

WEST VIRGINIA LEGISLATURE

2024 REGULAR SESSION

Introduced

House Bill 5166

By Delegates Summers and Tully

[Introduced January 25, 2024; Referred to the
Committee on Prevention and Treatment of
Substance Abuse then Health and Human
Resources]

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; providing penalties; and
 3 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.

1 (a) As used in this article:

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

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

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

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

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

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

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

18 (b) (1) A manufacturer, wholesale drug distributor, third-party logistics provider, or an agent
 19 or affiliate of such manufacturer, wholesale drug distributor, or third-party logistics provider, may
 20 not deny, restrict, or prohibit, either directly or indirectly, the acquisition of a 340B drug by, or

21 delivery of a 340B drug to, a location authorized by a 340B entity to receive such 340B drug unless
22 the receipt of the 340B drug is prohibited by the United States Department of Health and Human
23 Services.

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

30 (c) (1) The commission of any act prohibited by subsection (b) of this section constitutes:

31 (A) A violation of §46A-6-104 of this code and shall subject the violator to a civil penalty of
32 \$50,000 for each violation, as well as any and all actions, including investigative demands,
33 remedies, and penalties provided for in §46A-7-1 et seq. of this code, except that there is no right
34 to bring a private cause of action; and

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

38 (2) Each package of 340B drugs determined to be subject to a prohibited act under
39 subsection (b) of this section constitutes a separate violation under subsection (b) of this section.

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

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

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

47 (4) The attorney general, board of pharmacy, and commissioner may promulgate rules to
48 implement the provisions of subsection (b) of this section.

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

52 (A) Applicable federal law and related regulation.

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

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

NOTE: The purpose of this bill is to prohibit certain action concerning the distribution of safety-net drugs to contract pharmacies.

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