Code of Virginia, as amended by this act, that are applied to the prescription drug benefits of a policy, contract, or plan amended, delivered, issued, or renewed in the Commonwealth after January 1, 2026.