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

3904

2013-2014 Regular Sessions

I N S E N A T E

February 26, 2013

Introduced by Sen. HANNON -- read twice and ordered printed, and when printed to be committed to the Committee on Health

AN ACT to amend the public health law, in relation to pedigree for prescription drugs

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

Section 1. Section 270 of the public health law is amended by adding a new subdivision 15 to read as follows:

15. "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 TWO HUNDRED EIGHTY-A OF THIS ARTICLE.

S 2. The public health law is amended by adding a new section 280-a to read as follows:

S 280-A. 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

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

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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 IN CONSULTATION WITH THE DEPARTMENT OF EDUCATION. 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 OR THE FEDERAL NUCLEAR REGULATORY COMMISSION.

(II) THE EXEMPTION IN THIS PARAGRAPH SHALL REMAIN IN EFFECT UNLESS THE DEPARTMENT, IN CONSULTATION WITH THE DEPARTMENT OF EDUCATION, 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 MANUFACTURER, WHOLESALER, OR PHARMACY SHALL NOTIFY THE DEPARTMENT AND THE

DEPARTMENT OF EDUCATION 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, IN CONSULTATION WITH THE DEPARTMENT OF EDUCATION, AND SHALL BE MADE AVAILABLE FOR INSPECTION, UPON REASONABLE NOTICE, BY THE DEPARTMENT AND THE DEPARTMENT OF EDUCATION.

9. A. A PEDIGREE SHALL BE MAINTAINED IN AN ELECTRONIC PEDIGREE TRACKING OR ALTERNATIVE SYSTEM DETERMINED BY THE DEPARTMENT, IN CONSULTATION WITH THE DEPARTMENT OF EDUCATION, TO BE FEASIBLE. IN DETERMINING WHETHER AN ELECTRONIC PEDIGREE TRACKING OR ALTERNATIVE SYSTEM IS FEASIBLE, THE DEPARTMENT, IN CONSULTATION WITH THE DEPARTMENT OF EDUCATION, 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, IN CONSULTATION WITH THE DEPARTMENT OF EDUCATION, SHALL ISSUE ONE-YEAR EXTENSIONS OF THE PEDIGREE EFFECTIVE DATE UNTIL THE DEPARTMENT, IN CONSULTATION WITH THE DEPARTMENT OF EDUCATION, 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, IN CONSULTATION WITH THE DEPARTMENT OF EDUCATION, 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, IN CONSULTATION WITH THE DEPARTMENT OF EDUCATION, 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 CONSULTATION WITH THE DEPARTMENT OF EDUCATION, 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, IN CONSULTATION WITH THE DEPARTMENT OF EDUCATION, 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 3. This act shall take effect on the one hundred eightieth day after it shall have become a law. The department of health, in consultation with 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 280-a of the public health law, as added by section two of this act.