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STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

Enforcement Committee Meeting

Workgroup on E-Pedigree
March 16, 2006

9:30 a.m. – 3:30 p.m.
Red Lion Hotel
1401 Arden Way
Sacramento, CA 95815
(916) 649-4728

MEETING MATERIALS

1. Presentation on California's Requirements for an Electronic Prescription Drug Pedigree
   Judi Nurse, Supervising Inspector – Board of Pharmacy **(Attachment A)**

2. Presentation on the Status of ePedigree and Radio Frequency Identification (RFID) Standards
   Mike Rose (Johnson & Johnson) and Ron Bone (McKesson), Co-Chairs
   of EPCglobal Healthcare and Life Sciences Business Action Group **(Attachment B)**

3. E-Pedigree Pilot Programs

   "Viagra RFID Pilot Program"
   Presentation by Walt Slijepcevich, Director of Pharmacy Development, Pfizer

   "Use of RFID"
   Presentation by Bob Dufour R.Ph., Director of Pharmacy, Professional Services and Government Relations, Wal-Mart Stores, Inc.

4. Implementation of E-Pedigree – Questions and Answers

   For the Enforcement Committee meeting in December 2005, a question and answer document was prepared and provided to all interested parties. Based on the discussions at that meeting as well as additional questions that were submitted, the document was revised. Questions with a shaded background identify those questions that are new or have been revised from the original December document. This document is also marked "draft" because it is a work in process and is intended for discussion purposes as the Board of Pharmacy is seeking input from all stakeholders. **(Attachment C)**

5. Implementation Date – January 1, 2007

Business and Professions Code § 4034 and 4163 become operative on January 1, 2007, and as of that date prohibit any wholesale sales, trades, or transfers of prescription drugs, or any acquisitions of prescription drugs, absent a pedigree recording and accompanying the transaction. Pursuant to Sections 4163.5 and 4163.6, this prohibition and/or the requirement of a pedigree may be delayed by the Board of Pharmacy until January 1, 2008, upon a demonstration of need by the industry, and the by the Legislature (for pharmacies) until January 1, 2009.

The law as enacted does not contemplate a phased implementation, or application only to particular drugs.

The board has received requests for delay in implementation. At the September 2005 Enforcement Committee meeting, Lew Kontnik, Director of Brand Protection/Business Continuity for Amgen demonstrated the challenges that Amgen has encountered in developing an electronic pedigree and the implementation of RFID to track its liquid products. At the conclusion of the presentation, Mr. Kontnik stated that it his company's position that it will be extremely difficult to meet the January 1, 2007 deadline.

The Board of Pharmacy is seeking input and requests from all stakeholders regarding the implementation date. **(Attachment D)**

ATTACHMENT A

California Prescription Drug Pedigree

3/8/2006 1

Pedigree - Overview

- 2004 legislation passed
- 1/1/2005 legislation enacted and some sections implemented
- 1/1/2007 pedigree implementation

3/8/2006 2

Pedigree Overview (cont)

- CA Board of Pharmacy may delay implementation of pedigree requirement until 1/1/08
- CA legislature may delay implementation of pharmacy pedigree requirement until 1/1/09

3/8/2006 3

Pedigree Definition

- Electronic record, containing information regarding each transaction resulting in a change of ownership of a prescription drug, from sale by manufacturer, through acquisition and sale by a wholesaler, until final sale to a pharmacy or person furnishing, administering or dispensing the prescription drug

3/8/2006 4

Electronic Pedigree Requirements

- Prescription Drug information
- Transaction & Source information
- Ownership information
- Certification

3/8/2006 5

Prescription Drug Information

- Drug name
- Dosage form
- Strength
- Container size
- Number of containers
- Expiration date
- Lot numbers

3/8/2006 6

Transaction & Source Information

- Source of prescription drug (prior owner)
  - Business name
  - State license number, including CA license if required
  - Principal address of source
- Sales invoice number for transaction
- Date of transaction

3/8/2006 7

Ownership Information

- For each prior owner of the drug the pedigree must contain
  - Prescription drug information
  - Source information
  - Transaction information
  - Name and address of each person certifying delivery or receipt of prescription drug

3/8/2006 8

Pedigree Certification

- A certification under penalty of perjury from a responsible party of the source of the dangerous drugs that the information contained in the pedigree is true and accurate

3/8/2006 9

Related Legislation

- All wholesale distributors selling into or located in CA must be licensed in CA (effective 1/1/05)
- Surety bond required for all licensed wholesale distributors (effective 1/1/06)
- Restrictions on pharmacy furnishing, manufacturers and wholesale distributors (effective 1/1/05)
- Wholesale or pharmacy may not purchase, sell, trade or transfer without receiving or issuing a pedigree (effective 1/1/07)

3/8/2006 10

Pharmacy Furnishing Restrictions

- Pharmacy may only furnish prescription drugs to:
  - Wholesaler/manufacturer from whom drugs acquired
  - Licensed wholesale reverse distributor
  - Pharmacy or wholesale in sufficient quantity to alleviate a specific shortage

3/8/2006 11

Pharmacy Furnishing Requirements (cont)

- Patient or pharmacy pursuant to a prescription
- Health care provider authorized to purchase prescription drugs
- Pharmacy under common control

3/8/2006 12

Manufacturer/Wholesale Distributor Restrictions

- Furnish prescription drugs only to licensed business or prescriber
- Acquire prescription drugs only from a manufacturer or licensed wholesaler
- Effective 1/1/07 a wholesaler or pharmacy may not sell trade or transfer a dangerous drug without a pedigree

3/8/2006 13

ATTACHMENT B

FOR IMMEDIATE RELEASE

For More Information Contact:
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EPC Value Model for Healthcare Lets Pharmaceutical Manufacturers Analyze the Value of EPC-based RFID Implementations

Stanford, Eindhoven universities develop online tool that lets pharmaceutical makers quantify value based on unique business characteristics

LAWRENCEVILLE, New Jersey – Oct. 25, 2005 – EPCglobal US, a not-for-profit-standards organization, today announced the release of the EPC Value Model for the pharmaceutical industry. This work was done in partnership with the Stanford University Global Supply Chain Forum and Eindhoven University in the Netherlands, and gives pharmaceutical manufacturers insight into the costs and benefits of employing Electronic Product Code (EPC) technology to automatically track goods in the supply chain anywhere in the world.

The Value Model is included in a comprehensive white paper released today called *Assessing the Value of EPC/RFID in the Pharmaceutical Industry*. Both the model and the report provide detailed qualitative analysis of the main business drivers for adopting EPC technology and the potential resulting impact.

"Pharmaceutical manufacturers are working with EPCglobal as part of their strategy to ensure a safe and secure supply chain," said Mike Meranda, president of EPCglobal US. "Several states and the federal government have either regulated or suggested the need to secure this vital supply chain. EPC technologies offer an ideal way to meet this challenge," Meranda said. "We look forward to helping to advance this vital effort."

The Value Model is designed to provide companies with specific projections based on the real-world variables they input themselves. Researchers built it after exhaustive interviews with seven of the world's largest pharmaceutical manufacturers and three wholesalers. When polled, each identified counterfeiting, product diversion and reconciliation as the three major business issues that could be most effectively addressed with EPC/RFID, in addition to out-of-stocks and shrinkage.

-more-

The World Health Organization estimates that as much as 5 percent to 10 percent of the world's pharmaceuticals are counterfeit, with about 25 percent counterfeit in Third World Countries.

In the white paper and Value Model, which are available to EPCglobal US subscribers at www.epcglobalus.org, companies will see estimates of the expected benefits (as measured in the reduction of counterfeiting, product diversion, and in reconciliation, among other benchmarks), as well as the expected costs of implementing EPC-based RFID over five years. The Value Model will even estimate an expected payback period, and a five-year discounted net present value of the RFID implementation process. This analysis is crucial for developing an internal business case for deploying EPC technologies.

About EPCglobal US
EPCglobal US™ is a subsidiary of GS1 US (formerly the Uniform Code Council) serving subscribers in the United States to help foster the adoption of the EPCglobal Network and related technology. The EPCglobal Network combines radio frequency identification (RFID) technology, existing communications network infrastructure, the Electronic Product Code™ (a number for uniquely identifying an item) to enable accurate, cost-efficient visibility of information in the supply chain. The end result helps organizations be more efficient, flexible, and responsive to customer needs. For more information about EPCglobal US, please visit www.EPCglobalUS.org.

# # #

Drug Pedigree Messaging Interface JWG Requirements Document

Working Draft Version 1 as of 05th February 2006

This version:

http://...

Latest version:

http://...

Previous versions:

http://...

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Status of this document

This section describes the status of this document at the time of its publication. Other documents may supersede this document. The latest status of this document series is maintained at the EPCglobal. This document is the first public working draft.

This is an EPCglobal Working Draft for review by EPCglobal Members and other interested parties. It is a draft document and may be updated, replaced or made obsolete by other documents at any time. It is inappropriate to use EPCglobal Working Drafts as reference material or to cite them as other than "work in progress". This is work in progress and does not imply endorsement by the EPCglobal membership.

Comments on this document should be sent to the EPCglobal JWG mailing list drugpedigreemessagingjrg@epclinklist.epcglobalinc.org .

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Table of Contents

1 Introduction 4
2 Overview 5
3 Utilization of ePedigree in the Supply Chain 6
4 Intersection with EPCIS 7
4.1 The Role of EPCIS in ePedigree document distribution 7
4.2 EPCIS as a source of master data 8
4.3 Augmentation of EPC events with ePedigree reference 8
4.4 Kill Code Management 8
5 Support for Alternate ePedigree Formats 9
6 ePedigree Data Definition 9
6.1 Electronic Pedigree Format 9
6.1.1 Forms for Specific Business Situations 10
6.1.2 XML Elements 15
6.2 Pedigree Envelope Format 49
6.2.1 Forms for Specific Business Situations 49
6.2.2 XML Elements 49
7 ePedigree Implementation Requirements/Rationale 56
8 XML Schema Implementation 57
9 Usage Guidelines 57
9.1.1 Usage Guidelines for Creating and Appending Information to Pedigrees 57
9.1.2 Usage Guidelines for Creating Pedigree Envelopes 65
10 Recommendations to EPCglobal 67
11 References 68
12 APPENDIX A – Summary of Pedigree Data Elements 69
13 APPENDIX B – Electronic Pedigree XSD 72
14 APPENDIX C – Pedigree Envelope XSD 77

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1 Introduction

This document and its associated attachments are the final deliverables of the EPCGlobal Drug Pedigree Messaging Joint Work Group (JWG) to be delivered to the EPCGlobal Software Action Group (SAG). This group's charter was to create the technical requirements for a software application programming interface (API), associated data specifications, and security mechanisms, through which various clients may capture, secure, and access Drug Pedigree data via the EPCIS interface. Due to fast approaching deadlines from state and federal regulatory bodies it was necessary for this group to work on an accelerated schedule.

The primary result of this effort is an XML Schema that the team believes is suitable for defining a standard electronic pedigree format that can be used in all states with existing drug pedigree laws. The great benefit of this schema is that it will provide standardization between supply chain partners for the exchange and extensibility of electronic pedigrees as they pass down the supply chain.

Enough flexibility was built into the schema to allow for multiple interpretations of the existing and possible future, state, federal and even international laws. Even so, a version mechanism is included to allow for changes that may be necessary as the result of future laws.

Interpretation of and compliance with the various pedigree laws is left entirely up to the user. That is, *use of this schema will not guarantee compliance with the laws*. On the other hand, the team believes that all of the necessary ingredients are present to enable the users to comply with those laws.

Electronic pedigree documents created using this schema and applied as intended will become *legal documents*. Their contents are tightly regulated by law and the digital signatures applied are legally binding with severe penalties imposable for fraud. For this reason the members of the work group felt that it was inappropriate to add data elements to the main pedigree schema that were not directly related to existing or anticipated pedigree laws. The inclusion of purely supply chain related information was rejected and is expected to be more appropriately held in the EPC-IS directly.

In compliance with the Florida pedigree law, the digital signatures defined in the proposed schema comply with several of the FIPS (Federal Information Processing Standards). The use of FIPS for the digital signatures qualifies them as legally binding signatures just as if an individual had signed a paper legal document with pen in hand. There is an important distinction between digital signatures used to encrypt a document simply to keep it private, and the signatures in an electronic pedigree document, where the signature is used to legally bind an individual or company to the contents of the document. The reader is cautioned to keep this distinction in mind.

Five software vendors contributed intellectual property (IP) and technical resources to EPCGlobal for this effort: Cognizant, Cyclone Commerce, Raining Data, SupplyScape and Verisign. These contributions have had a significant positive impact on the quality and the speed of the team's work. The team would like to thank these vendors for their contributions and their assistance.

2 Overview

Although the FDA believes domestic counterfeiting of pharmaceutical products is not widespread, regulators have witnessed an increase in the number of pharmaceutical counterfeiting activities. In an attempt to help ensure only authentic pharmaceutical products are distributed through the supply chain, some regulatory agencies have implemented or are considering provisions requiring a "pedigree" for drug products.

A pedigree is a certified record that contains information about each distribution of a prescription drug. It records the sale of an item by a pharmaceutical manufacturer, any acquisitions and sales by wholesalers or repackagers, and final sale to a pharmacy or other entity administering or dispensing the drug. The pedigree contains product information, transaction information, distributor information, recipient information, and signatures.

At this time the specific pedigree requirements vary by state. Some states require the manufacturer to initiate the pedigree, while other states do not. In states where the manufacturer is not required to provide pedigrees, the first wholesaler or repackager is responsible for creating the pedigrees for the items acquired directly from the manufacturer. Some states allow paper pedigrees or electronic pedigrees, other states require electronic pedigrees.

Compliance with state pedigree laws is mandatory and failure to comply could result in administrative fines, revocation of license and/or criminal prosecution. A pedigree received by or provided by an organization is a document of record for that organization and is subject to regulatory recordkeeping, record retention, and record availability requirements. The state of Florida is the viewed as the first state to require pedigrees for all pharmaceutical products regardless of their source and the path they follow through the supply chain. The effective date of the Florida pedigree legislation is July 1, 2006.

Each party engaged in the wholesale distribution of prescription drugs is required to provide pedigrees to the recipients of those drugs. A pedigree contains a signed certification from the originating party that the product is authentic. The recipient must authenticate each previous transaction in the pedigree and add their own certification of receipt and authentication to the pedigree.

A high level, simplified pedigree process would be similar to the following:

- Create pedigree
- Add information to pedigree
- Certify (digitally sign) pedigree
- Send pedigrees for products in shipment to customer
- Receive pedigrees
- Electronically authenticate pedigrees
- Manually authenticate transactions that were not electronic
- Verify products received against authenticated pedigrees
- Certify (digitally sign) pedigree for receipt and authentication

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3 Utilization of ePedigree in the Supply Chain

The following is an inventory of actions (use cases) where a Pedigree would be utilized in the pharmaceutical supply chain.

- Creation of pedigrees by a manufacturer before the first wholesale distribution
- Creation of pedigrees by the first wholesaler, including the transaction information for the first wholesale distribution
- Creation of pedigrees by repackagers for repackaged items that include pedigree information from source items
- Adding outbound transaction information to pedigrees as part of a sales, transfer or return transaction
- Adding certification (signature) to pedigrees, signing the transaction information added, and all prior content
- Adding item serial number to pedigrees (if a wholesaler serializes a non-serialized item)
- Adding manual authentication information (for example, invoice, shipping document) to pedigrees to facilitate downstream manual authentication
- Adding receipt information and recipient signature to pedigrees, signing this information and all prior content
- Creating a pedigree for an individual item
- Creating a pedigree for a repackaged item, and including pedigree information for one or more "parent" items
- Creating a pedigree for an item that has a unique serial number
- Creating a pedigree for an item that does not have a serial number
- Creating a "singular" pedigree for each saleable item
- Creating an "aggregate" pedigree for a collection of saleable items that share the same product information (NDC and multiple lots) and prior chain of custody
- Creating an electronic pedigree from a paper pedigree or alternate form, and embedding a copy of the original pedigree in the electronic format
- Including "attachments" to a pedigree, such as scanned and EDI representations of invoices or shipping documents to satisfy regulatory manual authentication requirements
- Accommodating additional data elements in an extensible manner as regulatory requirements evolve
- Displaying all pedigree regulatory information in the pedigree (for example, drug product information, distributor information, recipient information, transaction information, receiving information, digital signatures)

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- Representation of pedigrees in a portable format that can be transmitted electronically or via media
- Including container information (for example, relationship of products to cases) in addition to the pedigrees in the pedigree envelope
- Exchange of pedigrees between trading partners using existing business data transfer mechanisms (for example, EDIINT AS2)
- Exchange using a peer-to-peer model
- Electronic verification of each prior signature on the pedigree
- Electronic verification that the original, previously-signed content of the pedigree was unchanged since it was signed
- Attaching copies of manual authentication documents (for example, invoice, shipping document) with an electronic pedigree to facilitate 'self-authenticating' pedigrees
- Creating an "electronic envelope" for transmitting a collection of pedigrees associated with an outbound customer shipment
- Including key routing and identifying information in the "electronic envelope" (for example, shipment identifier, shipment date, originating trading partner, recipient trading partner) to facilitate system-to-system interaction
- Including optional aggregation (for example, association of products to cases) in addition to pedigree information in the transmission envelope

4 Intersection with EPCIS

This working group sees a collection of opportunities for appropriate intersection of EPCIS and the creation and distribution of ePedigree information. Some of these are tightly coupled, others are more loosely coupled.

4.1 The Role of EPCIS in ePedigree document distribution

One can imagine a day when all of the components of an ePedigree are distributed across the network and single query is issued that collects those components into a complete ePedigree document for validation. However, *this vision is inconsistent with the legislation as it stands today.* States are looking at an ePedigree as a complete electronic legal document directly containing and signing over pedigree documents created earlier in the chain.

As such, the model for the distribution of ePedigree documents will be the direct transfer of an entire ePedigree document from one trading partner to another. This group believes that there are a several mechanisms which are likely to be utilized for this transfer. Certainly many existing b2b systems could be augmented to include the ePedigree document. Even mechanisms like FTP or email could be utilized for this exchange.

The group believes that EPCIS could also be used for the transfer of an ePedigree from one trading partner to another if the EPCIS model can meet the following requirements:

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- The ePedigree must be able to be captured and delivered as a single immutable document.
- The transfer of ePedigree documents must be able to conform to a push based transfer. (Subscription based queries may suffice).
- The transfer should occur via secure and authenticated mechanisms.
- The transfer must meet the expectation of Non-Repudiation.

4.2 EPCIS as a source of master data

In certain states the initial pedigree may be created by the wholesaler as opposed to the manufacturer. In the creation of this initial pedigree the wholesaler may require certain meta data about the products in process in order to create that pedigree. For instance the wholesaler may be trying to populate the expiration date element of their pedigree for a particular item. If this information were also stored in the manufacturer EPCIS then the wholesaler could query that EPCIS in order to retrieve and populate the pedigree with that information.

4.3 Augmentation of EPC events with ePedigree reference

At several points in the lifecycle of a product, a pedigree will be created or updated for a particular item. As EPCIS is designed to capture many of the events in the lifecycle of a product, this seems like a logical one. This may be immediately achievable by simply creating an Observe event with a BusinessStep of "Pedigree Creation", or "Pedigree Update" and utilizing the BusinessTransaction to capture the unique identifier of the Pedigree.

The key requirement is that when given an EPC one could utilize EPCIS to determine the ePedigree document(s) actually associated to that item.

This may be utilized in multiple ways. One party may supply another with a set of ePedigree documents and then a set of products. The later party may want a fast method of associating each pedigree doc to the appropriate product without having to parse the pedigree itself.

As well, this information becomes an interesting augmentation of the Track and Trace lifecycle that can be exposed via EPCIS. In fact at any point in the chain one could actually compare the ePedigree document's representation of the history of a product to the history of that product in EPCIS. A successful comparison can lead to even stronger assuredness that one is dealing with a valid product.

The group is unclear as to whether EPCIS could be utilized as described above in cases where we are not utilizing EPCs to identify products.

4.4 Kill Code Management

This group had conversations about including Kill Codes inside of the Pedigrees as a mechanism for distributing Kill Codes to Retailers and others at the end of the chain. We abandoned this concept based on our confidence that other systems, such as EPCIS, could be more appropriately utilized for an authorized downstream partner to access the kill codes of the product in their inventory.

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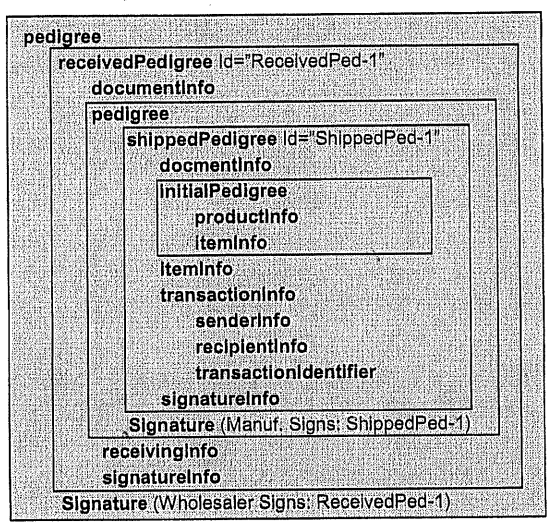
5 Support for Alternate ePedigree Formats

Current legislation in multiple states dictates the creation and updating of electronic pedigrees at each stop in the pharmaceutical supply chain. Each state law specifies the data content of the electronic pedigree and the digital signature standards but none of them specifies the actual format of the document. The need for a standard electronic document format that can be updated by each supply chain participant is what has driven our efforts. However, there is recognition that not all members of the pharmaceutical supply chain will adopt the XML Schema that is proposed in this document. Toward that end, the schema includes elements that allow the attachment of other document types as MIME documents. This could include scanned images, PDF documents or X.12 documents. Electronic pedigree documents stored in some structured alternate formats will require specialized software to allow them to be auto-authenticated. Some formats, such as PDF's and scanned images, will always require manual authentication.

6 ePedigree Data Definition

6.1 Electronic Pedigree Format

The basic components of a pedigree are shown in the following figure. The components in an actual pedigree depend on the specific business situation in which it is used (e.g., pedigree initiated by manufacturer, pedigree initiated by wholesaler, pedigree for repackaged item, etc.).



As each transaction occurs, the preexisting pedigree for an item is wrapped inside one of the `LayerType` elements of the `Pedigree` element. These successive layers represent the entire chain of ownership and the product description.

ATTACHMENT C

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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

DRAFT

PRESCIPTION DRUG PEDIGREE

March 2006

Introduction
In 2004, the California State Board of Pharmacy sponsored legislation that made comprehensive changes to the wholesale distribution system to protect against counterfeit drugs.

The Center for Medicines in the Public Interest projects that the number of counterfeit drug sales will reach $75 billion by 2010, a 92 per cent increase from 2005. The board's statutes require the development of a "pedigree" that tracks each prescription drug through the distribution system beginning January 1, 2007. The statutes also require licensure of out-of-state wholesalers, the posting of a $100,000 surety bond (or equivalent security), and authorize the board to embargo drugs when the board suspects drugs are adulterated or counterfeit.

The following are questions that the Board of Pharmacy has received regarding the implementation of the pedigree requirement and proposed answers.

QUESTIONS AND ANSWERS

General Questions

Q1 What is a pedigree?

A pedigree is an electronic record containing information regarding each transaction resulting in a change of ownership of a prescription drug (dangerous drug) from the sale by the manufacturer through each acquisition and sale of the drug until the final sale to a pharmacy or prescriber who will furnish, administer or dispense the prescription drug to a patient. (B & P § 4034(a))

Q1.1 Is the pharmacy required to track the pedigree to the patient?

The pedigree ends with the pharmacy or other entity (person) that dispenses, administers or furnishes the prescription drug. Thus, it is not required that the pedigree record the transaction between the pharmacy and the patient.

Q2 What are the requirements for a pedigree in California?

Source of the Prescription Drugs
At each stage or link in the distribution chain down to the end user, a pedigree must contain information on each source/prior owner of the prescription drug. Information regarding the source will include the manufacturer, wholesaler and in some instances, the pharmacy from which the prescription drug was acquired and/or through whose ownership the prescription drug passed. It is any entity that is selling, trading or transferring the prescription drug. The pedigree must include each source's name and principal address and California license number if available.

Prescription Drugs and Transaction Information
The pedigree shall include the name of the prescription drug, its quantity, its dosage form and strength, the date of each transaction in its distribution to that point, the sales invoice number(s) associated with each such transaction, the container size(s) for each transaction, the number of containers for each transaction, the expiration dates and the lot number(s).

Prescription Drug Ownership Information
The business name, address, and if appropriate, the state license number, including a California license number if available, of each owner of the prescription drug, and the prescription drug shipping information, including the name and address, of each person certifying to delivery and receipt of the prescription drug.

A California license is required to authorize an entity to possess, acquire, sell or transfer prescription drugs in California.

Certification of Transaction Authenticity
A certification under penalty of perjury from a responsible party of the source of the prescription drug that the information contained in the pedigree is true and accurate. (B & P § 4034(b))

Q2.1 Does the law require that the NDC number be included in the pedigree?

Section 4034 does not require the NDC number as part of the pedigree, nor does it prohibit inclusion thereof along with the required pedigree data.

Q2.2 Please clarify "California license number."

Section 4034, subparts (b)(1) and (b)(3), specify that the pedigree shall include, for the source of the prescription drug and each owner thereof, a California license number if available.

Q2.3 Can the person who authenticates receipt of the prescription drug be an agent of the manufacturer, wholesaler or pharmacy?

The person certifying the authenticity of the pedigree must be a "responsible party," i.e., an individual authorized to act on behalf of the entity selling or receiving the prescription drug, and whose attestation/signature may bind the entity.

Q3 When does the pedigree requirement become effective? (B & P § 4034(e))

The pedigree requirement becomes effective January 1, 2007.

Q4 What types of drugs require a pedigree?

All prescription drugs (dangerous drugs), including controlled substances, require a pedigree.

Q5 Does prescription drugs include prescription drugs for animals?

The definition of "dangerous drug" means any drug unsafe for self-use in humans or animals and includes any drug bearing the legend: "Caution: federal law prohibits the dispensing without prescription, "Rx only," or words of similar import. (B & P § 4022)

Q6 When is a pedigree required?

Beginning January 1, 2007, a California licensed wholesaler or pharmacy may not acquire a prescription drug (dangerous drug) without a pedigree. A California licensed wholesaler or pharmacy also may not sell, trade or transfer a prescription drug at wholesale without providing a pedigree.

Q7 Who creates or starts a pedigree?

The pedigree must reflect every change of ownership of the prescription drug beginning with sale by a manufacturer. The manufacturer initiates the pedigree.

Q8 When does the required information need to be recorded on the pedigree? When there is movement of the prescription drug or a change of ownership of the prescription drug?

Any change of ownership of the prescription drug requires documentation of the transaction information on the pedigree.

Q8.1 What does "change of ownership" mean?

Section 4034 defines the required pedigree to be an electronic record containing, among other things, information regarding each transaction resulting in a change of ownership of a given prescription drug. "Change of ownership" is not given to specific meaning by the statute that would depart from the generally understood meaning thereof, and shall be determined on a case-by-case basis according to that generally understood meaning. Change of ownership may or may

not always coincide with a change in possession. Possession is a strong indication of ownership, so the presumption is that change in possession is an indicator of change of ownership. However, this is not a conclusive presumption, and it may be appropriately rebutted.

Q 9 When are additional entries made on the pedigree?

Each time that the ownership of the prescription drug changes, the required transaction information must be recorded on the pedigree. The responsible party of the source who is selling, trading or transferring the prescription drug must certify that the pedigree is true and accurate and thereby authenticate the transaction information.

Q10 What types of "change of ownership" transactions require documentation on the pedigree?

While not a comprehensive list, the following transactions may require documentation on the pedigree if a change of ownership has occurred:

- Any sale, trade, or transfer of prescription drugs between a manufacturer and wholesaler
- Any wholesale sale to a pharmacy, other wholesaler, clinic or prescriber (This would include "wholesale brokering" where the wholesaler doesn't take possession of the prescription drug but makes arrangements for the delivery of the prescription drug and processes the paperwork.)
- Drop ship deliveries for a manufacturer, wholesaler or pharmacy
- Consignment transactions
- Third party logistics transactions
- Pharmacy sales to another pharmacy as authorized by B&P § 4126.5
- Pharmacy returns to the wholesaler or manufacturer from whom the prescription drugs were originally purchased
- Pharmacy sales to a prescriber or other licensed entities authorized to receive drugs
- Pharmacy or wholesale transfers to a reverse distributor.

In this sample question and answer (and others following), the board has provided examples of transactions that do or may constitute a "change of ownership." This is neither a comprehensive list nor does the inclusion of a transaction type on the board's list mean that in every case such a transaction creates or constitutes a "change of ownership." Except where the board is aware that certain transfers of possession do not constitute changes in ownership, the board begins with the presumption that change in possession indicates a change in ownership. But that is not always the case and that presumption can be rebutted. What is significant is not whether a transaction fits a type identified by the board as presumably constituting a "change of ownership," but whether an actual change of ownership has occurred.

While a particular transfer/transaction may not need to be recorded on the pedigree, the record-keeping requirement for acquisitions and dispositions is separate from and additional to the

pedigree requirement. The transferring entity must still provide the pedigree (recording the transactions to that point) to the transferee, and the transferee (and/or the first entity) must still provide that pedigree to any subsequent transferee.

Q10.1 What is a third party logistics provider and why is it included? How is a third party logistics provider different from a common carrier?

The board's working definition of a third party logistics provider is a provider that stores the prescription drugs and then delivers the drugs at some time in the future at the direction of the manufacturer. A common carrier takes possession of prescription drugs for however long it takes to deliver the prescription drugs to their destination (e.g. UPS ground, or next day air, yellow freight, or federal express.) A common carrier is not licensed in California; however, a third party logistic provider is licensed as a wholesaler because they store prescription drugs. In addition, a third party logistics provider could commonly receive 10 cases of a particular prescription drug and may deliver either a case, or an individual manufacturer's container to a pharmacy. A common carrier does not manipulate the product in any way; they just deliver it.

Q11 What transactions are not required to be recorded on the pedigree?

The following transactions do not require a pedigree entry:

- Any transfer of a prescription drug between individuals or entities that does not constitute or result in a change of ownership of the prescription drug.
- Any transaction of dangerous devices
- Any transaction of non-prescription drugs (over-the-counter drugs)
- Prescription drugs provided as a part of a manufacturer's patient assistance program, i.e., where the prescriber requests the prescription drugs from a drug manufacturer and the prescription drugs are delivered to the prescriber by the manufacturer, to be dispensed to the prescriber's patient
- Complimentary prescription drug samples ordered by a prescriber from a manufacturer and delivered to the prescriber for future dispensing to a patient at no charge

The pedigree is considered part of the records of acquisition and/or disposition of any prescription drug that are required to be maintained and immediately retrievable for inspection (e.g. per Section 4081 and 4105) wherever the prescription drug may travel or be stored. If a particular transfer of possession does not result in a transfer of ownership, it may not need to be recorded on the pedigree. However, it will still be necessary for the pedigree to transfer to any entity (person) taking possession, for record-keeping purposes.

Q11.1 Do prescription drug samples provided to a wholesaler from a manufacturer require a pedigree?

A drug sample is a prescription drug. A wholesaler may not acquire a drug sample (prescription drug) without receiving a pedigree. There is no exemption for acquisitions by wholesalers that

are complimentary or otherwise not purchases, and this transaction would be a change of ownership requiring documentation on the pedigree.

This is different from direct acquisition by a prescriber from a manufacturer where no pedigree is required by statute.

Q12 What other types of transactions are not considered a change of ownership and therefore would not require documentation on the pedigree?

Prescription drugs distributed or transferred between, within or among a licensed health care services plan, a hospital organization, and one or more physicians organizations having an exclusive contractual relationships to provide health care services, are not deemed to have changed ownership. (B&P § 4034(c))

The pedigree is considered part of the records of acquisition and/or disposition of any prescription drug that are required to be maintained and immediately retrievable for inspection (e.g. per Section 4081 and 4105) wherever the prescription drug may travel or be stored. If a particular transfer of possession does not result in a transfer of ownership, it may not need to be recorded on the pedigree. However, it will still be necessary for the pedigree to transfer to any entity (person) taking possession, for record-keeping purposes.

Q12.1 Who is responsible for the record-keeping requirement for the pedigree if the prescription drug is transferred to another entity (person) and the transaction does not constitute a change of ownership of the prescription drug?

The pedigree is considered part of the records of acquisition and/or disposition of any prescription drug that are required to be maintained and immediately retrievable for inspection (e.g. per Section 4081 and 4105) wherever the prescription drug may travel or be stored. If a particular transfer of possession does not result in a transfer of ownership, it may not need to be recorded on the pedigree. However, it will still be necessary for the pedigree to transfer to any entity (person) taking possession, for record-keeping purposes.

Q 13 When does the pedigree need to be verified and authenticated?

The pedigree needs to be verified and authenticated when any recipient in the chain of distribution (e.g., wholesaler, pharmacy, prescriber) receives the prescription drug and the pedigree.

Manufacturer/Wholesaler Questions

Q1 Where in the supply chain does the pedigree start?

The pedigree starts at the manufacturer.

Q2 Does a wholesaler or pharmacy have to use the pedigree it receives or can it create a different pedigree?

A wholesaler or pharmacy must use the pedigree in the form that it is received. The wholesaler or pharmacy cannot create a different pedigree.

Q3 If a pharmacy returns prescription drugs to the manufacturer or wholesaler from which the prescription drugs were purchased, does this transaction need to be recorded on the pedigree? If the prescription drugs are sold to a pharmacy and the pharmacy returns the prescription drugs within 7 days, is that transaction exempt from documentation on the pedigree?

Any returns to a manufacturer or wholesaler, or any other change of ownership, requires documentation on the pedigree. There is no exemption from the pedigree for prescription drugs that are returned within 7 days. All prescription drug returns require a pedigree. Returns to the manufacturer or wholesaler must be in accordance with B & P § 4126.5.

Q4 Do wholesalers who only broker prescription drugs have to receive a pedigree when making arrangements for shipment of prescription drugs, and do wholesalers in such transaction have to provide a pedigree when the prescription drugs are sold?

Yes, a wholesaler who brokers prescription drugs must receive a pedigree and provide a pedigree to the individual or entity receiving the prescription drugs.

The pedigree is considered part of the records of acquisition and/or disposition of any prescription drug that are required to be maintained and immediately retrievable for inspection (e.g. per Section 4081 and 4105) wherever the prescription drug may travel or be stored. If a particular transfer of possession does not result in a transfer of ownership, it may not need to be recorded on the pedigree. However, it will still be necessary for the pedigree to transfer to any entity (person) taking possession, for record-keeping purposes.

Q5 Would a third party logistics provider that receives a prescription drug from the manufacturer and ships the prescription drug to the wholesaler be considered a manufacturer and therefore be required to start the pedigree?

The manufacturer is required to start the pedigree. If the manufacturer ships the prescription drug to a third party logistics provider, that third party provider must be licensed as a wholesaler and

the transaction must be recorded on the pedigree that started with the manufacturer if there is a change of ownership of the prescription drug.

Each licensed wholesaler that receives the prescription drug and ships the prescription drug would be required to be on the pedigree if the prescription drug changes ownership.

The pedigree is considered part of the records of acquisition and/or disposition of any prescription drug that are required to be maintained and immediately retrievable for inspection (e.g. per Section 4081 and 4105) wherever the prescription drug may travel or be stored. If a particular transfer of possession does not result in a transfer of ownership, it may not need to be recorded on the pedigree. However, it will still be necessary for the pedigree to transfer to any entity (person) taking possession, for record-keeping purposes.

Q6 Do wholesalers who only store and ship consigned prescription drugs have to receive a pedigree when they receive the prescription drugs? Would a pedigree be required when the prescription drugs are distributed?

Yes, wholesalers who receive consigned prescription drugs and then deliver the prescriptions drugs upon request of the consignor must receive a pedigree upon receipt of the prescription drugs and must issue a pedigree to the individual or entity to whom or which the prescription drugs are delivered.

Another example is where a manufacturer or wholesaler owns the prescription drugs, but the prescription drugs reside at another licensed wholesale facility and are billed by the original manufacturer or wholesaler at the time of sale, while they are delivered by the wholesaler storing the prescription drugs. A pedigree would be required that documents each change of ownership, including the transaction from the manufacturer to the wholesaler where the prescription drugs reside, as well as the subsequent sale and delivery.

The pedigree is considered part of the records of acquisition and/or disposition of any prescription drug that are required to be maintained and immediately retrievable for inspection (e.g. per Section 4081 and 4105) wherever the prescription drug may travel or be stored. If a particular transfer of possession does not result in a transfer of ownership, it may not need to be recorded on the pedigree. However, it will still be necessary for the pedigree to transfer to any entity (person) taking possession, for record-keeping purposes.

Q7 Do manufacturers or wholesalers who have another wholesaler drop ship a prescription drug have to receive a pedigree when arranging for the drop shipment and issue a pedigree when distributing the prescription drug?

Yes, a drop shipment requires a pedigree entry if there is a change of ownership of the prescription drug.

The pedigree is considered part of the records of acquisition and/or disposition of any prescription drug that are required to be maintained and immediately retrievable for inspection (e.g. per Section 4081 and 4105) wherever the prescription drug may travel or be stored. If a particular transfer of possession does not result in a transfer of ownership, it may not need to be recorded on the pedigree. However, it will still be necessary for the pedigree to transfer to any entity (person) taking possession, for record-keeping purposes.

Q8 What does a wholesaler do with prescription drugs in their possession on January 1, 2007 that do not have a pedigree?

A licensed wholesaler may create a pedigree with the wholesaler listed as the original creator of the pedigree only for those prescription drugs in its possession on January 1, 2007. The wholesaler (creating the pedigree) should retain purchase invoices or other documentation confirming the date of purchase and receipt of any prescription drugs in its possession before January 1, 2007 for which a pedigree is created until all prescription drug stock held on January 1, 2007 is sold, traded or transferred or 3 years whichever is longer.

Q9 Is the shipping address required on the pedigree? If so, does that mean the corporate office or the actual location from where the prescription drug was shipped?

The shipping address is the address of the location **from** which the prescription drug was actually shipped or the actual address **to** which the prescription drug was shipped and delivered.

Q10 What is a sales invoice number?

The board's operational definition is that a sales invoice number is a unique number created by each manufacturer or wholesaler in the chain of distribution and used by each manufacturer or wholesaler to identify the invoice that documents the sale transaction of a prescription drug. The sale transaction would include any purchase, trade or transfer of a prescription drug resulting in a change of ownership. The statute specifies sales invoice number.

Q11 The pedigree requires the "source" of the drug. What is the source?

The source is the entity or entities selling, trading or transferring the prescription drug. Depending on the transaction, the "entity" may be the manufacturer, wholesaler, pharmacy, and/or prescriber.

Q12 What happens to a pedigree when a licensed repackager repackages a prescription drug?

In California, an entity that repackages prescription drugs must be licensed as a manufacturer. When a prescription drug is repackaged, it will typically acquire a new NDC number, lot number

and perhaps expiration date. The repackager must receive a pedigree with the prescription drug and the new pedigree information (new NDC number, etc.) must be documented on the original pedigree and continue with the newly repackaged prescription drug.

Q12.1 By affixing a new NDC number to a repackaged prescription drug, is a repackager exempt from the requirement of providing a pedigree?

No, when the pedigree requirement becomes effective, a repackager will be required to provide a pedigree back to the original manufacturer.

Q13 Is a pedigree required for an intra-company transfer between manufacturer and wholesaler?

A pedigree is required to contain information regarding each transaction resulting in a change of ownership of a given prescription drug.

The pedigree is considered part of the records of acquisition and/or disposition of any prescription drug that are required to be maintained and immediately retrievable for inspection (e.g. per Section 4081 and 4105) wherever the prescription drug may travel or be stored. If a particular transfer of possession does not result in a transfer of ownership, it may not need to be recorded on the pedigree. However, it will still be necessary for the pedigree to transfer to any entity (person) taking possession, for record-keeping purposes.

Q14 What are the pedigree requirements for prescription drugs that are shipped into California?

Prescription drugs that are shipped into California are required to have documentation of each transaction from the manufacturer, to acquisition and sale by a wholesaler until final sale to the pharmacy. Only those transactions that result in a change of ownership of the prescription drug are required to be documented on the pedigree.

Q15 Is it possible for a wholesaler or pharmacy to update its inventory before a pedigree is authenticated?

If a wholesaler or pharmacy receives delivery of a prescription drug but has not authenticated the pedigree, the prescription drugs may be stored under secure conditions for a brief period of time, separated from the regular inventory, until the pedigree may be verified. Any such unverified prescription drugs may not be stored with regular inventory or be available for sale until the pedigree is authenticated.

Q16 Is it acceptable to list multiple prescription drugs, which were all purchased from the same manufacturer at different times on a single pedigree as long as the date of purchase and associated invoice number(s) are listed with each drug?

It is expected that the required pedigree elements will be kept at all times in a readily retrievable form at the facility or pharmacy from which, by which, or to which prescription drugs are distributed. The statutes do not specify how the pedigree data is stored.

Q17 Would it be acceptable to post pedigree information on a secure site for customers to access? There is concern about the amount of paper recipients of pedigrees at the pharmacy and wholesalers would need to manage, as well as the funds they would have to invest to secure their own pedigree solution. With this approach, all they would need to invest in would be an Internet access to their supplier's existing infrastructure?

It is expected that the required pedigree elements will be kept at all times in a readily retrievable form at the facility or pharmacy for which, by which, or to which prescription drugs are distributed. The statutes do not specify how the pedigree data is stored.

Pharmacy Questions

Q1 Are pharmacies required to obtain a pedigree when buying prescription drugs?

Effective January 1, 2007, a pharmacy may not acquire any prescription drugs (dangerous drugs) without obtaining a certified pedigree at the time the drugs are acquired.

Q2 Are pharmacies ever required to provide a pedigree?

A pharmacy is required to provide a pedigree as part of any transaction resulting in a change of ownership of a given prescription drug, including but not limited to when the pharmacy returns a prescription drug to the wholesaler or manufacturer from which the prescription drug was obtained, when the pharmacy wholesales the prescription drug to another pharmacy to alleviate a temporary shortage, when the pharmacy transfers the prescription drug to a health care provider authorized to purchase prescription drugs, or when the pharmacy sends a prescription drug to a reverse distributor. The pharmacy is required to provide a pedigree at the time of any sale, trade or transfer of a prescription drug resulting in a change of ownership.

A pedigree is not required if the transaction does not result in the change in ownership of the prescription drug. However, the transaction must be one of the transactions authorized by B& P § 4126.5.

The pedigree is considered part of the records of acquisition and/or disposition of any prescription drug that are required to be maintained and immediately retrievable for inspection (e.g. per Section 4081 and 4105) wherever the prescription drug may travel or be stored. If a particular transfer of possession does not result in a transfer of ownership, it may not need to be

recorded on the pedigree. However, it will still be necessary for the pedigree to transfer to any entity (person) taking possession, for record-keeping purposes.

Q3 To whom can a pharmacy furnish prescription drugs? (B& P § 4126.5)

- A wholesaler owned or under common control by the wholesaler from which the prescription drug was acquired.
- The pharmaceutical manufacturer from which the prescription drug was acquired.
- A licensed wholesaler acting as a reverse distributor.
- Another pharmacy or wholesaler to alleviate a temporary shortage of a dangerous drug that could result in the denial of health care. Only a quantity sufficient to alleviate the temporary shortage may be furnished.
- A patient or another pharmacy pursuant to a prescription or as otherwise authorized by law.
- A health care provider that is not a pharmacy but that is authorized to purchase dangerous drugs.
- To another pharmacy under common control.

Q4 Is a pedigree required for an intra-company transfer of drugs between pharmacies?

A pedigree is required to contain information regarding each transaction resulting in the change of ownership of a given prescription drug. Any transfer from or by a pharmacy must be in compliance with B& P § 4126.5.

The pedigree is considered part of the records of acquisition and/or disposition of any prescription drug that are required to be maintained and immediately retrievable for inspection (e.g. per Section 4081 and 4105) wherever the prescription drug may travel or be stored. If a particular transfer of possession does not result in a transfer of ownership, it may not need to be recorded on the pedigree. However, it will still be necessary for the pedigree to transfer to any entity (person) taking possession, for record-keeping purposes.

Q5 What does under "common control" mean?

Common control means the power to direct or cause the direction of the management and policies of another person whether by ownership, by voting rights, by contract, or by other means.

Q6 Is a pedigree required when a prescription drug is transferred between pharmacies under common control?

A pedigree is required to contain information regarding each transaction resulting in the change of ownership of a given prescription drug. Any transfer from or by a pharmacy must be in compliance with B& P § 4126.5.

The pedigree is considered part of the records of acquisition and/or disposition of any prescription drug that are required to be maintained and immediately retrievable for inspection (e.g. per Section 4081 and 4105) wherever the prescription drug may travel or be stored. If a particular transfer of possession does not result in a transfer of ownership, it may not need to be recorded on the pedigree. However, it will still be necessary for the pedigree to transfer to any entity (person) taking possession, for record-keeping purposes.

Q7 What does a pharmacy do with prescription drugs in their possession on January 1, 2007 that do not have a pedigree?

A pharmacy must be able to document those prescription drugs that it has in its possession on January 1, 2007. The documentation should include lot numbers and expiration dates. A pharmacy would be required to create a pedigree for those prescription drugs that are transferred from or by the pharmacy in compliance with B& P § 4126.5.

Prescriber Questions

Q1 Are prescribers required to receive a pedigree when they purchase prescription drugs?

The wholesaler or pharmacy is required to provide a pedigree for any change of ownership including to a prescriber.

Q2 Are prescribers required to provide a pedigree?

A wholesaler or pharmacy is required to receive a pedigree for any prescription drug that is acquired including from prescribers.

General Technology Questions

Q1 What type of technology is required?

The only requirement is that the pedigree be electronic; no specific technology is required.

California wholesalers, pharmacies and other healthcare providers that sell, trade, transfer or receive prescription drugs must ensure the authenticity, integrity, and non-repudiation of the electronic pedigree.

The California Board of Pharmacy does not provide specific directions or technological requirements on how to ensure the authenticity, integrity and non-repudiation of the electronic pedigree. It is the responsibility of the involved parties to meet these requirements in whatever way best suits the circumstances in question.

Q2 What does "in electronic form" mean?

The statute does not define "in electronic form" or the technology required. With input from the stakeholders, if necessary that can be accomplished by regulation, or by subsequent statute.

Q3 Can the wholesaler and pharmacy maintain the pedigree record electronically?

California law requires that records of the manufacture, sale, acquisition and distribution of prescription drugs be available on the licensed premises for three years from the date of making (B&P § 4081, 4105, and 4333.) The pedigree record may be kept electronically so long as a hard copy and an electronic copy can during that period always be produced (B&P § 4105.)

Q4 Can a manufacturer or wholesaler provide a database containing more information than required by California as long as the electronic pedigree requirements for California are part of the data?

As long as the required pedigree data is provided and is readily retrievable upon inspection or otherwise, additional data may also be collected.

Q5 Is the lot number of a drug required on the pedigree? Can multiple lot numbers be on the pedigree document?

The lot number is required. Multiple lot numbers can be on the pedigree as long as the wholesaler or pharmacy can readily retrieve the lot number upon request without having to do a manual search for the required lot number.

Q6 Is Radio Frequency Identification (RFID) technology required?

No, RFID is not required.

Q7 If a California wholesaler or pharmacy ships out of state, how will the out of state entity receive the pedigree if they do not have the appropriate software?

If another state requires a pedigree, then the California wholesaler or pharmacy must comply with the receiving state's pedigree requirement as well as California's requirements. If the state does not require a pedigree, the California wholesaler or pharmacy would still be required to document the transaction on the electronic pedigree and provide it to the receiving entity. If the receiving entity does not have the software to read the pedigree, it would be advisable for the California business selling the prescription drug to provide a printed hard copy of the electronic

pedigree. In order to be shipped back into or received in California, the prescription drug would have to have a complete electronic pedigree.

Q8 Is there a clearinghouse for the transaction data for electronic pedigrees?

At the current time, there is no clearinghouse for pedigree data.

Q9 Is there a hotline to verify pedigree data provided by the wholesaler?

At the current time there is no hotline to verify the authenticity of data provided in a pedigree.

Q10 To read and accept an electronic pedigree, is a wholesaler required to provide software to its customer pharmacies or will pharmacies have to procure the needed software?

There is no requirement for a manufacturer or wholesaler to provide the necessary software to read an electronic pedigree.

Q11 Will everyone need a scanner or other hardware to comply with the pedigree requirement?

The type of technology used will determine the hardware and software needs of a business. There is no requirement for a particular type of technology.

Regulatory Questions

Q1 Is any additional legislation regarding the pedigree being considered in California?

No legislation is pending or proposed at this time.

Q2 California law provides for an extension to implement the pedigree requirement until January 1, 2008, if the Board of Pharmacy determines that manufacturers or wholesalers require additional time to implement electronic technologies to track prescription drugs within California. How would the board grant this extension?

The Board of Pharmacy would have to grant the request at a public meeting. A written request to extend the implementation date for the pedigree can be sent to the attention of the Executive Officer Patricia Harris, at 1625 N. Market Blvd. Ste N219, Sacramento, CA 95834.

Q3 Does a manufacturer have to be licensed in California to sell prescription drugs in California?

No, if the manufacturer only sells the prescription drugs it actually manufactures, and the prescription drugs are distributed solely from the premises of the licensed manufacturer.

Q4 How will the Board of Pharmacy be enforcing the pedigree requirement for pharmacies and wholesalers?

Compliance will be confirmed through board inspections and complaint investigations.

Q5 How will the board's inspector know if a pedigree has been provided to a pharmacy or wholesaler for a specific drug?

As a part of an inspection or investigation of a California wholesaler or pharmacy, the inspector would verify the receipt and verification of pedigree documents and the procedure for providing a pedigree when drugs are sold, traded or transferred.

Q6 If an inspector asks for the pedigree of a specific prescription drug, does the pharmacy need to provide one single pedigree, or it is acceptable for the pharmacy to state that it is one of these 10 pedigrees?

The pedigree must be provided upon request for the exact prescription drug that is requested by the inspector. It may be contained in a document with 10 other products, but the pharmacy would have to locate and provide the exact pedigree to the inspector.

Strategies to avoid Counterfeit, Misbranded or Adulterated Drugs

1. Know your supplier. Deal only with trustworthy, reputable wholesalers. Just because a wholesaler has a license does not necessarily mean it is trustworthy.
2. Be careful of the "good deal." If something appears to be too good to be true, be careful, especially with a new supplier. Due diligence is needed to check on suppliers.
3. Be careful of fax and email deals you receive.
4. Look for signs of removed labels – look for a tacky adhesive residue on or near the label.
5. Look for discolored labels. The solvent used to remove original print may discolor the label.
6. Look for slight differences in bottle or container size
7. Listen to patients – many drug counterfeits are caught by patients

8. Look for changes in lab/test values; a worsening in the patient may be due to an ineffective and/or counterfeit medication.
9. Ask the patient if they are using drugs purchased from foreign sources
10. If you suspect something is wrong contact the FDA at hhtp://www.fda/gove/medwatch or 1-800-FDA-1088 , contact the manufacturer, contact the State Board of Pharmacy

Related Pharmacy Law

Effective January 1, 2007
4034. (a) "Pedigree" means a record, in electronic form, containing information regarding each transaction resulting in a change of ownership of a given dangerous drug, from sale by a manufacturer, through acquisition and sale by a wholesaler, until final sale to a pharmacy or other person furnishing, administering, or dispensing the dangerous drug.
(b) A pedigree shall include all of the following information:
(1) The source of the dangerous drug, including the name, state license number, including California license number if available, and principal address of the source.
(2) The quantity of the dangerous drug, its dosage form and strength, the date of the transaction, the sales invoice number, the container size, the number of containers, the expiration dates, and the lot numbers.
(3) The business name, address, and if appropriate, the state license number, including a California license number if available, of each owner of the dangerous drug, 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 of the dangerous drug that the information contained in the pedigree is true and accurate.
(c) If a licensed health care service plan, hospital organization, and one or more physician organizations have exclusive contractual relationships to provide health care services, drugs distributed between these persons shall be deemed not to have changed ownership.
(d) The application of the pedigree requirement in pharmacies shall be subject to review during the board's sunset review to be conducted as described in subdivision (f) of Section 4001.
(e) This section shall become operative on January 1, 2007.

4126.5. (a) A pharmacy may furnish dangerous drugs only to the following:
(1) A wholesaler owned or under common control by the wholesaler from whom the dangerous drug was acquired.
(2) The pharmaceutical manufacturer from whom the dangerous drug was acquired.
(3) A licensed wholesaler acting as a reverse distributor.
(4) Another pharmacy or wholesaler to alleviate a temporary shortage of a dangerous drug that could result in the denial of health care. A pharmacy furnishing dangerous drugs pursuant to this paragraph may only furnish a quantity sufficient to alleviate the temporary shortage.
(5) A patient or to another pharmacy pursuant to a prescription or as otherwise authorized by law.
(6) A health care provider that is not a pharmacy but that is authorized to purchase dangerous drugs.

(7) To another pharmacy under common control.
(b) Notwithstanding any other provision of law, a violation of this section by either a pharmacy whose primary or sole business is filling prescriptions for patients of long-term care facilities or a person engaged in a prohibited transaction with a pharmacy whose primary or sole business is filling prescriptions for patients of long-term care facilities may subject the persons who committed the violation to a fine not to exceed the amount specified in Section 125.9 for each occurrence pursuant to a citation issued by the board.
(c) Amounts due from any person under this section on or after January 1, 2005, shall be offset as provided under Section 12419.5 of the Government Code. Amounts received by the board under this section shall be deposited into the Pharmacy Board Contingent Fund.
(d) For purposes of this section, "common control" means the power to direct or cause the direction of the management and policies of another person whether by ownership, by voting rights, by contract, or by other means.
(e) For purposes of subdivision (b) of this section and subdivision (s) of Section 4301, "long-term care facility" shall have the same meaning given the term in Section 1418 of the Health and Safety Code.

Effective January 1, 2007
4163. (a) A manufacturer or wholesaler may not furnish a dangerous drug or dangerous device to an unauthorized person.
(b) Dangerous drugs or dangerous devices shall be acquired from a person authorized by law to possess or furnish dangerous drugs or dangerous devices. When the person acquiring the dangerous drugs or dangerous devices is a wholesaler, the obligation of the wholesaler shall be limited to obtaining confirmation of licensure of those sources from whom it has not previously acquired dangerous drugs or dangerous devices.
(c) A wholesaler or pharmacy may not sell, trade, or transfer a dangerous drug at wholesale without providing a pedigree.
(d) A wholesaler or pharmacy may not acquire a dangerous drug without receiving a pedigree.
(e) This section shall become operative on January 1, 2007.

4163.5. The board may extend the date for compliance with the requirement for a pedigree set forth in Section 4163 until January 1, 2008, if it determines that manufacturers or wholesalers require additional time to implement electronic technologies to track the distribution of dangerous drugs within the state. A determination by the board to extend the deadline for providing pedigrees shall not be subject to the requirements of Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code.

4163.6. If the Legislature determines that it is not yet economically and technically feasible for pharmacies to implement electronic technologies to track the distribution of dangerous drugs within the state, the Legislature may extend the date for compliance with the requirement for a pedigree for pharmacies set forth in Section 4163 until January 1, 2009.

ATTACHMENT D

Patricia Harris, Executive Officer
California Board of Pharmacy
1625 N. Market Blvd., Suite N219
Sacramento, CA 95834

Dear Ms. Harris:

At AstraZeneca Pharmaceuticals, the security of the supply chain for our products is always of paramount concern. We are pleased to support the State of California's efforts to secure the integrity of the drug supply by initiating a drug pedigree system. We also believe it is important to approach the implementation of this pedigree program in a measured manner that can enable all material issues, including technology-related issues, to be adequately addressed. To this end, we request that implementation of SB 1307 (Figueroa, 2003) be delayed until 2008.

As you are aware, SB 1307 is due to take effect in January 2007. However, the statute allows the Board of Pharmacy to delay implementation until January 2008. We believe the later implementation date will facilitate the development of needed technology to effectively implement pedigrees and to learn from the findings of the various pilot programs that exist and are in operation today. In one year's time, the Department should be in a better position to assess the technological progress that has been made and thereby ensure a successful implementation of the pedigree program.

Once again, we strongly support your efforts on behalf of patient safety. If you would like to discuss our request in greater detail, please feel free to contact me at (916) 457-3703.

We also understand that the Board of Pharmacy may be launching a working group on pedigree implementation. If so, we would welcome the opportunity to participate as a member of that working group so that we might lend our perspective and expertise to this timely and important discussion.

Thank you for your consideration in this important matter.

Sincerely yours,

Ellen McCormick
Director, State Government Affairs
AstraZeneca

FFF enterprises
Helping Healthcare Care®

07 March 2006

William Powers, Chair
Stan Goldenberg, RPh.
David Fong, PharmD.
California State Board of Pharmacy
1625 N. Market Blvd, Suite N 219
Sacramento, CA 95834

Dear Enforcement Committee Members,

Thank you for the opportunity to address the issue of California's pedigree requirements and the question of extending their implementation date. This is an issue we at FFF Enterprises hold near and dear. I am eager to contribute in any way I can to the committee's discussions and to answer any questions that may arise about what it takes to secure a distribution channel and our e-pedigree solution, Verified Electronic Pedigree (VEP).

Headquartered in Temecula, Calif., FFF is the nation's largest distributor of human plasma products. We have, for 18 years, been acutely aware of the vulnerabilities of the traditional U.S. pharmaceutical supply channel. Our customers—including hospitals, public health agencies, long-term care facilities and physician practices—have come to rely on our unique distribution model to assure they are receiving their biopharmaceuticals through the most secure, responsible channel available: We buy only from manufacturers and ship only to healthcare providers. It is as simple as it is secure.

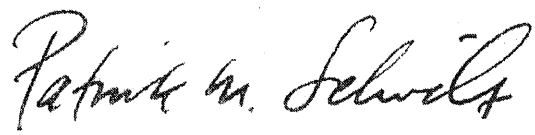
FFF's business model protects the precious human proteins that we manage from the inherent risks and irresponsible pricing of secondary and gray channels, as it protects our customers' patients from the life-threatening risks of diverted, counterfeit, tampered and mishandled biopharmaceuticals.

As an additional safeguard, and to document the security of our channel, FFF implemented our initial e-pedigree solution in July 2004, called VEP or Verified Electronic Pedigree. It was obvious to the entire industry that many states, including California, were intent upon pursuing pedigree solutions. We took—and continue to take—the states' desire to secure safe pharmaceuticals for their residents to heart. It is a passion we share. In response to these developing requirements, FFF has engaged in a recent comprehensive upgrade of VEP that assures it will match the most stringent requirements in the country. We will launch the upgraded VEP well before the end of this year.

FFF's long-term investment in our channel, including our e-pedigree system, is based on the clear and present risks to patients that result from the vulnerabilities of the traditional pharmaceutical supply channel. The risks are so great—and so pervasive—that we encourage this committee and the Board of Pharmacy to honor the original deadline for implementation of California's pedigree requirements. Postponing implementation of the requirements does not put on hold the irresponsible and illicit deeds of those who mishandle, tamper, divert and counterfeit the very products patients trust to make them well.

Additionally, a number of other pedigree requirements are scheduled to become effective this year. California's leadership on such a critical issue as pharmaceutical consumer safety is both a benefit to the state's citizens and a responsibility we must collectively honor, regardless of the financial and operational challenges. FFF Enterprises will implement a regulatory-compliant e-pedigree solution before the year is out, and we invite our colleagues to join us.

Sincerely,



Patrick M. Schmidt
President and CEO

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fortuna favet fortibus

NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

CALIFORNIA RETAILERS ASSOCIATION

January 30, 2006

Ms. Patricia Harris
California State Board of Pharmacy
1625 North Market Blvd, Suite N 219
Sacramento, CA 95834

Dear Ms. Harris:

RE: Implementation of the Electronic Pedigree Requirement for Prescription Drugs Effective January 1, 2007

Introduction

On behalf of our 31 member companies operating approximately 3,122 chain pharmacies in the State of California, the National Association of Chain Drug Stores (NACDS) would like to share with the California State Board of Pharmacy ("Board") our concerns about the pending implementation date of January 1, 2007 of the electronic pedigree requirement for prescription drugs.

We have grave concerns that January 1, 2007 is an unrealistic compliance date for the entire pharmaceutical supply chain, from manufacturers to pharmacies and every entity between, to implement and comply with the requirements of an electronic pedigree. Moreover, we believe that the requirements are overly broad and unnecessarily burdensome, and should be amended so that the requirements are reasonable while still ensuring that counterfeit pharmaceuticals do not enter the pharmaceutical supply chain. Ideally, these amendments should be adopted through additional legislation. However, we believe that the Board may adopt the necessary amendments through rulemaking.

Including California, twelve states have adopted legislation requiring pedigrees for prescription drugs. However, no state has imposed requirements as broad and far-reaching as California. The Florida legislature was the first state to adopt pedigree requirements, in 2003. The Florida legislature originally passed overly burdensome pedigree requirements. However, both state officials and the regulated industries have worked together through countless face-to-face meetings, conference calls, emails, and one-on-one telephone calls to implement a workable pedigree system that will become operational by July 1, 2006. While the Florida pedigree system is not ideal, and we do not recommend that California adopt the Florida system, we do appreciate Florida state

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officials' willingness to work toward achieving a workable pedigree system. It is our hope that the California Board of Pharmacy would do the same.

"Normal Distribution Channel"

Many other states have passed pedigree legislation that we believe is more reasonable while still ensuring that counterfeit products do not enter the pharmaceutical supply chain. A provision we recommend is the concept of a "normal distribution channel," which has been adopted by states such as Arizona, Oklahoma and Texas. Moreover, this concept is almost universally supported by the regulated industries: manufacturers, primary wholesalers, and pharmacies. NACDS has developed a model definition of normal distribution channel:

"Normal distribution channel means a chain of custody during distribution of a prescription drug that goes from a manufacturer to a wholesale distributor to a pharmacy to a patient or a chain of custody for a drug that goes from a manufacturer to a wholesale distributor to a chain pharmacy warehouse to their intracompany pharmacy to a patient. Direct sales of prescription drugs by a manufacturer to a pharmacy or a chain pharmacy warehouse are within the normal distribution channel."

Coordinating with the concept of the normal distribution channel is the requirement that a pedigree must be passed only when a prescription drug goes outside the normal distribution channel, that is, to an entity such as a secondary wholesaler. These concepts work because the entities that comprise the normal distribution channel are trusted entities; the additional documentation as to source (i.e. pedigree) is not necessary unless the prescription drug is from a source outside this chain of trusted entities. To add additional layers of security, we would support requirements that within the normal distribution channel, invoices must include a statement that the product was purchased directly from a manufacturer. This requirement provides the pharmacy with assurances that the product is within one transaction from the manufacturer. All other scenarios would require a pedigree.

We are aware that CA Bus & Prof §4163 requires that a wholesaler or pharmacy may not sell, trade, or transfer a prescription drug at wholesale without providing a pedigree, nor may receive a prescription drug without receiving a pedigree. However, we believe that the Board has the authority to exempt entities within the normal distribution channel from these requirements. If the Board does this, then the pedigree requirements would apply when a pharmacy or wholesaler sells, trades, or transfers a prescription drug to an entity that is outside the normal distribution channel, or receives a prescription drug from outside the normal distribution channel. We ask that the Board refer this matter to your legal counsel for an opinion.

In the alternative, if the Board's opinion is that it does not have the statutory authority to exempt from the pedigree requirements those entities within the normal distribution

channel, then NACDS and our member companies would support a legislative effort to amend the requirements of CA Bus & Prof §4163.

Impact Upon Generic Drugs

Finally, we are concerned about the impact a January 1, 2007 pedigree requirement may have upon the generic prescription drug market. The majority of generic drug manufacturers operate on very slim profit margins. Consequently, they may not have the financial resources to implement electronic pedigree technology for their products within the next few months. Moreover, many of them have not even started to think about providing an electronic pedigree and/or adding RFID technology to their products. We believe that these factors will cause many generic drug manufacturers not to be able to meet the January 1, 2007 deadline, and will therefore be shut out of the California market. The unfortunate result would be less generic drug availability, less competition, and higher prescription drug prices for California residents.

We ask the Board to consider the impact of a January 1, 2007 pedigree requirement on the generic drug market, in addition to our recommendations with respect to the normal distribution channel. We recommend a delay in the effective date of the pedigree requirement, as well as recognition that pedigrees are not required within the normal distribution channel.

Thank you for your consideration of these comments.

Sincerely,

Kevin N. Nicholson, R.Ph, J.D.
Vice President, Pharmacy Regulatory Affairs
National Association of Chain Drug Stores

Bill Dombrowski
President
California Retailers Association