

STATE OF NEW YORK

1067

2023-2024 Regular Sessions

IN ASSEMBLY

January 13, 2023

Introduced by M. of A. DINOWITZ, SEAWRIGHT, HEVESI, COOK, BENEDETTO, BICHOTTE HERMELYN, REYES, L. ROSENTHAL, SEPTIMO, BYRNES, STIRPE -- read once and referred 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:

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:

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

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

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

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

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

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

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

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

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

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

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

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

48 (e) For purposes of this subdivision "specific patient need" is
49 defined as the transfer of a product from one pharmacy to another to
50 fill a prescription for an identified patient. Such term does not
51 include the transfer of a product from one pharmacy to another for the
52 purpose of increasing or replenishing stock in anticipation of a poten-
53 tial need in accordance with the federal Drug Supply Chain Security Act.

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