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

4592

2009-2010 Regular Sessions

I N S E N A T E

April 24, 2009

Introduced by Sen. SCHNEIDERMAN -- read twice and ordered printed, and when printed to be committed to the Committee on Higher Education

AN ACT to amend the education law, in relation to penalties for counterfeit drugs

THE PEOPLE OF THE STATE OF NEW YORK, REPRESENTED IN SENATE AND ASSEMBLY, DO ENACT AS FOLLOWS:

Section 1. Section 6802 of the education law is amended by adding a new subdivision 23 to read as follows:

23. "PEDIGREE" MEANS AN ELECTRONIC RECORD CONTAINING INFORMATION REGARDING EACH DISTRIBUTION OF A PRESCRIPTION DRUG, ORIGINATING FROM A MANUFACTURER, THROUGH ACQUISITION BY OR TRANSFER TO ONE OR MORE WHOLESALERS, MANUFACTURERS, OR PHARMACIES, UNTIL FINAL SALE OR TRANSFER TO A PHARMACY OR OTHER PERSON FURNISHING, ADMINISTERING, OR DISPENSING THE PRESCRIPTION DRUG, AS PROVIDED IN SECTION SIXTY-EIGHT HUNDRED TEN-B OF THIS ARTICLE.

S 2. 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:

(2) The application shall be accompanied by a fee of [eight hundred twenty-five] TWELVE HUNDRED dollars.

S 3. 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

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

LBD09701-01-9

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.

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

E. APPLICANT REGISTRATION. ANY APPLICANT FOR REGISTRATION AS A WHOLESALER OR MANUFACTURER SHALL BE OF GOOD MORAL CHARACTER, AS DETERMINED BY THE DEPARTMENT. THE REQUIREMENTS SHALL EXTEND TO ALL PERSONS RESPONSIBLE FOR THE DISTRIBUTION OF A PRESCRIPTION DRUG FOR THE APPLICANT, AS DETERMINED BY THE DEPARTMENT. SUBJECT TO THE PROVISIONS OF PARAGRAPHS F AND G OF THIS SUBDIVISION, THE DEPARTMENT SHALL REQUIRE PHOTOGRAPHS, CRIMINAL HISTORY RECORDS SEARCH AND FINGERPRINTS.

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 TO THE COMMISSIONER IN A TIMELY MANNER. THE RELEASE OF SUCH CRIMINAL HISTORY RECORD BY THE DIVISION OF CRIMINAL JUSTICE SERVICES SHALL BE SUBJECT TO THE PROVISIONS OF SUBDIVISION SIXTEEN OF SECTION TWO HUNDRED NINETY-SIX OF THE EXECUTIVE LAW. THE COMMISSIONER SHALL CONSIDER SUCH CRIMINAL HISTORY RECORD IN ACCORDANCE WITH THE REQUIREMENTS OF ARTICLE TWENTY-THREE-A OF THE CORRECTION LAW, FOR THE PURPOSE OF ESTABLISHING THE GOOD MORAL CHARACTER OF AN INDIVIDUAL AS REQUIRED IN PARAGRAPH E OF THIS SUBDIVISION.

(2) FOR THE PURPOSES OF THIS SECTION THE TERM "CRIMINAL HISTORY RECORD" SHALL MEAN A RECORD OF ALL CONVICTIONS OF CRIMES AND ANY PENDING CRIMINAL CHARGES MAINTAINED ON AN INDIVIDUAL 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.

(3) NOTWITHSTANDING ANY OTHER PROVISION OF LAW TO THE CONTRARY, THE COMMISSIONER IS AUTHORIZED TO CHARGE ADDITIONAL FEES TO APPLICANTS FOR REGISTRATION IN AN AMOUNT EQUAL TO THE FEES ESTABLISHED PURSUANT TO LAW

BY THE DIVISION OF CRIMINAL JUSTICE SERVICES AND THE FEDERAL BUREAU OF INVESTIGATION FOR THE CRIMINAL HISTORY RECORD SEARCHES MANDATED BY THIS SUBDIVISION.

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 FINGERPRINTING OF THE INDIVIDUALS IDENTIFIED IN PARAGRAPH E OF THIS SUBDIVISION, AND FOR THE USE OF INFORMATION DERIVED FROM SEARCHES OF THE RECORDS OF THE DIVISION OF CRIMINAL JUSTICE SERVICES AND THE FEDERAL BUREAU OF INVESTIGATION BASED ON THE USE OF SUCH FINGERPRINTS, AS PROVIDED IN PARAGRAPH F 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 CRIMINAL 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.

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 THAT LIMIT DISTRIBUTION TO THEIR OWN FACILITIES AND DO NOT RETURN SUCH MEDICATIONS TO OTHER ENTITIES. SUCH WAIVER SHALL BE MADE ON THE RECOM-

MENDATION OF THE STATE BOARD OF PHARMACY. THE DEPARTMENT MAY ALSO EXEMPT A WHOLESALER 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 OPERATIONS 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 REGISTRATION UNDER THIS SUBDIVISION, THE COMMISSIONER SHALL EXEMPT A MANUFACTURER LICENSED OR APPROVED BY THE FEDERAL FOOD AND DRUG ADMINISTRATION (FDA) OR ITS SUCCESSOR AGENCY TO MANUFACTURE DRUGS OR DEVICES WITH REGARD TO SUCH DRUGS OR DEVICES FROM THE REQUIREMENTS OF PARAGRAPHS E, F, G AND H OF THIS SUBDIVISION IN THE EVENT THAT SUCH REQUIREMENTS ARE NOT REQUIRED BY FEDERAL LAW OR REGULATION UNLESS THE COMMISSIONER DETERMINES THAT SUCH REQUIREMENTS ARE NECESSARY TO PREVENT A RISK TO PRESCRIPTION DRUG DISTRIBUTION IN THE STATE.

S 5. The education law is amended by adding a new section 6810-a to read as follows:

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

1. INTENTIONALLY PACKAGE, SELL, TRANSFER, DISTRIBUTE OR DELIVER ANY PRESCRIPTION DRUG THAT HE OR SHE KNOWS IS ADULTERATED, MISBRANDED, COUNTERFEIT OR HAS OTHERWISE BEEN RENDERED UNFIT FOR DISTRIBUTION.

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

A PERSON WHO VIOLATES THIS SECTION SHALL BE GUILTY OF A CLASS D FELONY. IN ADDITION, ANY DRUG PACKAGED, SOLD, TRANSFERRED, DISTRIBUTED OR DELIVERED IN VIOLATION OF THIS SECTION SHALL BE CONTRABAND AND SUBJECT TO SEIZURE BY THE BOARD OF PHARMACY, THE DEPARTMENT OF HEALTH OR ANY LAW ENFORCEMENT OFFICER OF THE STATE.

S 6. The education law is amended by adding a new section 6810-b to read as follows:

S 6810-B. PEDIGREE. 1. EVERY MANUFACTURER SHALL ESTABLISH AND MAINTAIN A PEDIGREE FOR EACH PRESCRIPTION DRUG, AND EVERY WHOLESALER, PHARMACY OR OTHER PERSON FURNISHING OR DISPENSING A PRESCRIPTION DRUG SHALL MAINTAIN, A PEDIGREE FOR EACH PRESCRIPTION DRUG.

2. A PEDIGREE SHALL BE IN SUCH FORM AND CONTAIN SUCH INFORMATION AS SHALL BE DETERMINED BY THE DEPARTMENT. EACH PEDIGREE SHALL MINIMALLY INCLUDE FOR EACH DISTRIBUTION ALL OF THE FOLLOWING INFORMATION:

A. THE SOURCE OF THE PRESCRIPTION DRUG, INCLUDING THE NAME AND PRINCIPAL ADDRESS OF THE SELLER OR TRANSFEROR;

B. THE PROPRIETARY AND ESTABLISHED NAME OF THE PRESCRIPTION DRUG, THE AMOUNT OF THE PRESCRIPTION DRUG, ITS DOSAGE FORM AND DOSAGE STRENGTH, THE DATE OF THE PURCHASE OR TRANSFER, THE INVOICE NUMBER, CONTAINER SIZE, NUMBER OF CONTAINERS, EXPIRATION DATE, LOT NUMBER, NATIONAL DRUG CODE, AND, IF AVAILABLE, STANDARDIZED NUMERICAL IDENTIFIER, OF THE PRESCRIPTION DRUG;

C. THE BUSINESS NAME AND ADDRESS OF EACH OWNER OF THE PRESCRIPTION DRUG AND ITS SHIPPING INFORMATION, INCLUDING THE NAME AND ADDRESS OF THE FACILITY OF EACH PERSON CERTIFYING DELIVERY OR RECEIPT OF THE PRESCRIPTION DRUG; AND

D. A CERTIFICATION UNDER PENALTY OF PERJURY FROM THE DESIGNATED REPRESENTATIVE OF THE MANUFACTURER, WHOLESALER OR PHARMACY THAT THE INFORMATION CONTAINED THEREIN IS TRUE AND ACCURATE.

3. EVERY PEDIGREE SHALL BE MAINTAINED FOR A PERIOD OF THREE YEARS OR A REASONABLE PERIOD OF TIME AS DETERMINED BY THE COMMISSIONER, AND SHALL BE MADE AVAILABLE FOR INSPECTION, UPON REASONABLE NOTICE, BY THE DEPARTMENT.

4. A PEDIGREE SHALL BE MAINTAINED IN AN ELECTRONIC PEDIGREE TRACKING SYSTEM OR OTHER TECHNOLOGY FORMAT ACCEPTABLE TO THE DEPARTMENT BEGINNING JANUARY FIRST, TWO THOUSAND TWELVE, WHICH SHALL BE THE PEDIGREE EFFECTIVE DATE. IF AN ELECTRONIC PEDIGREE TRACKING SYSTEM OR ALTERNATIVE FORMAT IS NOT FEASIBLE BY THE PEDIGREE EFFECTIVE DATE, THE DEPARTMENT SHALL ISSUE ONE-YEAR EXTENSIONS OF THE PEDIGREE EFFECTIVE DATE UNTIL THE DEPARTMENT DETERMINES SUCH FORMAT TO BE FEASIBLE. IN DETERMINING WHETHER AN ELECTRONIC PEDIGREE TRACKING SYSTEM OR ALTERNATIVE TECHNOLOGY FORMAT IS FEASIBLE, THE DEPARTMENT SHALL CONSIDER WHETHER SUCH SYSTEM OR FORMAT IS:

A. READILY AVAILABLE WITH RESPECT TO ALL PRESCRIPTION DRUGS,

B. IN A STANDARDIZED NON-PROPRIETARY DATA FORMAT AND ARCHITECTURE, AND WIDELY AVAILABLE TO MANUFACTURERS, WHOLESALERS AND PHARMACIES SO THAT THE SYSTEM OR FORMAT IS CAPABLE OF BEING USED BY MANUFACTURERS, WHOLESALERS AND PHARMACIES FROM SALE BY THE MANUFACTURER THROUGH ACQUISITION BY OR TRANSFER TO A WHOLESALER, MANUFACTURER OR PHARMACY UNTIL FINAL SALE OR TRANSFER TO A PHARMACY OR OTHER PERSON FURNISHING, ADMINISTERING OR DISPENSING THE PRESCRIPTION DRUG, AND

C. CONSISTENT WITH FEDERAL REQUIREMENTS FOR A STANDARDIZED NUMERICAL IDENTIFIER.

5. ANY PERSON WHO VIOLATES ANY PROVISION OF THIS SECTION SHALL BE SUBJECT TO A FINE OF NOT MORE THAN TWO THOUSAND DOLLARS PER VIOLATION. IN ADDITION, ANY PRESCRIPTION DRUG DISTRIBUTED, TRANSFERRED, ADMINISTERED, FURNISHED, OR DISPENSED IN VIOLATION OF THIS SECTION SHALL BE CONTRABAND AND SUBJECT TO SEIZURE EITHER BY THE DEPARTMENT, THE STATE BOARD OF PHARMACY OR ANY LAW ENFORCEMENT OFFICER OF THE STATE.

S 7. Section 6824 of the education law, as added by chapter 987 of the laws of 1971, is amended to read as follows:

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

S 8. This act shall take effect on the one hundred eightieth day after it shall have become a law. The department of education shall promulgate rules and regulations, issue forms and take any other action necessary to implement the provisions of this act on or before the pedigree effective date, as provided in subdivision 4 of section 6810-b of the education law, as added by section six of this act.