

Board of Pharmacy

Initial Statement of Reasons

Subject Matter of Proposed Regulation: Electronic Pedigree Requirements for Drop Shipments

Sections Affected: Add Section 1747.2 to Article 5.5 of
Title 16 of the California Code of Regulations

Background and Specific Purpose of the Proposed Changes:

In 2004, in an attempt to prevent counterfeit prescription medicine from entering the legitimate supply chain in California, the State passed anti-counterfeiting and anti-diversion legislation (SB 1307), including provisions pertaining to the licensure and qualifications of wholesalers, restrictions on furnishing, and the requirement of an electronic “pedigree” (data record) to accompany or validate drug distributions. The electronic “pedigree” that is passed with the prescription drug (“dangerous drug”) is required to show each change of ownership of a given dangerous drug from its initial manufacture through its final transaction to a pharmacy or other authorized purchaser. California’s pedigree requirements for dangerous drugs will take effect on a staggered basis from January 1, 2015, through July 1, 2017.

Business and Professions Code section 4163.1 also authorizes the Board of Pharmacy (“Board”) to develop regulations to establish an “alternative process” for conveying the pedigree information for dangerous drugs sold by drop shipment. The Board proposes to add Section 1747.2 to Article 5.5 of Division 17 of Title 16 of the California Code of Regulations (“CCR”) entitled “Drop Shipments”, which would set forth this alternative process.

The sale of a dangerous drug by “drop shipment” occurs when that drug is purchased and delivered directly to the pharmacy or other person authorized by law to dispense or administer the drug (“authorized purchaser”) by the drug’s manufacturer. A wholesaler permit is required before any firm or organization may distribute, broker or transact the sale or return of dangerous drugs in California. However, in the case of a drop shipment sale, the wholesale distributor never takes actual physical possession of the dangerous drug, since the drug is shipped directly to the authorized purchaser. Nevertheless, the wholesaler does legally “own” the drug as the authorized distributor and invoices the purchaser in place of the manufacturer as part of the sale.

The board’s proposal would specify that when a manufacturer utilizes the “drop shipment” method of sale, as defined, for a dangerous drug, the manufacturer may omit data elements from the pedigree showing transfers of ownership to and from the wholesale distributor, including any certifications of receipt and delivery of the drug by the wholesaler. That pedigree would then be required to be conveyed directly from the manufacturer to the authorized purchaser prior to or contemporaneously with the delivery of the dangerous drug.

Factual Basis/Rationale/Problem Addressed

Business and Professions Code section 4005 generally authorizes the board to amend rules and regulations necessary for the protection of the public pertaining to the practice of pharmacy and the administration of Chapter 9 of Division 2 of the Business and Professions Code. Business and Professions Code section 4163.1 specifically authorizes the Board to develop regulations to establish an “alternative process” to convey the pedigree information required in Section 4034 of the Business and Professions Code for dangerous drugs that are sold by drop shipment.

In 2004, the California State Board of Pharmacy (the board) sponsored legislation, Senate Bill (SB) 1307 (Stats.2004, ch. 857), that made comprehensive changes to the drug distribution system to protect against counterfeit drugs. Among other requirements that were enacted, the Pharmacy Law required development of an electronic “pedigree” that tracks each prescription drug (“dangerous drug”) at the smallest package or immediate container (saleable item) distributed by the manufacturer through the distribution system by way of an interoperable electronic system (track and trace). In 2008, SB 1307 was enacted, and implemented a staggered timeline for compliance with California’s electronic pedigree requirements for manufacturers, wholesalers, repackagers, pharmacies and pharmacy warehouses. (California Business and Professions Code sections 4163 and 4163.5.)

Business and Professions Code section 4034 defines a “pedigree” as 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. A single pedigree must 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. Further, Section 4034 also requires 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.

Business and Professions Code section 4163.1 defines “drop shipment” to mean 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; and (3) The wholesale distributor invoices the pharmacy or other person authorized by law to dispense or administer the drug in place of the manufacturer.

Over the course of several Board and Committee meetings, participants discussed the need for regulations to clarify how “drop shipments” would comply with the pedigree laws. Drop shipments are relevant to the pedigree laws for reasons including that: (a) current law requires the pedigree to pass with every transfer of ownership or possession of the drugs, and (b) drop shipment wholesalers do not take possession of the drugs they buy and sell on paper on behalf of their manufacturer and end purchaser clients. The main problems discussed over the course of many meetings were the timing of the provision of the pedigree and the certifications

required to be provided under the pedigree laws because the wholesaler often does not become aware of the transaction until after a shipment is received – where the paperwork is generated after the fact. This would make it problematic for the wholesaler to provide the pedigree or “pass” it at the time of transfer to the purchaser as currently required and to certify to the truth and accuracy of the receipt and delivery of the drug(s) when the wholesale distributor never actually physically received or delivered the dangerous drug(s).

Consequently, without an alternative pedigree process for passing the pedigree to the authorized purchaser, it was determined that compliance with the pedigree laws would be legally problematic and add unnecessary complexity to the pedigree compliance process for these types of sales that could add unnecessary delays to the drug distribution system, which could impact patient care. The Board was advised that drop shipments frequently are needed for specialty dangerous drugs requiring special handling, unique administration to the patient, and/or low stock in the supply chain. Further, drop shipment is used in emergency and critical patient need cases as the distribution time is dramatically decreased.

With input from stakeholders, the Board developed the current proposal, which would allow for the provision of the pedigree without data elements showing transfers of ownership to and from the wholesale distributor, including any certifications of receipt and delivery of the drug by the wholesaler. The goal of public protection would not be compromised in providing this alternative process since the delivery and receipt of dangerous drugs between the parties who actually possessed the drug would still be tracked and recorded on the pedigree, which would then be passed along with the drug to the authorized purchaser.

Accordingly, adoption of Section 1747.2 in Title 16 of the California Code of Regulations is necessary to resolve compliance questions regarding how to process a pedigree in a drop shipment method of sale and to enable the Board to provide advance direction to manufacturers, wholesalers, pharmacies and repackagers to begin the process of meeting Section 4163’s mandates.

As specified in Business and Professions Code Section 4001.1, protection of the public shall be the highest priority for the California State Board of Pharmacy in exercising its licensing, regulatory, and disciplinary functions. This section further states that whenever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount. This proposal supports that mandate by continuing the process of pedigree requirements that will ultimately help ensure the safety of California’s prescription drug supply for the consumers of California.

Underlying Data

1. Senate Bill 1307, Chapter 713, Filed with the Secretary of State on September 30, 2008
2. Board of Pharmacy “Questions and Answers Relating to the California Electronic Prescription Drug Pedigree Law(s),” January 2008
3. Letter dated August 25, 2008, by Mark Ridley-Thomas, Senator, 26th District, Chair of the Senate Committee on Business, Professions & Economic Development to Mr. Gregory Schmidt, Secretary of the Senate

4. **The Script** (Board of Pharmacy Newsletter), February 2009, “Changes in Pharmacy Law” and “Compliance Dates Extended for e-Pedigree Requirements” (pp. 1-6)
5. Board of Pharmacy Comments re: Securing Pharmaceutical Distribution Integrity, H.R. 3026 – Safeguarding America’s Pharmaceuticals Act of 2011, Securing Pharmaceutical Distribution Integrity Act of 2012 (Senate), Letter Dated May 9, 2012, Signed by Stan Weisser, RPh, President of the Board of Pharmacy
6. Board of Pharmacy Comments re: Enhancing Pharmaceutical Distribution Integrity Act of 2012, Letter Dated June 17, 2012, Signed by Stan Weisser, RPh, President of the Board of Pharmacy, and by Virginia Herold, Executive Officer of the Board of Pharmacy
7. Board of Pharmacy Comments re: Federal Efforts to Secure Drug Distribution Security, Draft Proposal to Improve Drug Distribution Security, Letter Dated November 7, 2012, Signed by Stanley Weisser, RPh, President of the Board of Pharmacy
8. Relevant Meeting Materials and Minutes from the Board of Pharmacy, Enforcement Committee and E-Pedigree Public Meeting held December 4, 2012
9. Notice to All Interested Parties from the Board of Pharmacy Regarding an Opportunity to Submit Information Necessary to Possible Board Rulemaking on Drop Shipment and Certification of Individual Package Units for Drug Pedigree Law dated March 5, 2013.
10. Response to Board’s Notice Regarding Drop Shipment Received from John R. Valencia of Wilke, Fleury, Hoffelt, Gould & Birney, LLP dated March 14, 2013.
11. Relevant Meeting Materials and Minutes from the Board of Pharmacy, Enforcement Committee and E-Pedigree Public Meeting held March 14, 2013
12. Relevant Meeting Materials and Minutes from the Board of Pharmacy Board Meeting held April 24-25, 2013
13. Board Comments re: Federal Efforts to Secure Drug Distribution Security, Draft Proposal to Improve Drug Distribution Security, Letter Dated April 26, 2013, Signed by Stanley Weisser, RPh, President of the Board of Pharmacy
14. Board Comments re: Federal Efforts to Secure Drug Distribution Security, H.R. 1919, “Safeguarding America’s Pharmaceuticals Act of 2013,” Letter Dated May 28, 2013, Signed by Signed by Stanley Weisser, RPh, President of the Board of Pharmacy
15. Relevant Meeting Materials and Minutes from the Board of Pharmacy, E-Pedigree Public Meeting held June 24, 2013
16. Relevant Meeting Materials and Minutes from the Board of Pharmacy Board Meeting held July 30-31, 2013
17. Article “What you need to know now about California e-Pedigree,” **Healthcare Packaging**, July 20, 2012 (viewed August 24, 2013)
http://www.healthcarepackaging.com/archives/2012/07/what_you_need_to_know_now_abou.php
18. “California Staggering Its E-Pedigree Regulations,” **PMPNews.com**, Published August 7, 2012, on *Pharmaceutical & Medical Packaging News* (<http://www.pmpnews.com>)
19. Economic Impact Analysis

Business Impact

The board has made an initial determination that the proposed regulatory action would have no significant statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states. The following types of businesses licensed by the board would be affected by this regulation: drug manufacturers, wholesalers, repackagers, pharmacies, and pharmacy warehouses. Additionally, entities owned by other persons authorized by law to dispense or administer dangerous drugs would be affected by this regulation. However, this regulation specifically applies to the pedigree requirements when drop shipment is utilized by a manufacturer where the wholesale distributor takes ownership of the dangerous drug but never takes possession as the manufacturer ships directly to the pharmacy or the person authorized by law to dispense or administer the dangerous drug. Based on this application of the pedigree requirement, the board has determined the regulatory action would have no significant statewide adverse economic impact directly affecting businesses nor prohibit the ability of California businesses to compete with businesses in other states.

Drop shipment is utilized within the pharmaceutical drug supply industry by manufacturers that contract with wholesalers for administrative functions (e.g., invoicing) related to the distribution of dangerous drugs to pharmacies and other persons authorized to dispense or administer dangerous drugs. When drop shipment is utilized by a manufacturer, the ownership of the dangerous drugs is transferred to the wholesale distributor but the manufacturer retains physical possession and ships the dangerous drugs directly to the pharmacy or other authorized person authorized to dispense or administer dangerous drugs. The wholesaler is typically responsible for invoicing and accounting duties. Drop shipment has proven to assist the pharmaceutical drug supply industry's ability to efficiently ship and manage dangerous drugs from manufacturer to pharmacy/authorized person to dispense dangerous drugs. Drop shipment is used in the industry for medications that are needed for specialty dangerous drugs requiring special handling, unique administration to the patient, and/or low stock in the supply chain. Additionally, drop shipment is used in emergency and critical patient need cases as the distribution time is dramatically decreased.

After conducting numerous meetings discussing pedigree implementation and specifically drop shipment method of sale, the board has been encouraged by industry to further specify drop shipment requirements as well as relieve the wholesaler involved in drop shipment from adding their respective ownership information to the electronic pedigree. This would reduce potential confusion and compliance problems with the pedigree law, thereby eliminating potential costs to businesses in implementing the new pedigree requirements and avoiding possible unnecessary delays in drug delivery to patients.

The board's proposal will allow wholesalers involved in drop shipment to omit their ownership information from the electronic pedigree. This ensures entities that never physically possess the dangerous drugs are not subject to reporting requirements of the pedigree; thereby, the electronic pedigree stands to be a true documentation of the possessors of the dangerous drugs.

Manufacturers and wholesalers do not report financial data related to the cost of shipping the dangerous drugs to the pharmacy or authorized purchaser. Once pedigree is implemented, the manufacturers and wholesalers will still not report financial data related to the cost of shipping the dangerous drugs. The board is unable to demonstrate cost savings to manufacturers or wholesalers. However, the patients ultimately benefit from drop shipment utilization as it allows for a more efficient distribution process for dangerous drugs required for specialty purposes (e.g., chemotherapy, etc.) or when there is a low inventory in the drug chain supply for the specific dangerous drug.

Benefits

Business and Professions Code section 4005 states that “the board may adopt rules and regulations....pertaining to the practice of pharmacy....” As specified in Business and Professions Code Section 4001.1, protection of the public shall be the highest priority for the California State Board of Pharmacy in exercising its licensing, regulatory, and disciplinary functions. This section further states that whenever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount. The initial phase of compliance with California’s electronic pedigree requirements must be completed by January 1, 2015, and the board’s proposal provides requirements so that manufacturers can meet the statutory requirement. Compliance helps ensure that tracking of drug products occurs consistent with the pedigree laws, resulting in the public being better protected from counterfeited and adulterated dangerous drugs entering California’s prescription drug supply chain.

Additionally, manufacturers will be able to retain and realize important efficiencies in the distribution of dangerous drugs to pharmacies and other authorized persons authorized to dispense dangerous drugs as well as expedite these deliveries for patient administration.

Specific Technologies or Equipment

This regulation does not mandate the use of specific technologies or equipment.

Consideration of Alternatives

The Board of Pharmacy has made an initial determination that no reasonable alternative to the regulatory proposal would be either more effective in carrying out the purpose for which the action is proposed or would be as effective or less burdensome to affected private persons and equally effective in achieving the purposes of the regulation in a manner that ensures full compliance with the law being implemented or made specific.

Set forth below are the alternatives which were considered and the reasons each alternative was rejected:

The Board considered three different options over the course of many meetings to resolve compliance concerns raised over drop shipments and existing interpretations of pedigree laws. The board unanimously voted on regulatory language as described in Option 3. Options 1 and 2

were considered by the Board and rejected for the reasons set forth below:

Option 1 - Rejected:

The first option would have provided for no regulatory action. If no regulatory action is taken, a wholesaler involved in drop shipment (as defined by Business and Professions Code section 4163.1) would be required to provide data elements pertaining to transfers of ownership to and from the wholesaler. This information would be required when the wholesaler did not have physical possession of the dangerous drugs shipped from manufacturer to pharmacy or a person authorized to dispense or administer the dangerous drugs.

The Board considered this option to be too burdensome. Wholesalers expressed concern about being responsible to provide certifications of receipt and delivery of dangerous drugs that were owned by the wholesalers but were not in their physical possession. Along with this option is the added time and logistics required for the wholesaler to provide such certifications. Ultimately, this option would negatively impact the industry and the patients receiving the medications. Therefore, this option was rejected.

Option 2 - Rejected:

The second option would have provided wholesalers additional time and/or tolerances for the wholesalers involved in drop shipment (as defined by Business and Professions Code section 4163.1) to later provide the data elements pertaining to transfers of ownership to and from the wholesaler in the pedigree. The pedigree is defined in Business and Professions Code section 4034 and specifies according to a staggered timeline under Section 4163 that dangerous drugs are to be provided with a pedigree if a dangerous drug is sold, traded, transferred or acquired. The board considered this option. However, such regulatory action would be contrary to statute; therefore, this option was rejected.

Option 3 - Accepted:

The third option provides for an alternative process to convey the pedigree requirements in the unique situation of a drop shipment where a manufacturer utilizes a wholesaler for administrative and invoicing purposes. In drop shipment, the wholesaler retains ownership but not physical possession of the dangerous drugs. This option allows for the data elements related to the wholesaler's ownership to be omitted from the pedigree, and the pedigree is conveyed directly to the authorized purchaser.

With this option, the pedigree accurately reflects who physically possessed the dangerous drugs as intended by the Legislature when the pedigree statutes were enacted. This option does not reduce public protection nor does it burden the industry; rather, industry is in support of this option as demonstrated at multiple board and committee meetings held to discuss this matter. This option was unanimously accepted by the board.