ASSEMBLY, No. 4186

STATE OF NEW JERSEY

218th LEGISLATURE

INTRODUCED JUNE 18, 2018

Sponsored by:
Assemblywoman PATRICIA EGAN JONES
District 5 (Camden and Gloucester)
Assemblywoman ELIANA PINTOR MARIN
District 29 (Essex)

SYNOPSIS

Prohibits resale of non-prescription diabetes test devices by pharmacists.

CURRENT VERSION OF TEXT

As introduced.

(Sponsorship Updated As Of: 5/14/2019)

AN ACT concerning non-prescription diabetes test devices and supplementing Title 45 of the Revised Statutes.

BE IT ENACTED *by the Senate and General Assembly of the State of New Jersey:*

1. As used in this act:

"Board" means the New Jersey State Board of Pharmacy established pursuant to P.L.2003, c.280 (C.45:14-40 et seq.)

"Non-prescription diabetes test device" means a glucose meter or test strip for use in the treatment of prediabetic or diabetic individuals that may be sold without a prescription and that is labeled for use by the consumer in accordance with applicable State and federal law.

2. A manufacturer of a non-prescription diabetes test device that is distributed within New Jersey shall make the names of its authorized distributors available on its Internet Web site and shall provide the board with the names of its authorized distributors. Within 30 days of receiving that information from a manufacturer of a non-prescription diabetes test device, the board shall post the names of authorized distributors of non-prescription diabetes test devices on the board's Internet Web site. A manufacturer of a non-prescription diabetes test device shall, within 30 days of making a change to its authorized distributors, update its Internet Web site and inform the board of changes to its authorized distributors. Within 30 days of receiving notice of any change from a manufacturer of a non-prescription diabetes test device, the board shall post the updated list of the manufacturer's authorized distributors on its Internet Web site.

3. In addition to the responsibilities given to the board pursuant to the "New Jersey Pharmacy Practice Act," P.L.2003, c.280 (C.45:14-40 et seq.), the board shall require that a pharmacy that dispenses non-prescription diabetes test devices pursuant to prescriptions shall retain records of its acquisition, inventory, and sale of those non-prescription diabetes test devices. The records shall be maintained in a manner prescribed by the board by regulation, and shall be retained for a period of not less than three years. The board shall have authority to inspect records at all reasonable hours.

4. The board may embargo any non-prescription diabetes test device that a board inspector finds or has probable cause to believe was not purchased either directly from the manufacturer or from the non-prescription diabetes test device manufacturer's authorized distributors as identified in section 2 of P.L. , c. (C.) (pending before the Legislature as this bill). Procedures for embargoing of such devices shall be established by the board by

regulation pursuant to the "Administrative Procedure Act," P.L.1968, c.410 (C.52:14B-1 et seq.), consistent with the requirements of subsection c. of section 9 of P.L.2003, c.280 (C.45:14-48).

5. A pharmacist who submits a reimbursement claim for a non-prescription diabetes test device to a health insurance carrier, pharmacy benefit manager, government agency, or other third-party payer when the pharmacist knew or reasonably should have known that the pharmacy did not purchase the diabetes test device either directly from the manufacturer or from one of the manufacturer's authorized distributors identified pursuant to section 2 of P.L. , c. (C.) (pending before the Legislature as this bill) shall be subject to disciplinary action pursuant to section 8 of P.L.1978, c.73 (C.45:1-21).

6. The New Jersey State Board of Pharmacy shall, in accordance with the "Administrative Procedure Act," P.L.1968, c.410 (C.52:14B-1 et seq.), adopt any rules and regulations as the board deems necessary to carry out the provisions of this act.

7. This act shall take effect on the first day of the seventh month next following the date of enactment.

STATEMENT

This bill prohibits the resale of non-prescription diabetes test devices by pharmacists.

The intent of the bill is to police the "grey market" for non-prescription diabetes test devices that are acquired outside of the authorized supply chain. Some unethical pharmacies and medical equipment suppliers acquire devices illegally from foreign countries, or acquire unused devices from patients at a price lower than wholesale but higher than the patient's out-of-pocket cost. These pharmacies and medical equipment suppliers then repackage and sell the products for a profit, billing insurers and government programs for the full price of the product and collecting rebates from manufacturers.

The bill requires that a manufacturer of a non-prescription diabetes test device that is distributed within New Jersey must make the names of its authorized distributors available on its Internet Web site, and provide the Board of Pharmacy with the names of its authorized distributors, and update that list within 30 days of making any change in its authorized distributors. Within 30 days of receiving that information, the board would post the names of authorized distributors of non-prescription diabetes test devices on the board's Internet Web site.

The bill further provides that a pharmacy that dispenses non-prescription diabetes test devices pursuant to prescriptions shall retain records of its acquisition, inventory, and sale of those non-prescription diabetes test devices. The records must be maintained in a manner prescribed by the board by regulation, and must be retained for a period of not less than three years. The board would have authority to inspect records at all reasonable hours.

The bill grants the board authority to embargo any non-prescription diabetes test device that a board inspector finds or has probable cause to believe was not purchased either directly from the manufacturer or from the non-prescription diabetes test device manufacturer's authorized distributors. Procedures for embargoing of such devices would be established by the board by regulation, consistent with the requirements of current law for the embargo of products held by a pharmacist whose license is suspended or revoked.

A pharmacist who submits a reimbursement claim for a non-prescription diabetes test device to a health insurance carrier, pharmacy benefit manager, government agency, or other third-party payer when the pharmacist knew or reasonably should have known that the pharmacy did not purchase the diabetes test device either directly from the manufacturer or from one of the manufacturer's authorized distributors would be subject to disciplinary action by the board.