



# 131st MAINE LEGISLATURE

## SECOND REGULAR SESSION-2024

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Legislative Document

No. 2114

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S.P. 907

In Senate, January 3, 2024

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

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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.

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.  
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.

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

11 C. "Equivalent" means:

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

15 (2) With respect to a biosimilar, the brand drug biological product as defined in  
16 42 United States Code, Section 262(i).

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

## 27 SUMMARY

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