Attachment 5

SB 1307 (Ridley Thomas)

AMENDED IN ASSEMBLY JUNE 17, 2008

AMENDED IN SENATE MAY 23, 2008

AMENDED IN SENATE APRIL 29, 2008

AMENDED IN SENATE MARCH 25, 2008

SENATE BILL No. 1307

Introduced by Senator Ridley-Thomas

February 20, 2008

An act to amend Sections 4034 and 4163 of, to add Sections 4034.1, 4163.2, ~~and 4163.3~~ *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, as amended, 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, 2011, define a pedigree, *as specified,* and would require a pedigree to include a specified unique identification number. The bill would also require the board to immediately require the use of federally required standardized numerical identifiers and standardized data elements of a pedigree record if federal standards in that regard are developed under federal law.

The bill would instead prohibit a wholesaler, on and after January 1, ~~2012~~ *2015*, or a pharmacy, on and after July 1, ~~2012~~ *2015*, 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 require wholesalers and pharmacies, between January 1, 2011, and December 31, 2014, to initiate steps to accept and pass electronic pedigrees for all dangerous drugs subject to the pedigree requirements to enable full readiness to meet the above requirement.* The bill would delete the board's authority to extend these compliance dates. 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 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 these 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~~, for up to 18 months following the operative date of the pedigree requirements,~~ authorize specified dangerous drugs to be purchased, sold, acquired, returned, or otherwise transferred, without meeting the pedigree requirements if the transfer complies with specified requirements~~, including a written declaration under penalty of perjury stating that the specified dangerous drug met certain 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 ~~where the board deems it appropriate for manufacturers, wholesalers, or pharmacies, to~~ *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 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.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

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

1 SECTION 1. Section 4034 of the Business and Professions
2 Code is amended to read:
3 4034. (a) "Pedigree" means a record, in electronic form,
4 containing information regarding each transaction resulting in a
5 change of ownership of a given dangerous drug, from sale by a
6 manufacturer, through acquisition and sale by one or more
7 wholesalers, manufacturers, *repackagers,* or pharmacies, until
8 final sale to a pharmacy or other person furnishing, administering,
9 or dispensing the dangerous drug. The pedigree shall be created
10 and maintained in an interoperable electronic system, ensuring
11 compatibility throughout all stages of distribution.
12 (b) A pedigree shall include all of the following information:
13 (1) The source of the dangerous drug, including the name, the
14 federal manufacturer's registration number or a state license
15 number as determined by the board, and principal address of the
16 source.

(2) The trade or generic name of the drug, the quantity of the dangerous drug, its dosage form and strength, the date of the transaction, 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.

(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, 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 be 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) 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.

(2) (A) An injectable dangerous drug that is delivered by the manufacturer directly to an authorized prescriber or other entity directly responsible for administration of the injectable dangerous drug, only for an injectable dangerous drug that by law may only be administered under the professional supervision of the prescriber or other entity directly responsible for administration of the drug. Injectable dangerous drugs exempted from the pedigree requirement by this paragraph may not be dispensed to a patient or a patient's agent for self-administration, and shall only be administered to the patient, as defined in Section 4016, by the prescriber or other authorized entity that received the drug directly from the manufacturer.

(B) The exemption in this paragraph shall expire and be inoperative on January 1, 2012, unless prior to that date the board receives, at a public hearing, evidence that entities involved in the distribution of the injectable dangerous drugs subject to that paragraph are not able to provide a pedigree in compliance with all of the provisions of California law, and the board votes to extend the expiration date for the exemption until January 1, 2013. The decision as to whether to extend the expiration date shall be within the sole discretion of the board, and shall not be subject to the requirements of Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of the Government Code.

(3) (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.

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

(5) 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.

(6) 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.

(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, contained within a standardized nonproprietary data format and architecture, that is uniformly used by manufacturers, wholesalers, and pharmacies for the pedigree of a dangerous drug.

(j) The application of the pedigree requirement in pharmacies shall be subject to review during the board's sunset review to be conducted as described in subdivision (f) of Section 4001.

(k) This section shall become operative on January 1, 2011. However, the board may extend the date for compliance with this section and Section 4163 in accordance with Section 4163.5.

SEC. 2. Section 4034.1 is added to the Business and Professions Code, to read:

4034.1. Notwithstanding anything to the contrary in Section 4034 or 4163, if federal standards are developed pursuant to Section 505D of the federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 355e) regarding the identification, validation, authentication, tracking, and tracing of prescription drugs, and with respect to a standardized numerical identifier to be applied to a prescription drug at the point of manufacturing and repacking at the package or pallet level, the board shall immediately issue emergency regulations or take other action within 30 days to require use of the federally identified standardized numerical identifier as the unique identification number otherwise required by subdivision (i) of Section 4034. In addition, if the federal standards developed pursuant to the above-referenced section of the federal act include a specification of standardized data elements of a pedigree record, those data elements shall be automatically substituted by the board for those otherwise required by subdivision (b) of Section 4034. Notwithstanding subdivision (k) of Section 4034, the requirements of this section with respect to the use of standardized numerical identifiers and specification of standarized data elements shall be in effect immediately upon the board's action to implement this section.

SEC. 3. Section 4163 of the Business and Professions Code is amended to read:

4163. (a) A manufacturer or wholesaler 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) From January 1, 2011, to December 31, 2014, inclusive, wholesalers and pharmacies shall initiate steps to accept and pass electronic pedigrees for all dangerous drugs subject to the

requirements of Section 4034, in order to enable full readiness to comply with subdivisions (d) to (g), inclusive.

~~(c)~~

(d) Except as otherwise provided in Section 4163.5, commencing on January 1, ~~2012~~ *2015*, a wholesaler may not sell, trade, or transfer a dangerous drug at wholesale without providing a pedigree.

~~(d)~~

(e) Except as otherwise provided in Section 4163.5, commencing on January 1, ~~2012~~ *2015*, a wholesaler may not acquire a dangerous drug without receiving a pedigree.

~~(e)~~

(f) Except as otherwise provided in Section 4163.5, commencing on July 1, ~~2012~~ *2015*, a pharmacy may not sell, trade, or transfer a dangerous drug at wholesale without providing a pedigree.

~~(f)~~

(g) Except as otherwise provided in Section 4163.5, commencing on July 1, ~~2012~~ *2015*, a pharmacy may not acquire a dangerous drug without receiving a pedigree.

SEC. 4. 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 ~~number and batch number and the dates of manufacture~~ *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) (1) For up to 18 months following the operative date of the pedigree requirements, any~~

(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.

~~(2) Any transfer of a dangerous drug without meeting the pedigree requirements shall be accompanied by a written declaration made under penalty of perjury by a responsible party of the transferring entity or person stating that the dangerous drug, identified by its National Drug Code Directory number and batch number and date of manufacture, met the requirements of subdivision (a) and the written declaration prepared pursuant to subdivision (a) shall be attached to this written declaration.~~

~~(3) Both the transferring and receiving parties shall retain for a period of three years and make available for inspection by the board a copy of each written declaration.~~

~~(4) The board may, by regulation, further specify the requirements and procedures for these transfers and the necessary documentation.~~

~~(5) The board may, by regulation, further extend beyond 18 months the period for transfers of nonpedigreed drugs, either for all drugs or for specified categories or subcategories of drugs.~~

SEC. 5. 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 ~~the board deems it appropriate for~~

participants in the distribution chain ~~to~~ *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. 6. 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. 6.~~

SEC. 7. Section 4163.5 of the Business and Professions Code is repealed.

~~SEC. 7.~~

SEC. 8. 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, pharmacies, and other supply chain participants. The Legislature seeks to ensure continued availability of prescription drugs in California while drug manufacturers implement these requirements.

(b) ~~On or before January 1, 2010~~ *Before January 1, 2011*, each manufacturer of a dangerous drug to be distributed in California shall designate drugs representing a minimum of 20 percent of the drugs, generic or single source, 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, 2011, deadline of* the state's serialized pedigree requirement set forth in Sections 4034 and 4163. The manufacturer shall notify the Board of Pharmacy of the drugs so designated and shall include in the notification the technology to be used to meet the serialized electronic pedigree requirement.

(c) ~~On or before January 1, 2011~~ *Before January 1, 2013*, each manufacturer shall designate a minimum of an additional 30 percent of the drugs for which it is listed as the manufacturer by the federal Food and Drug Administration that are subject to the pedigree requirements set forth in Sections 4034 and 4163, which shall comply with the state's serialized electronic pedigree requirement by January 1, ~~2012~~ *2013*. The manufacturer shall notify the Board of Pharmacy of the drugs so designated and shall include in the notification the technology to be used to meet the serialized electronic pedigree requirement.

(d) ~~On or before January 1, 2012~~ *Before January 1, 2015*, each manufacturer shall designate a minimum of an additional 50 percent of the drugs for which it is listed as the manufacturer by the federal Food and Drug Administration that are subject to the pedigree requirements set forth in Sections 4034 and 4163, which shall comply with the state's serialized electronic pedigree requirement by January 1, ~~2013~~ *2015*. The manufacturer shall notify the Board of Pharmacy of the drugs so designated and shall include in the notification the technology to be used to meet the serialized electronic pedigree requirement.

~~(e) All new dangerous drugs that are approved for sale on or after January 1, 2011, shall be subject to the serialized electronic pedigree requirements set forth in Sections 4034 and 4163 when introduced on the market, and shall not be included in a manufacturer's yearly implementation quota.~~

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

(1) Unit volume.

(2) Product package (SKU) type.

(3) Drug product family.

(f) 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. 8.~~

SEC. 9. 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.

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