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

6546--A

2009-2010 Regular Sessions

I N A S S E M B L Y

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Introduced by M. of A. PAULIN, TITONE, GOTTFRIED, GALEF, CLARK -- Multi-Sponsored by -- M. of A. ALFANO, BARRA, BOYLAND, CHRISTENSEN, COLTON, COOK, DINOWITZ, HIKIND, HOOPER, JOHN, LATIMER, MILLER, ORTIZ, RAIA, P. RIVERA, ROBINSON, SWEENEY, TOBACCO, WRIGHT -- read once and referred to the Committee on Higher Education -- committee discharged, bill amended, ordered reprinted as amended and recommitted to said committee

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 TRANSACTION, RESULTING IN A CHANGE OF OWNERSHIP, OF A PRESCRIPTION DRUG, ORIGINATING FROM A MANUFACTURER, THROUGH ACQUISITION BY OR TRANSFER TO ONE OR MORE WHOLESALERS, MANUFACTURERS, REPACKAGERS, 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

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

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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.

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 RECOMMENDATION 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. A. 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.

B. FOR PURPOSES OF THIS SECTION, "MANUFACTURER" MEANS A PERSON WHO PREPARES, DERIVES, MANUFACTURES, PRODUCES OR REPACKAGES A PRESCRIPTION DRUG. MANUFACTURER ALSO MEANS THE HOLDER OR HOLDERS OF A NEW DRUG APPLICATION (NDA), AN ABBREVIATED NEW DRUG APPLICATION (ANDA), OR A BIOLOGICS LICENSE APPLICATION (BLA), PROVIDED THAT SUCH APPLICATION HAS BEEN APPROVED; A MANUFACTURER'S THIRD PARTY LOGISTICS PROVIDER; A PRIVATE LABEL DISTRIBUTOR (INCLUDING COLICENSED PARTNERS) FOR WHOM THE PRIVATE

LABEL DISTRIBUTOR'S PRESCRIPTION DRUGS ARE ORIGINALLY MANUFACTURED AND LABELED FOR THE DISTRIBUTOR AND HAVE NOT BEEN REPACKAGED; OR THE DISTRIBUTOR AGENT FOR THE MANUFACTURER, CONTRACT MANUFACTURER, OR PRIVATE LABEL DISTRIBUTOR, WHETHER THE ESTABLISHMENT IS A MEMBER OF THE MANUFACTURER'S AFFILIATED GROUP (REGARDLESS OF WHETHER THE MEMBER TAKES TITLE TO THE DRUG) OR IS A CONTRACT DISTRIBUTOR SITE.

C. FOR PURPOSES OF THIS SECTION, "REPACKAGER" MEANS A PERSON OR ENTITY THAT IS REGISTERED WITH THE FEDERAL FOOD AND DRUG ADMINISTRATION AS A REPACKAGER AND OPERATES AN ESTABLISHMENT THAT PACKAGES FINISHED DRUGS FROM BULK OR THAT REPACKAGES PRESCRIPTION DRUGS INTO DIFFERENT CONTAINERS, EXCLUDING SHIPPING CONTAINERS.

D. FOR PURPOSES OF THIS SECTION, "THIRD PARTY LOGISTICS PROVIDER" MEANS AN ENTITY LICENSED AS A WHOLESALER THAT CONTRACTS WITH A MANUFACTURER OF PRESCRIPTION DRUGS TO PROVIDE OR COORDINATE WAREHOUSING, DISTRIBUTION OR OTHER SIMILAR SERVICES ON BEHALF OF A MANUFACTURER, BUT FOR WHICH THERE IS NO CHANGE OF OWNERSHIP IN THE PRESCRIPTION DRUGS.

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 QUANTITY OF THE PRESCRIPTION DRUG, ITS DOSAGE FORM AND DOSAGE STRENGTH, THE DATE OF THE PURCHASE OR TRANSFER, THE INVOICE NUMBER, CONTAINER SIZE, EXPIRATION DATE, LOT NUMBER, NATIONAL DRUG CODE, AND, WHEN 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. A SINGLE PEDIGREE SHALL INCLUDE EVERY CHANGE OF OWNERSHIP OF A PRESCRIPTION DRUG FROM ITS INITIAL MANUFACTURE THROUGH TO ITS FINAL TRANSACTION TO A PHARMACY OR OTHER PERSON FOR FURNISHING, ADMINISTERING, OR DISPENSING THE PRESCRIPTION DRUG, REGARDLESS OF REPACKAGING OR ASSIGNMENT OF ANOTHER NATIONAL DRUG CODE DIRECTORY NUMBER. PRESCRIPTION DRUGS THAT ARE REPACKAGED SHALL BE SERIALIZED BY THE REPACKAGER AND A PEDIGREE SHALL BE PROVIDED THAT REFERENCES THE PEDIGREE OF THE ORIGINAL PACKAGE OR PACKAGES PROVIDED BY THE MANUFACTURER.

4. A PEDIGREE SHALL TRACK EACH PRESCRIPTION DRUG AT THE SMALLEST PACKAGE OR IMMEDIATE CONTAINER DISTRIBUTED BY THE MANUFACTURER, RECEIVED AND DISTRIBUTED BY THE WHOLESALER OR REPACKAGER, AND RECEIVED BY THE PHARMACY OR ANOTHER PERSON FURNISHING, ADMINISTERING, OR DISPENSING THE PRESCRIPTION DRUG. FOR PURPOSES OF THIS SECTION, "SMALLEST PACKAGE OR IMMEDIATE CONTAINER" OF A PRESCRIPTION DRUG SHALL INCLUDE ANY PRESCRIPTION DRUG PACKAGE OR CONTAINER MADE AVAILABLE TO A REPACKAGER, WHOLESALER, PHARMACY, OR OTHER ENTITY FOR REPACKAGING OR REDISTRIBUTION, AS WELL AS THE SMALLEST UNIT MADE BY THE MANUFACTURER FOR SALE TO THE PHARMACY OR OTHER PERSON FURNISHING, ADMINISTERING, OR DISPENSING THE DRUG.

5. ANY RETURN OF A PRESCRIPTION DRUG TO A WHOLESALER OR MANUFACTURER SHALL BE DOCUMENTED ON THE SAME PEDIGREE AS THE TRANSACTION THAT RESULTED IN THE RECEIPT OF THE PRESCRIPTION DRUG BY THE PARTY RETURNING IT.

6. THE FOLLOWING TRANSACTIONS ARE EXEMPT FROM THE PEDIGREE REQUIREMENTS CREATED BY THIS SECTION:

A. AN INTRACOMPANY SALE OR TRANSFER OF A PRESCRIPTION DRUG. FOR PURPOSES OF THIS SECTION, "INTRACOMPANY SALE OR TRANSFER" MEANS ANY TRANSACTION FOR ANY VALID BUSINESS PURPOSE BETWEEN A DIVISION, SUBSIDIARY, PARENT, OR AFFILIATED OR RELATED COMPANY UNDER THE COMMON OWNERSHIP AND CONTROL OF THE SAME CORPORATE OR LEGAL ENTITY.

B. PRESCRIPTION DRUGS RECEIVED BY THE STATE OR A LOCAL GOVERNMENT ENTITY FROM A DEPARTMENT OR AGENCY OF THE FEDERAL GOVERNMENT OR AN AGENT OF THE FEDERAL GOVERNMENT SPECIFICALLY AUTHORIZED TO DELIVER PRESCRIPTION DRUGS TO THE STATE OR LOCAL GOVERNMENT ENTITY.

C. THE PROVISION OF SAMPLES OF PRESCRIPTION DRUGS BY A MANUFACTURER'S EMPLOYEE TO AN AUTHORIZED PRESCRIBER, PROVIDED THE SAMPLES ARE DISPENSED WITHOUT CHARGE ONLY TO A PATIENT OF THE PRESCRIBER.

D. (I) A SALE, TRADE, OR TRANSFER OF A RADIOACTIVE DRUG BETWEEN ANY TWO ENTITIES LICENSED BY THE DEPARTMENT OF HEALTH OR THE FEDERAL NUCLEAR REGULATORY COMMISSION.

(II) THE EXEMPTION IN THIS PARAGRAPH SHALL REMAIN IN EFFECT UNLESS THE DEPARTMENT DETERMINES THAT THE RISK OF COUNTERFEITING OR DIVERSION OF A RADIOACTIVE DRUG IS SUFFICIENT TO REQUIRE A PEDIGREE, IN WHICH EVENT THE EXEMPTION IN THIS PARAGRAPH SHALL BECOME INOPERATIVE AS PROVIDED IN A REGULATION PROMULGATED BY THE DEPARTMENT.

E. THE SALE, TRADE, OR TRANSFER OF A DANGEROUS DRUG THAT IS LABELED BY THE MANUFACTURER AS "FOR VETERINARY USE ONLY".

F. THE SALE, TRADE, OR TRANSFER OF COMPRESSED MEDICAL GAS. FOR PURPOSES OF THIS SECTION, "COMPRESSED MEDICAL GAS" MEANS ANY SUBSTANCE IN ITS GASEOUS OR CRYOGENIC LIQUID FORM THAT MEETS MEDICAL PURITY STANDARDS AND HAS APPLICATION IN A MEDICAL OR HOMECARE ENVIRONMENT, INCLUDING, BUT NOT LIMITED TO, OXYGEN AND NITROUS OXIDE.

G. THE SALE, TRADE, OR TRANSFER OF SOLUTIONS. FOR PURPOSES OF THIS SECTION, "SOLUTIONS" MEANS ANY OF THE FOLLOWING:

(I) THOSE INTRAVENOUS PRODUCTS THAT, BY THEIR FORMULATION, ARE INTENDED FOR THE REPLENISHMENT OF FLUIDS AND ELECTROLYTES, SUCH AS SODIUM, CHLORIDE, AND POTASSIUM AND CALORIES, SUCH AS DEXTROSE AND AMINO ACIDS, OR BOTH.

(II) THOSE INTRAVENOUS PRODUCTS USED TO MAINTAIN THE EQUILIBRIUM OF WATER AND MINERALS IN THE BODY, SUCH AS DIALYSIS SOLUTIONS.

(III) PRODUCTS THAT ARE INTENDED FOR IRRIGATION OR RECONSTITUTION, AS WELL AS STERILE WATER, WHETHER INTENDED FOR THOSE PURPOSES OR FOR INJECTION.

H. PRESCRIPTION DRUGS THAT ARE PLACED IN A SEALED PACKAGE WITH A MEDICAL DEVICE OR MEDICAL SUPPLIES AT THE POINT OF FIRST SHIPMENT INTO COMMERCE BY THE MANUFACTURER AND THE PACKAGE REMAINS SEALED UNTIL THE DRUG AND DEVICE ARE USED, PROVIDED THAT THE PACKAGE IS ONLY USED FOR SURGICAL PURPOSES.

I. A PRODUCT THAT MEETS EITHER OF THE FOLLOWING CRITERIA:

(I) A PRODUCT COMPRISED OF TWO OR MORE REGULATED COMPONENTS, SUCH AS A DRUG/DEVICE, BIOLOGIC/DEVICE, OR DRUG/DEVICE/BIOLOGIC, THAT ARE PHYSICALLY, CHEMICALLY, OR OTHERWISE COMBINED OR MIXED AND PRODUCED AS A SINGLE ENTITY.

(II) TWO OR MORE SEPARATE PRODUCTS PACKAGED TOGETHER IN A SINGLE PACKAGE OR AS A UNIT AND COMPRISED OF DRUG AND DEVICE PRODUCTS OR DEVICE AND BIOLOGICAL PRODUCTS.

7. IF A MANUFACTURER, WHOLESALER, OR PHARMACY HAS REASONABLE CAUSE TO BELIEVE THAT A PRESCRIPTION DRUG IN, OR HAVING BEEN IN, ITS POSSESSION IS COUNTERFEIT OR THE SUBJECT OF A FRAUDULENT TRANSACTION, THE MANUFAC-

TURE, WHOLESALER, OR PHARMACY SHALL NOTIFY THE DEPARTMENT WITHIN SEVENTY-TWO HOURS OF OBTAINING SUCH KNOWLEDGE. THIS SUBDIVISION SHALL APPLY TO ANY PRESCRIPTION DRUG THAT HAS BEEN SOLD OR DISTRIBUTED IN OR THROUGH THIS STATE.

8. 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.

9. A. A PEDIGREE SHALL BE MAINTAINED IN AN ELECTRONIC PEDIGREE TRACKING OR ALTERNATIVE SYSTEM DETERMINED BY THE DEPARTMENT TO BE FEASIBLE. IN DETERMINING WHETHER AN ELECTRONIC PEDIGREE TRACKING OR ALTERNATIVE SYSTEM IS FEASIBLE, THE DEPARTMENT SHALL CONSIDER WHETHER SUCH SYSTEM OR FORMAT IS:

(I) READILY AVAILABLE WITH RESPECT TO ALL PRESCRIPTION DRUGS,

(II) 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

(III) CONSISTENT AND COMPATIBLE WITH FEDERAL REQUIREMENTS FOR AN ELECTRONIC PEDIGREE TRACKING OR ALTERNATIVE SYSTEM AND A STANDARDIZED NUMERICAL IDENTIFIER.

B. THE PROVISIONS OF THIS SECTION SHALL BECOME OPERATIVE ON JANUARY FIRST, TWO THOUSAND SIXTEEN, WHICH SHALL BE THE PEDIGREE EFFECTIVE DATE; PROVIDED, HOWEVER, IF AN ELECTRONIC PEDIGREE TRACKING OR ALTERNATIVE SYSTEM 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 SYSTEM TO BE FEASIBLE.

10. A. COMMENCING ON JULY FIRST, TWO THOUSAND SIXTEEN, A WHOLESALER OR OTHER PERSON FURNISHING A PRESCRIPTION DRUG SHALL NOT (I) SELL, TRANSFER, DISTRIBUTE, OR DELIVER A PRESCRIPTION DRUG WITHOUT PROVIDING A PEDIGREE, OR (II) ACQUIRE A PRESCRIPTION DRUG WITHOUT RECEIVING A PEDIGREE. IF AN ELECTRONIC PEDIGREE TRACKING OR ALTERNATIVE SYSTEM IS NOT FEASIBLE BY THE PEDIGREE EFFECTIVE DATE, THE DEPARTMENT MAY EXTEND THE DATE UPON WHICH THE PROVISIONS OF THIS PARAGRAPH SHALL BECOME OPERATIVE AS IT SHALL DETERMINE IN ITS DISCRETION.

B. COMMENCING ON JULY FIRST, TWO THOUSAND SEVENTEEN, A PHARMACY OR OTHER PERSON FURNISHING OR DISPENSING A PRESCRIPTION DRUG SHALL NOT (I) SELL, TRANSFER, DISTRIBUTE, OR DELIVER A PRESCRIPTION DRUG WITHOUT PROVIDING A PEDIGREE, OR (II) ACQUIRE A PRESCRIPTION DRUG WITHOUT RECEIVING A PEDIGREE. IF AN ELECTRONIC PEDIGREE TRACKING OR ALTERNATIVE SYSTEM IS NOT FEASIBLE BY THE PEDIGREE EFFECTIVE DATE, THE DEPARTMENT MAY EXTEND THE DATE UPON WHICH THE PROVISIONS OF THIS PARAGRAPH SHALL BECOME OPERATIVE AS IT SHALL DETERMINE IN ITS DISCRETION.

11. A. (I) UPON THE EFFECTIVE DATE OF FEDERAL LEGISLATION OR ADOPTION OF A FEDERAL REGULATION GOVERNING THE FORM OR CONTENT OF PEDIGREE OR THE STANDARDS AND TECHNOLOGIES FOR THE IDENTIFICATION, VALIDATION, TRACKING AND TRACING AND AUTHENTICATION FOR PRESCRIPTION DRUGS, THE PROVISIONS OF THIS SECTION THAT ARE INCONSISTENT WITH SUCH FEDERAL LEGISLATION OR FEDERAL REGULATION SHALL BECOME INOPERATIVE.

(II) WITHIN NINETY DAYS OF THE ENACTMENT OF FEDERAL LEGISLATION OR ADOPTION OF A FEDERAL REGULATION THAT IS INCONSISTENT WITH THE PROVISIONS OF THIS SECTION AS PROVIDED IN SUBPARAGRAPH (I) OF THIS PARAGRAPH, THE DEPARTMENT SHALL PUBLISH A NOTICE STATING WHICH PROVISIONS OF

THIS SECTION ARE INOPERATIVE. THE DEPARTMENT SHALL HAVE THE AUTHORITY TO ADOPT EMERGENCY REGULATIONS AS IT DEEMS NECESSARY IN ITS DETERMINATION TO REFLECT THE INOPERATION OF ANY PROVISION OF THIS SECTION AS PROVIDED IN THIS PARAGRAPH.

B. (I) IF THE FEDERAL FOOD AND DRUG ADMINISTRATION ENACTS ANY RULE OR STANDARD OR TAKES ANY OTHER ACTION THAT IS INCONSISTENT WITH ANY PROVISION OF THIS SECTION GOVERNING THE FORM OR CONTENT OF PEDIGREE OR THE STANDARDS AND TECHNOLOGIES FOR THE IDENTIFICATION, VALIDATION, TRACKING AND TRACING, AND AUTHENTICATION FOR PRESCRIPTION DRUGS, SUCH PROVISION OF THIS SECTION SHALL BE DEEMED INOPERATIVE.

(II) WITHIN NINETY DAYS OF THE FEDERAL FOOD AND DRUG ADMINISTRATION ENACTING ANY RULE OR STANDARD OR TAKING ANY OTHER ACTION THAT IS INCONSISTENT WITH THE PROVISIONS OF THIS SECTION AS PROVIDED IN SUBPARAGRAPH (I) OF THIS PARAGRAPH, THE DEPARTMENT SHALL PUBLISH A NOTICE STATING WHICH PROVISIONS OF THIS SECTION ARE INOPERATIVE. THE DEPARTMENT SHALL HAVE THE AUTHORITY TO ADOPT EMERGENCY REGULATIONS AS IT DEEMS NECESSARY IN ITS DETERMINATION TO REFLECT THE INOPERATION OF ANY PROVISION OF THIS SECTION AS PROVIDED IN THIS PARAGRAPH.

12. A. ALL UNITS OF PRESCRIPTION DRUGS IN THE POSSESSION OF A WHOLESALER OR PHARMACY FOR WHICH THE MANUFACTURER DOES NOT HOLD LEGAL TITLE ON THE PEDIGREE EFFECTIVE DATE SHALL NOT BE SUBJECT TO THE PEDIGREE REQUIREMENTS SET FORTH IN THIS SECTION; PROVIDED, HOWEVER, IF ANY SUCH UNITS OF PRESCRIPTION DRUGS ARE SUBSEQUENTLY RETURNED TO THE MANUFACTURER, THEY SHALL BE SUBJECT TO THE PEDIGREE REQUIREMENTS IF THE MANUFACTURER DISTRIBUTES SUCH UNITS IN THIS STATE.

B. ALL UNITS OF PRESCRIPTION DRUGS IN THE POSSESSION OF A MANUFACTURER FOR WHICH THE MANUFACTURER DOES NOT HOLD LEGAL TITLE ON THE PEDIGREE EFFECTIVE DATE SHALL NOT BE SUBJECT TO THE PEDIGREE REQUIREMENTS SET FORTH IN THIS SECTION.

13. 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 paragraph b of subdivision 9 of section 6810-b of the education law, as added by section six of this act.