

Senate Bill No. 1307

Passed the Senate August 21, 2008

Secretary of the Senate

Passed the Assembly August 18, 2008

Chief Clerk of the Assembly

This bill was received by the Governor this _____ day
of _____, 2008, at _____ o'clock ____M.

Private Secretary of the Governor

CHAPTER _____

An act to amend Sections 4033, 4034, 4162, 4162.5, and 4163 of, to add Sections 4034.1, 4044, 4045, 4163.1, 4163.2, 4163.3, and 4163.4 to, and to repeal and add Section 4163.5 of, the Business and Professions Code, relating to pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

SB 1307, Ridley-Thomas. Pharmacy: pedigree.

Existing law, the Pharmacy Law, provides for the licensure and regulation of the practice of pharmacy and the sale of dangerous drugs or dangerous devices by the California State Board of Pharmacy, in the Department of Consumer Affairs. Under existing law, on and after January 1, 2009, pedigree means an electronic record containing information regarding each transaction resulting in a change of ownership of a given dangerous drug, from sale by a manufacturer, through acquisition and sale by one or more wholesalers, manufacturers, or pharmacies, until final sale to a pharmacy or other person furnishing, administering, or dispensing the dangerous drug. On and after January 1, 2009, existing law prohibits a wholesaler or pharmacy from selling, trading, or transferring a dangerous drug without a pedigree or from acquiring a dangerous drug without receiving a pedigree. Existing law, on and after January 1, 2009, requires that a pedigree include certain information, including, but not limited to, the source of the dangerous drug and the trade or generic name of the drug. Existing law exempts specified transactions from the pedigree requirement, and authorizes the board to extend the January 1, 2009, compliance date to January 1, 2011, in specified circumstances. Existing law makes it a crime to knowingly violate the Pharmacy Law.

This bill would instead, on and after January 1, 2015, define a pedigree, as specified, and would revise the information required to be contained in a pedigree to, among other things, include a specified unique identification number.

The bill would prohibit a wholesaler or repackager, as defined, on and after July 1, 2016, or a pharmacy, on and after July 1, 2017, from selling, trading, or transferring a dangerous drug without a pedigree or from acquiring a dangerous drug without receiving a

pedigree, except as specified. The bill would prohibit a pharmacy warehouse, as defined, on and after July 1, 2017, from acquiring a dangerous drug without receiving a pedigree. The bill would delete the board's authority to extend these compliance dates. The bill would also prohibit a repackager or pharmacy from furnishing a dangerous drug or dangerous device to an unauthorized person. The bill would require a manufacturer of a dangerous drug distributed in California to designate certain percentages of the drugs that it manufactures to comply with the pedigree requirement by specified dates, and to notify the board of the drugs so designated and of the technology to be used to meet that requirement. The bill would also revise certain exemptions from the pedigree requirement and would exempt specified additional transactions from the pedigree requirement.

The bill would authorize a manufacturer, wholesaler, or pharmacy in possession of dangerous drugs manufactured or distributed prior to the operative date of the pedigree requirements to designate those drugs as not subject to the requirements by preparing a specified written declaration under penalty of perjury, which would be considered trade secrets and kept confidential by the board. The bill would authorize dangerous drugs designated on such a declaration to be purchased, sold, acquired, returned, or otherwise transferred, without meeting the pedigree requirements if the transfer complies with specified requirements. Because a knowing violation of the bill's provisions would be a crime under the Pharmacy Law and because the bill would expand the crime of perjury, the bill would impose a state-mandated local program.

The bill would require the board to promulgate regulations defining the circumstances under which participants in the distribution chain may infer the contents of a case, pallet, or other aggregate of individual units, packages, or containers of dangerous drugs, from a unique identifier associated with the case, pallet, or other aggregate, if certain standard operating procedures are complied with and made available for the board to review. The bill would require board regulations to specify liability associated with accuracy of product information and pedigree using inference. The bill would declare the intent of the Legislature in this regard.

The bill would make the pedigree requirements inoperative upon the effective date of federal law addressing pedigree or serialization

measures for dangerous drugs, or as otherwise specified in the event of a conflict with federal law.

Existing law requires an applicant for issuance or renewal of a wholesaler or nonresident wholesaler license to submit a surety bond of \$100,000 or an equivalent means of security to secure payment of any administrative fines and costs imposed by the board. Existing law makes this requirement inoperative and repeals it on January 1, 2015.

This bill would delete the date upon which these provisions become inoperative and are repealed.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

The people of the State of California do enact as follows:

SECTION 1. Section 4033 of the Business and Professions Code is amended to read:

4033. (a) (1) “Manufacturer” means and includes every person who prepares, derives, produces, compounds, or repackages any drug or device except a pharmacy that manufactures on the immediate premises where the drug or device is sold to the ultimate consumer.

(2) Notwithstanding paragraph (1), “manufacturer” shall not mean a pharmacy compounding a drug for parenteral therapy, pursuant to a prescription, for delivery to another pharmacy for the purpose of delivering or administering the drug to the patient or patients named in the prescription, provided that neither the components for the drug nor the drug are compounded, fabricated, packaged, or otherwise prepared prior to receipt of the prescription.

(3) Notwithstanding paragraph (1), “manufacturer” shall not mean a pharmacy that, at a patient’s request, repackages a drug previously dispensed to the patient, or to the patient’s agent, pursuant to a prescription.

(b) Notwithstanding subdivision (a), as used in Sections 4034, 4163, 4163.1, 4163.2, 4163.3, 4163.4, and 4163.5, “manufacturer” means a person who prepares, derives, manufactures, produces,

or repackages a dangerous drug, as defined in Section 4022, device, or cosmetic. 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.

SEC. 2. Section 4034 of the Business and Professions Code is amended to read:

4034. (a) "Pedigree" means a record, in electronic form, containing information regarding each transaction resulting in a change of ownership of a given dangerous drug, from sale by a manufacturer, through acquisition and sale by one or more wholesalers, manufacturers, repackagers, or pharmacies, until final sale to a pharmacy or other person furnishing, administering, or dispensing the dangerous drug. The pedigree shall be created and maintained in an interoperable electronic system, ensuring compatibility throughout all stages of distribution.

(b) A pedigree shall include all of the following information:

(1) The source of the dangerous drug, including the name, the federal manufacturer's registration number or a state license number as determined by the board, and principal address of the source.

(2) The trade or generic name of the dangerous drug, the quantity of the dangerous drug, its dosage form and strength, the date of the transaction, the sales invoice number or, if not immediately available, a customer-specific shipping reference number linked to the sales invoice number, the container size, the number of containers, the expiration dates, and the lot numbers.

(3) The business name, address, and the federal manufacturer's registration number or a state license number as determined by the board, of each owner of the dangerous drug, and the dangerous drug shipping information, including the name and address of each person certifying delivery or receipt of the dangerous drug.

(4) A certification under penalty of perjury from a responsible party of the source of the dangerous drug that the information contained in the pedigree is true and accurate.

(5) The unique identification number described in subdivision (i).

(c) A single pedigree shall include every change of ownership of a given dangerous drug from its initial manufacture through to its final transaction to a pharmacy or other person for furnishing, administering, or dispensing the drug, regardless of repackaging or assignment of another National Drug Code (NDC) Directory number. Dangerous 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.

(d) A pedigree shall track each dangerous 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 dangerous drug. For purposes of this section, the “smallest package or immediate container” of a dangerous drug shall include any dangerous 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.

(e) Any return of a dangerous drug to a wholesaler or manufacturer shall be documented on the same pedigree as the transaction that resulted in the receipt of the drug by the party returning it.

(f) If a licensed health care service plan, hospital organization, and one or more physician organizations have exclusive contractual relationships to provide health care services, drugs distributed between these persons shall be deemed not to have changed ownership.

(g) The following transactions are exempt from the pedigree requirement created by this section:

(1) An intracompany sale or transfer of a dangerous 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.

(2) Dangerous 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 dangerous drugs to the state or local government entity.

(3) The provision of samples of dangerous drugs by a manufacturer's employee to an authorized prescriber, provided the samples are dispensed to a patient of the prescriber without charge.

(4) (A) A sale, trade, or transfer of a radioactive drug, as defined in Section 1708.3 of Title 16 of the California Code of Regulations, between any two entities licensed by the Radiologic Health Branch of the State Department of Public Health, the federal Nuclear Regulatory Commission, or an Agreement state.

(B) The exemption in this paragraph shall remain in effect unless the board, no earlier than the date that is two years after the compliance date for manufacturers set forth in subdivision (k) of Section 4034 or Section 4163.5, determines after consultation with the Radiologic Health Branch of the State Department of Public Health that the risk of counterfeiting or diversion of a radioactive drug is sufficient to require a pedigree. Two years following the date of any such determination, this paragraph shall become inoperative.

(5) The sale, trade, or transfer of a dangerous drug that is labeled by the manufacturer as "for veterinary use only."

(6) 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.

(7) The sale, trade, or transfer of solutions. For purposes of this section, "solutions" means any of the following:

(A) Those intravenous products that, by their formulation, are intended for the replenishment of fluids and electrolytes, such as sodium, chloride, and potassium, calories, such as dextrose and amino acids, or both.

(B) Those intravenous products used to maintain the equilibrium of water and minerals in the body, such as dialysis solutions.

(C) Products that are intended for irrigation or reconstitution, as well as sterile water, whether intended for those purposes or for injection.

(8) Dangerous 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.

(9) A product that meets either of the following criteria:

(A) 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.

(B) 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.

(h) If a manufacturer, wholesaler, or pharmacy has reasonable cause to believe that a dangerous 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 board within 72 hours of obtaining that knowledge. This subdivision shall apply to any dangerous drug that has been sold or distributed in or through this state.

(i) “Interoperable electronic system” as used in this chapter means an electronic track and trace system for dangerous drugs that uses a unique identification number, established at the point of manufacture and supplemented by a linked unique identification number in the event that drug is repackaged, contained within a standardized nonproprietary data format and architecture, that is uniformly used by manufacturers, wholesalers, repackagers, and pharmacies for the pedigree of a dangerous drug. No particular data carrier or other technology is mandated to accomplish the attachment of the unique identification number described in this subdivision.

(j) The application of the pedigree requirement shall be subject to review during the board’s evaluation pursuant to Section 473.4.

(k) This section shall become operative on January 1, 2015.

SEC. 3. Section 4034.1 is added to the Business and Professions Code, to read:

4034.1. (a) (1) Upon the effective date of federal legislation or adoption of a federal regulation addressing pedigree or serialization measures for dangerous drugs, Sections 4034, 4163, 4163.1, 4163.2, 4163.4, and 4163.5 shall become inoperative.

(2) Within 90 days of the enactment of federal legislation or adoption of a regulation addressing pedigree or serialization measures for dangerous drugs, the board shall publish a notice that Sections 4034, 4163, 4163.1, 4163.2, 4163.4, and 4163.5 are inoperative.

(3) Within 90 days of the enactment of federal legislation or adoption of a regulation that is inconsistent with any provision of California law governing the application of any pedigree or serialization requirement or standard, the board shall adopt emergency regulations necessary to reflect the inoperation of state law.

(b) (1) If the Food and Drug Administration (FDA) enacts any rule, standard, or takes any other action that is inconsistent with any provision of California law governing application of a pedigree to a dangerous drug, that provision of California law shall be inoperative.

(2) Within 90 days of the FDA enacting any rule, standard, or taking any other action that is inconsistent with any provision of California law governing application of a pedigree to a dangerous drug, the board shall publish a notice that the provision is inoperative.

(3) Within 90 days of the FDA enacting any rule, standard, or taking any other action that is inconsistent with any provision of California law governing application of a pedigree to a dangerous drug, the board shall adopt emergency regulations necessary to reflect the inoperation of state law.

(c) If the board fails to recognize the inoperation within 90 days pursuant to this section, nothing in this section shall preclude a party from filing an action in state or federal court for declaratory or injunctive relief as an alternative to filing a petition with the board.

SEC. 4. Section 4044 is added to the Business and Professions Code, to read:

4044. "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 dangerous drugs into different containers, excluding shipping containers.

SEC. 5. Section 4045 is added to the Business and Professions Code, to read:

4045. “Third-party logistics provider” or “reverse third-party logistic provider” means an entity licensed as a wholesaler that contracts with a dangerous drug manufacturer 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 dangerous drugs. For purposes of Sections 4034, 4163, 4163.1, 4163.2, 4163.3, 4163.4, and 4163.5, a third-party logistics provider shall not be responsible for generating or updating pedigree documentation, but shall maintain copies of the pedigree. To be exempt from documentation for pedigrees, a reverse third-party logistic provider may only accept decommissioned drugs from pharmacies or wholesalers.

SEC. 6. Section 4162 of the Business and Professions Code is amended to read:

4162. (a) (1) An applicant, that is not a government owned and operated wholesaler, for the issuance or renewal of a wholesaler license shall submit a surety bond of one hundred thousand dollars (\$100,000) or other equivalent means of security acceptable to the board payable to the Pharmacy Board Contingent Fund. The purpose of the surety bond is to secure payment of any administrative fine imposed by the board and any cost recovery ordered pursuant to Section 125.3.

(2) For purposes of paragraph (1), the board may accept a surety bond less than one hundred thousand dollars (\$100,000) if the annual gross receipts of the previous tax year for the wholesaler is ten million dollars (\$10,000,000) or less, in which case the surety bond shall be twenty-five thousand dollars (\$25,000).

(3) A person to whom an approved new drug application has been issued by the United States Food and Drug Administration who engages in the wholesale distribution of only the dangerous drug specified in the new drug application, and is licensed or applies for licensure as a wholesaler, shall not be required to post a surety bond as provided in paragraph (1).

(4) For licensees subject to paragraph (2) or (3), the board may require a bond up to one hundred thousand dollars (\$100,000) for any licensee who has been disciplined by any state or federal

agency or has been issued an administrative fine pursuant to this chapter.

(b) The board may make a claim against the bond if the licensee fails to pay a fine within 30 days after the order imposing the fine, or costs become final.

(c) A single surety bond or other equivalent means of security acceptable to the board shall satisfy the requirement of subdivision (a) for all licensed sites under common control as defined in Section 4126.5.

SEC. 7. Section 4162.5 of the Business and Professions Code is amended to read:

4162.5. (a) (1) An applicant for the issuance or renewal of a nonresident wholesaler license shall submit a surety bond of one hundred thousand dollars (\$100,000), or other equivalent means of security acceptable to the board, such as an irrevocable letter of credit, or a deposit in a trust account or financial institution, payable to the Pharmacy Board Contingent Fund. The purpose of the surety bond is to secure payment of any administrative fine imposed by the board and any cost recovery ordered pursuant to Section 125.3.

(2) For purposes of paragraph (1), the board may accept a surety bond less than one hundred thousand dollars (\$100,000) if the annual gross receipts of the previous tax year for the nonresident wholesaler is ten million dollars (\$10,000,000) or less in which the surety bond shall be twenty-five thousand dollars (\$25,000).

(3) For applicants who satisfy paragraph (2), the board may require a bond up to one hundred thousand dollars (\$100,000) for any nonresident wholesaler who has been disciplined by any state or federal agency or has been issued an administrative fine pursuant to this chapter.

(4) A person to whom an approved new drug application or a biologics license application has been issued by the United States Food and Drug Administration who engages in the wholesale distribution of only the dangerous drug specified in the new drug application or biologics license application, and is licensed or applies for licensure as a nonresident wholesaler, shall not be required to post a surety bond as provided in this section.

(b) The board may make a claim against the bond if the licensee fails to pay a fine within 30 days of the issuance of the fine or when the costs become final.

(c) A single surety bond or other equivalent means of security acceptable to the board shall satisfy the requirement of subdivision (a) for all licensed sites under common control as defined in Section 4126.5.

SEC. 8. Section 4163 of the Business and Professions Code is amended to read:

4163. (a) A manufacturer, wholesaler, repackager, or pharmacy may not furnish a dangerous drug or dangerous device to an unauthorized person.

(b) Dangerous drugs or dangerous devices shall be acquired from a person authorized by law to possess or furnish dangerous drugs or dangerous devices. When the person acquiring the dangerous drugs or dangerous devices is a wholesaler, the obligation of the wholesaler shall be limited to obtaining confirmation of licensure of those sources from whom it has not previously acquired dangerous drugs or dangerous devices.

(c) Except as otherwise provided in Section 4163.5, commencing on July 1, 2016, a wholesaler or repackager may not sell, trade, or transfer a dangerous drug at wholesale without providing a pedigree.

(d) Except as otherwise provided in Section 4163.5, commencing on July 1, 2016, a wholesaler or repackager may not acquire a dangerous drug without receiving a pedigree.

(e) Except as otherwise provided in Section 4163.5, commencing on July 1, 2017, a pharmacy may not sell, trade, or transfer a dangerous drug at wholesale without providing a pedigree.

(f) Except as otherwise provided in Section 4163.5, commencing on July 1, 2017, a pharmacy may not acquire a dangerous drug without receiving a pedigree.

(g) Except as otherwise provided in Section 4163.5, commencing on July 1, 2017, a pharmacy warehouse may not acquire a dangerous drug without receiving a pedigree. For purposes of this section and Section 4034, a “pharmacy warehouse” means a physical location licensed as a wholesaler for prescription drugs that acts as a central warehouse and performs intracompany sales or transfers of those drugs to a group of pharmacies under common ownership and control.

SEC. 9. Section 4163.1 is added to the Business and Professions Code, to read:

4163.1. (a) For purposes of Sections 4034 and 4163, “drop shipment” means a sale of a dangerous drug by the manufacturer of the dangerous drug whereby all of the following occur:

(1) The pharmacy, or other person authorized by law to dispense or administer the drug, receives delivery of the dangerous drug directly from the manufacturer.

(2) The wholesale distributor takes ownership of, but not physical possession of, the dangerous drug.

(3) The wholesale distributor invoices the pharmacy or other person authorized by law to dispense or administer the drug in place of the manufacturer.

(b) The board may develop regulations to establish an alternative process to convey the pedigree information required in Section 4034 for dangerous drugs that are sold by drop shipment.

SEC. 10. Section 4163.2 is added to the Business and Professions Code, to read:

4163.2. (a) (1) A manufacturer, wholesaler, or pharmacy lawfully possessing or owning dangerous drugs manufactured or distributed prior to the operative date of the pedigree requirements, specified in Sections 4034 and 4163, may designate these dangerous drugs as not subject to the pedigree requirements by preparing a written declaration made under penalty of perjury that lists those dangerous drugs.

(2) The written declaration shall include the National Drug Code Directory lot number for each dangerous drug designated. The written declaration shall be submitted to and received by the board no later than 30 days after the operative date of the pedigree requirements. The entity or person submitting the written declaration shall also retain for a period of three years and make available for inspection by the board a copy of each written declaration submitted.

(3) The board may, by regulation, further specify the requirements and procedures for the creation and submission of these written declarations. Information contained in these declarations shall be considered trade secrets and kept confidential by the board.

(b) Any dangerous drugs designated on a written declaration timely created and submitted to the board may be purchased, sold, acquired, returned, or otherwise transferred without meeting the

pedigree requirements, if the transfer complies with the other requirements of this chapter.

SEC. 11. Section 4163.3 is added to the Business and Professions Code, to read:

4163.3. (a) It is the intent of the Legislature that participants in the distribution chain for dangerous drugs, including manufacturers, wholesalers, or pharmacies furnishing, administering, or dispensing dangerous drugs, distribute and receive electronic pedigrees, and verify and validate the delivery and receipt of dangerous drugs against those pedigrees at the unit level, in a manner that maintains the integrity of the pedigree system without an unacceptable increase in the risk of diversion or counterfeiting.

(b) To meet this goal, and to facilitate efficiency and safety in the distribution chain, the board shall, by regulation, define the circumstances under which participants in the distribution chain may infer the contents of a case, pallet, or other aggregate of individual units, packages, or containers of dangerous drugs, from a unique identifier associated with the case, pallet, or other aggregate, without opening each case, pallet, or other aggregate or otherwise individually validating each unit.

(c) Manufacturers, wholesalers, and pharmacies opting to employ the use of inference as authorized by the board to comply with the pedigree requirements shall document their processes and procedures in their standard operating procedures (SOPs) and shall make those SOPs available for board review.

(d) SOPs regarding inference shall include a process for statistically sampling the accuracy of information sent with inbound product.

(e) Liability associated with accuracy of product information and pedigree using inference shall be specified in the board's regulations.

SEC. 12. Section 4163.4 is added to the Business and Professions Code, to read:

4163.4. (a) All units of dangerous drug in the possession of a wholesaler or pharmacy, for which the manufacturer does not hold legal title on the effective date of the pedigree requirement set forth in Section 4163.5, shall not be subject to the pedigree requirements set forth in Sections 4034 and 4163. However, if any units of those drugs are subsequently returned to the manufacturer,

they shall be subject to the pedigree requirements if the manufacturer distributes those units in California.

(b) All units of dangerous drug manufactured in California but distributed outside the state for dispensing outside the state shall not be subject to the pedigree requirements set forth in Sections 4034 and 4163 at either the time of initial distribution or in the event that any of those units are subsequently returned to the manufacturer.

SEC. 13. Section 4163.5 of the Business and Professions Code is repealed.

SEC. 14. Section 4163.5 is added to the Business and Professions Code, to read:

4163.5. (a) The Legislature hereby finds and declares that:

(1) The electronic pedigree system required by Sections 4034 and 4163 will provide tremendous benefits to the public and to all participants in the distribution chain. Those benefits should be made available as quickly as possible through the full cooperation of prescription drug supply chain participants. To this end, all drug manufacturers and repackagers are strongly encouraged to serialize drug products and initiate electronic pedigrees as soon as possible, and all participants in the supply chain are encouraged to immediately ready themselves to receive and pass electronic pedigrees.

(2) At the same time, it is recognized that the process of implementing serialized electronic pedigree for all prescription drugs in the entire chain of distribution is a complicated technological and logistical undertaking for manufacturers, wholesalers, repackagers, pharmacies, and other supply chain participants. The Legislature seeks to ensure continued availability of prescription drugs in California while participants implement these requirements.

(b) Before January 1, 2015, each manufacturer of a dangerous drug distributed in California shall designate those dangerous drugs representing a minimum of 50 percent of its drugs, generic or single source, distributed in California, for which it is listed as the manufacturer by the federal Food and Drug Administration, which shall be the subject of its initial phase of compliance with the January 1, 2015, deadline of the state's serialized electronic pedigree requirements set forth in Sections 4034 and 4163. Each manufacturer shall notify the Board of Pharmacy of the drugs so

designated and the measure or measures used in designating its drugs to be serialized, and shall include in the notification the technology to be used to meet the serialized electronic pedigree requirements. The notification process for these specific actions may be specified by the board.

(c) Before January 1, 2016, each manufacturer of a dangerous drug distributed in California shall designate the final 50 percent of its drugs, generic or single source, distributed in California for which it is listed as the manufacturer by the federal Food and Drug Administration that are subject to the state's serialized electronic pedigree requirements set forth in Sections 4034 and 4163, which shall comply with the state's serialized electronic pedigree requirement by January 1, 2016. Each manufacturer shall notify the Board of Pharmacy of the drugs so designated and the measure or measures used in designating its drugs to be serialized, and shall include in the notification the technology to be used to meet the serialized electronic pedigree requirements. The notification process for these specific actions may be specified by the board.

(d) For purposes of designating drugs to be serialized as required by subdivisions (b) and (c), manufacturers shall select from any of the following measures:

- (1) Unit volume.
- (2) Product package (SKU) type.
- (3) Drug product family.

(e) Drugs not subject to compliance with the pedigree requirements set forth in Sections 4034 and 4163 under this section shall not be subject to the provisions of subdivisions (c), (d), (e), and (f) of Section 4163.

SEC. 15. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

Approved _____, 2008

Governor