

TITLE 16. BOARD OF PHARMACY

NOTICE IS HEREBY GIVEN that the Board of Pharmacy is proposing to take the action described in the Informative Digest. Any person interested may present statements or arguments relevant to the action proposed in writing. Written comments, including those sent by mail, facsimile, or e-mail to the addresses listed under Contact Person in this Notice, must be received by the Board of Pharmacy at its office not later than 5:00 p.m. on October 28, 2013.

Any person interested may present statements or arguments orally or in writing relevant to the action proposed at a hearing to be held at the Sheraton Garden Grove, 12221 Harbor Blvd., Garden Grove, CA 92840, on October 29, 2013, at 4:00 p.m.

The Board of Pharmacy, upon its own motion or at the instance of any interested party, may thereafter adopt the proposals substantially as described below or may modify such proposals if such modifications are sufficiently related to the original text. With the exception of technical or grammatical changes, the full text of any modified proposal will be available for 15 days prior to its adoption from the person designated in this Notice as contact person and will be mailed to those persons who submit written or oral testimony related to this proposal or who have requested notification of any changes to the proposal.

Authority and Reference. Pursuant to the authority vested by Sections 4005, 4034 and 4163.1 of the Business and Professions Code, and to implement, interpret or make specific Sections 4005, 4034, 4037, 4163, 4163.1, 4170, 4180, and 4190 of the Business and Professions Code, the Board of Pharmacy is proposing to add Section 1747.2 to Article 5.5 of Division 17 of Title 16 of the California Code of Regulations.

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

In 2004, the California State Board of Pharmacy (the board) sponsored legislation, Senate Bill (SB) 1307, 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. California’s pedigree requirements for dangerous drugs will take effect on a staggered basis from January 1, 2015, through July 1, 2017. (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.

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.

Business and Professions Code section 4163.1 also authorizes the 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 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.

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 setting forth compliance standards for implementation of the pedigree laws in a way that addresses both drug delivery concerns and patient safety issues.

CONSISTENCY AND COMPATIBILITY WITH EXISTING REGULATIONS

The board conducted a search of Title 21 Code of Federal Regulations (Food and Drugs), as well as the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) and found no existing federal regulations or statutes that are comparable to the board’s proposal. Further, the board conducted a search of the California Code of Regulations and found a definition of “drop shipment” in Section 1706 of Division 2 of Title 18 of the California Code of Regulations. The term “drop shipment” is defined for the purposes of establishing sales and use tax liability for the purchase of tangible personal property from a retailer to a consumer. This definition is not applicable as dangerous drugs are not sold directly to consumers but to a pharmacy or other person authorized by law to dispense or administer the dangerous drug. The board found no existing state regulation that duplicates or addresses the scope of changes proposed by the board.

Based on this initial evaluation, the board does not believe that the proposed regulation is inconsistent or incompatible with existing state or federal regulations. Finally, existing statute at Section 4034.1 of the Business and Professions Code specifies that 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. As of the date of this Notice, the board is not aware of any federal laws or regulations that have been enacted or established.

Anticipated Benefits of the Proposed Regulations: Please see “Benefits” below under “Results of the Economic Impact Analysis.” In coming to this conclusion, the board considered specific benefits anticipated by the proposed amendment of the sections described, including, to the extent applicable, nonmonetary benefits such as the protection of public health and safety, worker safety, or the environment, the prevention of discrimination, the promotion of fairness or social equity, and the increase in openness and transparency in business and government, among other things.

FISCAL IMPACT ESTIMATES

Fiscal Impact on Public Agencies Including Costs or Savings to State Agencies or Costs/Savings in Federal Funding to the State: None

Nondiscretionary Costs/Savings to Local Agencies: None

Local Mandate: None

Cost to Any Local Agency or School District for Which Government Code Sections 17500 – 17630 Require Reimbursement: None

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 business 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 wholesaler maintains 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.

Cost Impact on Representative Private Person or Business: In assessing the potential for adverse economic impact on California business enterprises and individuals, the board considered the following.

Drop Shipment. Existing statute at Section 4163.1 of the Business and Professions Code defines "drop shipment" to mean a sale of a dangerous drug by the manufacturer of the dangerous drug whereby 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. In establishing statutory requirements to establish an electronic pedigree system, the Legislature strongly encouraged all drug manufacturers and repackagers to serialize drug products and initiate electronic pedigrees, and to ready themselves to receive and pass electronic pedigrees.

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.

Effect on Housing Costs: None

Small Businesses: The board's proposal may affect small businesses; however, the board does not have nor does it maintain data to determine if any of its licensed pharmacies are "small businesses" as defined in Government Code Section 11342.610.

RESULTS OF THE ECONOMIC IMPACT ANALYSIS

The Board of Pharmacy conducted an Economic Impact Analysis (EIA) and has made an initial determination that the proposed regulatory action would not have a significant impact on the creation of jobs or new businesses or the elimination of jobs or existing businesses, or the expansion of businesses in the State of California.

Existing statute at Section 4163 of the Business and Professions Code specifies requirements related to the acquisition of dangerous drugs and devices from manufacturers, wholesalers, repackagers and pharmacies, and specifies dates on which pedigree requirements must be met.

This proposed regulation proposes to specify when the drop shipment defined by Business and Professions Code section 4163.1 is utilized by a manufacturer, the wholesale distributor who takes ownership but not physical possession of the dangerous drug does not have to be conveyed on the pedigree record for the dangerous drug.

Comparable Federal Regulations: The board conducted a search of Title 21 Code of Federal Regulations (Food and Drugs), as well as the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) and found no existing federal regulations or statutes that are comparable to the board's proposal. Further, the board conducted a search of the California Code of Regulations and found a definition of "drop shipment" in Section 1706 of Division 2 of Title 18 of the California Code of Regulations. The term "drop shipment" is defined for the purposes of establishing sales and use tax liability for the purchase of tangible personal property from a retailer to a consumer. This definition is not applicable as dangerous drugs are not sold directly to consumers but to a pharmacy or other person authorized by law to dispense or administer the dangerous drug. The board found no existing state regulations that duplicate or address the scope of changes proposed by the board.

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 drug manufacturers, wholesalers, repackagers, and pharmacy warehouses 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.

CONSIDERATION OF ALTERNATIVES

The Board of Pharmacy must determine that no reasonable alternative it considered to the regulation or that has otherwise been identified and brought to its attention would be more effective in carrying out the purpose for which the action is proposed, would be as effective and less burdensome to affected private persons than the proposal described in this Notice, or would be more cost-effective to affected private persons and equally effective in implementing the statutory policy or other provision of law .

Any interested person may present statements or arguments in writing relevant to the above determinations at the address listed for the Contact Person.

INITIAL STATEMENT OF REASONS AND INFORMATION

The Board of Pharmacy has prepared an initial statement of the reasons for the proposed action and has available all the information upon which the proposal is based.

TEXT OF PROPOSAL

Copies of the exact language of the proposed regulations and of the initial statement of reasons, and all of the information upon which the proposal is based, may be obtained upon request from the Board of Pharmacy at 1625 N. Market Blvd., N219, Sacramento, California 95834, or from the Board of Pharmacy's Web site <http://www.pharmacy.ca.gov>.

AVAILABILITY AND LOCATION OF THE FINAL STATEMENT OF REASONS AND RULEMAKING FILE

All the information upon which the proposed regulations are based is contained in the rulemaking file which is available for public inspection by contacting the person named below.

You may obtain a copy of the final statement of reasons once it has been prepared, by making a written request to the contact person named below or by accessing the Board of Pharmacy's Web site (www.pharmacy.ca.gov).

CONTACT PERSON

Inquiries or comments concerning the proposed rulemaking action may be addressed to:

Name: Debbie Damoth
Address: 1625 N. Market Blvd., N219
Sacramento, CA 95834
Telephone No.: (916) 574-7935
Fax No.: (916) 574-8618
E-Mail Address: Debbie.Damoth@dca.ca.gov

The backup contact person is:

Name: Carolyn Klein
Address: 1625 N. Market Blvd., N219
Sacramento, CA 95834
Telephone No.: (916) 574-7913
Fax No.: (916) 574-8618
E-Mail Address: Carolyn.Klein@dca.ca.gov

Website Access. Materials regarding this proposal can be found at www.pharmacy.ca.gov.