SENATE, No. 4222

STATE OF NEW JERSEY

222nd LEGISLATURE

INTRODUCED MAY 14, 2026

Sponsored by:
Senator GORDON M. JOHNSON
District 37 (Bergen)

SYNOPSIS

Improves access to lower-cost generic and biosimilar drugs.

CURRENT VERSION OF TEXT

As introduced.

AN ACT concerning generic and biosimilar drugs and supplementing Titles 30 and 52 of the Revised Statutes.

BE IT ENACTED *by the Senate and General Assembly of the State of New Jersey:*

1. As used in this act:

"Biosimilar" means a drug that is produced or distributed pursuant to a biologics license application approved under 42 U.S.C. s.262(k) and that is not listed as “discontinued” in the Database of Licensed Biological Products by the federal Food and Drug Administration.

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

"Generic drug" means a drug that is approved under 21 U.S.C. s.355(j) and is listed in the Approved Drug Products with Therapeutic Equivalence Evaluations publication by the federal Food and Drug Administration as therapeutically equivalent to a reference drug, even if the manufacturer of the reference drug applies a trade name to the drug.

“Managed care organization” means a health maintenance organization contracted with the Division of Medical Assistance and Health Services in the Department of Human Services to provide benefits to enrolled beneficiaries under the Medicaid program, established pursuant to P.L.1968, c. 413 (C.30:4D-1 et seq.).

“Reference listed drug” means the listed drug identified by the federal 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. s.355(j).

“Reference product” means a single biological product, licensed pursuant to 42 U.S.C. s.262(a), against which a proposed biosimilar or interchangeable product is compared, and listed as a reference product in the Database of Licensed Biological Products by the federal Food and Drug Administration.

“Wholesale acquisition cost” means the manufacturer’s listed price for the drug or biological to wholesalers or direct purchasers in New Jersey, as defined in 42 U.S.C. s.1847A(c)(6)(B), not including prompt pay or other discounts, rebates or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug or biological pricing data.

2. a. When a brand drug is prescribed to treat an enrollee who has not previously been treated with the prescribed drug, the enrollee shall receive a biosimilar product, if one is available.

b. A healthcare provider may appeal the application of subsection a. of this section to a particular patient pursuant to subsection d. of section 4 of P.L.2025, c.50 (C.30:4D-7xx).

3. a. A managed care organization shall publish and maintain an accurate and complete list of all covered drugs on the organization's formulary, including any tiering structure that the organization has adopted and any restrictions on the manner in which a drug is obtained, in a manner that is easily accessible to current and prospective enrollees, the State, and the general public.

b. (1) A formulary shall be easily accessible on the managed care organization'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.

(2) If a managed care organization makes a change to the formulary during the plan year, it shall be updated within 30 calendar days and contain, in bold type, the date of the update, with the updates clearly identifiable.

4. a. If a generic drug is approved by the federal Food and Drug Administration, marketed pursuant to the approval, and has a wholesale acquisition cost that is less than the wholesale acquisition cost of the reference listed drug on the generic drug's initial date of marketing, then a managed care organization that provides coverage for the generic drug's reference listed drug at the time of the generic drug's marketing date shall:

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

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

b. A generic drug added to a formulary pursuant to subsection a. of this section shall remain on the formulary for as long as the wholesale acquisition cost of the generic drug is lower than the wholesale acquisition cost of the reference listed drug.

5. a. If a biosimilar is licensed by the federal Food and Drug Administration, is marketed pursuant to the licensure, and has a wholesale acquisition cost that is less than the wholesale acquisition cost of the reference product of the biosimilar on the initial date of marketing, then a managed care organization that provides coverage for the biosimilar's reference product at the time of the biosimilar's marketing date shall:

(1) 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

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

b. A biosimilar added to a formulary pursuant to subsection a. of this section shall remain on the formulary for so long as the wholesale acquisition cost of the biosimilar is lower than the wholesale acquisition cost of the reference listed drug.

6. Nothing in this act shall require a managed care organization to continue providing coverage for a brand drug after a generic drug or biosimilar is approved or licensed, as applicable, and marketed.

7. Nothing in sections 1 through 6 of this act shall require a managed care organization to provide coverage for a brand drug, generic drug, or biosimilar if the individuals who develop the formulary of the organization determine that the drug or biosimilar is no longer medically appropriate or cost-effective.

8. Nothing in sections 1 through 7 of this act shall interfere with a pharmacist complying with the “New Jersey Pharmacy Practice Act,” P.L.2003, c.280 (C.45:14-40 et seq.).

9. The Department of Human Services shall adopt rules and regulations, pursuant to the “Administrative Procedure Act," P.L.1968, c.410 (C.52:14B-1 et seq.), as may be necessary to implement sections 1 through 8 of this act.

10. As used in this act:

"Biosimilar" means a drug that is produced or distributed pursuant to a biologics license application approved under 42 U.S.C. s.262(k) and that is not listed as “discontinued” in the Database of Licensed Biological Products of the federal Food and Drug Administration.

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

“Covered person” means a person on whose behalf the State Health Benefits Program or the School Employees’ Health Benefits Program is obligated to pay benefits or provide services pursuant to the health benefits plan.

"Generic drug" means a drug that is approved under 21 U.S.C. s.355(j) and is listed in the Approved Drug Products with Therapeutic Equivalence Evaluations of the federal Food and Drug Administration as therapeutically equivalent to a reference drug, even if the manufacturer of such drug applies a trade name to the drug.

“Health benefits plan” means a plan providing health care benefits coverage for public employees and their dependents offered by the State Health Benefits Program or the School Employees’ Health Benefits Program.

“Reference listed drug” means the listed drug identified by the federal 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. s.355(j).

“Reference product” means a single biological product, licensed pursuant to 42 U.S.C. s.262(a), against which a proposed biosimilar or interchangeable product is compared, and listed as a reference product in the Database of Licensed Biological Products of the federal Food and Drug Administration.

“Vendor” means a third-party administrator that conducts claims administration, network management, claims processing, or other related services for the State Health Benefits Commission or the School Employees’ Health Benefits Commission.

“Wholesale acquisition cost” means the manufacturer’s list price for the drug or biological to wholesalers or direct purchasers in New Jersey, as defined in 42 U.S.C. s.1847A(c)(6)(B), not including prompt pay or other discounts, rebates or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug or biological pricing data.

11. a. When a brand drug is prescribed to treat a covered person who has not previously been treated with the prescribed drug, the covered person shall receive a biosimilar product, if one is available.

b. A healthcare provider may appeal the application of subsection a. of this section to a particular patient pursuant to section 9 of P.L.2025, c.50 (C.52:14-17.28j).

12. a. A vendor shall publish and maintain an accurate and complete list of all covered drugs on the vendor’s formulary, including any tiering structure that the vendor has adopted and any restrictions on the manner in which a drug is obtained, in a manner that is easily accessible to a covered person, the State, and the general public.

b. (1) A formulary shall be easily accessible on the vendor’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.

(2) If a vendor makes a change to the formulary during the plan year, the formulary shall be updated within 30 calendar days and shall contain, in bold type, the date of the update, with the updates clearly identifiable.

13. a. If a generic drug is approved by the federal Food and Drug Administration, 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 the generic drug's initial date of marketing, then a vendor that provides coverage for the generic drug's reference listed drug at the time of the generic drug's marketing date shall:

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

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

b. A generic drug added to a formulary pursuant to subsection a. of this section shall remain on the formulary for so long as the wholesale acquisition cost of the generic drug is lower than the wholesale acquisition cost of the reference listed drug.

14. a. If a biosimilar is licensed by the federal Food and Drug Administration, is marketed pursuant to the licensure, and has a wholesale acquisition cost that is less than the wholesale acquisition cost of the reference product of the biosimilar on the initial date of marketing, then a vendor that provides coverage for the biosimilar's reference product at the time of the biosimilar's marketing date shall:

(1) 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

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

b. A biosimilar added to a formulary pursuant to subsection a. of this section shall remain on the formulary for so long as the

wholesale acquisition cost of the biosimilar is lower than the wholesale acquisition cost of the reference listed drug.

15. Nothing in this act shall require a vendor to continue providing coverage for a brand drug after a generic drug or biosimilar is approved or licensed, as applicable, and marketed.

16. Nothing in sections 10 through 15 of this act shall require a vendor to provide coverage for a brand drug, generic drug, or biosimilar if the individuals that develop the organization's formulary determine that the drug or biosimilar is no longer medically appropriate or cost-effective.

17. Nothing in sections 10 through 16 of this act shall interfere with a pharmacist complying with the "New Jersey Pharmacy Practice Act," P.L.2003, c.280 (C.45:14-40 et seq.).

18. The Department of Banking and Insurance shall adopt rules and regulations, pursuant to the "Administrative Procedure Act," P.L.1968, c.410 (C.52:14B-1 et seq.), as may be necessary to implement sections 10 through 17 of this act.

19. This act shall take effect on January 1, 2027 and shall apply to all contracts and policies delivered, issued, executed, or renewed on or after that date.

STATEMENT

This bill improves access to lower cost generic and biosimilar drugs.

Under the bill, certain guidelines are established to improve patient access to generic and biosimilar drugs in the State Health Benefits Program, School Employees Health Benefits Program, and the State Medicaid program. Among the bill's provisions, the bill provides a preference to biosimilars if a covered person or enrollee is prescribed a brand drug that the covered person or enrollee has not previously been prescribed, if a biosimilar drug is available. The bill provides that vendors that contract with the State Health Benefits Program and the School Employees Health Benefits Program, and managed care organizations that administer the State Medicaid program, publish an up-to-date, accurate, and complete list of all covered drugs in its formulary, including any tiering structure that they have adopted and any restrictions on the manner in which a drug can be obtained, in a manner that is easily accessible to covered persons, enrollees, and the general public.

The bill also provides that if a generic or biosimilar drug is licensed by the FDA, is marketed pursuant to the generic or

biosimilar drug's licensure, and has a wholesale acquisition cost that is less than the wholesale acquisition cost of the reference listed drug or reference product on the initial date of the generic or biosimilar drug's marketing, then vendors and managed care organizations that provide coverage for the generic drug or biosimilar's reference listed drug or reference product at the time of the generic drug or biosimilar's marketing date shall:

(1) 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

(2) not impose any prior authorization, step therapy, or other limitation on coverage of a biosimilar for which formulary placement is required under the provisions of the bill, nor impose any restriction on a pharmacy through which a covered person or enrollee may obtain the generic drug or biosimilar that makes it more difficult for a covered person or enrollee to obtain coverage of, or obtain access to, the generic drug or biosimilar than the reference listed drug or reference product.

Finally, the bill provides that a vendor or managed care organization does not have to provide coverage for a brand drug, generic drug, or biosimilar if the clinical and pharmacy experts that develop the formulary determine that the drug or biosimilar is no longer medically appropriate or cost-effective.

For the purposes of this bill, "Biosimilar" means a drug that is produced or distributed pursuant to a biologics license application approved under 42 U.S.C. s.262(k) and that is not listed as "discontinued" in the Database of Licensed Biological Products of the FDA. .

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

"Generic drug" means a drug that is approved under 21 U.S.C. s.355(j) and is listed in the Approved Drug Products with Therapeutic Equivalence Evaluations of the FDA as therapeutically equivalent to a reference drug, even if the manufacturer of such drug applies a trade name to the drug.