

STATE OF NEW YORK

2848

2017-2018 Regular Sessions

IN ASSEMBLY

January 23, 2017

Introduced by M. of A. PAULIN, TITONE, GOTTFRIED, GALEF -- read once and referred to the Committee on Higher Education

AN ACT to amend the education law, in relation to wholesalers and manufacturers of prescription drugs

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

1 Section 1. Subparagraph 2 of paragraph a of subdivision 4 of section
2 6808 of the education law, as amended by chapter 62 of the laws of 1989,
3 is amended to read as follows:

4 (2) The application shall be accompanied by a fee of [~~eight hundred~~
5 ~~twenty-five~~] twelve hundred dollars.

6 § 2. Paragraphs b and d of subdivision 4 of section 6808 of the educa-
7 tion law, paragraph b as amended by chapter 538 of the laws of 2001 and
8 paragraph d as amended by chapter 62 of the laws of 1989, are amended to
9 read as follows:

10 b. Renewal of registration. All wholesalers' and manufacturers' regis-
11 trations shall be renewed on dates set by the department. The triennial
12 registration fee shall be [~~five hundred twenty~~] eight hundred dollars or
13 a pro rated portion thereof as determined by the department.

14 d. Change of location. In the event that the location of such place of
15 business shall be changed, the owner shall apply to the department for
16 inspection of the new location and endorsement of the registration for
17 the new location. The fee for inspection and endorsement shall be [~~one~~
18 ~~hundred seventy~~] three hundred dollars, unless it appears to the satis-
19 faction of the department that the change in location is of a temporary
20 nature due to fire, flood or other disaster.

21 § 3. Subdivision 4 of section 6808 of the education law is amended by
22 adding six new paragraphs e, f, g, h, i and j to read as follows:

23 e. Applicant registration. Any applicant for registration as a whole-
24 saler or manufacturer shall be of good moral character, as determined by
25 the department. Subject to the provisions of paragraphs f and g of this

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

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subdivision, the department shall require a criminal history records search for officers, directors and owners of such wholesaler or manufacturer. For the purposes of this paragraph, "owner" shall mean a person who has a ten percent or greater ownership interest in such wholesaler or manufacturer.

f. Criminal history records search. (1) Upon receipt of an application for registration pursuant to this subdivision, the commissioner shall, subject to the rules and regulations of the division of criminal justice services, initiate a criminal history records search of the persons identified in paragraph e of this subdivision. Prior to initiating the background checks and fingerprinting process, the commissioner shall furnish the applicant with the form described in paragraph g of this subdivision and shall obtain the applicant's consent to the criminal history records search. The commissioner shall obtain from each applicant two sets of fingerprints and the division of criminal justice services processing fee imposed pursuant to subdivision eight-a of section eight hundred thirty-seven of the executive law and any fee imposed by the federal bureau of investigation for a national criminal history record check. The commissioner shall promptly transmit such fingerprints and fees to the division of criminal justice services for its full search and retain processing. The division of criminal justice services is authorized to submit the fingerprints and the appropriate fee to the federal bureau of investigation for a national criminal history record check. The division of criminal justice services and the federal bureau of investigation shall forward such criminal history record, if any, to the commissioner in a timely manner. Criminal history information provided by the division of criminal justice services pursuant to this subdivision shall be furnished only by mail or other method of secure and confidential delivery, addressed to the commissioner. Such information and the envelope in which it is enclosed, if any, shall be prominently marked "confidential," and shall at all times be maintained by the office in a secure place. The commissioner shall consider such criminal history record in accordance with the requirements of article twenty-three-A of the correction law and subdivisions fifteen and sixteen of section two hundred ninety-six of the executive law.

(2) For the purposes of this section the term "criminal history record" shall mean a record of all convictions of crimes that have not been vacated, reversed or sealed, and any pending criminal charges maintained by the division of criminal justice services and the federal bureau of investigation.

Furthermore, upon notification that such applicant has been registered, the division of criminal justice services shall have the authority to provide subsequent criminal history notifications directly to the commissioner. All such criminal history records processed and sent pursuant to this subdivision shall be confidential pursuant to the applicable federal and state laws, rules and regulations, and shall not be published or in any way disclosed to persons other than the commissioner, unless otherwise authorized by law. Any person who willfully permits the release of any confidential criminal history information contained in the report to persons not permitted by this section to receive such information shall be guilty of a misdemeanor.

g. Additional duties of the commissioner and department. (1) The commissioner, in cooperation with the division of criminal justice services and in accordance with all applicable provisions of law, shall promulgate rules and regulations to require the performance of a crimi-

1 nal history records check of the individuals identified in paragraph e
2 of this subdivision.

3 (2) The commissioner, in cooperation with the division of criminal
4 justice services, shall promulgate a form to be provided to all appli-
5 cants for registration pursuant to this subdivision that shall:

6 (i) inform the prospective applicant that the commissioner is required
7 to request his or her criminal history information from the division of
8 criminal justice services and the federal bureau of investigation and
9 review such information pursuant to this section, and provide a
10 description of the manner in which his or her fingerprint cards will be
11 used upon submission to the division of criminal justice services; and

12 (ii) inform the prospective applicant that he or she has the right to
13 obtain, review and seek correction of his or her criminal history infor-
14 mation pursuant to regulations and procedures established by the divi-
15 sion of criminal justice services.

16 (3) The department shall obtain the signed, informed consent of each
17 individual identified in paragraph e of this subdivision, on such form
18 supplied by the commissioner, which indicates that such person has:

19 (i) been informed of the rights and procedures necessary to obtain,
20 review and seek correction of his or her criminal history information;

21 (ii) been informed of the reason for the request for his or her crimi-
22 nal history information;

23 (iii) consented to such request for a report;

24 (iv) supplied on the form a current mailing or home address for such
25 individual;

26 (v) been informed that he or she may withdraw his or her consent,
27 regardless of whether the department has reviewed such individual's
28 criminal history information;

29 (vi) been informed that in the event the wholesaler's or manufactur-
30 er's registration pursuant to this subdivision has expired or otherwise
31 terminated, the commissioner shall notify the division of criminal
32 justice services of such expiration or termination, and the division of
33 criminal justice services shall destroy the fingerprints of the individ-
34 ual or individuals associated with such wholesaler's or manufacturer's
35 registration; and

36 (vii) been informed of the manner in which he or she may submit to the
37 commissioner any information that may be relevant to the consideration
38 of the applicant's registration including, where applicable, information
39 in support of his or her good moral character or rehabilitation thereof.

40 (4) Upon receipt of criminal history information pursuant to this
41 section and before making any determination thereon, the commissioner
42 shall provide the individual with a copy of such criminal history infor-
43 mation and a copy of article twenty-three-A of the correction law and
44 inform such individual of his or her right to seek correction of any
45 incorrect information contained in such criminal history information
46 pursuant to the regulations and procedures established by the division
47 of criminal justice services.

48 h. Performance or surety bond. Every wholesaler shall submit a
49 performance or surety bond of not less than one hundred thousand dollars
50 to the department to ensure compliance with the provisions of this arti-
51 cle, except that the department may waive such bond for certain not-for-
52 profit entities such as hospitals and correctional facilities that limit
53 distribution to their own facilities and do not return such medications
54 to other entities. The department may also exempt a wholesaler from the
55 surety bond requirement when such wholesaler is owned and operated by a
56 facility, subject to the provisions of article twenty-eight of the

1 public health law and other facilities governed by a state agency that
2 limits its distribution of prescription drugs to facilities and practi-
3 tioners within the institution's network and operations and does not
4 sell or return such medications to manufacturers or to other whole-
5 salers.

6 i. Wholesaler registration. The department may promulgate rules and
7 regulations to exempt from the requirements of paragraphs e, f, g and h
8 of this subdivision a wholesaler that has received accreditation from a
9 nationally recognized accreditation body approved by the commissioner
10 and that meets the licensing standards under this subdivision. The stan-
11 dards shall be defined by the commissioner pursuant to regulations.

12 j. Manufacturer registration. Notwithstanding the requirements for
13 registration under this subdivision, the commissioner shall exempt a
14 manufacturer licensed or approved by the federal food and drug adminis-
15 tration (FDA) or its successor agency to manufacture drugs or devices
16 with regard to such drugs or devices from the requirements of paragraphs
17 e, f, g and h of this subdivision in the event that such requirements
18 are not required by federal law or regulation unless the commissioner
19 determines that such requirements are necessary to prevent a risk to
20 prescription drug distribution in the state.

21 § 4. This act shall take effect on the one hundred eightieth day after
22 it shall have become a law.