STATE OF NEW YORK

11256

IN ASSEMBLY

May 4, 2026

Introduced by M. of A. JENSEN -- read once and referred to the Committee on Insurance

AN ACT to amend the insurance law, in relation to requiring health plan coverage to include certain generic drugs and biosimilars

The People of the State of New York, represented in Senate and Assembly, do enact as follows:

Section 1. Section 3242 of the insurance law is amended by adding a new subsection (d) to read as follows:

(d) (1) For the purposes of this subsection, the following terms shall have the following meanings:

(A) "Biosimilar" means any biological product that is licensed under 42 U.S.C.§ 262(k) and has been listed in the FDA's database of licensed biological products, commonly referred to as the purple book, as biosimilar to or interchangeable with a reference biological product.

(B) "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).

(C) "FDA" means the U.S. Food and Drug Administration.

(D) "Formulary" means a list of prescription drugs that is developed by a pharmacy and therapeutics committee or other clinical and pharmacy experts and represents a policy's prescription drugs approved for use.

(E) "Generic drug" means a drug for which an application has been approved under 21 U.S.C. §355(j) and which has been listed in the FDA's approved drug products with therapeutic equivalence evaluations, commonly referred to as the orange book, as therapeutically equivalent to a reference drug, even if the manufacturer of such drug applies a trade name to the drug.

(F) "Policy" means a policy delivered or issued for delivery in this state that provides coverage for prescription drugs.

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

(H) "Reference product" is a single biological product, licensed by the FDA under 42 U.S.C. § 262(a), against which a proposed biosimilar or

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

LBD14739-01-6

interchangeable product is compared, and listed as a reference product in the FDA's database of licensed biological products, commonly referred to as the purple book.

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

(2) (A) If a generic drug is approved by the FDA, is marketed pursuant to such approval, and has a wholesale acquisition cost that is less than the wholesale acquisition cost of the reference listed drug on such generic drug's initial date of marketing, then policies that provide coverage for such generic drug's reference listed drug at the time of such generic drug's marketing date shall:

(i) immediately make such generic drug available on the formulary with more favorable cost sharing, including actual out-of-pocket costs, relative to such reference listed drug; and

(ii) not impose any prior authorization, step therapy, or other limitation on coverage of a generic drug for which formulary placement is required under clause (i) of this subparagraph, nor impose any restriction on a pharmacy through which an enrollee may obtain such generic drug, that makes it more difficult for an enrollee to obtain coverage of or access to such generic drug than the reference listed drug.

(B) The provisions of subparagraph (A) of this paragraph shall apply as long as the wholesale acquisition cost of the generic drug is lower than the wholesale acquisition cost of the reference listed drug.

(3) (A) If a biosimilar is licensed by the FDA, is marketed pursuant to such licensure, and has a wholesale acquisition cost that is less than the wholesale acquisition cost of the reference product of such biosimilar on the initial date of marketing, then policies that provide coverage for such biosimilar's reference product at the time of such biosimilar's marketing date shall:

(i) immediately make at least one biosimilar available on the formulary on a tier with more favorable cost sharing, including actual out-of-pocket costs, relative to the reference product; and

(ii) not impose any prior authorization, step therapy, or other limitation on coverage of a biosimilar for which formulary placement is required under clause (i) of this subparagraph, nor impose any restriction on a pharmacy through which an enrollee may obtain such biosimilar, that makes it more difficult for an enrollee to obtain coverage of or access to such biosimilar than the reference product.

(B) Subparagraph (A) of this paragraph shall apply as long as the wholesale acquisition cost of the biosimilar is lower than the wholesale acquisition cost of the reference product.

(4) Nothing in this subsection shall require a policy to continue providing coverage for a brand drug after a generic drug or biosimilar is approved or licensed, as applicable, and marketed.

(5) Nothing in this subsection shall require a policy to provide coverage for a brand drug, generic drug, or biosimilar if the clinical and pharmacy experts that develop such policy's formulary determine that such drug or biosimilar is no longer medically appropriate or cost-effective.

(6) The superintendent shall be authorized to promulgate any rules and/or regulations necessary to effectuate the provisions of this subsection.

§ 2. Section 4329 of the insurance law is amended by adding a new subsection (d) to read as follows:

(d) (1) For the purposes of this subsection, the following terms shall have the following meanings:

(A) "Biosimilar" means any biological product that is licensed under 42 U.S.C.§ 262(k) and has been listed in the FDA's database of licensed biological products, commonly referred to as the purple book, as biosimilar to or interchangeable with a reference biological product.

(B) "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).

(C) "FDA" means the U.S. Food and Drug Administration.

(D) "Formulary" means a list of prescription drugs that is developed by a pharmacy and therapeutics committee or other clinical and pharmacy experts and represents a plan's prescription drugs approved for use.

(E) "Generic drug" means a drug for which an application has been approved under 21 U.S.C. § 355(j) and which has been listed in the FDA's approved drug products with therapeutic equivalence evaluations, commonly referred to as the orange book, as therapeutically equivalent to a reference drug, even if the manufacturer of such drug applies a trade name to the drug.

(F) "Plan" means a contract issued by a corporation subject to the provisions of this article that provides coverage for prescription drugs.

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

(H) "Reference product" is a single biological product, licensed by the FDA 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, commonly referred to as the purple book.

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

(2) (A) If a generic drug is approved by the FDA, is marketed pursuant to such approval, and has a wholesale acquisition cost that is less than the wholesale acquisition cost of the reference listed drug on such generic drug's initial date of marketing, then plans that provide coverage for such generic drug's reference listed drug at the time of such generic drug's marketing date shall:

(i) immediately make such generic drug available on the formulary with more favorable cost sharing, including actual out-of-pocket costs, relative to such reference listed drug; and

(ii) not impose any prior authorization, step therapy, or other limitation on coverage of a generic drug for which formulary placement is required under clause (i) of this subparagraph, nor impose any restriction on a pharmacy through which an enrollee may obtain such generic drug, that makes it more difficult for an enrollee to obtain coverage of or access to such generic drug than the reference listed drug.

(B) The provisions of subparagraph (A) of this paragraph shall apply as long as the wholesale acquisition cost of the generic drug is lower than the wholesale acquisition cost of the reference listed drug.

(3) (A) If a biosimilar is licensed by the FDA, is marketed pursuant to such licensure, and has a wholesale acquisition cost that is less than the wholesale acquisition cost of the reference product of such biosimilar on the initial date of marketing, then plans that provide

coverage for such biosimilar's reference product at the time of such biosimilar's marketing date shall:

(i) immediately make at least one biosimilar available on the formulary on a tier with more favorable cost sharing, including actual out-of-pocket costs, relative to the reference product; and

(ii) not impose any prior authorization, step therapy, or other limitation on coverage of a biosimilar for which formulary placement is required under clause (i) of this subparagraph, nor impose any restriction on a pharmacy through which an enrollee may obtain such biosimilar, that makes it more difficult for an enrollee to obtain coverage of or access to such biosimilar than the reference product.

(B) Subparagraph (A) of this paragraph shall apply as long as the wholesale acquisition cost of the biosimilar is lower than the wholesale acquisition cost of the reference product.

(4) Nothing in this subsection shall require a plan to continue providing coverage for a brand drug after a generic drug or biosimilar is approved or licensed, as applicable, and marketed.

(5) Nothing in this subsection shall require a plan to provide coverage for a brand drug, generic drug, or biosimilar if the clinical and pharmacy experts that develop such plan's formulary determine that such drug or biosimilar is no longer medically appropriate or cost-effective.

(6) The superintendent shall be authorized to promulgate any rules and/or regulations necessary to effectuate the provisions of this subsection.

§ 3. This act shall take effect on the first of January next succeeding the date on which it shall have become a law, and shall apply to policies and contracts issued, renewed or amended on or after such effective date. Effective immediately, the addition, amendment and/or repeal of any rule or regulation necessary for the implementation of this act on its effective date are authorized to be made and completed on or before such effective date.