131st MAINE LEGISLATURE

SECOND REGULAR SESSION-2024

Legislative Document **No. 2114**

S.P. 907 In Senate, January 3, 2024

An Act to Improve Patient Access to and Savings from Generic Drugs and Biosimilars

Approved for introduction by a majority of the Legislative Council pursuant to Joint Rule 203.

Reference to the Committee on Health Coverage, Insurance and Financial Services suggested and ordered printed.

DAREK M. GRANT
Secretary of the Senate

Presented by President JACKSON of Aroostook.
Cosponsored by Representative PERRY of Calais and
Senators: DAUGHTRY of Cumberland, HICKMAN of Kennebec, INGWERSEN of York, RENY of Lincoln, Representatives: CYRWAY of Albion, DODGE of Belfast, PRINGLE of Windham, Speaker TALBOT ROSS of Portland.

Be it enacted by the People of the State of Maine as follows:

Sec. 1. 24-A MRSA §4311-A is enacted to read:

§4311-A. Coverage for generic drugs and biosimilars

1. Definitions. As used in this section, unless the context otherwise indicates, the following terms have the following meanings.

A. "Biosimilar" means any biological product that is licensed under 42 United States Code, Section 262(k).

B. "Brand drug" means a drug for which an application has been approved under 21 United States Code, Section 355(c) or a biological product other than a biosimilar that is licensed under 42 United States Code, Section 262(a).

C. "Equivalent" means:

(1) With respect to a generic drug, the brand drug against which the generic drug is evaluated by the United States Food and Drug Administration under 21 United States Code, Section 355(j); and

(2) With respect to a biosimilar, the brand drug biological product as defined in 42 United States Code, Section 262(i).

D. "Formulary" means a list of prescription drugs that are medically appropriate, cost-effective and approved for use and that is developed by a carrier's pharmacy and therapeutics committee or other clinical and pharmacy experts.

E. "Generic drug" means a drug for which an application has been approved under 21 United States Code, Section 355(j), including a drug for which the manufacturer of the drug applies a trade name.

F. "Pharmacy and therapeutics committee" has the same meaning as in section 4347, subsection 16.

G. "Wholesale acquisition cost" has the same meaning as in Title 22, section 8731, subsection 6.

2. Notification of formulary change. A carrier that provides coverage for prescription drugs and that amends its formulary pursuant to this section shall notify all insureds of that change in the formulary. Notification may be made by posting the formulary change on the carrier's publicly accessible website.

3. Generic drugs. If a generic drug is approved by the United States Food and Drug Administration, is marketed pursuant to that approval and has a wholesale acquisition cost that is less than the wholesale acquisition cost of the brand drug to which the generic drug is equivalent, a carrier that provides coverage for that brand drug:

A. Shall immediately make the generic drug available on the carrier's formulary with a lower out-of-pocket cost to an insured than the brand drug; and

B. Notwithstanding anything to the contrary in section 4304 or 4320-N, may not impose any prior authorization or step therapy requirement or other limitation on coverage of the generic drug or impose a restriction on a pharmacy that makes it more difficult for an insured to obtain coverage of or access to the generic drug than the brand drug to which the generic drug is equivalent.

4. Biosimilars. If a biosimilar is approved by the United States Food and Drug Administration, is marketed pursuant to that approval and has a wholesale acquisition cost that is less than the wholesale acquisition cost of the brand drug to which the biosimilar is equivalent, a carrier that provides coverage for that brand drug:

A. Shall immediately make at least one biosimilar for that brand drug available on the carrier's formulary with a lower out-of-pocket cost to an insured than the brand drug; and

B. Notwithstanding anything to the contrary in section 4304 or 4320-N, may not impose any prior authorization or step therapy requirement or other limitation on coverage of the biosimilar or impose a restriction on a pharmacy that makes it more difficult for an insured to obtain coverage of or access to the biosimilar than the brand drug to which the biosimilar is equivalent.

5. Coverage for brand drug after approval of generic drug or biosimilar. A carrier is not required to continue providing coverage for a brand drug after a generic drug or biosimilar is approved by the United States Food and Drug Administration.

6. Coverage for brand drug, generic drug or biosimilar upon determination that not medically appropriate or cost-effective. A carrier is not required to provide coverage for a brand drug, generic drug or biosimilar if the clinical and pharmacy experts that develop the carrier's formulary determine that the brand drug, generic drug or biosimilar is no longer medically appropriate or cost-effective.

7. Pharmacists. Nothing in this section is intended to interfere with a pharmacist's compliance with the Maine Pharmacy Act.

8. Rules. The department may adopt rules to implement this section. Rules adopted pursuant to this subsection are routine technical rules as defined in Title 5, chapter 375, subchapter 2-A.

Sec. 2. Effective date. This Act takes effect January 1, 2025.

SUMMARY

This bill requires health insurance companies and other carriers that provide coverage for prescription drugs to include on the carrier's formulary generic drugs and biosimilars that are approved by the United States Food and Drug Administration and that have a wholesale acquisition cost that is less than the wholesale acquisition cost of the brand drug to which the generic drug or biosimilar is equivalent. The generic drug or biosimilar must be made available on the carrier's formulary with a lower out-of-pocket cost to an insured than the brand drug. The bill prohibits carriers from imposing any prior authorization or step therapy requirement or other limitation on coverage for the generic drug or biosimilar.