

1075

2011-2012 Regular Sessions

I N A S S E M B L Y

(PREFILED)

January 5, 2011

Introduced by M. of A. PAULIN, TITONE, GOTTFRIED, GALEF, CLARK --
Multi-Sponsored by -- M. of A. BOYLAND, BURLING, COLTON, COOK, DINOW-
ITZ, HIKIND, HOOPER, LATIMER, J. MILLER, ORTIZ, RAIA, P. RIVERA,
ROBINSON, SWEENEY, TOBACCO, WRIGHT -- read once and referred to the
Committee on Higher Education

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

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

1 Section 1. Section 6802 of the education law is amended by adding a
2 new subdivision 23 to read as follows:
3 23. "PEDIGREE" MEANS AN ELECTRONIC RECORD CONTAINING INFORMATION
4 REGARDING EACH TRANSACTION, RESULTING IN A CHANGE OF OWNERSHIP, OF A
5 PRESCRIPTION DRUG, ORIGINATING FROM A MANUFACTURER, THROUGH ACQUISITION
6 BY OR TRANSFER TO ONE OR MORE WHOLESALERS, MANUFACTURERS, REPACKAGERS,
7 OR PHARMACIES, UNTIL FINAL SALE OR TRANSFER TO A PHARMACY OR OTHER
8 PERSON FURNISHING, ADMINISTERING, OR DISPENSING THE PRESCRIPTION DRUG,
9 AS PROVIDED IN SECTION SIXTY-EIGHT HUNDRED TEN-B OF THIS ARTICLE.
10 S 2. The education law is amended by adding a new section 6810-b to
11 read as follows:
12 S 6810-B. PEDIGREE. 1. A. EVERY MANUFACTURER SHALL ESTABLISH AND MAIN-
13 TAIN A PEDIGREE FOR EACH PRESCRIPTION DRUG, AND EVERY WHOLESALER, PHAR-
14 MACY OR OTHER PERSON FURNISHING OR DISPENSING A PRESCRIPTION DRUG SHALL
15 MAINTAIN A PEDIGREE FOR EACH PRESCRIPTION DRUG.
16 B. FOR PURPOSES OF THIS SECTION, "MANUFACTURER" MEANS A PERSON WHO
17 PREPARES, DERIVES, MANUFACTURES, PRODUCES OR REPACKAGES A PRESCRIPTION
18 DRUG. MANUFACTURER ALSO MEANS THE HOLDER OR HOLDERS OF A NEW DRUG APPLI-
19 CATION (NDA), AN ABBREVIATED NEW DRUG APPLICATION (ANDA), OR A BIOLOGICS
20 LICENSE APPLICATION (BLA), PROVIDED THAT SUCH APPLICATION HAS BEEN
21 APPROVED; A MANUFACTURER'S THIRD PARTY LOGISTICS PROVIDER; A PRIVATE

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

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1 LABEL DISTRIBUTOR (INCLUDING COLICENSED PARTNERS) FOR WHOM THE PRIVATE
2 LABEL DISTRIBUTOR'S PRESCRIPTION DRUGS ARE ORIGINALLY MANUFACTURED AND
3 LABELED FOR THE DISTRIBUTOR AND HAVE NOT BEEN REPACKAGED; OR THE
4 DISTRIBUTOR AGENT FOR THE MANUFACTURER, CONTRACT MANUFACTURER, OR
5 PRIVATE LABEL DISTRIBUTOR, WHETHER THE ESTABLISHMENT IS A MEMBER OF THE
6 MANUFACTURER'S AFFILIATED GROUP (REGARDLESS OF WHETHER THE MEMBER TAKES
7 TITLE TO THE DRUG) OR IS A CONTRACT DISTRIBUTOR SITE.

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

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

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

21 A. THE SOURCE OF THE PRESCRIPTION DRUG, INCLUDING THE NAME AND PRINCI-
22 PAL ADDRESS OF THE SELLER OR TRANSFEROR;

23 B. THE PROPRIETARY AND ESTABLISHED NAME OF THE PRESCRIPTION DRUG, THE
24 QUANTITY OF THE PRESCRIPTION DRUG, ITS DOSAGE FORM AND DOSAGE STRENGTH,
25 THE DATE OF THE PURCHASE OR TRANSFER, THE INVOICE NUMBER, CONTAINER
26 SIZE, EXPIRATION DATE, LOT NUMBER, NATIONAL DRUG CODE, AND, WHEN AVAIL-
27 ABLE, STANDARDIZED NUMERICAL IDENTIFIER, OF THE PRESCRIPTION DRUG;

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

32 D. A CERTIFICATION UNDER PENALTY OF PERJURY FROM THE DESIGNATED REPRE-
33 SENTATIVE OF THE MANUFACTURER, WHOLESALER OR PHARMACY THAT THE INFORMA-
34 TION CONTAINED THEREIN IS TRUE AND ACCURATE.

35 3. A SINGLE PEDIGREE SHALL INCLUDE EVERY CHANGE OF OWNERSHIP OF A
36 PRESCRIPTION DRUG FROM ITS INITIAL MANUFACTURE THROUGH TO ITS FINAL
37 TRANSACTION TO A PHARMACY OR OTHER PERSON FOR FURNISHING, ADMINISTERING,
38 OR DISPENSING THE PRESCRIPTION DRUG, REGARDLESS OF REPACKAGING OR
39 ASSIGNMENT OF ANOTHER NATIONAL DRUG CODE DIRECTORY NUMBER. PRESCRIPTION
40 DRUGS THAT ARE REPACKAGED SHALL BE SERIALIZED BY THE REPACKAGER AND A
41 PEDIGREE SHALL BE PROVIDED THAT REFERENCES THE PEDIGREE OF THE ORIGINAL
42 PACKAGE OR PACKAGES PROVIDED BY THE MANUFACTURER.

43 4. A PEDIGREE SHALL TRACK EACH PRESCRIPTION DRUG AT THE SMALLEST PACK-
44 AGE OR IMMEDIATE CONTAINER DISTRIBUTED BY THE MANUFACTURER, RECEIVED AND
45 DISTRIBUTED BY THE WHOLESALER OR REPACKAGER, AND RECEIVED BY THE PHARMA-
46 CY OR ANOTHER PERSON FURNISHING, ADMINISTERING, OR DISPENSING THE
47 PRESCRIPTION DRUG. FOR PURPOSES OF THIS SECTION, "SMALLEST PACKAGE OR
48 IMMEDIATE CONTAINER" OF A PRESCRIPTION DRUG SHALL INCLUDE ANY
49 PRESCRIPTION DRUG PACKAGE OR CONTAINER MADE AVAILABLE TO A REPACKAGER,
50 WHOLESALER, PHARMACY, OR OTHER ENTITY FOR REPACKAGING OR REDISTRIBUTION,
51 AS WELL AS THE SMALLEST UNIT MADE BY THE MANUFACTURER FOR SALE TO THE
52 PHARMACY OR OTHER PERSON FURNISHING, ADMINISTERING, OR DISPENSING THE
53 DRUG.

54 5. ANY RETURN OF A PRESCRIPTION DRUG TO A WHOLESALER OR MANUFACTURER
55 SHALL BE DOCUMENTED ON THE SAME PEDIGREE AS THE TRANSACTION THAT

1 RESULTED IN THE RECEIPT OF THE PRESCRIPTION DRUG BY THE PARTY RETURNING
2 IT.

3 6. THE FOLLOWING TRANSACTIONS ARE EXEMPT FROM THE PEDIGREE REQUIRE-
4 MENTS CREATED BY THIS SECTION:

5 A. AN INTRACOMPANY SALE OR TRANSFER OF A PRESCRIPTION DRUG. FOR
6 PURPOSES OF THIS SECTION, "INTRACOMPANY SALE OR TRANSFER" MEANS ANY
7 TRANSACTION FOR ANY VALID BUSINESS PURPOSE BETWEEN A DIVISION, SUBSID-
8 IARY, PARENT, OR AFFILIATED OR RELATED COMPANY UNDER THE COMMON OWNER-
9 SHIP AND CONTROL OF THE SAME CORPORATE OR LEGAL ENTITY.

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

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

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

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

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

27 F. THE SALE, TRADE, OR TRANSFER OF COMPRESSED MEDICAL GAS. FOR
28 PURPOSES OF THIS SECTION, "COMPRESSED MEDICAL GAS" MEANS ANY SUBSTANCE
29 IN ITS GASEOUS OR CRYOGENIC LIQUID FORM THAT MEETS MEDICAL PURITY STAND-
30 ARDS AND HAS APPLICATION IN A MEDICAL OR HOMECARE ENVIRONMENT, INCLUD-
31 ING, BUT NOT LIMITED TO, OXYGEN AND NITROUS OXIDE.

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

34 (I) THOSE INTRAVENOUS PRODUCTS THAT, BY THEIR FORMULATION, ARE
35 INTENDED FOR THE REPLENISHMENT OF FLUIDS AND ELECTROLYTES, SUCH AS SODI-
36 UM, CHLORIDE, AND POTASSIUM AND CALORIES, SUCH AS DEXTROSE AND AMINO
37 ACIDS, OR BOTH.

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

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

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

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

49 (I) A PRODUCT COMPRISED OF TWO OR MORE REGULATED COMPONENTS, SUCH AS A
50 DRUG/DEVICE, BIOLOGIC/DEVICE, OR DRUG/DEVICE/BIOLOGIC, THAT ARE PHYS-
51 ICALLY, CHEMICALLY, OR OTHERWISE COMBINED OR MIXED AND PRODUCED AS A
52 SINGLE ENTITY.

53 (II) TWO OR MORE SEPARATE PRODUCTS PACKAGED TOGETHER IN A SINGLE PACK-
54 AGE OR AS A UNIT AND COMPRISED OF DRUG AND DEVICE PRODUCTS OR DEVICE AND
55 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 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 WHOLE-SALER 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 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 two of this act.