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2015-2016 Regular Sessions

IN ASSEMBLY

(PREFILED)

January 7, 2015

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:

Section 1. Subparagraph 2 of paragraph a of subdivision 4 of section 8808 of the education law, as amended by chapter 62 of the laws of 1989, 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:

b. Renewal of registration. All wholesalers' and manufacturers' registrations shall be renewed on dates set by the department. The triennial registration fee shall be [five hundred twenty] EIGHT HUNDRED dollars or a pro rated portion thereof as determined by the department.

d. Change of location. In the event that the location of such place of business shall be changed, the owner shall apply to the department for inspection of the new location and endorsement of the registration for the new location. The fee for inspection and endorsement shall be [one hundred seventy] THREE HUNDRED dollars, unless it appears to the satisfaction of the department that the change in location is of a temporary 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:

23 E. APPLICANT REGISTRATION. ANY APPLICANT FOR REGISTRATION AS A WHOLE-24 SALER OR MANUFACTURER SHALL BE OF GOOD MORAL CHARACTER, AS DETERMINED BY

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

LBD00540-01-5

1 THE DEPARTMENT. SUBJECT TO THE PROVISIONS OF PARAGRAPHS F AND G OF THIS 2 SUBDIVISION, THE DEPARTMENT SHALL REQUIRE A CRIMINAL HISTORY RECORDS 3 SEARCH FOR OFFICERS, DIRECTORS AND OWNERS OF SUCH WHOLESALER OR MANUFAC-4 TURER. FOR THE PURPOSES OF THIS PARAGRAPH, "OWNER" SHALL MEAN A PERSON 5 WHO HAS A TEN PERCENT OR GREATER OWNERSHIP INTEREST IN SUCH WHOLESALER 6 OR MANUFACTURER.

7 F. CRIMINAL HISTORY RECORDS SEARCH. (1) UPON RECEIPT OF AN APPLICATION 8 FOR REGISTRATION PURSUANT TO THIS SUBDIVISION, THE COMMISSIONER SHALL, 9 SUBJECT TO THE RULES AND REGULATIONS OF THE DIVISION OF CRIMINAL JUSTICE 10 SERVICES, INITIATE A CRIMINAL HISTORY RECORDS SEARCH OF THE PERSONS 11 IDENTIFIED IN PARAGRAPH E OF THIS SUBDIVISION. PRIOR TO INITIATING THE 12 BACKGROUND CHECKS AND FINGERPRINTING PROCESS, THE COMMISSIONER SHALL FURNISH THE APPLICANT WITH THE FORM DESCRIBED IN PARAGRAPH G OF THIS 13 14 SUBDIVISION AND SHALL OBTAIN THE APPLICANT'S CONSENT TO THE CRIMINAL 15 HISTORY RECORDS SEARCH. THE COMMISSIONER SHALL OBTAIN FROM EACH APPLI-CANT TWO SETS OF FINGERPRINTS AND THE DIVISION OF CRIMINAL JUSTICE 16 17 SERVICES PROCESSING FEE IMPOSED PURSUANT TO SUBDIVISION EIGHT-A OF 18 SECTION EIGHT HUNDRED THIRTY-SEVEN OF THE EXECUTIVE LAW AND ANY FEE 19 IMPOSED BY THE FEDERAL BUREAU OF INVESTIGATION FOR A NATIONAL CRIMINAL 20 HISTORY RECORD CHECK. THE COMMISSIONER SHALL PROMPTLY TRANSMIT SUCH 21 FINGERPRINTS AND FEES TO THE DIVISION OF CRIMINAL JUSTICE SERVICES FOR ITS FULL SEARCH AND RETAIN PROCESSING. THE DIVISION OF CRIMINAL JUSTICE 22 23 SERVICES IS AUTHORIZED TO SUBMIT THE FINGERPRINTS AND THE APPROPRIATE FEE TO THE FEDERAL BUREAU OF INVESTIGATION FOR A NATIONAL CRIMINAL 24 25 HISTORY RECORD CHECK. THE DIVISION OF CRIMINAL JUSTICE SERVICES AND THE 26 FEDERAL BUREAU OF INVESTIGATION SHALL FORWARD SUCH CRIMINAL HISTORY 27 RECORD, IF ANY, TO THE COMMISSIONER IN A TIMELY MANNER. CRIMINAL HISTO-INFORMATION PROVIDED BY THE DIVISION OF CRIMINAL JUSTICE SERVICES 28 RY PURSUANT TO THIS SUBDIVISION SHALL BE FURNISHED ONLY BY MAIL OR OTHER 29 METHOD OF SECURE AND CONFIDENTIAL DELIVERY, ADDRESSED TO THE COMMISSION-30 ER. SUCH INFORMATION AND THE ENVELOPE IN WHICH IT IS ENCLOSED, IF ANY, 31 32 SHALL BE PROMINENTLY MARKED "CONFIDENTIAL," AND SHALL AT ALL TIMES BE MAINTAINED BY THE OFFICE IN A SECURE PLACE. THE COMMISSIONER SHALL 33 34 CONSIDER SUCH CRIMINAL HISTORY RECORD IN ACCORDANCE WITH THE REQUIRE-35 MENTS OF ARTICLE TWENTY-THREE-A OF THE CORRECTION LAW AND SUBDIVISIONS FIFTEEN AND SIXTEEN OF SECTION TWO HUNDRED NINETY-SIX OF THE EXECUTIVE 36 37 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.

43 FURTHERMORE, UPON NOTIFICATION THAT SUCH APPLICANT HAS BEEN REGIS-44 TERED, THE DIVISION OF CRIMINAL JUSTICE SERVICES SHALL HAVE THE AUTHORI-45 TO PROVIDE SUBSEQUENT CRIMINAL HISTORY NOTIFICATIONS DIRECTLY TO THE ΤY COMMISSIONER. ALL SUCH CRIMINAL HISTORY RECORDS PROCESSED AND SENT 46 47 PURSUANT TO THIS SUBDIVISION SHALL BE CONFIDENTIAL PURSUANT TO THE 48 APPLICABLE FEDERAL AND STATE LAWS, RULES AND REGULATIONS, AND SHALL NOT 49 ΒE PUBLISHED OR IN ANY WAY DISCLOSED TO PERSONS OTHER THAN THE COMMIS-50 SIONER, UNLESS OTHERWISE AUTHORIZED BY LAW. ANY PERSON WHO WILLFULLY 51 PERMITS THE RELEASE OF ANY CONFIDENTIAL CRIMINAL HISTORY INFORMATION CONTAINED IN THE REPORT TO PERSONS NOT PERMITTED BY 52 THIS SECTION TO RECEIVE SUCH INFORMATION SHALL BE GUILTY OF A MISDEMEANOR. 53

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 NAL

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PROMULGATE RULES AND REGULATIONS TO REQUIRE THE PERFORMANCE OF A CRIMI-HISTORY RECORDS CHECK OF THE INDIVIDUALS IDENTIFIED IN PARAGRAPH E OF THIS SUBDIVISION. THE COMMISSIONER, IN COOPERATION WITH THE DIVISION OF CRIMINAL JUSTICE SERVICES, SHALL PROMULGATE A FORM TO BE PROVIDED TO ALL APPLI-CANTS FOR REGISTRATION PURSUANT TO THIS SUBDIVISION THAT SHALL: (I) INFORM THE PROSPECTIVE APPLICANT THAT THE COMMISSIONER IS REQUIRED REQUEST HIS OR HER CRIMINAL HISTORY INFORMATION FROM THE DIVISION OF CRIMINAL JUSTICE SERVICES AND THE FEDERAL BUREAU OF INVESTIGATION AND REVIEW SUCH INFORMATION PURSUANT TO THIS SECTION, AND PROVIDE A DESCRIPTION OF THE MANNER IN WHICH HIS OR HER FINGERPRINT CARDS WILL USED UPON SUBMISSION TO THE DIVISION OF CRIMINAL JUSTICE SERVICES; AND INFORM THE PROSPECTIVE APPLICANT THAT HE OR SHE HAS THE RIGHT TO OBTAIN, REVIEW AND SEEK CORRECTION OF HIS OR HER CRIMINAL HISTORY INFOR-MATION PURSUANT TO REGULATIONS AND PROCEDURES ESTABLISHED BY THE SION OF CRIMINAL JUSTICE SERVICES. DEPARTMENT SHALL OBTAIN THE SIGNED, INFORMED CONSENT OF EACH THE

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18 INDIVIDUAL IDENTIFIED IN PARAGRAPH E OF THIS SUBDIVISION, ON SUCH FORM 19 SUPPLIED BY THE COMMISSIONER, WHICH INDICATES THAT SUCH PERSON HAS: INFORMED OF THE RIGHTS AND PROCEDURES NECESSARY TO OBTAIN, 20 (I) BEEN

21 REVIEW AND SEEK CORRECTION OF HIS OR HER CRIMINAL HISTORY INFORMATION; (II) BEEN INFORMED OF THE REASON FOR THE REQUEST FOR HIS OR HER CRIMI-22 23 NAL HISTORY INFORMATION;

(III) CONSENTED TO SUCH REQUEST FOR A REPORT;

25 (IV) SUPPLIED ON THE FORM A CURRENT MAILING OR HOME ADDRESS FOR SUCH 26 INDIVIDUAL;

27 BEEN INFORMED THAT HE OR SHE MAY WITHDRAW HIS OR HER CONSENT, (V) 28 REGARDLESS OF WHETHER THE DEPARTMENT HAS REVIEWED SUCH INDIVIDUAL'S 29 CRIMINAL HISTORY INFORMATION;

(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 32 TERMINATED, THE COMMISSIONER SHALL NOTIFY THE DIVISION OF CRIMINAL 33 JUSTICE SERVICES OF SUCH EXPIRATION OR TERMINATION, AND THE DIVISION OF CRIMINAL JUSTICE SERVICES SHALL DESTROY THE FINGERPRINTS OF THE INDIVID-34 35 INDIVIDUALS ASSOCIATED WITH SUCH WHOLESALER'S OR MANUFACTURER'S UAL OR 36 REGISTRATION; AND

37 (VII) BEEN INFORMED OF THE MANNER IN WHICH HE OR SHE MAY SUBMIT TO THE 38 COMMISSIONER ANY INFORMATION THAT MAY BE RELEVANT TO THE CONSIDERATION OF THE APPLICANT'S REGISTRATION INCLUDING, WHERE APPLICABLE, INFORMATION 39 40 IN SUPPORT OF HIS OR HER GOOD MORAL CHARACTER OR REHABILITATION THEREOF.

UPON RECEIPT OF CRIMINAL HISTORY INFORMATION PURSUANT TO THIS 41 (4) SECTION AND BEFORE MAKING ANY DETERMINATION THEREON, 42 THE COMMISSIONER 43 SHALL PROVIDE THE INDIVIDUAL WITH A COPY OF SUCH CRIMINAL HISTORY INFOR-44 MATION AND A COPY OF ARTICLE TWENTY-THREE-A OF THE CORRECTION LAW AND 45 INFORM SUCH INDIVIDUAL OF HIS OR HER RIGHT TO SEEK CORRECTION OF ANY INCORRECT INFORMATION CONTAINED IN SUCH CRIMINAL HISTORY INFORMATION 46 47 PURSUANT TO THE REGULATIONS AND PROCEDURES ESTABLISHED BY THE DIVISION 48 OF CRIMINAL JUSTICE SERVICES.

49 PERFORMANCE OR SURETY BOND. EVERY WHOLESALER SHALL SUBMIT A н. 50 PERFORMANCE OR SURETY BOND OF NOT LESS THAN ONE HUNDRED THOUSAND DOLLARS 51 TO THE DEPARTMENT TO ENSURE COMPLIANCE WITH THE PROVISIONS OF THIS ARTI-CLE, EXCEPT THAT THE DEPARTMENT MAY WAIVE 52 SUCH BOND FOR CERTAIN NOT-FOR-PROFIT ENTITIES SUCH AS HOSPITALS AND CORRECTIONAL FACILITIES 53 54 THAT LIMIT DISTRIBUTION TO THEIR OWN FACILITIES AND DO NOT RETURN SUCH 55 MEDICATIONS TO OTHER ENTITIES. THE DEPARTMENT MAY ALSO EXEMPT A WHOLE-56 SALER FROM THE SURETY BOND REQUIREMENT WHEN SUCH WHOLESALER IS OWNED AND 1 OPERATED BY A FACILITY, SUBJECT TO THE PROVISIONS OF ARTICLE 2 TWENTY-EIGHT OF THE PUBLIC HEALTH LAW AND OTHER FACILITIES GOVERNED BY A 3 STATE AGENCY THAT LIMITS ITS DISTRIBUTION OF PRESCRIPTION DRUGS TO 4 FACILITIES AND PRACTITIONERS WITHIN THE INSTITUTION'S NETWORK AND OPER-5 ATIONS AND DOES NOT SELL OR RETURN SUCH MEDICATIONS TO MANUFACTURERS OR 6 TO OTHER WHOLESALERS.

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

J. MANUFACTURER REGISTRATION. NOTWITHSTANDING THE REQUIREMENTS FOR 13 14 REGISTRATION UNDER THIS SUBDIVISION, THE COMMISSIONER SHALL EXEMPT A 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 REOUIREMENTS 18 19 ARE NOT REQUIRED BY FEDERAL LAW OR REGULATION UNLESS THE COMMISSIONER DETERMINES THAT SUCH REQUIREMENTS ARE NECESSARY TO PREVENT A RISK TO 20 21 PRESCRIPTION DRUG DISTRIBUTION IN THE STATE.

22 S 4. This act shall take effect on the one hundred eightieth day after 23 it shall have become a law.