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2013-2014 Regular Sessions

IN ASSEMBLY

March 8, 2013

Introduced by M. of A. PAULIN, TITONE, GOTTFRIED, GALEF -- Multi-Sponsored by -- M. of A. BOYLAND, COLTON, COOK, DINOWITZ, FARRELL, HIKIND, HOOPER, ORTIZ, RAIA, ROBINSON, SWEENEY, WRIGHT -- 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 6808 of the education law, as amended by chapter 62 of the laws of 1989, is amended to read as follows:

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- (2) The application shall be accompanied by a fee of [eight hundred twenty-five] TWELVE HUNDRED dollars.
- S 2. Paragraphs b and d of subdivision 4 of section 6808 of the education law, paragraph b as amended by chapter 538 of the laws of 2001 and paragraph d as amended by chapter 62 of the laws of 1989, are amended to 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:

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

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E. APPLICANT REGISTRATION. ANY APPLICANT FOR REGISTRATION AS A WHOLE-SALER OR MANUFACTURER SHALL BE OF GOOD MORAL CHARACTER, AS DETERMINED BY THE DEPARTMENT. SUBJECT TO THE PROVISIONS OF PARAGRAPHS F AND G OF THIS SUBDIVISION, THE DEPARTMENT SHALL REQUIRE A CRIMINAL HISTORY RECORDS SEARCH FOR OFFICERS, DIRECTORS AND OWNERS OF SUCH WHOLESALER OR MANUFAC-TURER. 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 REGISTRATION PURSUANT TO THIS SUBDIVISION, THE COMMISSIONER SHALL, SUBJECT TO THE RULES AND REGULATIONS OF THE DIVISION OF CRIMINAL JUSTICE 12 SERVICES, INITIATE A CRIMINAL HISTORY RECORDS SEARCH OF THE PERSONS IDENTIFIED IN PARAGRAPH E OF THIS SUBDIVISION. PRIOR TO INITIATING THE 13 14 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 APPLI-18 CANT TWO SETS OF FINGERPRINTS AND THE DIVISION OF CRIMINAL JUSTICE 19 SERVICES PROCESSING FEE IMPOSED PURSUANT TO SUBDIVISION EIGHT-A OF SECTION EIGHT HUNDRED THIRTY-SEVEN OF THE EXECUTIVE LAW AND ANY FEE 21 IMPOSED BY THE FEDERAL BUREAU OF INVESTIGATION FOR A NATIONAL CRIMINAL HISTORY RECORD CHECK. THE COMMISSIONER SHALL PROMPTLY TRANSMIT FINGERPRINTS AND FEES TO THE DIVISION OF CRIMINAL JUSTICE SERVICES FOR 23 ITS FULL SEARCH AND RETAIN PROCESSING. THE DIVISION OF CRIMINAL JUSTICE SERVICES IS AUTHORIZED TO SUBMIT THE FINGERPRINTS AND THE APPROPRIATE 26 FEE TO THE FEDERAL BUREAU OF INVESTIGATION FOR A NATIONAL CRIMINAL HISTORY RECORD CHECK. THE DIVISION OF CRIMINAL JUSTICE SERVICES AND THE 27 FEDERAL BUREAU OF INVESTIGATION SHALL FORWARD SUCH CRIMINAL HISTORY RECORD, IF ANY, TO THE COMMISSIONER IN A TIMELY MANNER. CRIMINAL HISTO-29 INFORMATION PROVIDED BY THE DIVISION OF CRIMINAL JUSTICE SERVICES 30 PURSUANT TO THIS SUBDIVISION SHALL BE FURNISHED ONLY BY MAIL OR OTHER METHOD OF SECURE AND CONFIDENTIAL DELIVERY, ADDRESSED TO THE COMMISSION-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 REQUIRE-MENTS OF ARTICLE TWENTY-THREE-A OF THE CORRECTION LAW AND SUBDIVISIONS 37 FIFTEEN AND SIXTEEN OF SECTION TWO-HUNDRED NINETY-SIX OF THE EXECUTIVE LAW.

PURPOSES OF THIS SECTION THE TERM "CRIMINAL HISTORY FOR THE RECORD" SHALL MEAN A RECORD OF ALL CONVICTIONS OF CRIMES THAT HAVE NOT BEEN VACATED, REVERSED OR SEALED, AND ANY PENDING CRIMINAL CHARGES MAIN-TAINED BY THE DIVISION OF CRIMINAL JUSTICE SERVICES AND THE FEDERAL BUREAU OF INVESTIGATION.

FURTHERMORE, UPON NOTIFICATION THAT SUCH APPLICANT HAS BEEN REGIS-TERED, THE DIVISION OF CRIMINAL JUSTICE SERVICES SHALL HAVE THE AUTHORI-TO PROVIDE SUBSEQUENT CRIMINAL HISTORY NOTIFICATIONS DIRECTLY TO THE COMMISSIONER. ALL SUCH CRIMINAL HISTORY RECORDS PROCESSED AND PURSUANT TO THIS SUBDIVISION SHALL BE CONFIDENTIAL PURSUANT TO THE APPLICABLE FEDERAL AND STATE LAWS, RULES AND REGULATIONS, AND SHALL NOT PUBLISHED OR IN ANY WAY DISCLOSED TO PERSONS OTHER THAN THE COMMIS-SIONER, 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.

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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 CRIMINAL HISTORY RECORDS CHECK OF THE INDIVIDUALS IDENTIFIED IN PARAGRAPH E OF THIS SUBDIVISION.

- (2) THE COMMISSIONER, IN COOPERATION WITH THE DIVISION OF CRIMINAL JUSTICE SERVICES, SHALL PROMULGATE A FORM TO BE PROVIDED TO ALL APPLICANTS FOR REGISTRATION PURSUANT TO THIS SUBDIVISION THAT SHALL:
- (I) INFORM THE PROSPECTIVE APPLICANT THAT THE COMMISSIONER IS REQUIRED TO 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 BE USED UPON SUBMISSION TO THE DIVISION OF CRIMINAL JUSTICE SERVICES; AND
- (II) INFORM THE PROSPECTIVE APPLICANT THAT HE OR SHE HAS THE RIGHT TO OBTAIN, REVIEW AND SEEK CORRECTION OF HIS OR HER CRIMINAL HISTORY INFORMATION PURSUANT TO REGULATIONS AND PROCEDURES ESTABLISHED BY THE DIVISION OF CRIMINAL JUSTICE SERVICES.
- (3) THE DEPARTMENT SHALL OBTAIN THE SIGNED, INFORMED CONSENT OF EACH INDIVIDUAL IDENTIFIED IN PARAGRAPH E OF THIS SUBDIVISION, ON SUCH FORM SUPPLIED BY THE COMMISSIONER, WHICH INDICATES THAT SUCH PERSON HAS:
- (I) BEEN INFORMED OF THE RIGHTS AND PROCEDURES NECESSARY TO OBTAIN, 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-NAL HISTORY INFORMATION;
 - (III) CONSENTED TO SUCH REQUEST FOR A REPORT;
- (IV) SUPPLIED ON THE FORM A CURRENT MAILING OR HOME ADDRESS FOR SUCH INDIVIDUAL;
- (V) BEEN INFORMED THAT HE OR SHE MAY WITHDRAW HIS OR HER CONSENT, REGARDLESS OF WHETHER THE DEPARTMENT HAS REVIEWED SUCH INDIVIDUAL'S CRIMINAL HISTORY INFORMATION;
- (VI) BEEN INFORMED THAT IN THE EVENT THE WHOLESALER'S OR MANUFACTURER'S REGISTRATION PURSUANT TO THIS SUBDIVISION HAS EXPIRED OR OTHERWISE TERMINATED, THE COMMISSIONER SHALL NOTIFY THE DIVISION OF CRIMINAL JUSTICE SERVICES OF SUCH EXPIRATION OR TERMINATION, AND THE DIVISION OF CRIMINAL JUSTICE SERVICES SHALL DESTROY THE FINGERPRINTS OF THE INDIVIDUAL OR INDIVIDUALS ASSOCIATED WITH SUCH WHOLESALER'S OR MANUFACTURER'S REGISTRATION; AND
- (VII) BEEN INFORMED OF THE MANNER IN WHICH HE OR SHE MAY SUBMIT TO THE COMMISSIONER ANY INFORMATION THAT MAY BE RELEVANT TO THE CONSIDERATION OF THE APPLICANT'S REGISTRATION INCLUDING, WHERE APPLICABLE, INFORMATION IN SUPPORT OF HIS OR HER GOOD MORAL CHARACTER OR REHABILITATION THEREOF.
- (4) UPON RECEIPT OF CRIMINAL HISTORY INFORMATION PURSUANT TO THIS SECTION AND BEFORE MAKING ANY DETERMINATION THEREON, THE COMMISSIONER SHALL PROVIDE THE INDIVIDUAL WITH A COPY OF SUCH CRIMINAL HISTORY INFORMATION AND A COPY OF ARTICLE TWENTY-THREE-A OF THE CORRECTION LAW AND INFORM SUCH INDIVIDUAL OF HIS OR HER RIGHT TO SEEK CORRECTION OF ANY INCORRECT INFORMATION CONTAINED IN SUCH CRIMINAL HISTORY INFORMATION PURSUANT TO THE REGULATIONS AND PROCEDURES ESTABLISHED BY THE DIVISION OF CRIMINAL JUSTICE SERVICES.
- H. PERFORMANCE OR SURETY BOND. EVERY WHOLESALER SHALL SUBMIT A PERFORMANCE OR SURETY BOND OF NOT LESS THAN ONE HUNDRED THOUSAND DOLLARS TO THE DEPARTMENT TO ENSURE COMPLIANCE WITH THE PROVISIONS OF THIS ARTICLE, EXCEPT THAT THE DEPARTMENT MAY WAIVE SUCH BOND FOR CERTAIN NOT-FOR-PROFIT ENTITIES SUCH AS HOSPITALS AND CORRECTIONAL FACILITIES

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THAT LIMIT DISTRIBUTION TO THEIR OWN FACILITIES AND DO NOT RETURN SUCH MEDICATIONS TO OTHER ENTITIES. THE DEPARTMENT MAY ALSO EXEMPT A WHOLE-SALER FROM THE SURETY BOND REQUIREMENT WHEN SUCH WHOLESALER IS OWNED AND OPERATED BY A FACILITY, SUBJECT TO THE PROVISIONS OF ARTICLE TWENTY-EIGHT OF THE PUBLIC HEALTH LAW AND OTHER FACILITIES GOVERNED BY A STATE AGENCY THAT LIMITS ITS DISTRIBUTION OF PRESCRIPTION DRUGS TO FACILITIES AND PRACTITIONERS WITHIN THE INSTITUTION'S NETWORK AND OPER-ATIONS AND DOES NOT SELL OR RETURN SUCH MEDICATIONS TO MANUFACTURERS OR 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 16 REGISTRATION UNDER THIS SUBDIVISION, THE COMMISSIONER SHALL EXEMPT A 17 MANUFACTURER LICENSED OR APPROVED BY THE FEDERAL FOOD AND DRUG ADMINIS-18 TRATION (FDA) OR ITS SUCCESSOR AGENCY TO MANUFACTURE DRUGS OR DEVICES 19 WITH REGARD TO SUCH DRUGS OR DEVICES FROM THE REQUIREMENTS OF PARAGRAPHS 20 21 F, G AND H OF THIS SUBDIVISION IN THE EVENT THAT SUCH REQUIREMENTS ARE NOT REQUIRED BY FEDERAL LAW OR REGULATION UNLESS THE COMMISSIONER 23 DETERMINES THAT SUCH REQUIREMENTS ARE NECESSARY TO PREVENT A RISK TO 24 PRESCRIPTION DRUG DISTRIBUTION IN THE STATE.
- 25 S 4. This act shall take effect on the one hundred eightieth day after 26 it shall have become a law.