WEST VIRGINIA LEGISLATURE

2024 REGULAR SESSION

Committee Substitute

for

Committee Substitute

for

Senate Bill 325

By Senators Takubo, Plymale, Woodrum, Woelfel,

Weld, Hamilton, and Deeds

[Originating in the Committee on the Judiciary;

reported February 2, 2024]

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

(a) *Definitions*. — As used in this section:

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

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

(B) Has been subject to any offer for reduced prices by a manufacturer under 42 U.S.C. §256b(a)(1); and

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

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

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

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

(5) "Commissioner" means the West Virginia Insurance Commissioner, his or her deputies, or the West Virginia Offices of the Insurance Commissioner.

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

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

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

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

(1) A manufacturer, agent, or affiliate of such manufacturer shall not, either directly or

indirectly, deny, restrict, or prohibit the acquisition of a 340B drug by, or delivery of a 340B drug to, a location authorized by a 340B entity to receive such 340B drug, unless the receipt of the 340B drug is prohibited by the United States Department of Health and Human Services.

(2) A manufacturer, agent, or affiliate of such manufacturer shall not, either directly or indirectly, require a 340B entity to submit any claims or utilization data as a condition for allowing the acquisition of a 340B drug by, or delivery of a 340B drug to, a 340B entity unless the claims or utilization data sharing is required by the United States Department of Health and Human Services.

(c) *Penalties and investigations*. —

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

(A) A violation of §46A-6-104 of this code and shall subject the violator to a civil penalty of $50,000 per each violation, as well as any and all actions, including investigative demands, remedies, and penalties provided for in §46A-7-101 *et seq*. of this code, except that there shall be no right to bring a private cause of action; and

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

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

(3) Upon receipt by the Board of Pharmacy of a complaint that a manufacturer has violated subsection (b) of this section, the Board of Pharmacy:

(A) May investigate the complaint, including by investigating the manufacturer or any agent, affiliate, or contractor thereof, including any wholesaler or third-party logistics provider that may possess evidence supporting such complaint; and

(B) Shall consider appropriate penalties, including imposing discipline, or suspending, or revoking the license or permit of any manufacturer; and

(C) Shall share the results of the investigation with the Attorney General and commissioner if an investigation is conducted.

(3) The Board of Pharmacy and commissioner may promulgate rules to implement the provisions of subsection (b) of this section.

(d) *Preemption*. —

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

(A) Applicable federal law and related regulations.

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

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