

S T A T E O F N E W Y O R K

5286--A

2011-2012 Regular Sessions

I N S E N A T E

May 3, 2011

Introduced by Sen. LANZA -- read twice and ordered printed, and when printed to be committed to the Committee on Higher Education -- recommended to the Committee on Higher Education in accordance with Senate Rule 6, sec. 8 -- committee discharged, bill amended, ordered reprinted as amended and recommitted to said committee

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 S 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 S 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:

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

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1 E. APPLICANT REGISTRATION. ANY APPLICANT FOR REGISTRATION AS A WHOLE-
2 SALER OR MANUFACTURER SHALL BE OF GOOD MORAL CHARACTER, AS DETERMINED BY
3 THE DEPARTMENT. THE REQUIREMENTS SHALL EXTEND TO ALL PERSONS RESPONSIB-
4 LE FOR THE DISTRIBUTION OF A PRESCRIPTION DRUG FOR THE APPLICANT, AS
5 DETERMINED BY THE DEPARTMENT. SUBJECT TO THE PROVISIONS OF PARAGRAPHS F
6 AND G OF THIS SUBDIVISION, THE DEPARTMENT SHALL REQUIRE PHOTOGRAPHS,
7 CRIMINAL HISTORY RECORDS SEARCH AND FINGERPRINTS.

8 F. CRIMINAL HISTORY RECORDS SEARCH. (1) UPON RECEIPT OF AN APPLICATION
9 FOR REGISTRATION PURSUANT TO THIS SUBDIVISION, THE COMMISSIONER SHALL,
10 SUBJECT TO THE RULES AND REGULATIONS OF THE DIVISION OF CRIMINAL JUSTICE
11 SERVICES, INITIATE A CRIMINAL HISTORY RECORDS SEARCH OF THE PERSONS
12 IDENTIFIED IN PARAGRAPH E OF THIS SUBDIVISION. PRIOR TO INITIATING THE
13 BACKGROUND CHECKS AND FINGERPRINTING PROCESS, THE COMMISSIONER SHALL
14 FURNISH THE APPLICANT WITH THE FORM DESCRIBED IN PARAGRAPH G OF THIS
15 SUBDIVISION AND SHALL OBTAIN THE APPLICANT'S CONSENT TO THE CRIMINAL
16 HISTORY RECORDS SEARCH. THE COMMISSIONER SHALL OBTAIN FROM EACH APPLI-
17 CANT TWO SETS OF FINGERPRINTS AND THE DIVISION OF CRIMINAL JUSTICE
18 SERVICES PROCESSING FEE IMPOSED PURSUANT TO SUBDIVISION EIGHT-A OF
19 SECTION EIGHT HUNDRED THIRTY-SEVEN OF THE EXECUTIVE LAW AND ANY FEE
20 IMPOSED BY THE FEDERAL BUREAU OF INVESTIGATION FOR A NATIONAL CRIMINAL
21 HISTORY RECORD CHECK. THE COMMISSIONER SHALL PROMPTLY TRANSMIT SUCH
22 FINGERPRINTS AND FEES TO THE DIVISION OF CRIMINAL JUSTICE SERVICES FOR
23 ITS FULL SEARCH AND RETAIN PROCESSING. THE DIVISION OF CRIMINAL JUSTICE
24 SERVICES IS AUTHORIZED TO SUBMIT THE FINGERPRINTS AND THE APPROPRIATE
25 FEE TO THE FEDERAL BUREAU OF INVESTIGATION FOR A NATIONAL CRIMINAL
26 HISTORY RECORD CHECK. THE DIVISION OF CRIMINAL JUSTICE SERVICES AND THE
27 FEDERAL BUREAU OF INVESTIGATION SHALL FORWARD SUCH CRIMINAL HISTORY
28 RECORD TO THE COMMISSIONER IN A TIMELY MANNER. THE RELEASE OF SUCH CRIM-
29 INAL HISTORY RECORD BY THE DIVISION OF CRIMINAL JUSTICE SERVICES SHALL
30 BE SUBJECT TO THE PROVISIONS OF SUBDIVISION SIXTEEN OF SECTION TWO
31 HUNDRED NINETY-SIX OF THE EXECUTIVE LAW. THE COMMISSIONER SHALL CONSIDER
32 SUCH CRIMINAL HISTORY RECORD IN ACCORDANCE WITH THE REQUIREMENTS OF
33 ARTICLE TWENTY-THREE-A OF THE CORRECTION LAW, FOR THE PURPOSE OF ESTAB-
34 LISHING THE GOOD MORAL CHARACTER OF AN INDIVIDUAL AS REQUIRED IN PARA-
35 GRAPH E OF THIS SUBDIVISION.

36 (2) FOR THE PURPOSES OF THIS SECTION THE TERM "CRIMINAL HISTORY
37 RECORD" SHALL MEAN A RECORD OF ALL CONVICTIONS OF CRIMES AND ANY PENDING
38 CRIMINAL CHARGES MAINTAINED ON AN INDIVIDUAL BY THE DIVISION OF CRIMINAL
39 JUSTICE SERVICES AND THE FEDERAL BUREAU OF INVESTIGATION.

40 FURTHERMORE, UPON NOTIFICATION THAT SUCH APPLICANT HAS BEEN REGIS-
41 TERED, THE DIVISION OF CRIMINAL JUSTICE SERVICES SHALL HAVE THE AUTHORI-
42 TY TO PROVIDE SUBSEQUENT CRIMINAL HISTORY NOTIFICATIONS DIRECTLY TO THE
43 COMMISSIONER. ALL SUCH CRIMINAL HISTORY RECORDS PROCESSED AND SENT
44 PURSUANT TO THIS SUBDIVISION SHALL BE CONFIDENTIAL PURSUANT TO THE
45 APPLICABLE FEDERAL AND STATE LAWS, RULES AND REGULATIONS, AND SHALL NOT
46 BE PUBLISHED OR IN ANY WAY DISCLOSED TO PERSONS OTHER THAN THE COMMIS-
47 SIONER, UNLESS OTHERWISE AUTHORIZED BY LAW.

48 (3) NOTWITHSTANDING ANY OTHER PROVISION OF LAW TO THE CONTRARY, THE
49 COMMISSIONER IS AUTHORIZED TO CHARGE ADDITIONAL FEES TO APPLICANTS FOR
50 REGISTRATION IN AN AMOUNT EQUAL TO THE FEES ESTABLISHED PURSUANT TO LAW
51 BY THE DIVISION OF CRIMINAL JUSTICE SERVICES AND THE FEDERAL BUREAU OF
52 INVESTIGATION FOR THE CRIMINAL HISTORY RECORD SEARCHES MANDATED BY THIS
53 SUBDIVISION.

54 G. ADDITIONAL DUTIES OF THE COMMISSIONER AND DEPARTMENT. (1) THE
55 COMMISSIONER, IN COOPERATION WITH THE DIVISION OF CRIMINAL JUSTICE
56 SERVICES AND IN ACCORDANCE WITH ALL APPLICABLE PROVISIONS OF LAW, SHALL

1 PROMULGATE RULES AND REGULATIONS TO REQUIRE THE FINGERPRINTING OF THE
2 INDIVIDUALS IDENTIFIED IN PARAGRAPH E OF THIS SUBDIVISION, AND FOR THE
3 USE OF INFORMATION DERIVED FROM SEARCHES OF THE RECORDS OF THE DIVISION
4 OF CRIMINAL JUSTICE SERVICES AND THE FEDERAL BUREAU OF INVESTIGATION
5 BASED ON THE USE OF SUCH FINGERPRINTS, AS PROVIDED IN PARAGRAPH F OF
6 THIS SUBDIVISION.

7 (2) THE COMMISSIONER, IN COOPERATION WITH THE DIVISION OF CRIMINAL
8 JUSTICE SERVICES, SHALL PROMULGATE A FORM TO BE PROVIDED TO ALL APPLI-
9 CANTS FOR REGISTRATION PURSUANT TO THIS SUBDIVISION THAT SHALL:

10 (I) INFORM THE PROSPECTIVE APPLICANT THAT THE COMMISSIONER IS REQUIRED
11 TO REQUEST HIS OR HER CRIMINAL HISTORY INFORMATION FROM THE DIVISION OF
12 CRIMINAL JUSTICE SERVICES AND THE FEDERAL BUREAU OF INVESTIGATION AND
13 REVIEW SUCH INFORMATION PURSUANT TO THIS SECTION, AND PROVIDE A
14 DESCRIPTION OF THE MANNER IN WHICH HIS OR HER FINGERPRINT CARDS WILL BE
15 USED UPON SUBMISSION TO THE DIVISION OF CRIMINAL JUSTICE SERVICES; AND

16 (II) INFORM THE PROSPECTIVE APPLICANT THAT HE OR SHE HAS THE RIGHT TO
17 OBTAIN, REVIEW AND SEEK CORRECTION OF HIS OR HER CRIMINAL HISTORY INFOR-
18 MATION PURSUANT TO REGULATIONS AND PROCEDURES ESTABLISHED BY THE DIVI-
19 SION OF CRIMINAL JUSTICE SERVICES.

20 (3) THE DEPARTMENT SHALL OBTAIN THE SIGNED, INFORMED CONSENT OF EACH
21 INDIVIDUAL IDENTIFIED IN PARAGRAPH E OF THIS SUBDIVISION, ON SUCH FORM
22 SUPPLIED BY THE COMMISSIONER, WHICH INDICATES THAT SUCH PERSON HAS:

23 (I) BEEN INFORMED OF THE RIGHTS AND PROCEDURES NECESSARY TO OBTAIN,
24 REVIEW AND SEEK CORRECTION OF HIS OR HER CRIMINAL HISTORY INFORMATION;

25 (II) BEEN INFORMED OF THE REASON FOR THE REQUEST FOR HIS OR HER CRIMI-
26 NAL HISTORY INFORMATION;

27 (III) CONSENTED TO SUCH REQUEST FOR A REPORT;

28 (IV) SUPPLIED ON THE FORM A CURRENT MAILING OR HOME ADDRESS FOR SUCH
29 INDIVIDUAL;

30 (V) BEEN INFORMED THAT HE OR SHE MAY WITHDRAW HIS OR HER CONSENT,
31 REGARDLESS OF WHETHER THE DEPARTMENT HAS REVIEWED SUCH INDIVIDUAL'S
32 CRIMINAL HISTORY INFORMATION;

33 (VI) BEEN INFORMED THAT IN THE EVENT THE WHOLESALER'S OR MANUFACTUR-
34 ER'S REGISTRATION PURSUANT TO THIS SUBDIVISION HAS EXPIRED OR OTHERWISE
35 TERMINATED, THE COMMISSIONER SHALL NOTIFY THE DIVISION OF CRIMINAL
36 JUSTICE SERVICES OF SUCH EXPIRATION OR TERMINATION, AND THE DIVISION OF
37 CRIMINAL JUSTICE SERVICES SHALL DESTROY THE FINGERPRINTS OF THE INDIVID-
38 UAL OR INDIVIDUALS ASSOCIATED WITH SUCH WHOLESALER'S OR MANUFACTURER'S
39 REGISTRATION; AND

40 (VII) BEEN INFORMED OF THE MANNER IN WHICH HE OR SHE MAY SUBMIT TO THE
41 COMMISSIONER ANY INFORMATION THAT MAY BE RELEVANT TO THE CONSIDERATION
42 OF THE APPLICANT'S REGISTRATION INCLUDING, WHERE APPLICABLE, INFORMATION
43 IN SUPPORT OF HIS OR HER GOOD MORAL CHARACTER OR REHABILITATION THEREOF.

44 H. PERFORMANCE OR SURETY BOND. EVERY WHOLESALER SHALL SUBMIT A
45 PERFORMANCE OR SURETY BOND OF NOT LESS THAN ONE HUNDRED THOUSAND DOLLARS
46 TO THE DEPARTMENT TO ENSURE COMPLIANCE WITH THE PROVISIONS OF THIS ARTI-
47 CLE, EXCEPT THAT THE DEPARTMENT MAY WAIVE SUCH BOND FOR CERTAIN
48 NOT-FOR-PROFIT ENTITIES SUCH AS HOSPITALS AND CORRECTIONAL FACILITIES
49 THAT LIMIT DISTRIBUTION TO THEIR OWN FACILITIES AND DO NOT RETURN SUCH
50 MEDICATIONS TO OTHER ENTITIES. THE DEPARTMENT MAY ALSO EXEMPT A WHOLE-
51 SALER FROM THE SURETY BOND REQUIREMENT WHEN SUCH WHOLESALER IS OWNED AND
52 OPERATED BY A FACILITY, SUBJECT TO THE PROVISIONS OF ARTICLE
53 TWENTY-EIGHT OF THE PUBLIC HEALTH LAW AND OTHER FACILITIES GOVERNED BY A
54 STATE AGENCY THAT LIMITS ITS DISTRIBUTION OF PRESCRIPTION DRUGS TO
55 FACILITIES AND PRACTITIONERS WITHIN THE INSTITUTION'S NETWORK AND OPER-

1 ATIONS AND DOES NOT SELL OR RETURN SUCH MEDICATIONS TO MANUFACTURERS OR
2 TO OTHER WHOLESALERS.

3 I. WHOLESALER REGISTRATION. THE DEPARTMENT MAY PROMULGATE RULES AND
4 REGULATIONS TO EXEMPT FROM THE REQUIREMENTS OF PARAGRAPHS E, F, G AND H
5 OF THIS SUBDIVISION A WHOLESALER THAT HAS RECEIVED ACCREDITATION FROM A
6 NATIONALLY RECOGNIZED ACCREDITATION BODY APPROVED BY THE COMMISSIONER
7 AND THAT MEETS THE LICENSING STANDARDS UNDER THIS SUBDIVISION. THE STANDARDS SHALL BE DEFINED BY THE COMMISSIONER PURSUANT TO REGULATIONS.

8
9 J. MANUFACTURER REGISTRATION. NOTWITHSTANDING THE REQUIREMENTS FOR
10 REGISTRATION UNDER THIS SUBDIVISION, THE COMMISSIONER SHALL EXEMPT A
11 MANUFACTURER LICENSED OR APPROVED BY THE FEDERAL FOOD AND DRUG ADMINIS-
12 TRATION (FDA) OR ITS SUCCESSOR AGENCY TO MANUFACTURE DRUGS OR DEVICES
13 WITH REGARD TO SUCH DRUGS OR DEVICES FROM THE REQUIREMENTS OF PARAGRAPHS
14 E, F, G AND H OF THIS SUBDIVISION IN THE EVENT THAT SUCH REQUIREMENTS
15 ARE NOT REQUIRED BY FEDERAL LAW OR REGULATION UNLESS THE COMMISSIONER
16 DETERMINES THAT SUCH REQUIREMENTS ARE NECESSARY TO PREVENT A RISK TO
17 PRESCRIPTION DRUG DISTRIBUTION IN THE STATE.

18 S 4. The education law is amended by adding a new section 6810-a to
19 read as follows:

20 S 6810-A. UNLAWFUL TRANSACTIONS BY MANUFACTURERS AND WHOLESALERS. IT
21 SHALL BE UNLAWFUL FOR A MANUFACTURER, WHOLESALER OR OTHER PERSON TO:

22 1. INTENTIONALLY PACKAGE, SELL, TRANSFER, DISTRIBUTE OR DELIVER ANY
23 PRESCRIPTION DRUG THAT HE OR SHE KNOWS IS ADULTERATED, MISBRANDED, COUN-
24 TERFEIT OR HAS OTHERWISE BEEN RENDERED UNFIT FOR DISTRIBUTION.

25 2. INTENTIONALLY PACKAGE, SELL, TRANSFER, DISTRIBUTE OR DELIVER A
26 PRESCRIPTION DRUG TO ANY WHOLESALER WHO IS NOT LICENSED OR REGISTERED
27 PURSUANT TO THIS ARTICLE.

28 A PERSON WHO VIOLATES THIS SECTION SHALL BE GUILTY OF A CLASS D FELO-
29 NY. IN ADDITION, ANY DRUG PACKAGED, SOLD, TRANSFERRED, DISTRIBUTED OR
30 DELIVERED IN VIOLATION OF THIS SECTION SHALL BE CONTRABAND AND SUBJECT
31 TO SEIZURE BY THE DEPARTMENT, THE DEPARTMENT OF HEALTH OR ANY LAW
32 ENFORCEMENT OFFICER OF THE STATE.

33 S 5. Section 6824 of the education law, as added by chapter 987 of the
34 laws of 1971, is amended to read as follows:

35 S 6824. Injunction proceedings. In addition to the remedies hereinaft-
36 er provided, the secretary is hereby authorized to apply to the court of
37 the proper venue for an injunction to restrain any person from (a)
38 introducing or causing to be introduced into commerce any adulterated or
39 misbranded drug, device or cosmetic; or (b) from introducing or causing
40 to be introduced in commerce any new drug which does not comply with the
41 provisions of this article; or (c) from disseminating or causing to be
42 disseminated a false advertisement; OR (D) VIOLATING ANY PROVISION OF
43 SECTION SIXTY-EIGHT HUNDRED TEN-A OF THIS ARTICLE, without being
44 compelled to allege or prove that an adequate remedy at law does not
45 exist.

46 S 6. This act shall take effect on the one hundred eightieth day after
47 it shall have become a law.