September 20, 2013

To: Members, E-Pedigree Committee

Subject: Subject Memorandum for the September Meeting

I. Next Scheduled Meetings of the E-Pedigree Committee for 2013

Mark your calendars:
- December 10: Likely San Francisco

II. Update on the Status of Proposed Regulations to Implement Serialized Numeric Identifiers, Grandfathering and Manufacturer Reporting of How the 50 Percent Threshold of Serialized Products on January 1, 2015 Has Been Determined (Proposals to Add Title 16 California Code of Regulations, Sections 1747 and 17471.)

Attachment B

At the February 2013 Board Meeting, the board held a regulation hearing and approved regulation requirements for the following items (the specific language is provided in Attachment B):

1. The serialized numeric identifier (section 1747)
2. The process for advising the board how a manufacturer will reach the 50 percent of its products that will be sold in California after January 1, 2015, and the remaining 50 percent by January 1, 2016 (section 1747.1)
3. How to designate unserialized product that may exist in the supply chain after the staggered implementation dates (section 1747.1).

The rulemaking was initiated on September 21, 2012. Following the adoption of the rulemaking, the file was prepared and submitted to the Department of Consumer Affairs in early April. On September 13, 2013, the board received the final review approval from the Department of Finance and the rulemaking was submitted to the Office of Administrative Law that day.

The Office of Administrative Law has 30 working days to review the file, thus, OAL’s deadline to complete the review is October 25, 2013.

III. Update on the Status of Proposed Regulations For Use of Drop Shipments in an E-Pedigree System (Proposal to Add Title 16 California Code of Regulations, Section 1747.2) – Public Comment Period Underway

At the July 2013 Board Meeting, the board approved proposed language to add Section 1747.2 to Title 16 California Code of Regulations to specify the process by which drop shipments will be
utilized in E-Pedigree. The board noticed this rulemaking for public comment on September 23, 2013, and the 45-day public comment period will conclude on October 28, 2013. Likewise, the board will conduct a Regulation Hearing on the matter on October 29, 2013.

The language noticed for public comment is below:

Proposal to Add a New Section 1747.2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1747.2 Drop Shipments.
For the purposes of Business and Professions Code section 4163.1, when a manufacturer utilizes the "drop shipment" method of sale as defined by that section, the data elements pertaining to transfers of ownership to and from the wholesale distributor, including any certifications of receipt and delivery thereby, may be omitted from the pedigree, in which case the manufacturer shall convey the pedigree directly to the pharmacy or other person authorized by law to dispense or administer the dangerous drug prior to or contemporaneous with delivery of the corresponding dangerous drug.

Note: Authority cited: Sections 4005, 4034, and 4163.1, Business and Professions Code.
Reference: Sections 4034, 4037, 4163, 4163.1, 4170, 4180, and 4190, Business and Professions Code.

IV. Discussion Concerning Possible Regulation Requirements to Permit Inference as Provided by California Business and Professions Code Section 4163

Since July 2012, the board has several times released written requests for specific comments needed to develop possible regulations to authorize inference. Until the March e-pedigree meeting, the board received only a few comments directly responsive to these requests. The initial comments provided by the supply chain are available in the meeting materials for the December 4, 2012 Meeting Materials of the Enforcement Committee: http://www.pharmacy.ca.gov/about/meetings.shtml#enforce

At the March Enforcement and E-Pedigree Meeting, draft language was released for discussion purposes to develop the regulation language for inference. A copy of this proposal is provided in the meeting materials.

Following the March meeting, the board received additional comments specific to the draft language released. These comments are also provided in the meeting materials.

During the June meeting, the committee considered inference requirements. There was general discussion about the written comments received on the draft requirements (intended for discussion) that were prepared by staff. As recommended by staff, the matter was taken to the July Board Meeting so that the board could determine the direction for the regulation in advance of the October 2013 Board Meeting.

At the July 2013 Board Meeting, the board made the following policy decisions related to Inference:
From a manufacturer to a wholesaler, inference could be applied to a sealed, homogeneous case which contains only one dangerous drug product, where the case remains unopened by the wholesaler and the package shows no signs of tampering (there is no requirement for trusted trading partners).

- When a sealed case is opened, its entire contents must be scanned immediately to validate Inference.
- When discrepancies are discovered in the data or the product, it must be reported within three (3) business days.

At this meeting, the committee is reviewing possible regulation language that integrates the decisions of the board as noted above.

### V. Discussion Concerning Possible Regulation Requirements on the Certification Process to Comply with California’s E-Pedigree Law

**Attachment D**

At the March Enforcement and E-Pedigree Meeting, the board distributed possible regulation language for the certification of each sale and purchase into the e-pedigree record. Included in the draft was proposed language related to the board’s access to e-pedigree information during inspections.

Written comments submitted following the March meeting were considered along with a discussion draft at the committee’s June 2013 meeting. Thereafter, the board discussed the policy related to the certification of e-pedigree information at the July Board Meeting.

At this meeting, the committee will review and discuss possible regulation text that incorporates comments received (following the March meeting) as well as comments made at the June committee meeting and July Board Meeting. It was noted that the board needs to resolve the issue as to what each party is actually certifying. In other words, to what level of information are they verifying or confirming as true and correct for the next recipient of the product.

### VI. Presentations and Questions From the Pharmaceutical Supply Chain on Their Readiness to Meet California’s Staggered E-Pedigree Implementation Schedule

Time has been set aside at this meeting to provide interested parties with the opportunity to provide information or presentations to the committee about implementation matters or simply to ask questions.

### VII. General Discussion

### VIII. Closing Comments
Article 5.5. Pedigree Requirements.

1747. Unique Identification Number.

For the purposes of Section 4034 of the Business and Professions Code, the "unique identification number" that is to be established and applied to the smallest package or immediate container as defined in subdivision (d) of Section 4034 by the manufacturer or repackager shall conform to requirements for Standardized Numerical Identifiers (SNIs) set forth in a March 2010 publication by the U.S. Food and Drug Administration (FDA) titled “Guidance for Industry, Standards for Securing the Drug Supply Chain – Standardized Numerical Identification for Prescription Drug Packages,” (FDA’s Guidance Document), hereby incorporated by reference. As stated therein, an SNI consists of a serialized National Drug Code (NDC) product identifier combined with a unique numeric or alphanumeric serial number of no more than twenty (20) digits or characters. For dangerous drugs for which no NDC product identifier is assigned or is in use, an equivalent serialized product identifier may be used in place of the NDC consistent with the FDA’s Guidance Document. This number shall be combined with a unique numeric or alphanumeric serial number that is not more than 20 digits or characters in length to establish the unique identification number.

This regulation shall become operative on January 1, 2015.


1747.1. Specification of Pedigreed Dangerous Drugs; Specification of Existing Stock

(a)(1) To comply with Business and Professions Code section 4163.5, each manufacturer of a dangerous drug distributed in California shall submit to the board no later than December 31, 2014, a declaration signed under penalty of perjury by an owner, officer, or employee with authority to bind the manufacturer, containing the following:

(A) A list and quantity of dangerous drugs by name and product package (SKU) type representing at least fifty (50) percent of the manufacturer's total that are ready for initial implementation of the serialized electronic pedigree requirements as of January 1, 2015;
(B) A statement identifying which one of the following methods was used to measure the percentage of drugs ready to be serialized: (i) unit volume, (ii) product package (SKU) type, or (iii) drug product family;

(C) A statement describing the calculation(s) used to arrive at the percentage figure of dangerous drugs ready for serialized pedigree requirements;

(D) A list and quantity of dangerous drugs by name and product package (SKU) type that are in the remaining percentage not yet ready to be serialized or subject to pedigree requirements; and,

(E) a statement specifying the technology employed to meet the pedigree requirements, including but not limited to any platform(s), vendor(s), hardware, software, and communication technologies deployed.

(2) To comply with Business and Professions Code section 4163.5, each manufacturer of a dangerous drug distributed in California shall also submit to the board no later than December 31, 2015, a declaration signed under penalty of perjury by an owner, officer, or employee with authority to bind the manufacturer, containing the following:

(A) A list and quantity of its remaining dangerous drugs by name and product package (SKU) type that are ready for implementation of serialized electronic pedigree requirements as of January 1, 2016.

(B) A statement identifying which one of the following methods was used to measure the final percentage of drugs to be serialized: (i) unit volume, (ii) product package (SKU) type, or (iii) drug product family;

(C) A statement describing the calculation(s) used to arrive at the final percentage figure; and,

(D) A statement specifying the technology employed to meet the pedigree requirements, including but not limited to any platform(s), vendor(s), hardware, software, and communication technologies deployed.

(3) Any failure to submit to the board a declaration compliant with subdivision (a)(1) by December 31, 2014, any failure to submit to the board a declaration compliant with subdivision (a)(2) by December 31, 2015, or any failure to re-submit either declaration to the board in fully compliant form within ten (10) days after notice of deficiency by the board, shall constitute a violation of the Pharmacy Law.

(b) For the purposes of Business and Professions Code sections 4163.2 and 4163.4, any manufacturer, wholesaler or repackager seeking to designate dangerous drugs it possesses, owns, or controls that are not subject to the serialized electronic pedigree requirements, shall submit to the Board, by no later than July 31, 2016, a declaration signed under penalty of perjury by an owner, officer, or employee with authority to bind the manufacturer, wholesaler or repackager, containing the following:
(1) a list and quantity of dangerous drugs by name, product package (SKU) type and National Drug Code (NDC) product identifier in the possession, ownership, or control of the manufacturer, wholesaler or repackager that were acquired prior to July 1, 2016;

(2) a statement that specifies the means and source of acquisition; and,

(3) a statement that specifies the anticipated means of any subsequent distribution or disposition.

(c) For the purposes of Business and Professions Code sections 4163.2 and 4163.4, any pharmacy or pharmacy warehouse seeking to designate dangerous drugs it possesses, owns, or controls that are not subject to the serialized electronic pedigree requirements, shall submit to the Board, by no later than July 31, 2017, a declaration signed under penalty of perjury by an owner, officer, or employee with authority to bind the pharmacy or pharmacy warehouse, containing the following:

(1) A list and quantity of dangerous drugs by name, product package (SKU) type and National Drug Code (NDC) product identifier in the possession, ownership, or control of the pharmacy or pharmacy warehouse that were acquired prior to July 1, 2017;

(2) A statement that specifies the means and source of acquisition; and,

(3) a statement that specifies the anticipated means of any subsequent distribution or disposition.

(d) The Board or its designee shall have sole discretion to determine whether any of the declarations submitted pursuant to this Section are compliant, and to reject and require re-submission of any non-compliant declaration(s) until determined to be fully compliant.

Note: Authority cited: Sections 4005, 4034, 4163, 4163.2 and 4163.5, Business and Professions Code. Reference: Sections 4034, 4034.1, 4163, 4163.1, 4163.2, 4163.4, 4163.5, Business and Professions Code.
ATTACHMENT C
Inference

(a) Pursuant to Business and Professions Code sections 4034 and 4163.3, this regulation defines the circumstances under which participants in the distribution chain for dangerous drugs, including manufacturers, wholesalers, or pharmacies furnishing, administering, or dispensing dangerous drugs, may infer the contents of an aggregate container of individual units, packages, or containers of dangerous drugs, from a unique identifier associated with the aggregate container, without opening the aggregate container or otherwise individually validating each unit, consistent with the law’s intent that supply chain participants shall generally 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 of counterfeiting.

(b) For the purposes of this section, to “infer” or to rely on an “inference” means that a supply chain participant, in reliance on electronic pedigree information, received from the source of the delivery or transfer of dangerous drugs, which provides hierarchical relationships between those unique identifiers affixed to the smallest packages or immediate containers within a sealed case and a unique identifier affixed to the sealed case containing the smallest packages or immediate containers, substitutes scan or review of the unique identifier affixed to the aggregate container for scan or review of unique identifiers affixed to the smallest packages or immediate containers within the sealed case, thereby “inferring” for purposes of certifying delivery or receipt that the smallest packages or immediate containers within the sealed case are what they are expected to be, based on the pedigree information, and pairs expected shipments and receipts with the individual units without opening the sealed case and scanning or reviewing its contents.

(c) Recipients in the supply chain may infer smallest package or immediate container contents of a sealed case, without breaking the seal, thereby relying on the unique identifier affixed to the sealed case and the inference that hierarchical data relationships between the case identifier and the individual unit identifiers as stated in the electronic pedigree have been correctly stated and remain true, and accurately describe the case contents, only under the following circumstances:

(1) Where the source of delivery or transfer of dangerous drugs has transmitted to the recipient, prior to or contemporaneous with the receipt of the sealed case, a certified electronic pedigree record establishing a hierarchical data relationship between the
(2) Where the electronic pedigree data was received via a secured electronic transmission, and includes a certification under penalty of perjury by a responsible party for the source that the information contained in the pedigree is true and accurate, made under conditions preventing any alteration, tampering, or other change to the pedigree data received;

(3) Where the case is and has remained sealed with the original, unbroken, seal or tape affixed by the manufacturer, and shows no signs of tampering or being opened;

(4) Where the sealed case is homogenous, i.e., contains only one dangerous drug product;

(5) Where, once a sealed case is opened, the entire contents of the case are immediately scanned and confirmed to the pedigree data received, and any discrepancies are reported;

(6) Where any discrepancies discovered in pedigree data or dangerous drugs received are reported to trading partners within three (3) business days;

(7) Where the source and recipient have a written agreement in place regarding remediation of discrepancies discovered in pedigree data or dangerous drugs transferred; and

(8) Where the source and recipient have created and exchanged with one another written standard operating procedures (SOPs) that define, at minimum, the circumstances under which an inference will be deployed, the limitations on that deployment, the sampling plan for sampling sealed, homogenous cases for continued compliance, and the means and time limits for remediation of any data or product discrepancies discovered.

(d) All such written standard operating procedures (SOPs) shall require, at minimum, that:

(1) Prior to relying on an inference as to a sealed, homogenous, case received from a trading partner, the recipient shall have received at least five (5) sealed, homogenous cases from
that trading partner, shall have physically verified the individual unit contents of each of
those five (5) cases, and shall have confirmed the accuracy of the pedigree data received;

(2) The recipient conduct periodic sampling of sealed, homogenous, cases received from any
trading partner to confirm the continuing accuracy of pedigree data received;

(3) The trading partners have an agreement regarding remediation of any discrepancies
discovered in pedigree data or dangerous drugs transferred; and

(4) Any discrepancies discovered in pedigree data or dangerous drugs received shall be
reported by the discovering trading partner within three (3) business days.

(e) All agreements and written standard operating procedures (SOPs) regarding inference, all
electronic pedigree data sent or received, all records and results of verification processes, and all
records identifying or reporting discrepancies, shall be preserved and made available for
inspection upon request by an authorized officer of the law or by an authorized representative of
the board, for at least three years from the date of making.
Certification

(a) For the purposes of Business and Professions Code section 4034, and the delivery and receipt of electronic pedigrees, “certification” shall refer to the process by which each participant in the supply chain confirms and attests to the accuracy of electronic pedigrees transmitted or received in conjunction with delivery, transfer, receipt, or acceptance of corresponding dangerous drugs.

(b) Prior to or contemporaneous with any delivery or other transfer of a dangerous drug pursuant to a transaction requiring transmission and receipt of an electronic pedigree, the delivering or transferring party (hereinafter, the “source”) shall provide to the buying, receiving, or accepting party (hereinafter, the “recipient”), via a secured electronic transmission, the electronic pedigree data corresponding to the dangerous drug being delivered or transferred, including every change of ownership of the dangerous drug from its initial manufacture through to the transaction between source and recipient, tracked at the smallest package or immediate container as defined in section 4034, subdivision (d). The electronic pedigree data provided shall include, as to each such individual unit, at least the following:

1. The name and principal address of the source, and the federal or state registration and/or license number held by the source that permits transfer from the source to the recipient. If more than one registration or license held by the source would permit the transfer, then the source may elect to include one or more than one of the eligible numbers.

2. The trade or generic name of the dangerous drug, the quantity of the dangerous drug, its dosage form and strength, the date of the transaction, the sales invoice number or, if the sales invoice number is not immediately available, a customer-specific shipping reference number linked to the sales invoice number, the container size, the number of containers, the expiration dates, and the lot numbers.

3. For each owner of the dangerous drug prior to and including the source and the recipient, the business name, address, and federal or state registration and/or license number(s)
permitting sale or transfer, 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 that the information contained in the pedigree is true and accurate.

(5) The unique identification number affixed to the smallest package or immediate container.

c) The electronic pedigree record provided by the source to the recipient shall include a digital signature by a responsible party for the source, and shall be transmitted via a secured electronic transmission, to prevent any alteration, tampering, or other change to the pedigree.

(d) The certification under penalty of perjury by a responsible party for the source shall attest that, to the best of the ability of the responsible party to know or determine, the information contained in the pedigree data record is true and accurate, that there is nothing in the prior transaction history that raises suspicion for the source, and that the information in the pedigree data corresponds to the dangerous drug being transferred.

e) Prior to or contemporaneous with receiving a delivery or other transfer of a dangerous drug pursuant to a transaction requiring the transmission and receipt of an electronic pedigree, the recipient shall receive an electronic pedigree from the source that corresponds to the dangerous drug being delivered or transferred. The recipient shall certify receipt of the pedigree data for the dangerous drug by reviewing the prior transaction history and corresponding certifications to confirm there is nothing that raises suspicion, verifying correspondence between the pedigree data and the dangerous drug received, and by including in the pedigree a digital signature by a responsible party for the recipient that confirms receipt of the pedigree and corresponding dangerous drug and prevents alteration, tampering, or other change to the pedigree.