129th MAINE LEGISLATURE

SECOND REGULAR SESSION-2020

Legislative Document **No. 2095**

S.P. 745 In Senate, February 4, 2020

An Act To Require Appropriate Coverage of and Cost-sharing for 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 Speaker GIDEON of Freeport and
Senators: CARPENTER of Aroostook, FOLEY of York, SANBORN, H. of Cumberland,
Representatives: FECTEAU of Biddeford, PRESCOTT of Waterboro, STEWART of Presque Isle, WARREN of Hallowell.

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 of and cost-sharing 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. "Branded pharmaceutical" means:

(1) A drug for which an application has been approved under 21 United States Code, Section 355(d); or

(2) A biological product, other than a biosimilar, that is licensed under 42 United States Code, Section 262(a).

C. "Formulary" has the same meaning as in section 4347, subsection 8.

D. "Generic cost-sharing tier" means a cost-sharing tier that includes generic drugs and excludes branded pharmaceuticals and for which the enrollee cost-sharing amount is meaningfully lower than the cost-sharing amount applicable to the lowest branded cost-sharing tier.

E. "Generic drug" means a drug for which an application has been approved under 21 United States Code, Section 355(j).

F. "Lowest branded cost-sharing tier" means the cost-sharing tier of a formulary that includes branded pharmaceuticals and provides for a lower level of enrollee cost-sharing than any other cost-sharing tier of that formulary that includes branded pharmaceuticals.

G. "Meaningfully lower" means lower in cost by an amount that significantly encourages enrollees to use, as applicable:

(1) Generic drugs and biosimilars that are on a generic cost-sharing tier instead of branded pharmaceuticals on the formulary's lowest branded cost-sharing tier; or

(2) Generic drugs and biosimilars that are specialty pharmaceuticals instead of branded pharmaceutical reference products.

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

I. "Reference product" means:

(1) With respect to a generic drug, the listed branded pharmaceutical against which, in accordance with 21 United States Code, Section 355(j)(2)(A)(i), the generic drug was evaluated in the abbreviated application for that generic drug that was submitted and approved under 21 United States Code, Section 355(j); and

(2) With respect to a biosimilar, the reference biological product as defined in 42 United States Code, Section 1395w-3a(c)(6)(I).

J. "Specialty pharmaceutical" means a branded pharmaceutical, generic drug or biosimilar for which the wholesale acquisition cost exceeds the threshold set for a specialty drug under the Medicare Part D program. For the purposes of this paragraph, "Medicare Part D" has the same meaning as in Title 22, section 254-D, subsection 1, paragraph F.

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

2. Generic drug and biosimilar coverage and enrollee access requirements for health plans using a formulary. If a health plan offered by a carrier in this State provides coverage for prescription drugs and the plan limits coverage to drugs included on a formulary, the carrier offering that health plan, subject to the limitations set forth in subsection 4:

A. Shall include on the formulary at least one generic drug or biosimilar that has a wholesale acquisition cost that is lower than the wholesale acquisition cost for the generic drug or biosimilar's branded pharmaceutical reference product, unless the generic drug or biosimilar is a specialty pharmaceutical;

B. Shall include on the formulary each generic drug or biosimilar that is a specialty pharmaceutical if the formulary includes the branded pharmaceutical reference product for the generic drug or biosimilar and the generic drug or biosimilar has a lower wholesale acquisition cost than its branded pharmaceutical reference product;

C. May not impose any limitation on coverage of or enrollee access to a generic drug or biosimilar for which formulary placement is required under paragraph A or B that:

(1) Is more restrictive than any limitation applicable to the branded pharmaceutical reference product for that generic drug or biosimilar if that branded pharmaceutical reference product is included on the formulary;

(2) Has the effect of favoring the branded pharmaceutical product; or

(3) Restricts the pharmacies through which enrollees may obtain the generic drug or biosimilar that is not also applicable to the branded pharmaceutical reference product; and

D. With respect to any generic drug or biosimilar that is a specialty pharmaceutical and has a lower wholesale acquisition cost than the wholesale acquisition cost of its branded pharmaceutical reference product, if neither the generic drug or biosimilar nor its branded pharmaceutical reference product is included on the health plan's formulary, may not impose any requirement for coverage of that generic drug or biosimilar as an exception to the formulary that is more restrictive than the requirements for coverage of the branded pharmaceutical reference product as an exception to the formulary.

3. Cost-sharing requirements. Except as provided in subsection 4, if a health plan offered by a carrier in this State provides coverage for prescription drugs using a tiered formulary cost-sharing arrangement:

A. For each generic drug and biosimilar for which coverage is required under subsection 2, paragraph A, the carrier offering the health plan shall provide coverage on a generic cost-sharing tier; and

B. For each generic drug and biosimilar that is a specialty pharmaceutical and for which coverage is required under subsection 2, paragraph B, the carrier offering the health plan shall provide coverage at a meaningfully lower cost-sharing amount than the cost-sharing amount provided for the branded pharmaceutical reference product for that generic drug or biosimilar.

4. Application; limitations. The requirements set forth in subsections 2 and 3:

A. Apply only with respect to coverage of and cost-sharing for generic drugs, biosimilars and branded pharmaceuticals when dispensed by pharmacies as outpatient prescription drugs and do not apply to generic drugs, biosimilars or branded pharmaceuticals when provided by a hospital, physician or other provider of health care or palliative services, other than a pharmacy, incident to the services of that provider and paid for by or on behalf of the relevant health plan as part of the payment for such services under the medical benefit of the health plan;

B. Do not apply to the extent that they would require coverage of or enrollee cost-sharing for a generic drug or biosimilar under a health plan that is not permitted under any applicable federal law or any law of this State; and

C. Do not require that a health plan include on its formulary a generic drug or biosimilar if the carrier has not included the branded pharmaceutical for that generic drug or biosimilar on its formulary due to a determination by the pharmacy and therapeutics committee for that health plan that the branded pharmaceutical should not be covered due to clinical concerns about the safety or efficacy of the branded pharmaceutical based on the strength of scientific evidence.

5. No cost-sharing or single copayment amount not precluded. Nothing in this section precludes a carrier from offering a health plan providing coverage of those generic drugs and biosimilars for which coverage is required under subsection 2, paragraph A or B and all branded pharmaceuticals on the formulary of the given health plan without any enrollee cost-sharing or for a single copayment amount applicable to all covered pharmaceuticals.

SUMMARY

This bill establishes requirements for the coverage of and cost-sharing for generic drugs, biosimilars and branded pharmaceuticals when dispensed by pharmacies as outpatient prescription drugs under health plans offered by carriers that provide coverage for prescription drugs.