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SENATE BILL NO. 278

Offered January 14, 2026

Prefiled January 13, 2026

A BILL to amend and reenact §§ 54.1-3437 and 54.1-3442.01 of the Code of Virginia, relating to drug manufacturers; permitting and registration; certain conditions related to 340B-covered drugs.

Patron—Srinivasan

Referred to Committee on Education and Health

Be it enacted by the General Assembly of Virginia:

1. That §§ 54.1-3437 and 54.1-3442.01 of the Code of Virginia are amended and reenacted as follows:

§ 54.1-3437. Permit to manufacture drugs.

A. It shall be lawful to manufacture, make, produce, pack, package, repackage, relabel or prepare any drug not controlled by Schedule I after first obtaining the appropriate permit from the Board. Such permits shall be subject to the Board's regulations on sanitation, equipment, and safeguards against diversion, and shall allow the distribution of the drug manufactured, made, produced, packed, packaged, repackaged, relabeled, or prepared to anyone other than the end user without the need to obtain a wholesale distributor permit. This provision shall not apply to manufacturers or packers of medicated feeds who manufacture or package no other drugs.

B. The manufacturer shall, as a condition of obtaining a permit, certify that it does not limit the number of contract pharmacies or covered entities, as defined in § 38.2-3465, to which it ships 340B-covered drugs and that it complies with subdivision A 5 of § 38.2-3467.

§ 54.1-3442.01. Registration of nonresident manufacturer; renewal.

A. Any manufacturer located outside the Commonwealth who ships prescription drugs into the Commonwealth shall be registered with the Board. The nonresident manufacturer shall renew such registration annually on a date determined by the Board in regulation and shall notify the Board within 30 days of any substantive change in the information previously submitted.

B. The nonresident manufacturer shall at all times maintain a valid, unexpired license, permit, or registration in the state in which it is located or current registration as a manufacturer or repackager with the federal Food and Drug Administration and shall furnish proof of such upon application and at each renewal.

C. *The manufacturer shall, as a condition of registration or renewal of its registration, certify that it does not limit the number of contract pharmacies or covered entities, as defined in § 38.2-3465, to which it ships 340B-covered drugs and that it complies with subdivision A 5 of § 38.2-3467.*

D. Records of prescription drugs distributed into the Commonwealth shall be maintained in such a manner that they are readily retrievable from records of shipments into other jurisdictions and shall be provided to the Board, its authorized agent, or any agent designated by the Superintendent of the Department of State Police upon request within seven days of receipt of such request.