



E-Pedigree Committee

Randy Kajioka, PharmD, Chairperson

Shirley Wheat, Public Member

Ryan Brooks, Public Member

Rosalyn Hackworth, Public Member

Amy Gutierrez, PharmD

Deborah Veale, RPh

Report of the E-Pedigree Committee Meeting on September 26, 2013

- a. **FOR INFORMATION and POSSIBLE ACTION: Update on the Status of Proposed Regulations to Implement Serialized Numeric Identifiers, Grandfathering and Manufacturer Reporting of How 50 Percent Threshold of Serialized Products on January 1, 2015 (Proposals to Add Title 16, California Code of Regulations, Sections 1747 and 1747.1)**

Attachment 1

Background

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 reviewed and approved by the Department of Consumer Affairs; the Business, Consumer Services, and Housing Agency; and the Department of Finance. On September 13, 2013, the file was transmitted to the Office of Administrative Law (OAL) for final review. OAL's deadline to review the file is October 25, 2013.

Board staff was advised by the Office of Administrative Law on October 18, 2013, that OAL will be disapproving the file because the file does not sufficiently address the fiscal and economic impact assessment of the regulation. Specifically, the Board's Form 399 and its assessment of the impact the regulation has regarding the creation or elimination of jobs within the state; the creation of new businesses or the elimination of existing businesses within the state; and the expansion of businesses currently doing business within the state (see Government Code Section 11346.3(b)(1)). Staff understands that, outside of this issue,

there are no other substantive issues that need to be addressed with the file. The regulation language itself should not need to be adopted.

Following a disapproval by OAL, the board will have 120 days to address any deficiency identified in OAL's disapproval decision. Based on feedback, staff is preparing an Addendum to the Initial Statement of Reasons, as well as an Addendum to the Economic Impact Analysis. Both addendums will be noticed for a 15-day public comment period. If comments are received, the board would need to review and accept or reject comments related to the information that is noticed prior to resubmitting the file to OAL (within the 120-day period).

Staff recommendation: *Direct staff to prepare an Addendum to the Initial Statement of Reasons and an Addendum to the Economic Impact Analysis to address the necessity issues and to expand on the impact of the regulation with respect to the creation or elimination of jobs within the state; the creation of new businesses or the elimination of existing businesses within the state; and the expansion of businesses currently doing business within the state, and issue these addendums for a 15-day public comment period. If no negative comments are received, direct staff to take all steps necessary to complete the rulemaking process, including the filing of the final rulemaking package with the Office of Administrative Law and delegate to the Executive Officer the authority to make any non-substantive changes to the rulemaking before filing the rulemaking with the Office of Administrative Law prior to the expiration of the 120-day period.*

Attachment 1 contains the regulation language as adopted.

b. FOR INFORMATION and POSSIBLE DISCUSSION: Proposed Regulation on Requirements to Permit Inference as Provided by California Business and Profession Code Section 4163.3

Attachment 2

Background

Since July 2012, the board has several times released written requests for specific information helpful to developing 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 on inference was released for discussion purposes to develop the regulation text. 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.

During the June meeting, the committee again 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 September E-Pedigree 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, they must be reported within three (3) business days.

Committee Discussion

The committee had considerable discussion regarding the proposed language including discussions involving the conditions under which inference would be allowed and to what extent. This discussion is detailed in the September meeting minutes. The committee also discussed under what, if any, additional circumstances should inference be applied. Although the committee did not take action on this item, discussion from committee members resulted in the recommended to the board that additional discussion on the elements of inference is needed, and should be scheduled unless the pending federal legislation passes.

Chairperson Kajioka asked the public to submit any comments they have in writing. To date, no comments have been submitted since the September e-Pedigree Meeting.

Attachment 2 is a copy of the draft regulation language discussed during the committee meeting.

c. **FOR INFORMATION and POSSIBLE DISCUSSION: Possible Regulation Requirements on the Certification Process to Comply with California's E-Pedigree Law**

Attachment 3

Background

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.

Committee Discussion

The committee was provided with a brief explanation of the certification language and well as the basic concept of the regulation, to require each party in the supply chain to certify delivery and receipt of drugs. The committee did not discuss this proposal in great detail but received public comment that included that the new version of the regulation was much improved. Public comment also suggested that the board may want to define "responsible party" for purposes of the regulation.

Chairperson Kajioka asked the public to submit any comments they have in writing to allow for a more detailed discussion at the future December committee meeting. The committee did not take action on this item.

Attachment 3 is a copy of the draft regulation language discussed by the committee.

- d. **FOR INFORMATION: Update on the Status of Proposed Regulations for the Use of Drop Shipments in an E-Pedigree System Pursuant to California Business and Professions Code Section 4163.1**

Attachment 4

Background

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.

At this board meeting, the board will conduct a regulation hearing on the matter on October 29, 2013. As of October 24, 2013, the board has received one written comment during the comment period. If additional comments are received, the comments will be brought to the board meeting. **Attachment 4** is a copy of the comment received.

The language noticed for public comment is:

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.

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

Committee Discussion

There was not committee discussion or action on this item.

e. FOR INFORMATION: Future Meeting Dates

- December 10: likely San Francisco Bay Area (specific location not yet confirmed)

A summary of the committee meeting is provided in **Attachment 5**.

Attachment 1

Order of Adoption
Board of Pharmacy
California Code of Regulations

As of 9/13/13 under
review at the Office
of Administrative Law
OAL Deadline:
10/25/13

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.

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

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 2

1 **Inference**

2 (a) Pursuant to Business and Professions Code sections 4034 and 4163.3, this regulation defines
3 the circumstances under which participants in the distribution chain for dangerous drugs,
4 including manufacturers, wholesalers, or pharmacies furnishing, administering, or dispensing
5 dangerous drugs, may infer the contents of an aggregate container of individual units, packages,
6 or containers of dangerous drugs, from a unique identifier associated with the aggregate
7 container, without opening the aggregate container or otherwise individually validating each
8 unit, consistent with the law’s intent that supply chain participants shall generally distribute and
9 receive electronic pedigrees, and verify and validate the delivery and receipt of dangerous drugs
10 against those pedigrees at the unit level, in a manner that maintains the integrity of the pedigree
11 system without an unacceptable increase in the risk of diversion of counterfeiting.

12
13 (b) For the purposes of this section, to “infer” or to rely on an “inference” means that a supply
14 chain participant, in reliance on electronic pedigree information, received from the source of the
15 delivery or transfer of dangerous drugs, which provides hierarchical relationships between those
16 unique identifiers affixed to the smallest packages or immediate containers within a sealed case
17 and a unique identifier affixed to the sealed case containing the smallest packages or immediate
18 containers, substitutes scan or review of the unique identifier affixed to the aggregate container
19 for scan or review of unique identifiers affixed to the smallest packages or immediate containers
20 within the sealed case, thereby “inferring” for purposes of certifying delivery or receipt that the
21 smallest packages or immediate containers within the sealed case are what they are expected to
22 be, based on the pedigree information, and pairs expected shipments and receipts with the
23 individual units without opening the sealed case and scanning or reviewing its contents.

24
25 (c) Recipients in the supply chain may infer smallest package or immediate container contents
26 of a sealed case, without breaking the seal, thereby relying on the unique identifier affixed to the
27 sealed case and the inference that hierarchical data relationships between the case identifier and
28 the individual unit identifiers as stated in the electronic pedigree have been correctly stated and
29 remain true, and accurately describe the case contents, only under the following circumstances:

- 30 (1) Where the source of delivery or transfer of dangerous drugs has transmitted to the
31 recipient, prior to or contemporaneous with the receipt of the sealed case, a certified
32 electronic pedigree record establishing a hierarchical data relationship between the

- 33 unique identifier affixed to the sealed case and the unique identifiers affixed to the
34 smallest packages or immediate containers within the case;
- 35
- 36 (2) Where the electronic pedigree data was received via a secured electronic transmission,
37 and includes a certification under penalty of perjury by a responsible party for the source
38 that the information contained in the pedigree is true and accurate, made under conditions
39 preventing any alteration, tampering, or other change to the pedigree data received;
- 40
- 41 (3) Where the case is and has remained sealed with the original, unbroken, seal or tape
42 affixed by the manufacturer, and shows no signs of tampering or being opened;
- 43
- 44 (4) Where the sealed case is homogenous, i.e., contains only one dangerous drug product;
- 45
- 46 (5) Where, once a sealed case is opened, the entire contents of the case are immediately
47 scanned and confirmed to the pedigree data received, and any discrepancies are reported;
- 48
- 49 (6) Where any discrepancies discovered in pedigree data or dangerous drugs received are
50 reported to trading partners within three (3) business days;
- 51
- 52 (7) Where the source and recipient have a written agreement in place regarding remediation
53 of discrepancies discovered in pedigree data or dangerous drugs transferred; and
- 54
- 55 (8) Where the source and recipient have created and exchanged with one another written
56 standard operating procedures (SOPs) that define, at minimum, the circumstances under
57 which an inference will be deployed, the limitations on that deployment, the sampling
58 plan for sampling sealed, homogenous cases for continued compliance, and the means
59 and time limits for remediation of any data or product discrepancies discovered.
- 60
- 61 (d) All such written standard operating procedures (SOPs) shall require, at minimum, that:
- 62 (1) Prior to relying on an inference as to a sealed, homogenous, case received from a trading
63 partner, the recipient shall have received at least five (5) sealed, homogenous cases from

64 that trading partner, shall have physically verified the individual unit contents of each of
65 those five (5) cases, and shall have confirmed the accuracy of the pedigree data received;

66

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

69

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

72

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

75

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

Attachment 3

1 **Certification**

2
3 (a) For the purposes of Business and Professions Code section 4034, and the delivery and
4 receipt of electronic pedigrees, “certification” shall refer to the process by which each participant
5 in the supply chain confirms and attests to the accuracy of electronic pedigrees transmitted or
6 received in conjunction with delivery, transfer, receipt, or acceptance of corresponding
7 dangerous drugs.

8
9 (b) Prior to or contemporaneous with any delivery or other transfer of a dangerous drug
10 pursuant to a transaction requiring transmission and receipt of an electronic pedigree, the
11 delivering or transferring party (hereinafter, the “source”) shall provide to the buying, receiving,
12 or accepting party (hereinafter, the “recipient”), via a secured electronic transmission, the
13 electronic pedigree data corresponding to the dangerous drug being delivered or transferred,
14 including every change of ownership of the dangerous drug from its initial manufacture through
15 to the transaction between source and recipient, tracked at the smallest package or immediate
16 container as defined in section 4034, subdivision (d). The electronic pedigree data provided shall
17 include, as to each such individual unit, at least the following:

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

22
23 (2) The trade or generic name of the dangerous drug, the quantity of the dangerous drug, its
24 dosage form and strength, the date of the transaction, the sales invoice number or, if the
25 sales invoice number is not immediately available, a customer-specific shipping reference
26 number linked to the sales invoice number, the container size, the number of containers,
27 the expiration dates, and the lot numbers.

28
29 (3) For each owner of the dangerous drug prior to and including the source and the recipient,
30 the business name, address, and federal or state registration and/or license number(s)

31 permitting sale or transfer, and the dangerous drug shipping information, including the
32 name and address of each person certifying delivery or receipt of the dangerous drug.
33

34 (4) A certification under penalty of perjury from a responsible party of the source that the
35 information contained in the pedigree is true and accurate.
36

37 (5) The unique identification number affixed to the smallest package or immediate container.
38

39 (c) The electronic pedigree record provided by the source to the recipient shall include a digital
40 signature by a responsible party for the source, and shall be transmitted via a secured electronic
41 transmission, to prevent any alteration, tampering, or other change to the pedigree.
42

43 (d) The certification under penalty of perjury by a responsible party for the source shall attest
44 that, to the best of the ability of the responsible party to know or determine, the information
45 contained in the pedigree data record is true and accurate, that there is nothing in the prior
46 transaction history that raises suspicion for the source, and that the information in the pedigree
47 data corresponds to the dangerous drug being transferred.
48

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

Attachment 4

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October 24, 2013

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FOLLOWED BY U.S. MAIL

Ms. Debbie Damoth
Drop Shipment Regulation Coordinator
California Board of Pharmacy
1625 N. Market Blvd., N219
Sacramento, CA 95834

**Re: Support for Board of Pharmacy Proposed Regulation 1747.2 "Drop Shipments"
Notice Published September 13, 2013**

On behalf of our client, Millennium Pharmaceuticals, Inc. ("Millennium"), we are pleased to submit comments in support for the California State Board of Pharmacy ("Board") adoption of its proposed new regulation at Title 16, California Code of Regulations, Section 1747.2 – "Drop Shipments."

Millennium has worked closely with the Board to encourage its focus on a unique distribution model in the prescription drug supply chain, and one for which customized rulemaking is authorized in the state's electronic pedigree ("e-pedigree") statute at Section 4163.1(b) of the California Business and Professions Code.

Millennium supports the Board's proposal to specify that when a manufacturer utilizes the "drop shipment" method of distribution 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. Pedigree would then be required to be conveyed directly from the manufacturer or its designated distributor to the authorized purchaser prior to or contemporaneously with the delivery of the dangerous drug.

As the Board knows from our previous testimony and written submissions on this question, Millennium utilizes a "drop-shipment" distribution model that provides treating physicians and their patients with timely and efficient access to critical and time-sensitive therapies for cancer. This

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Drop Shipment Regulation Coordinator
California Board of Pharmacy
October 24, 2013
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model allows our client to facilitate the direct shipment of medications to a healthcare provider's office, and ultimately to the patient, within a day of placing an order.

In this model, wholesalers place orders for the product and consequently take title to the ordered product, but never take possession or physical control of the product. The role of the wholesaler in this model is thus limited to facilitating administrative services, such as the processing of orders and payments.

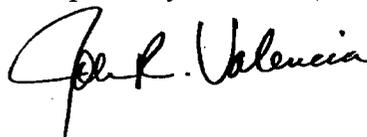
Section 4163.1(b) of the California Business and Professions Code expressly permits the Board to establish an alternative process to convey the pedigree information for drugs that are distributed by drop shipment. The intent of the drug pedigree requirements in California law is to provide the capability to track and trace drug shipments. As a result, only those stakeholders that actually take possession or physical control of the drugs are best positioned to satisfy the objectives of the law's pedigree requirements.

In the context of a drop shipment distribution model, pedigree information should include records of any shipments directly from manufacturers (or their designated distributors) to dispensers, as well as any returns. However, pedigree requirements need not apply to wholesale distributors who take only legal title of a drug product, but take neither possession nor physical control. Ensuring entities that *never* physically handle the product are not subject to the reporting requirements will allow companies, like Millennium, to maintain important efficiencies in its distribution system without subjecting its wholesalers to unnecessary regulation. All the while, the accurate tracking of pharmaceutical products throughout this unique chain of physical custody is ensured.

On behalf of Millennium, we wish to express our thanks to the Board and its staff for its sustained focus, and proposed action, on this important aspect of "e-pedigree." Millennium reiterates its support for the adoption of this regulation.

Should the Board require any additional information, please don't hesitate to contact me at (916) 441-2430.

Respectfully submitted,



JOHN R. VALENCIA

JRV:mb
Enclosures: Exhibits "A" & "B"
1020420.1

Ms. Debbie Damoth
Drop Shipment Regulation Coordinator
California Board of Pharmacy
October 24, 2013
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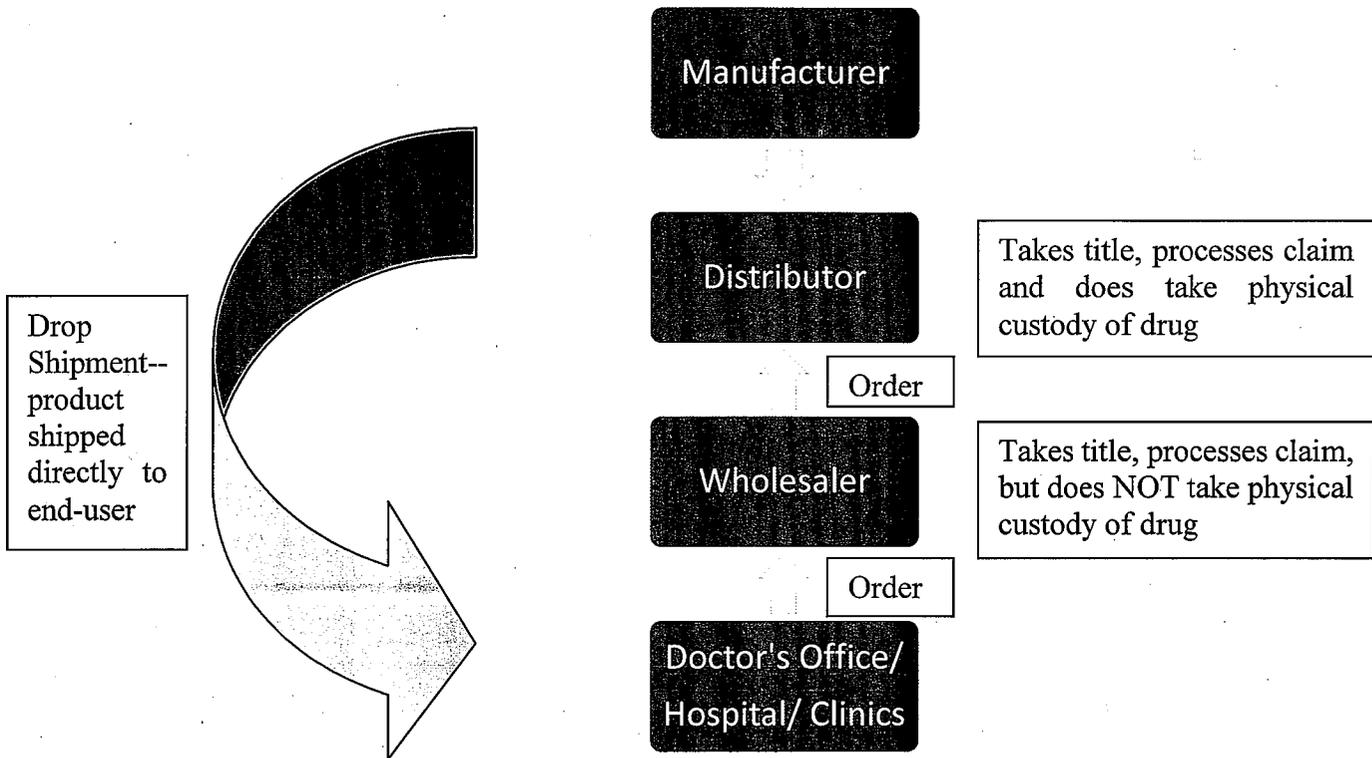
Exhibit "A"

"Drop Shipment" Distribution Process Summary

A variety of pharmaceutical manufacturers use a "drop-shipment" distribution model that provides treating physicians and their patients with timely and efficient access to drugs. By using a drop-ship model, the manufacturer can facilitate a direct shipment of its drug to a healthcare provider's office. In this model, wholesalers place orders with the manufacturer or a designated distributor for the product and consequently take title to the ordered product, but never take possession or physical control of the product. Instead, the manufacturer or designated distributor ships directly to the physician upon receipt of the order. The role of the wholesaler in this model is thus limited to facilitating drug distribution by providing administrative services, such as the processing of orders and payments.

Exhibit "B"

A 'DROP-SHIPMENT' DRUG DISTRIBUTION MODEL



Attachment 5



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BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

**STATE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
E-PEDIGREE COMMITTEE
MINUTES**

DATE: September 26, 2013

LOCATION: Embassy Suites, LAX South
1440 East Imperial Avenue
El Segundo, CA 90245

COMMITTEE MEMBERS

PRESENT: Randy Kajioka, PharmD, Chairperson
Deborah Veale, RPh
Shirley Wheat, Public Member
Rosalyn Hackworth, Public Member
Ryan Brooks, Public Member

COMMITTEE MEMBERS

NOT PRESENT: Amy Gutierrez, PharmD

STAFF

PRESENT: Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Judi Nurse, Supervising Inspector
Joshua Room, Supervising Deputy Attorney General
Carolyn Klein, Manager II
Laura Hendricks, Staff Analyst

**BOARD MEMBERS
IN AUDIENCE:** Stanley Weisser, RPh, Board President

Note: The webcast of this meeting is available at:
<http://www.pharmacy.ca.gov/about/meetings.shtml>

Call to Order

Chairperson Kajioka called the meeting to order at 9:40 a.m. and asked the audience members to introduce themselves to the committee.

I. Next Meeting Scheduled of the E-Pedigree Committee:

Chairperson Kajioka reported that the next committee meeting will be December 10, 2013. The meeting location has not been finalized, however it will be held in the bay area.

II. Update on Federal Legislation.

Chairperson Kajioka asked Board President, Stanley Weisser, to address the recent federal action regarding e-pedigree. President Weisser reported that a vote is expected to be taken in the House on September 28th regarding the Federal e-Pedigree bill. He added that the board is in the process of reviewing the most recent version of the bill, however the federal bill does not appear to be as comprehensive as California's nor will it be enacted as soon as California's would be. President Weisser thanked the public and the board for their work on California's e-Pedigree effort.

III. 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 1747.1)

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

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.

Discussion

No comments from the committee or from the public.

IV. 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.

Discussion

Ms. Herold encouraged the public to either provide comments in writing or attend the board meeting on October 29th to provide oral comments.

No public comments.

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

Mr. Bob Celeste from GS1 provided a presentation on GS1’s Electronic Product Code Information Service (EPCIS), the presentation has been provided on the board’s website at: http://www.pharmacy.ca.gov/meetings/agendas/2013/13_sep_eped_gs1_present.pdf

Discussion

Mr. Room discussed how EPCIS meshes with California’s legal requirements for e-Pedigree. He noted that the main difference between EPCIS and the document based model is what information is received with each change of ownership. With the EPCIS model the information

received is only that of the immediate trading partners, in the document based model the entire pedigree history is transmitted with each change of ownership. He added that while the document based model more obviously fits California's legal requirements, the EPCIS model does allow for the entire pedigree to be pulled forward by querying through a proxy. Therefore with the EPCIS model if an entity wanted to receive the entire pedigree for each drug received they would have to do a query for each shipment, otherwise all they see is the trading partner directly prior to them in the supply chain. Mr. Room provided that the committee will have to decide if the ability to query the entire pedigree meets California's law requirements.

Mr. Celste reported that the EPCIS model allows you to investigate a suspected bad player in the supply chain by collecting data from other members of the chain without alerting the suspected bad player that you are doing so. Mr. Room added that this system is more similar to how the board conducts investigations now, in that if the board suspects someone of being a bad player the board first goes to the wholesaler to get the pharmacy's purchasing patterns so they do not alert the pharmacy of the investigation.

Mr. Room added that he does not have an opinion as to which system is better, he only is trying to help the board decide if the EPCIS model fits the requirements for e-pedigree.

Chairperson Kajioka commented that the law was written many years ago when technology was different. He commented that if an entity has a trusted partnership it may be OK for them to only receive information on the player immediately preceding them in the supply chain. If they are doing business with a new vendor then they could pull the full report on each shipment until they established a trusted relationship.

Mr. Room commented that if the board chooses to accept the EPCIS model, they could exercise their enforcement discretion to create regulations that establish certain circumstances under which an entity would be required to pull the entire supply chain information (for example a new business relationship).

Mr. Room noted that if it accepts EPCIS, the board will have to decide if someone would have to pull forward all the previous certifications from the supply chain before they can certify.

Mr. Brooks asked if this system provided for any competitive advantage by allowing those further down the supply chain to see all the entities that their immediate trading partner is doing business with. Mr. Celeste clarified that the system limits the information to what is needed to corroborate the pedigree for items that they have received and does not allow members of the supply chain to gain information about those who are parallel to them in the supply chain.

Ms. Veale asked to clarify that if someone in the supply chain queried their product they would not be able to see where the rest of the drugs that may have been in the same case up the supply chain had been sold to. Mr. Celeste confirmed this.

Riya Cao, from LSPedia, asked if the EPCIS model only allows for queries to be made upstream and not downstream. Mr. Celeste answered that queries can be made both upstream and downstream and added that GS1 is just creating the system, it is up to the trading partners to decide what queries they will respond to and what data they will provide.

Stan Goldberg, commented that if a pharmacy was working within a trusted business relationship they would not have to query each item they received to get its entire history. Mr. Celeste responded that that decision would be left to the pharmacy, they could choose to query each shipment or they could choose to only do so if they are working with a new entity.

Mr. Goldberg asked if there was a recall for a certain lot number/expiration date if the eventual goal of EPCIS would be to allow a manufacturer to notify those they sold items to of the recall. Mr. Celeste responded that the advantage of the system is that it will immediately change the status of a drug in the system to “recalled” and stop it from moving forward in the chain toward the patient.

Mr. Goldberg asked the committee if a product was recalled and it had already been dispensed the board would want the pharmacy to take any specific action. Mr. Brooks responded that under current law, if there is a recall it is the responsibility of the pharmacy to notify patients that may have received the medication. Chairperson Kajioka added that current requirements for recalls would remain in place. Ms. Herold added that with e-Pedigree a pharmacy will know when they received the recalled medication so they can be more strategic in what patients they contact about the recall.

Riya Cao, from LSPedia, asked what happens if the system goes down at a particular point in the supply chain. Mr. Celeste responded that there is flexibility in the system to query further up the supply chain before the system error occurred to get pedigree data on the medications. Chairperson Kajioka answered that there would need to be policies in place in advance of a system problem occurring.

VI. 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 2013 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 2013 Enforcement and E-Pedigree Meeting, draft language was released for discussion purposes to develop the regulation language for inference. A copy of this proposal was provided in the meeting materials.

Following the March meeting, the board received additional comments specific to the draft language released. These comments were 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.

Discussion

Mr. Room reported that the language had been streamlined and updated based on the following policy decisions related to Inference made at the July 2013 Board Meeting:

- 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
- The trusted trading partners requirements have been removed.
- 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.

Ms. Veale commented that she thought the board decided *not* to require the contents of a case to be immediately scanned once it is opened. It was clarified that the following motions had been made at the July 2013 Board Meeting:

Motion: Remove the requirement to immediately scan the contents of a case when it is unsealed.

M/S: Veale/No Second

Motion tabled

Motion: When a sealed case is opened its entire contents must be scanned immediately.

M/S: Lippe/Gutierrez

Support: 7

Oppose: 2 (Veale and Brooks)

Abstain: 1 (Castellblanch)

Mr. Room clarified that this is not regulation language, rather draft language being brought to the committee for vetting, and added that there will be plenty additional opportunities for the board or the public to make comments on the draft language. Ms. Herold added that this was a good opportunity to clean up the language before it entered in the formal rulemaking process.

Ms. Veale asked if the language provided in the meeting materials incorporated all the changes and comments from the July Board Meeting and asked when it was received by the public. Mr.

Room confirmed that the language contained all the changes. Ms. Herold provided that the materials were made public on Monday (September 23, 2013).

Ms. Veale commented that she thought at the July Board Meeting there has been discussion on allowing inference in circumstances other than a transaction from a manufacturer to a wholesaler. Mr. Room responded that there is nothing in the current language that specified that it is only for a manufacturer to wholesaler transaction, in fact a sealed case could move all the way through the supply chain without being opened.

Ms. Veale asked Mr. Room if at the July Board Meeting there had been discussion on extending inference to pallets. Mr. Room responded that it had been discussed but no motion had been made.

Chairperson Kajioka and Ms. Veale asked Mr. Room to review the regulation language for those who had not been at the July Board Meeting. Mr. Room provided an overview of the language and pointed out where changes had been made based on comments and motions made at the July Board Meeting.

Ms. Veale commented that she would like to change the language to allow inference to be applied to a case, pallet, or other aggregate. She also would like to see the requirement to immediately scan each item when a case is opened removed.

Ms. Wheat asked Ms. Veale if she envisioned inference being allowed if a pallet contained different items or if it would be allowed only if pallets contained homogenous items. Ms. Veale answered the pallet could contain different items.

Mr. Room commented that the committee needs to consider if it will harm the integrity of the supply chain if inference is spread too far. He added that the board has been told by the industry that the error rate of items in a case is very low, but the error rate of the cases in a non-homogeneous pallet (particularly those in the center of the pallet) it fairly high.

Ms. Veale agreed that the board needs to be careful that they are not creating the opportunity for bad players to take advantage of inference; however she had not heard that there was an increase in errors from the case to the pallet level in the pharmaceutical industry. She asked that the board seek input from industry experts.

Chairperson Kajioka expressed that he would be OK with extending inference to the pallet level as long as it was a homogenous pallet.

Mr. Brooks asked how practical it was to require that a pallet be broken down to the case level then requiring the cases to be opened and each unit scanned. Mr. Room clarified that a non-homogenous pallet would only have to be broken down to the case level, not to the unit level (each unit would have to be scanned *only* if/when the case was unsealed).

Ms. Veale commented that there was concern at the last Board Meeting over the practicality of having to scan each unit once the case is unsealed. Mr. Room confirmed that many wholesalers have expressed to the board their concern over this requirement.

Mr. Room commented that if the board decides to allow the inference of pallets, it will also have to decide if scanning the cases is enough to confirm the pallet inference was correct or if each unit in each case will have to be scanned to confirm the inference. He reminded the committee that cases and pallets are nowhere in the board's law. The law requires the verification of individual units, so in theory one interpretation would be that you can only verify individual units by scanning the individual units.

Chairperson Kajioka agreed that true product verification would only occur when each unit is scanned.

Ms. Veale asked for public testimony before the board makes any motions on allowing inference at the pallet level.

Bill Fletcher, consultant for PharmaLogic Solutions, asked if "sealed" meant manufactures would be required to use of tamper evident tape. He also asked what a "case" would be defined as. Mr. Room answered that a case is defined as a box, sealed with the manufacture's tape.

Mr. Fletcher asked to clarify that once a case is unsealed, even if it is only to inspect the contents, from that moment on each time that case moves in the supply chain its entire contents will have to be scanned. Mr. Room and Ms. Wheat confirmed.

Mr. Room provided that the Federal Bill only allows inference to sealed homogenous cases.

Riya Cao, from LSPedia, asked if inference was only needed if you were working with someone who was not a trusted trading partner. Mr. Room answered that there is no longer a trusted trading partner requirement in the language. However you are required to exchange SOPs.

Ms. Cao asked if these requirements would change a manufacture's policies to no longer ship mixed cases. Mr. Room commented that he did not feel comfortable speaking for manufacturers.

Ms. Wheat provided that the reason the board is considering inference is because the industry asked for a way to not have to scan each individual item at each step in the supply chain.

Mary Staples, from The National Association of Chain Drug Stores, expressed her frustration of not receiving notice that the meeting materials had been posted online for the public and noted that the association would need time to review the language in detail and provide comments. Mr. Room responded that there would be plenty of time for additional comments.

Ms. Staples expressed her concern that the board made policy decisions on inference from the manufacturer to the wholesaler, but as the language is written the policies on inference will be applied to the entire supply chain. As such, the association feels that the language should include inference for pallets, cases, totes or containers so that inference can be used by the entire supply chain down to the pharmacy level. Ms. Veale asked to confirm if this would include mixed cases and totes. Ms. Staples confirmed.

Ms. Veale asked Ms. Staples if The National Association of Chain Drug Stores anticipated being able to submit alternative language. Ms. Staples confirmed that they would, and added that the comment letter they previously submitted contained the case, tote, pallet language.

Chairperson Kajioka asked Ms. Staples to clarify if in her proposal individual items would be scanned before they are dispensed. Ms. Staples answered that when the totes or cases are opened in a pharmacy to stock the shelves, each unit would be scanned.

Ms. Wheat asked if Ms. Staples is proposing not scanning the individual items immediately when they are received - rather when the case/tote is unsealed. Ms. Staples noted that often a shipment is received and it cannot be opened immediately. The association is proposing when a container is received the outside of the container will be scanned immediately, and then when the seal is broken each item would be scanned.

Mr. Room noted that at the July Board Meeting the manufacturer to wholesaler transaction was handled first because the law is staggered, making them the first members of the supply chain who will need to have processes in place. Ms. Herold added that some of Ms. Staples association members have their own distribution warehouses so when it arrives at the pharmacy there is no change of ownership, therefore they don't have to scan anything. She added that they may want to so they can track inventory and recalls but there is no requirement in the law to do so.

Rob Zachow, from Bracco Therapeutics, recommended that the committee to expand the definition of a sealed homogeneous case and clarify the definition of sampling.

Bill Fletcher, consultant for PharmaLogic Solutions, asked if generic shipping tape would serve as a sufficient manufacturer seal. Chairperson Kajioka responded that the type of seal used would be left up to the trading partners in the supply chain. He added that it is in the best interest of the manufacturer to use a seal that is tamper evident.

Ruby Raley, a member of the public, provided that some cases do not contain individual sellable units, rather the case itself is the sellable unit. In her opinion the use of term "case" may be confusing and lead people to believe they need to open every case, even if there are no sellable units inside. Mr. Room responded that inference is used is when a larger container contains smaller sellable units. As in Ms. Raley's example the case is the smallest sellable unit, there is no legal requirement to open it and scan the contents. He added that if the industry feels that the use of the term case is unclear, they should submit their comments in writing.

Jim Carpenter, from Excel Inc., commented that in his opinion requiring sealed, homogenous pallets to be broken down, scanned, and re-aggregated would increase the risk of corrupting the supply chain. He added that he would like the committee to allow inference on the pallet level.

Ms. Veale asked Mr. Carpenter if in his experience he had seen more errors of the center of the pallets. Mr. Carpenter responded that it is an infrequent occurrence.

Mandy Lee, from the California Retailer's Association, asked the committee to not take a vote on anything until more comments were received by stakeholders.

Ms. Veale provided that the committee recommendation to the board should be to wait to receive more comments and to see if the federal legislation passes. Mr. Brooks added that if the federal legislation passes it would be the duty of this committee to review it and make recommendations to the board. Mr. Room added that the committee will also have to send out a notice to the public that the board has been preempted by federal legislation.

Ms. Herold provided that they will schedule time at the October Board Meeting to briefly discuss inference with the full board.

Chairperson Kajioka again asked the public to submit any comments they may have in writing.

The committee recessed for a break at 11:45 a.m. and resumed at 12:03 p.m.

VII. Discussion Concerning Possible Regulation Requirements on the Certification Process to Comply with California's E-Pedigree Law

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.

Discussion

Mr. Room provided a brief explanation of certification and reported that the language has been simplified, but still contains the requirement of a digital signature. According to Mr. Room the basic idea of this regulation is to require each party in the supply chain to certify delivery and receipt of drugs. Certification essentially means comparing the electronic pedigree received with the actual drug products received and confirming the correspondence to those two. When an entity is shipping to a subsequent trading partner they are certifying the pedigree accurately reflects the drugs they are delivering.

Mr. Room then briefly walked through each section of the regulation. Mr. Room reported that the two issues that received the most comments from the industry was the digital signature requirement and the implication that the recipient of pedigree data has some responsibility to confirm that they have received a complete pedigree change of ownership.

Mary Staples, from The National Association of Chain Drug Stores, commented that this language is much improved from the last version.

Ms. Veale asked if Ms. Staples had any concern about the requirement to confirm that there is nothing suspicious when a shipment is received. Ms. Staples responded that this area has been improved from the previous draft and added that she will be sharing the new language with the association and preparing written comments.

Rob Zachow, from Bracco Diagnostics, recommended that the language be changed to say "responsible party" as the person certifying may leave the company. Mr. Room responded that many comments were received with possible definitions for responsible party and it is being taken into consideration.

Chairperson Kajioka asked the public to submit comments on certification so that the topic could be discussed in more detail at the December Committee Meeting.

VIII. General Discussion

No comments from the committee or from the public.

IX. Closing Comments

Chairperson Kajioka thanked the committee and the public for the work they have done on e-Pedigree to ensure the safety of consumers. He added that the federal government is watching California so the input provided to the committee is being considered in the federal legislation.

X. Public Comment on Items Not on the Agenda/Agenda Items For Future Meetings

No comments from the committee or from the public.

ADJOURNMENT

12: 14 p.m.