

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.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

3 (A) "Biosimilar" means any biological product that is licensed under
4 42 U.S.C. § 262(k) and has been listed in the FDA's database of licensed
5 biological products, commonly referred to as the purple book, as biosi-
6 milar to or interchangeable with a reference biological product.

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

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

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

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

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

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

26 (H) "Reference product" is a single biological product, licensed by
27 the FDA under 42 U.S.C. § 262(a), against which a proposed biosimilar or
28 interchangeable product is compared, and listed as a reference product
29 in the FDA's database of licensed biological products, commonly referred
30 to as the purple book.

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

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

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

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

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

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

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

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

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

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

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

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

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

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