STATE OF NEW YORK

5489

2021-2022 Regular Sessions

IN SENATE

March 9, 2021

Introduced by Sen. BROUK -- read twice and ordered printed, and when printed to be committed to the Committee on Higher Education

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:

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

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

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

LBD09095-01-1

(iii) the resident establishment complies with all record-keeping requirements for each drug or device received from any pharmacy not registered by the department;

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

(v) the prescription drug or device was manufactured by an authorized FDA registered drug manufacturer.

(c) For purposes of paragraph (b) of this subdivision, documents shall be deemed to be maintained, retained, or readily retrievable by the resident establishment if they are available within seventy-two hours from a third-party who arranged or facilitated the transaction.

(d) For purposes of paragraph (b) of this subdivision "specific patient need" means 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.

§ 2. This act shall take effect immediately.