



130th MAINE LEGISLATURE

FIRST SPECIAL SESSION-2021

Legislative Document

No. 1706

S.P. 558

In Senate, May 13, 2021

An Act To Require Appropriate Coverage of and Cost-sharing for Generic Drugs and Biosimilars

Received by the Secretary of the Senate on May 11, 2021. Referred to the Committee on Health Coverage, Insurance and Financial Services pursuant to Joint Rule 308.2 and ordered printed.

A handwritten signature in black ink, appearing to read 'D M Grant'.

DAREK M. GRANT
Secretary of the Senate

Presented by President JACKSON of Aroostook.

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

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

3 **§4311-A. Coverage of and cost-sharing for generic drugs and biosimilars**

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

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

8 B. "Biosimilar tier" means a cost-sharing tier of a formulary that includes a biosimilar,
9 may include a generic drug and does not include a branded drug and provides an
10 enrollee meaningfully lower cost-sharing for each biosimilar on the tier than the cost-
11 sharing applicable to the branded drug to which the biosimilar is equivalent. A single
12 cost-sharing tier of a formulary may be both a biosimilar and a generic tier for purposes
13 of this section.

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

17 D. "Cost-sharing" means the copayment amount or coinsurance percentage multiplied
18 by prescription drug cost used to determine the amount payable by an enrollee of a
19 health plan for a given covered prescription drug after satisfaction of any applicable
20 deductible under the plan when dispensed by a pharmacy.

21 E. "Equivalent" means:

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

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

27 F. "Generic drug" means a drug for which an application has been approved under 21
28 United States Code, Section 355(i).

29 G. "Generic tier" means a cost-sharing tier of a formulary drug that includes a generic
30 drug, may include a biosimilar and does not include a branded drug and provides an
31 enrollee meaningfully lower cost-sharing for each generic drug on the tier than the cost-
32 sharing applicable to the branded drug to which the generic drug is equivalent.

33 H. "Meaningfully lower" means lower by an amount that significantly incentivizes an
34 enrollee of a health plan to use a generic drug or biosimilar instead of an equivalent
35 branded drug.

36 I. "Step therapy" means a cost-savings measure that uses a less expensive drug to treat
37 a condition before using another drug that is more expensive for an insurer.

38 **2. Cost-sharing.** If cost-sharing for a generic drug or biosimilar and the equivalent
39 branded drug is based upon a coinsurance percentage, the coinsurance percentage for the
40 generic drug or biosimilar must be meaningfully lower than the coinsurance percentage for
41 the branded drug. If a copayment or coinsurance is used to determine cost-sharing, the

1 dollar amount payable to the enrollee for a generic drug or biosimilar must be meaningfully
2 lower than the dollar amount payable for the equivalent branded drug.

3 **3. Generic drug and biosimilar coverage and cost-sharing requirements for**
4 **health plans using a formulary.** If a health plan provides coverage for prescription drugs
5 and the plan limits coverage to a drug included on a formulary, the carrier offering the plan,
6 subject to subsection 4:

7 A. With respect to a generic drug, if the branded drug to which the generic drug is
8 equivalent is included on the formulary, shall include the equivalent generic drug on a
9 generic tier of the formulary;

10 B. With respect to a biosimilar, if the branded drug to which the biosimilar is
11 equivalent is included on the formulary, shall include at least one biosimilar equivalent
12 to the branded drug on a biosimilar tier of the formulary;

13 C. May not impose any prior authorization, step therapy or other limitation on
14 coverage of a generic drug or biosimilar for which formulary placement is required
15 under this subsection or any restriction on a pharmacy through which an enrollee may
16 obtain the generic drug or biosimilar that makes it more difficult for an enrollee to
17 obtain coverage of or access to the generic drug or biosimilar than the equivalent
18 branded drug; and

19 D. May not establish any benefit term or condition, pricing or other arrangement that
20 results in an enrollee of a health plan bearing a higher out-of-pocket cost for a generic
21 drug or biosimilar for which formulary placement is required under this subsection than
22 for the equivalent branded drug, including higher prices borne by an enrollee through
23 a deductible for the generic drug or biosimilar than for the equivalent branded drug.

24 **4. Limitation.** This section applies to a health plan offered by an insurer licensed
25 under this Title or a health maintenance organization licensed under chapter 56.

26 This section does not preclude a carrier from offering a health plan providing coverage of
27 all prescription drugs on a formulary with the same cost-sharing or no cost-sharing
28 applicable to the prescription drugs.

29 **SUMMARY**

30 This bill requires that formularies for prescription drugs approved for coverage under
31 a health plan contain tiers of generic drugs or biosimilars that are equivalent to the approved
32 branded drugs, and that cost-sharing through coinsurance or a copayment make the cost of
33 the generic drug or biosimilar meaningfully lower than the cost of the equivalent branded
34 drug. A biosimilar is a biological product licensed by the United States Food and Drug
35 Administration that is highly similar to a branded prescription drug.