

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:

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

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

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

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

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

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

7 (iii) the resident pharmacy complies with all recordkeeping require-
8 ments of the department for each drug or device received from any unreg-
9 istered nonresident establishment;

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

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

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

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

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

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

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

46 (d) Any unregistered nonresident establishment involved in a sale,
47 exchange, or transaction under this section is subject to the jurisdic-
48 tion of the state of New York regarding said sale, exchange or trans-
49 action. Such establishment shall cooperate with agents of the state of
50 New York if said agent is conducting an audit or investigation into the
51 sale, exchange or transaction, and violations of this section shall be
52 punishable according to regulations promulgated by the department and
53 the laws of this state.

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

1 include the transfer of a product from one pharmacy to another for the
2 purpose of increasing or replenishing stock in anticipation of a poten-
3 tial need in accordance with the federal Drug Supply Chain Security Act.
4 § 2. This act shall take effect on the ninetieth day after it shall
5 become a law.