

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.

1 (2) The trade or generic name of the drug, the quantity of the
2 dangerous drug, its dosage form and strength, the date of the
3 transaction, the sales invoice number, the container size, the
4 number of containers, the expiration dates, and the lot numbers.

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

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

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

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

21 (d) A pedigree shall track each dangerous drug at the smallest
22 package or immediate container distributed by the manufacturer,
23 received and distributed by the wholesaler, and received by the
24 pharmacy or another person furnishing, administering, or
25 dispensing the dangerous drug. For purposes of this section, the
26 "smallest package or immediate container" of a dangerous drug
27 shall be the smallest unit made by the manufacturer for sale to the
28 pharmacy or other person furnishing, administering, or dispensing
29 the drug.

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

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

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

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

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

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

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

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

1 date of any such determination, this paragraph shall become
2 inoperative.

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

5 (5) The sale, trade, or transfer of compressed medical gas. For
6 purposes of this section, “compressed medical gas” means any
7 substance *in its gaseous or cryogenic liquid form* that meets
8 medical purity standards and has application in a medical *or*
9 *homecare* environment, including, but not limited to, oxygen and
10 nitrous oxide.

11 (6) The sale, trade, or transfer of solutions. For purposes of this
12 section, “solutions” means any of the following:

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

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

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

22 (h) If a manufacturer, wholesaler, or pharmacy has reasonable
23 cause to believe that a dangerous drug in, or having been in, its
24 possession is counterfeit or the subject of a fraudulent transaction,
25 the manufacturer, wholesaler, or pharmacy shall notify the board
26 within 72 hours of obtaining that knowledge. This subdivision
27 shall apply to any dangerous drug that has been sold or distributed
28 in or through this state.

29 (i) “Interoperable electronic system” as used in this chapter
30 means an electronic track and trace system for dangerous drugs
31 that uses a unique identification number, established at the point
32 of manufacture, contained within a standardized nonproprietary
33 data format and architecture, that is uniformly used by
34 manufacturers, wholesalers, and pharmacies for the pedigree of a
35 dangerous drug.

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

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

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

6 4034.1. Notwithstanding anything to the contrary in Section
7 4034 or 4163, if federal standards are developed pursuant to
8 Section 505D of the federal Food, Drug, and Cosmetic Act (21
9 U.S.C. Sec. 355e) regarding the identification, validation,
10 authentication, tracking, and tracing of prescription drugs, and
11 with respect to a standardized numerical identifier to be applied
12 to a prescription drug at the point of manufacturing and repacking
13 at the package or pallet level, the board shall immediately issue
14 emergency regulations or take other action within 30 days to
15 require use of the federally identified standardized numerical
16 identifier as the unique identification number otherwise required
17 by subdivision (i) of Section 4034. In addition, if the federal
18 standards developed pursuant to the above-referenced section of
19 the federal act include a specification of standardized data elements
20 of a pedigree record, those data elements shall be automatically
21 substituted by the board for those otherwise required by subdivision
22 (b) of Section 4034. Notwithstanding subdivision (k) of Section
23 4034, the requirements of this section with respect to the use of
24 standardized numerical identifiers and specification of standardized
25 data elements shall be in effect immediately upon the board's
26 action to implement this section.

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

29 4163. (a) A manufacturer or wholesaler may not furnish a
30 dangerous drug or dangerous device to an unauthorized person.

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

38 (c) *From January 1, 2011, to December 31, 2014, inclusive,*
39 *wholesalers and pharmacies shall initiate steps to accept and pass*
40 *electronic pedigrees for all dangerous drugs subject to the*

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

3 (e)

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

8 (d)

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

12 (e)

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

16 (f)

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

20 SEC. 4. Section 4163.2 is added to the Business and Professions
21 Code, to read:

22 4163.2. (a) (1) A manufacturer, wholesaler, or pharmacy
23 lawfully possessing or owning dangerous drugs manufactured or
24 distributed prior to the operative date of the pedigree requirements,
25 specified in Sections 4034 and 4163, may designate these
26 dangerous drugs as not subject to the pedigree requirements by
27 preparing a written declaration made under penalty of perjury that
28 lists those dangerous drugs.

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

37 (3) The board may, by regulation, further specify the
38 requirements and procedures for the creation and submission of
39 these written declarations. *Information contained in these*

1 *declarations shall be considered trade secrets and kept confidential*
2 *by the board.*

3 ~~(b) (1) For up to 18 months following the operative date of the~~
4 ~~pedigree requirements, any~~

5 *(b) Any dangerous drugs designated on a written declaration*
6 *timely created and submitted to the board may be purchased, sold,*
7 *acquired, returned, or otherwise transferred without meeting the*
8 *pedigree requirements, if the transfer complies with the other*
9 *requirements of this chapter.*

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

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

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

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

27 SEC. 5. Section 4163.3 is added to the Business and Professions
28 Code, to read:

29 4163.3. (a) It is the intent of the Legislature that participants
30 in the distribution chain for dangerous drugs, including
31 manufacturers, wholesalers, or pharmacies furnishing,
32 administering, or dispensing dangerous drugs, distribute and
33 receive electronic pedigrees, and verify and validate the delivery
34 and receipt of dangerous drugs against those pedigrees at the unit
35 level, in a manner that maintains the integrity of the pedigree
36 system without an unacceptable increase in the risk of diversion
37 or counterfeiting.

38 (b) To meet this goal, *and to facilitate efficiency and safety in*
39 *the distribution chain*, the board shall, by regulation, define the
40 circumstances under which ~~the board deems it appropriate for~~

1 participants in the distribution chain to *may* infer the contents of
2 a case, pallet, or other aggregate of individual units, packages, or
3 containers of dangerous drugs, from a unique identifier associated
4 with the case, pallet, or other aggregate, without opening each
5 case, pallet, or other aggregate or otherwise individually validating
6 each unit.

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

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

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

18 *SEC. 6. Section 4163.4 is added to the Business and Professions*
19 *Code, to read:*

20 *4163.4. (a) All units of dangerous drug in the possession of a*
21 *wholesaler or pharmacy, for which the manufacturer does not hold*
22 *legal title on the effective date of the pedigree requirement set*
23 *forth in Section 4163.5, shall not be subject to the pedigree*
24 *requirements set forth in Sections 4034 and 4163. However, if any*
25 *units of those drugs are subsequently returned to the manufacturer,*
26 *they shall be subject to the pedigree requirements if the*
27 *manufacturer distributes those units in California.*

28 *(b) All units of dangerous drug manufactured in California but*
29 *distributed outside the state for dispensing outside the state shall*
30 *not be subject to the pedigree requirements set forth in Sections*
31 *4034 and 4163 at either the time of initial distribution or in the*
32 *event that any of those units are subsequently returned to the*
33 *manufacturer.*

34 ~~SEC. 6.~~

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

37 ~~SEC. 7.~~

38 *SEC. 8. Section 4163.5 is added to the Business and Professions*
39 *Code, to read:*

40 *4163.5. (a) The Legislature hereby finds and declares that:*

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

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

19 ~~(b) On or before January 1, 2010~~ *Before January 1, 2011*, each
20 manufacturer of a dangerous drug to be distributed in California
21 shall designate drugs representing a minimum of 20 percent of the
22 drugs, generic or single source, for which it is listed as the
23 manufacturer by the federal Food and Drug Administration, which
24 shall be the subject of its initial phase of compliance with *the*
25 *January 1, 2011, deadline of* the state's serialized pedigree
26 requirement set forth in Sections 4034 and 4163. The manufacturer
27 shall notify the Board of Pharmacy of the drugs so designated and
28 shall include in the notification the technology to be used to meet
29 the serialized electronic pedigree requirement.

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

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

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

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

19 ~~(1) Unit volume.~~

20 ~~(2) Product package (SKU) type.~~

21 ~~(3) Drug product family.~~

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

26 ~~SEC. 8.~~

27 ~~SEC. 9. No reimbursement is required by this act pursuant to~~
28 ~~Section 6 of Article XIII B of the California Constitution because~~
29 ~~the only costs that may be incurred by a local agency or school~~
30 ~~district will be incurred because this act creates a new crime or~~
31 ~~infraction, eliminates a crime or infraction, or changes the penalty~~
32 ~~for a crime or infraction, within the meaning of Section 17556 of~~
33 ~~the Government Code, or changes the definition of a crime within~~
34 ~~the meaning of Section 6 of Article XIII B of the California~~
35 ~~Constitution.~~