STATE OF NEW YORK

5413--A

2021-2022 Regular Sessions

IN ASSEMBLY

February 16, 2021

Introduced by M. of A. DINOWITZ, SEAWRIGHT, HEVESI, COOK, BENEDETTO, FERNANDEZ, BICHOTTE HERMELYN, REYES, L. ROSENTHAL, SEPTIMO, BYRNES -- read once and referred to the Committee on Higher Education -- recommitted to the Committee on Higher Education in accordance with Assembly Rule 3, sec. 2 -- committee discharged, bill amended, ordered reprinted as amended and recommitted to said committee

AN ACT to amend the education law, in relation to the registration of nonresident pharmacies, manufacturers, wholesalers and outsourcing facilities that deliver prescription drugs to other establishments, authorized prescribers and patients residing in this state

The People of the State of New York, represented in Senate and Assembly, do enact as follows:

Section 1. Subdivision 2 of section 6808-b of the education law, as amended by chapter 567 of the laws of 2002, is amended to read as follows:

2. Registration. **(a)** All nonresident establishments that ship, mail, or deliver prescription drugs and/or devices to other registered establishments, authorized prescribers, and/or patients into this state shall be registered with the department; except that such registration shall not apply to intra-company transfers between any division, affiliate, subsidiaries, parent or other entities under complete common ownership and control. The provisions of this subdivision shall apply solely to nonresident establishments and shall not affect any other provision of this article.

(b) Notwithstanding the provisions of this article, an unregistered nonresident establishment may ship, mail, or deliver prescription drugs and/or devices to registered establishments in this state in cases of a specific patient need or a declared public health emergency, provided that:

EXPLANATION--Matter in *italics* (underscored) is new; matter in brackets [-] is old law to be omitted.

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(i) the unlicensed establishment is appropriately licensed in its home state, and documentation of the license verification can be maintained by the resident establishment in a manner determined by the department;

(ii) in cases of specific patient need, the registered establishment shall maintain documentation that the transfer is for such purpose in a manner determined by the department;

(iii) the resident pharmacy complies with all recordkeeping requirements of the department for each drug or device received from any unregistered nonresident establishment;

(iv) all documentation and records are retained and are readily retrievable by the resident establishment for a period of six years;

(v) the prescription drug or device was manufactured by an authorized FDA registered drug manufacturer and is not a compounded drug. The unregistered nonresident establishment shall only deliver or trade a drug or device salable on prescription only that it receives from a manufacturer, a wholesale distributor or a pharmacy in accordance with the federal Drug Supply Chain Security Act (DSCSA);

(vi) the nonresident establishment from which the drug is being obtained receives a request for the drug that identifies the drug's brand name or generic name, quality, quantity, and size. Such drug shall not be expired at the time of the exchange;

(vii) the drug being obtained includes with the drug a packaging checklist confirming that the drug being delivered or traded matches the information identified on the request, and the drug is delivered or traded in the original manufacturer's packaging, whether sealed or unsealed, with package insert, the drug's national drug code, lot number, and expiration date conspicuously identified on the packaging. If the original manufacturer's packaging is unsealed at the time of the delivery or trade, the delivery or trade may include a quantity of the drug that is less than the quantity contained in the original manufacturer's packaging. However, a pharmacy shall not trade or deliver more than one unsealed or partial quantity of the drug during any consecutive ninety-day period;

(viii) notwithstanding the language of this section, nothing shall be interpreted to allow for the sale, trade or exchange of a controlled substance as defined by article thirty-three of the public health law; and

(ix) the sale/transfer price of any item exchanged under this section may not exceed one hundred percent of the item's Wholesale Acquisition Cost (WAC) at the time of the sale.

(c) A pharmacy that receives notification from an unregistered nonresident establishment that a delivery or trade involved a drug or device salable on prescription only that is an illegitimate, recalled, or counterfeit product shall immediately notify the state board of pharmacy, and the FDA.

(d) Any unregistered nonresident establishment involved in a sale, exchange, or transaction under this section is subject to the jurisdiction of the state of New York regarding said sale, exchange or transaction. Such establishment shall cooperate with agents of the state of New York if said agent is conducting an audit or investigation into the sale, exchange or transaction, and violations of this section shall be punishable according to regulations promulgated by the department and the laws of this state.

(e) For purposes of this subdivision "specific patient need" is defined as the transfer of a product from one pharmacy to another to fill a prescription for an identified patient. Such term does not

include the transfer of a product from one pharmacy to another for the purpose of increasing or replenishing stock in anticipation of a potential need in accordance with the federal Drug Supply Chain Security Act.

§ 2. This act shall take effect on the ninetieth day after it shall become a law.