

WEST VIRGINIA LEGISLATURE

2024 REGULAR SESSION

Introduced

Senate Bill 325

By Senators Takubo, Plymale, Woodrum, Woelfel,

Weld, Hamilton, and Deeds

[Introduced January 12, 2024; referred
to the Committee on Health and Human Resources;
and then to the Committee on the Judiciary]

1 A BILL to amend the Code of West Virginia, 1931, as amended, by adding thereto a new section,
 2 designated §60A-8-6a, relating to the distribution of drugs to safety net providers and
 3 contract pharmacies; penalties; and preemption.

Be it enacted by the Legislature of West Virginia:

ARTICLE 8. WHOLESALE DRUG DISTRIBUTION LICENSING ACT OF 1991.

§60A-8-6a. Distribution of Safety-Net Drugs to Contract Pharmacies; Penalties; and Preemption.

1 (a) Definitions. – As used in this section:

2 (1) "340B drug" means a drug that:

3 (A) Is a covered outpatient drug within the meaning of 42 U.S.C. §256b;

4 (B) Has been subject to any offer for reduced prices by a manufacturer under 42 U.S.C.

5 §256b(a)(1); and

6 (C) Is purchased by a covered entity within the meaning of 42 U.S.C. §256b.

7 (2) "340B entity" has the same meaning as that term is defined in §33-51-3 of this code.

8 (3) "Biological product" has the same meaning as that term is defined in 42 U.S.C. § 262.

9 (4) "Board of pharmacy" means the West Virginia Board of Pharmacy, which is the agency
 10 of this state authorized to issue and condition licensure and permitting of wholesale drug
 11 distributors, third-party logistics providers, and manufacturers.

12 (5) "Commissioner" means the West Virginia insurance commissioner, his or her deputies,
 13 or the West Virginia offices of the insurance commissioner, as appropriate.

14 (6) "Manufacturer" has the same meaning as that term is defined in §60A-8-5 of this code,
 15 except that such definition shall include manufacturers of biological products.

16 (7) "Package" has the same meaning as that term is defined in 21 U.S.C. §360eee(11)(A).

17 (8) "Pharmacy" has the same meaning as that term is defined in §30-5-4 of this code.

18 (b) Distribution of drugs to safety net providers and contract pharmacies.

19 (1) A manufacturer, wholesale drug distributor, third-party logistics provider, or an agent or

20 affiliate of such manufacturer, wholesale drug distributor, or third-party logistics provider, shall not
21 deny, restrict, or prohibit, either directly or indirectly, the acquisition of a 340B drug by, or delivery
22 of a 340B drug to, a location authorized by a 340B entity to receive such 340B drug unless the
23 receipt of the 340B drug is prohibited by the United States Department of Health and Human
24 Services.

25 (2) A manufacturer, wholesale drug distributor, third-party logistics provider, or an agent or
26 affiliate of such manufacturer, wholesale drug distributor, or third-party logistics provider, shall not
27 require a 340B entity to submit any claims or utilization data as a condition for allowing the
28 acquisition of a 340B drug by, or delivery of a 340B drug to, a 340B entity unless the claims or
29 utilization data sharing is required by the United States Department of Health and Human
30 Services.

31 (c) Penalties and investigations.

32 (1) The commission of any act prohibited by subsection (b) of this section shall constitute:

33 (A) A violation of §46A-6-104 of this code and shall subject the violator to a civil penalty of
34 \$50,000 per each violation, as well as any and all actions, including investigative demands,
35 remedies, and penalties provided for in article seven of chapter forty-six A of this code, except that
36 there shall be no right to bring a private cause of action; and

37 (B) A violation of §33-11-1 et seq. of this code and shall subject the violator to any and all
38 actions, including cease and desist orders, civil penalties, and restitution provided for in §33-11-6
39 of this code, except that there shall be no right to bring a private cause of action.

40 (2) Each package of 340B drugs determined to be subject to a prohibited act under
41 subsection (b) of this section shall constitute a separate violation under subsection (b) of this
42 section.

43 (3) Upon receipt by the board of pharmacy of a complaint that a person or other entity
44 licensed or permitted by the board of pharmacy has violated subsection (b) of this section, the
45 board of pharmacy:

46 (A) May investigate the complaint and consider appropriate penalties, including imposing
47 discipline or suspending or revoking the license or permit of any such person or entity; and

48 (B) Shall share the results of the investigation with the attorney general and commissioner
49 if an investigation is conducted.

50 (3) The Attorney General, board of pharmacy, and commissioner may promulgate rules to
51 implement the provisions of subsection (b) of this section.

52 (d) Preemption.

53 (1) Nothing in this section is to be construed or applied to be less restrictive than any
54 federal law as to any person or other entity regulated by this section. Nothing in this section is to
55 be construed or applied to be in conflict with any of the following:

56 (A) Applicable federal law and related regulation.

57 (B) Other laws of this state if the state law is compatible with applicable federal law.

58 (2) Limited distribution of a drug required under 21 U.S.C. §355-1 is not to be construed as
59 a violation of this section.

NOTE: The purpose of this bill generally relates to the distribution of drugs to safety net providers and contract pharmacies. The bill provides for penalties. Finally, the bill provides for preemption.

Strike-throughs indicate language that would be stricken from a heading or the present law and underscoring indicates new language that would be added.