



ISSUE DATE: July 23, 2012

**Opportunity to Submit Information Necessary to Possible Board Rulemaking
On Inference and Certification of Individual Package Units – Drug Pedigree Law**

Pursuant to Business and Professions Code section 4163.3 (see below), the Board of Pharmacy is confirming its willingness to receive information by written submission regarding supply chain participants' ability to use or rely on inference(s) as to the contents of aggregate containers for purposes of certification of delivery or receipt of individual package units of dangerous drugs, as required by the California electronic pedigree law. (Bus. & Prof. Code, §§ 4034, 4163 et seq.)

To be considered for purposes of developing a possible future Board rulemaking on this subject, we request that all written submissions contain at minimum the information outlined below, and be received by mail or personal delivery at the Board offices by no later than September 1, 2012.

§ 4163.3. Legislative intent; maintaining integrity of pedigree system; use of inference

- (a) It is the intent of the Legislature that participants in the distribution chain for dangerous drugs, including manufacturers, wholesalers, or pharmacies furnishing, administering, or dispensing dangerous drugs, distribute and receive electronic pedigrees, and verify and validate the delivery and receipt of dangerous drugs against those pedigrees at the unit level, in a manner that maintains the integrity of the pedigree system without an unacceptable increase in the risk of diversion or counterfeiting.
- (b) To meet this goal, and to facilitate efficiency and safety in the distribution chain, the board shall, by regulation, define the circumstances under which participants in the distribution chain may infer the contents of a case, pallet, or other aggregate of individual units, packages, or containers of dangerous drugs, from a unique identifier associated with the case, pallet, or other aggregate, without opening each case, pallet, or other aggregate or otherwise individually validating each unit.
- (c) Manufacturers, wholesalers, and pharmacies opting to employ the use of inference as authorized by the board to comply with the pedigree requirements shall document their processes and procedures in their standard operating procedures (SOPs) and shall make those SOPs available for board review.
- (d) SOPs regarding inference shall include a process for statistically sampling the accuracy of information sent with inbound product.
- (e) Liability associated with accuracy of product information and pedigree using inference shall be specified in the board's regulations.

Section 4163.3 affirms the base requirement of the California pedigree law that all participants in the dangerous drug supply chain will “verify and validate the delivery and receipt of dangerous drugs against [electronic] 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.” Accordingly, the subsequent direction to the Board, to issue regulations defining circumstances under which it would be permissible to substitute an inference as to the contents of an aggregate container for verification and validation of that container's individual unit contents, is similarly limited. Any allowance for inference(s) cannot unacceptably increase supply chain risk(s).

To meet this standard, the Board must base any regulation permitting inference on supply chain information and data demonstrating that use or reliance on inference in specified settings and/or under particular transactional circumstances will not unacceptably increase supply chain risk(s).

At its public meetings, the Board has repeatedly stated its willingness to receive this information. This notification confirms that the Board will accept written submissions from interested parties, in support of or in opposition to permitting inference under specified circumstances, to develop the record necessary to any Board rulemaking on the subject of inference and/or certification.

Necessary Information in Submissions

Any submission by an interested party¹ should include at least the following:

1. Identifying and contact information for the submitting person or entity.
2. A description of the submitting party's interest in this subject, including the submitting party's role, if any, in the supply chain (e.g., manufacturer, repackager, distributor, or dispenser) or other basis for interest (e.g., vendor, consultant, standards body) and a brief description of the person, company, or other entity responsible for the submission.
3. If the submitting party is a supply chain participant, a detailed description of the means and methodology, including hardware and software specifications, processes, and data carrier(s), that the submitting party has deployed or intends to deploy to "verify and validate the delivery and receipt of dangerous drugs against [electronic] pedigrees at the unit level," including specification of the means and methodology for certification.
4. If the submitting party is seeking a regulatory allowance for inference, a specific request for same along with a detailed description of the particular circumstance(s) and/or those transaction(s) under which or pursuant to which there is a perceived need for inference. Define the requested inference(s) as specifically as possible, and where possible provide a limiting descriptor for such transaction(s) that could be used in regulatory language. In addition, provide as much data as possible regarding the factual circumstance(s) and/or transaction(s) in question, including the number and percentage of transaction(s) to which such an inference might apply, both with regard to the submitting party and in the supply chain as a whole, and any trading partners that will be involved in the inference(s).
5. If the submitting party is opposed to a regulatory allowance for inference, either generally or with regard to particular circumstances/transactions, a detailed description of same that as closely as possible meets the requirements of item 4., above.
6. The detailed reason(s) that such an inference is necessary and/or advantageous, and either decreases risk(s) of diversion or counterfeiting (or other risk(s) in the supply chain), holds risk(s) constant, or does not unacceptably increase such risk(s). Or the detailed reason(s) any inference(s) is/are unnecessary, disadvantageous, or unacceptably increase(s) risk(s).

¹ The Board expects that submissions will be made primarily by individual persons, companies, or other entities that are themselves involved in the supply chain and able to supply information and data specific to their own operations regarding the potential benefits and risks of inference(s). Although the Board also welcomes input from associations and other groups, it is most interested in the kind of detail that individual submissions can better provide. The Board is also interested in hearing from vendors, consultants, standards bodies, hardware and software providers, and other experts in the field, regarding their viewpoints on and experience(s) with the use of inference(s).

7. Proposed SOPs that incorporate and explain the use of the inference(s), and describe the proposed process for statistical sampling to ensure the accuracy of pedigree information.
8. A proposal for the allocation of any liability that may be incurred due to use of inference.

Where and When to Submit

All written submissions should be mailed or delivered to Executive Officer Virginia Herold, Board of Pharmacy, 1625 N. Market Blvd., Suite N219, Sacramento, CA 95834. Materials received on or before September 1, 2012 will be considered by the Board in developing a possible rulemaking. These submissions will be considered at the Enforcement Committee meeting on September 11, 2012, and/or at the full Board meeting on October 25-26, 2012.