



California State Board of Pharmacy

1625 N. Market Blvd., Suite N219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

QUESTIONS AND ANSWERS RELATING TO THE CALIFORNIA ELECTRONIC PRESCRIPTION DRUG PEDIGREE LAW(S)

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Introduction

We face an increasing threat to the security of the world, U.S., and California drug supply from counterfeit as well as misbranded, adulterated, or diverted drugs. One estimate, from the Center for Medicines in the Public Interest, projects that revenues from global counterfeit drug sales will reach \$75 billion by 2010, a 92 per cent increase from 2005. In July 2003, the federal Food and Drug Administration (FDA) established the Counterfeit Drug Task Force to address this growing threat to the U.S. drug distribution system. From 2000 to 2004, the FDA registered a nearly ten-fold increase in the number of counterfeit drug investigations opened by the agency. In the same period, numerous reports of patient harm from counterfeit drugs were made throughout the U.S.

In 2004, the California State Board of Pharmacy (the board) sponsored legislation (SB 1307) that made comprehensive changes to the drug distribution system to protect against counterfeit drugs. Among other requirements, the board's statutes require development of an electronic "pedigree" that tracks each prescription drug at the saleable unit (item) level through the distribution system. The statutes also require licensure of out-of-state wholesalers, posting(s) of a \$100,000.00 surety bond (or equivalent security), and authorize the board to embargo drugs when the board suspects drugs are adulterated, misbranded, or counterfeit. In 2006, the board sponsored legislation (SB 1476) which strengthened and clarified some of the pedigree requirements, and which moved the effective date for the pedigree requirement from January 1, 2007 to January 1, 2009, to allow the industry additional time to implement technologies necessary for electronic pedigrees.

Since enactment of the pedigree requirement(s) and other features of the 2004 law, the board has engaged in a substantial public education effort, to help bring to the table the parties necessary to ensure compliance with the law by the January 1, 2009 date for the pedigree requirement. Since December 2005, in addition to other efforts including discussions of these issues at the quarterly public meetings of the full board and of the board's Enforcement Committee, the board has held quarterly public meetings of an E-Pedigree Workgroup dedicated entirely to implementation. In addition, the board and its staff have participated in numerous industry conferences and meetings with industry members, technology vendors, legislators, regulators, and other affected parties. A great deal of progress has been made toward timely compliance with the pedigree requirements.

This document is another step by the board in that public education effort. As it did prior to the initial January 1, 2007 implementation date of the pedigree law, the board has for several months encouraged interested parties to submit questions to the board about the pedigree law, to identify possible areas of confusion, and/or to identify areas where additional regulation may be required; the board has dedicated an email address (californiapedigree@dca.ca.gov) to such submissions.

What follow are Q&As based on questions received by the board. **The board cannot offer legal advice. These answers are advisory only, do not have the force of law, and are not binding on the board.** Some are excerpts from Q&As posted by the board prior to the January 1, 2007 implementation date, while others are responsive to more recent questions received in late 2007. Most of the questions have been rewritten to facilitate the most effective possible response.

These are in draft form, and the final answers may change based on further information acquired by or shared with the board. The board produces these Q&As as part of an ongoing conversation with affected parties, and welcomes comments or questions. Questions or responses concerning the pedigree law and/or this document may be submitted by email to the address given above.

QUESTIONS AND ANSWERS

General Questions

Q1 What is the purpose of the California pedigree law?

The pedigree law is an important part of a series of provisions that are intended to address threats to the prescription drug supply from counterfeit, misbranded, adulterated, or diverted drugs. The overall intent is to secure the drug distribution system, and to enable through heightened security a sustained and increased confidence in the authenticity and efficacy of prescription drugs.

Q2 Who will enforce the California pedigree law, and how?

The provisions mandating the pedigree requirements appear within the Pharmacy Law, for which the board has primary administration and enforcement responsibility. The board will do so with appropriate assistance from the California Department of Justice, Office of the Attorney General, and/or from other federal, state, or local agencies, District Attorneys, and other law enforcement.

In addition to other possible sanctions for non-compliance with pedigree requirements up to and including civil fines, injunctions, or criminal prosecutions, the board may cite and fine \$5,000.00 per occurrence (e.g., for each saleable unit) or take formal discipline against its licensees.

The board expects to monitor compliance with the pedigree requirements in much the same way that it does compliance with other laws: through routine unannounced inspections, investigation of consumer complaints, and referrals from other agencies or from other board investigations.

Q3 What is the best way to get information about the California pedigree law?

The text of several of the pertinent statutes is reprinted at the conclusion of this document. That text is also available from several public sources which make California statutes available free of charge to those with internet access, including the website of the California Legislative Counsel that can be found at <http://www.leginfo.ca.gov/> (click "California Law"). The California Office of Administrative Law site (<http://www.oal.ca.gov/>) has searchable text of current regulations.

The statutes and regulations are also available under a “Laws and Regulations” link on the board website (<http://www.pharmacy.ca.gov/>). That site also has a great deal more useful information for affected parties and/or the public about the pedigree law and its implementation, about other initiatives undertaken by the board, and about the board’s functions and duties.

Among the information available on the board site is its schedule of public meetings, including the quarterly meetings of the full board and the separate quarterly meetings of the committees of the board, including the Enforcement Committee and the E-Pedigree Workgroup subcommittee (click “About the Board and Public Meetings,” then “Board and Committee Meetings”). There are also copies of materials prepared by or for the board for these meetings (“Meeting Materials” for each meeting on the schedule), the agendas for these meetings, and other pertinent materials, including templates prepared by the board for submission of comment(s) on topical areas such as grandfathering and inference, and for comment(s) on the January 1, 2009 compliance date.

The board publishes a semi-annual newsletter, called *The Script*. The most recent edition may be accessed from the board website. The board also keeps an email notification list (click on “Join Our E-Mail List” to subscribe), and sends email alerts about major updates, such as the dates for upcoming implementation or public comment on regulations, the publication of *The Script*, the release of agendas and/or meeting materials for public meetings, the availability of Q&As about new laws, and the receipt of information about drug recalls or other public safety issues.

The board also intends to dedicate a portion of its website specifically to the pedigree law and its implementation, to collect together in one area of the website material that may also be available elsewhere, including on the site or at public meetings. The creation of this area of the website is something that would typically be announced using the email notification list discussed above.

Therefore, the best response to numerous questions received by the board regarding how to learn about the California pedigree law or its implementation is that those interested in doing so should take advantage of the material(s) made publicly available by the board by, for instance:

- Consulting the text of the applicable statutes and regulations;
- Attending, and/or reviewing agendas, documents, and minutes from, the quarterly public meetings of the E-Pedigree Workgroup, the Enforcement Committee, and the full board;
- Reviewing applicable portions of *The Script* newsletter(s);
- Consulting the board website at <http://www.pharmacy.ca.gov/>;
- Signing up on the website for email alerts;
- Submitting comments and questions to the board using the email address dedicated to all pedigree issues, californiapedigree@dca.ca.gov; and/or
- Submitting comments and questions to the board in writing.

The board further encourages anyone with information to share with the board about its pedigree law, or about related issues such as drug counterfeiting, misbranding, adulteration, or diversion, to use these or other contact mechanisms to get in touch with the board. All written submissions to the board should be addressed to the attention of Executive Officer Virginia Herold. Also, the board has a Complaint Form that can be used to submit specific allegations of misconduct.

Q4 When does the California pedigree requirement become effective?

The California pedigree requirement becomes effective January 1, 2009. (B&P § 4034(k).) The board is authorized to extend the date for compliance until January 1, 2011, if it determines that manufacturers or wholesalers require additional time to implement the electronic technologies to track the distribution of dangerous drugs within the state. (B&P §§ 4034(k), 4163.5.) The board is guided by its mandate to make protection of the public its highest priority. (B&P § 4001.1.)

Q5 Are pedigrees currently required for any sales into the State of California?

Prior to implementation of the California pedigree law, pedigrees required by federal law (under the Prescription Drug Marketing Act of 1987 (PDMA), as modified by the Prescription Drug Amendments of 1992 (PDA), 21 USC § 301 et seq., particularly 21 USC § 353, see also 21 CFR Parts 203 and 205) are required for any U.S. drug distribution, including in or into California.

Q6 Under what circumstances is a pedigree required to be provided or received?

As of the compliance date, a wholesaler or pharmacy may not sell, trade or transfer a dangerous drug at wholesale without providing a pedigree. As of that date, a wholesaler or pharmacy also may not acquire a dangerous drug without receiving a pedigree. (B&P § 4163(c), (d).)

Q7 What is a pedigree under California law?

A pedigree is an electronic record, created and maintained in an interoperable electronic system, containing information regarding each transaction resulting in a change of ownership of a given dangerous drug, from sale by the manufacturer through each acquisition and sale by one or more wholesalers, manufacturers or pharmacies, through to the final sale to a pharmacy or other entity or person furnishing, administering or dispensing the drug to a patient. (B&P § 4034(a).)

Q8 Does “dangerous drug” equal “prescription drug”? Does it include animal drugs?

Yes to both. A dangerous drug is a drug unsafe for self-use in humans or animals and includes any drug that bears the legend: “Caution: federal law prohibits dispensing without prescription,” “Rx only,” or words of similar import, or any other drug(s) that by federal or state law can be lawfully dispensed only pursuant to a prescription. (B&P § 4022.)

Q9 What is an interoperable electronic system?

To ensure compatibility throughout all stages of distribution, an interoperable electronic system is an electronic track and trace system for dangerous (prescription) drugs that utilizes a unique identification number, established at the point of manufacture, contained within a standardized nonproprietary data format and architecture, that is uniformly used by manufacturers, wholesalers, and pharmacies for the pedigree of a dangerous drug. (B&P § 4034(a), (i).)

Q10 What information is required to be included in the electronic pedigree record?

Source(s) of the Prescription Drug

For each stage or link in the distribution chain down to the dispenser, information on each source and/or prior owner of the prescription drug. Information regarding the source(s) will include the name(s) of the manufacturer, wholesaler, repackager, and in some instances, the pharmacy, from which the prescription drug was acquired and/or through whose ownership the prescription drug has previously passed. The pedigree must include each source's name and principal address, and federal manufacturer's registration number or state license number.

Prescription Drug and Transaction Information

The trade or generic name of the prescription drug, its quantity, 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 date(s) and the lot number(s).

Prescription Drug Ownership Information

The business name, address, and federal manufacturer's registration or state license number, for each owner of the prescription drug, and the prescription drug shipping information, including the name and address, of each person certifying delivery or receipt of the prescription drug.

Certification of Transaction Authenticity

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

Q11 Is a single pedigree required to track all changes in ownership of a dangerous drug?

Yes. A single pedigree shall include every change of ownership of a given dangerous drug from initial manufacture through to its final transaction to a pharmacy or other person for furnishing, administering, or dispensing of that drug, regardless of repackaging or assignment of another National Drug Code (NDC) Directory number. In addition, any return of a dangerous drug to a wholesaler or manufacturer shall be documented on the same pedigree as the transaction that resulted in the receipt of the drug by the party returning it. (B&P § 4034(c), (e).)

Q12 Where in the supply chain does the pedigree begin?

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

Q13 Is the pharmacy or other dispenser required to track the pedigree to the patient?

No. The pedigree is only required to extend to/document the change in ownership to a pharmacy or other entity (or person) that furnishes, administers, or dispenses the dangerous drug.

Q14 Is the pedigree required to track each drug to the individual saleable unit?

Yes. A pedigree shall track each dangerous drug at the smallest package or immediate container distributed by the manufacturer, received and distributed by the wholesaler, and received by the pharmacy or other person furnishing, administering, or dispensing the drug. (B&P § 4034(d).) The terminology “smallest package or immediate container” includes the smallest container in which the drug is made saleable, and/or for which a product label is required by federal law (21 USC § 321), and is intended to track each dangerous drug to the smallest such unit offered for sale or resale. Each individual saleable unit, for example each bottle of 100 tablets in a case of 48 bottles, must have a unique identification number, established at the point of manufacture, which corresponds that unit to the appropriate entries in the pedigree record. (B&P § 4034(i).)

Q15 What is meant by the “source” of the prescription drug?

A source is a person or entity selling, trading or transferring ownership of any prescription drug. It may at various times be a manufacturer, wholesaler, pharmacy, prescriber, or other transferor.

Q16 What does “change of ownership” mean?

“Change of ownership” is not given a specific meaning by the statutes that would depart from its generally accepted meaning. It will be determined on a case-by-case basis. A transfer or change of custody or possession may or may not also result in a change of ownership. Possession is one strong indicator of ownership, so a change in possession results in a presumption of a change of ownership. However, this is not a conclusive presumption, and it may be appropriately rebutted.

Q17 Can you clarify what is expected with regard to the required inclusion of a federal manufacturer’s registration number or state license number in the pedigree? Is this required for every transaction? Does it have to be a California license number?

It is expected that any person or entity that might be a source or owner of a dangerous drug will possess at least one federal registration number or state license number. Many persons/entities will possess more than one. For instance, a license is required for a wholesaler, pharmacy, clinic or prescriber to possess, acquire, sell or transfer dangerous (prescription) drugs in California.

Every pedigree must contain one such registration or license number for each source or owner. It is not required that persons or entities with multiple registration or license numbers include all or more than one of these numbers in the pedigree record. Nor is it prohibited that they do so. Where a source or owner possesses a California license number (e.g., a non-resident wholesaler license number for an out-of-state distributor selling drugs into California), it is the preference of the board that this number be included on the pedigree record. This is not a requirement.

Q18 Does the board expect that the pedigree record will include the serialized number?

Yes. Inclusion of the unique identifier in the pedigree enables correspondence to the item/unit.

Q19 What is a sales invoice number? Is this number required for every transaction?

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 any purchase, sale, trade or transfer resulting in a change of ownership. The statute requires that the pedigree include the sales invoice number for each transaction resulting in a change of ownership of a given unit of a dangerous drug.

Some affected parties assert that requiring inclusion of the invoice number in the pedigree record may present timing and/or technology difficulties. The board is open to suggestions regarding an alternative means to include sales invoice number in the pedigree record, as the statute requires.

Q20 Does the law require that the NDC number be included in the pedigree?

The pedigree law does not require that the National Drug Code (NDC) Directory number be part of the pedigree, nor does it prohibit inclusion thereof along with the required pedigree data.

Q21 What sort of certification of the contents of the pedigree does the law require ?

The law requires that the pedigree identify the individual (on behalf of each recipient) certifying delivery or receipt of a given dangerous drug, and further that the pedigree include a certification under penalty of perjury from a responsible party for each source of the dangerous drug that the information contained in the pedigree is true and accurate.

The board anticipates that the required certifications, of delivery or receipt, and of the truth and accuracy of the pedigree, will be achieved by use of or in combination with digital signatures.

Q22 Who is a “responsible party” capable of providing pedigree certification?

The person certifying the truth and accuracy of the pedigree on behalf of each source of the drug must be a “responsible party,” i.e., an individual authorized to act on behalf of that source, and whose attestation and accompanying (digital) signature may bind the person or entity.

Q23 The pedigree law refers to the “principal address” of the source, and then also to the “shipping information” for the owners of the dangerous drug, and the “address” of the person certifying the truth and accuracy of the pedigree? What address(es) do you want to be listed on the pedigree: corporate addresses or shipping addresses?

Where possible, the board does not object to the inclusion of more than one address for a source or prior owner of the drug in the recorded pedigree data. However, where only one address will be recorded, it should be the shipping address/actual location of storage and delivery of the drug. That is, 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.

Q24 When does the board expect that pedigrees will be received and validated?

The pedigree should be received by recipients in the chain of distribution prior to or along with delivery or receipt of the drug(s) to which the pedigree relates, be electronically authenticated, and be verified or validated against the drug shipment(s) to which the electronic pedigree relates.

Q25 What types of transactions may require documentation on the pedigree?

Each time ownership of a given prescription drug (unit) transfers, all of the required transaction information must be recorded on the pedigree, and the truth and accuracy of the pedigree must be certified under penalty of perjury by a responsible party for the transferring source.

The board cannot anticipate all of the circumstances under which the ownership of prescription drugs may (or may not) change hands. Whether or not a change of ownership has occurred will need to be determined on a case-by-case basis, and it may or may not coincide with a change in possession. However, while the following is not a comprehensive list, the following transactions may require documentation on the pedigree if a change of ownership has occurred:

- A sale, trade, or transfer of prescription drugs between a manufacturer and wholesaler;
- A wholesale sale to a pharmacy, other wholesaler, clinic or prescriber (including the practice of “wholesale brokering” where a wholesaler does not take possession of a prescription drug but makes arrangements for the delivery of a prescription drug and processes the paperwork);
- Drop ship deliveries by or for a manufacturer, wholesaler, pharmacy, or prescriber;
- Consignment transactions;
- Third party logistics (3PL) transactions;
- Repackaging transactions;
- Pharmacy sales to another pharmacy;
- Pharmacy or prescriber returns to a wholesaler or manufacturer;
- Pharmacy sales to a prescriber or other licensed entity authorized to receive drugs;
- Pharmacy, prescriber, 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 inclusion of a transaction type on this list mean that in every case such a transaction 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 change in ownership. But that is not always the case. What is significant is not whether a transaction fits a type herein identified by the board as presumably constituting a “change of ownership,” but whether an actual change of ownership has occurred.

Q26 Is the preceding a full list of all transactions that may be recorded on the pedigree?

No. The preceding list is not intended to be comprehensive. Moreover, California law sets out the minimum elements of the pedigree; it does not prohibit inclusion of additional transactions.

Q27 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);
- Any distribution of drugs between a licensed health care service plan, hospital organization, and one or more physician organizations with exclusive contractual relationships to provide health care services (B&P § 4034(f));
- Any provision of samples by a manufacturer's employee to an authorized prescriber, if the samples are dispensed to a patient of the prescriber without charge (B&P § 4034(g)(1));
- Until January 1, 2010 (or January 1, 2011 if the board extends the date for expiration of this exemption), injectable drugs delivered by a manufacturer directly to an authorized prescriber or other entity responsible for the administration of the injectable drug that by law may only be administered under the professional supervision of the prescriber or other entity directly responsible for administration of the drug, provided that the drug is not dispensed to be self-administered, and is only administered to the patient by the prescriber or other authorized entity that received the drug directly from the manufacturer (B&P § 4034(g)(2), (g)(3)).

Q28 What happens to the pedigree in transactions not involving a change of ownership?

It is important to distinguish between transactions that require an entry/addition to be made to the pedigree (transactions resulting in a change of ownership) and those transactions where no entry or addition needs to be made to the pedigree (no change of ownership), but where the pedigree is still required to be passed (any wholesaler or pharmacy that sells, trades, or transfers a dangerous drug at wholesale must provide a pedigree, and also any wholesaler or pharmacy that acquires a dangerous drug must receive a pedigree). (B&P §§ 4034(a), 4163(c), (d).) The pedigree in such cases simply may not include the transaction(s) in which no change of ownership occurred.

That is, even where a particular transaction may not need to be *recorded* on the pedigree because no change of ownership occurred, that transaction will still likely require provision and/or receipt of the pedigree (as it existed before the transaction not involving a change of ownership) as part of the sale, trade, transfer and/or acquisition of the dangerous drug.

Further, the pedigree is part of the records of manufacture, sale, acquisition, or disposition which must be maintained and preserved for board inspection for three years. (B&P §§ 4081, 4105.) It must therefore be transferred, received, and retained, regardless of change of ownership, as part of the licensee record-keeping requirements for acquisitions or dispositions of drugs, in addition to and separate from the pedigree requirement. A transferring entity must still provide a pedigree (recording the change of ownership transactions to that point) to the transferee, and the transferee (and/or the first entity) must still provide that pedigree to any subsequent transferee.

For example, if manufacturer M transfers ownership of dangerous drugs to wholesaler W, which then transfers ownership of those drugs to pharmacy chain P, which in turn transfers possession but not ownership to pharmacy chain store P1, the following is required: a pedigree showing the transfer of ownership (and all other required pedigree data) from M to W must be received by W; a pedigree showing transfer of ownership (and all other required pedigree data) from M to W to P must be received by P; and a pedigree showing transfer of ownership from M to W to P must be received by P1. These transmitted/received pedigrees must be retained for three years.

Q29 Do transfers of dangerous (prescription) devices require a pedigree?

No. The law applies only to dangerous (prescription) drugs.

Q30 Do drug samples provided by a manufacturer to a wholesaler require a pedigree?

A wholesaler (or pharmacy) may not acquire any prescription drug, including a sample, without receiving a pedigree. There is no exemption for samples provided to wholesalers.

Q31 Do returns to a wholesaler or manufacturer for purposes of destruction have to be recorded on the pedigree, or only returns that are intended for re-stocking/re-sale?

Any transaction resulting in a change of ownership of a dangerous drug, including a return for purposes of destruction, must be recorded on the pedigree. There is no exemption for returns that are not intended for re-stocking or re-sale; the law specifically requires that any return to a wholesaler or manufacturer be documented on the same pedigree as the original sale.

Q32 Does California pedigree law permit provision or receipt of paper pedigrees?

No. The law defines a pedigree as a “record, in electronic form.”

Q33 Does a recipient of a pedigree have to use and forward the pedigree it receives, or can it create a new pedigree for future transfer(s) of the related drug(s)?

The law requires that a single pedigree include every change of ownership, so the pedigree that is initiated by the manufacturer must be appended and used throughout the distribution chain.

Q34 Are there any exemptions in the law for university hospitals or veterinary schools?

No. These entities are also expected to comply with the law.

Q35 Does California pedigree law make any exceptions or distinctions for “authorized distributors of record,” a “normal distribution channel,” or the like?

No. California law does not use these terms, nor does it distinguish between certain channels of distribution and others with regard to the requirement(s) to provide and receive pedigrees.

Implementation Questions

Q36 Does the board have any current plans to implement an “authorized distributor of record” or “normal distribution channel” approach?

No. The legislation authorizing and requiring California pedigree does not adopt this approach, and the board is authorized only to implement and enforce the law as enacted.

Q37 Does the board have any current plans to apply a “risk-based approach” to pedigree and/or serialization requirements, to only certain drugs, transactions, or packaging?

No. The legislation authorizing and requiring California pedigree does not adopt this approach, and the board is authorized only to implement and enforce the law as enacted.

Q38 Does the board have any current plans to apply a “phased-in approach” to pedigree and/or serialization requirements, to only certain drugs, transactions, or packaging?

No. The legislation authorizing and requiring California pedigree does not adopt this approach, and the board is authorized only to implement and enforce the law as enacted.

Q39 Is any board action required for the pedigree law to be effective January 1, 2009?

No. The law as written makes the pedigree requirements effective as of January 1, 2009. If no further action is taken, the law will be effective as of that date.

Q40 May the board act to extend the compliance date beyond January 1, 2009? How?

Yes. The board is authorized to extend the date for compliance until January 1, 2011. (B&P §§ 4034(k), 4163.5.) The board may do so by vote of the board during a public board meeting with a quorum of the board (at least seven members) in attendance.

Q41 Under what circumstances may the board act to extend the date for compliance?

The board is authorized to extend the date for compliance if it determines that manufacturers or wholesalers require additional time to implement electronic technologies to track the distribution of dangerous drugs within the state. (B&P §§ 4034(k), 4163.5.) This discretion is guided by the board’s mandate to make protection of the public its highest priority. (B&P § 4001.1.)

In December 2007, the board disseminated a template for submissions regarding readiness for implementation of the pedigree law on January 1, 2009. That template is available on the board website at http://pharmacy.ca.gov/meetings/agendas/07_dec_template_for_submissions.pdf. It outlines criteria the board will apply to any request for a delay in implementation.

If the board takes no action to extend the date, the law will be effective January 1, 2009.

Q42 Is there a date by which the board expects to determine industry readiness for 2009, i.e., a “go/no go” date for implementation by January 1, 2009?

No. The board has stated that it will place on its agenda for its January 23-24, 2008 meeting, in San Diego, CA, a discussion item regarding readiness for the January 1, 2009 compliance date. It has not said that any vote on implementation will be held at that or any subsequent meeting.

Q43 Does the board have any current plans to permit or require partial implementation?

No. The legislation authorizing and requiring California pedigree permits the board to delay the implementation date for the pedigree law in its entirety to January 1, 2011, but otherwise sets out requirements with which full compliance is required by all affected parties.

Q44 At one industry meeting some stated that individuals/entities subject to the pedigree law must meet with the board to develop a pedigree plan, especially if they are not able to comply in full with the pedigree requirements by January 1, 2009. Others at the meeting thought full compliance is expected by January 1, 2009. Is compliance in part or in full something that may be negotiated with the board?

No. The legislation authorizing and requiring California pedigree requires full compliance by all by the date of compliance, and the board is authorized only to implement and enforce the law as enacted. There is no requirement that any person or entity present its pedigree plan to the board. However, the board and its staff are very interested in, and have made themselves available for, any and all information from members of the industry regarding their plans for implementation.

Q45 I have heard several references to “grandfathering” with regard to pedigree drugs. What is “grandfathering”? Does the pedigree law as written permit/require its use? Is the board considering use of / reliance on “grandfathering” for implementation?

“Grandfathering” is a term used by some in the industry and by the board to refer to one possible approach to drugs already in the distribution system as of the effective date of the pedigree law.

The working definition of “grandfathering” employed by the board is that it refers to some time- and/or quantity-limited exception or allowance that industry participants hope to secure from the board, which would permit transfers without pedigrees of prescription drugs otherwise requiring pedigrees for some time (and/or quantity) after the effective date of the law, because those drugs were transferred or acquired before the effective date of the law, without electronic pedigrees.

“Grandfathering” does not appear in the pedigree law, and the law does not presently contain any exemption or allowance for transfers of non-pedigreed drug stocks post-effective date. However, the board has stated a willingness to hear input from the industry regarding a perceived need for or possibility of “grandfathering” certain drug stocks, and has dedicated time during E-Pedigree Workgroup meeting(s) to “grandfathering.” The board seeks submissions on this topic using the template at http://www.pharmacy.ca.gov/meetings/agendas/07_dec_implementation.pdf.

The board also understands that there may be some initial period of adjustment immediately after the effective date of the pedigree law. The board has traditionally been flexible with regard to its enforcement discretion when new substantive laws come into effect. The board cannot waive or diminish the requirements of the law, but may be judicious in its enforcement thereof. The board is also aware that to a substantial degree downstream participants in the drug distribution system are reliant on their upstream partners to supply them with the necessary pedigree information and serialized product(s); the board may therefore “roll out” its enforcement of the law accordingly.

The board is exploring, and is interested in hearing from industry, whether and/or to what extent there are real or perceived issues of existing non-pedigreed drug stocks, what solution(s) to these issues might exist or might be created, and whether these solutions would require some statutory change, promulgation of regulations, or are a matter of enforcement discretion.

Q46 I have heard several references to the use of “inference” with regard to pedigrees. What is “inference”? Does the pedigree law as written permit/require its use? Is the board considering use of / reliance on “inference” for implementation?

“Inference” is a term used by some in the industry and by the board to refer to a varied category of possible practices with regard to (temporarily) substituting aggregate-level (e.g., pallet, case, tote) tracking and validation for item-level tracking and validation, based on the limitations of, particularly, non-line-of-sight tracking technologies, and of the distribution system partners.

The working definition of “inference” as it applies to serialization employed by the board is that it refers to the ability to “infer,” based on tracking and validation of a unique identifier attached to an aggregate package (e.g., pallet, case, tote) which has a hierarchical relationship with unique identifiers attached to each of the items/packages contained within the aggregate package – when appropriately combined with circumstances engendering confidence that an aggregate package is unchanged since the items/packages within it were matched to the aggregate package identifier – that the items/packages within the aggregate package are what they are represented to be on the pedigree data, without individually validating (e.g., scanning) each item/package (immediately).

“Inference” does not appear in the pedigree law, and the law does not presently permit the use of or reliance on “inference” in place of required item-level tracking or validation of pedigree data. However, the board has stated a willingness to hear input from the industry regarding a perceived need for or possibility of “inference,” and has dedicated time during its E-Pedigree Workgroup meeting(s) to “inference.” The board also seeks submissions on this topic using the template at http://www.pharmacy.ca.gov/meetings/agendas/07_dec_implementation.pdf.

The board is exploring, and is interested in hearing from industry, whether and/or to what extent there are real or perceived issues to be addressed regarding “inference,” what solution(s) to these issues might exist or might be created, and whether these solutions would require some statutory change, promulgation of regulations, or are a matter of enforcement discretion.

Q47 Are pedigree requirements among those that might be waived in an emergency?

The board cannot anticipate the scope or nature of any emergency, and so cannot state with any certainty whether or to what extent pedigree requirements might be applicable in the event of a natural disaster or other emergency. However, the board expects that pedigree requirements will receive similar treatment to other requirements in the event of an emergency, and may be waived to the extent these requirements would interfere with patient health. The board issued a policy statement on disaster and emergency response in October 2006, which included the following:

In the event of a declared disaster or emergency, the Board expects to utilize its authority under the California Business and Professions Code, including section 4062, subdivision (b) thereof, to encourage and permit emergency provision of care to affected patients and areas, including by waiver of requirements that it may be implausible to meet under these circumstances, such as prescription requirements, record-keeping requirements, labeling requirements, employee ratio requirements, consultation requirements, or other standard pharmacy practices and duties that may interfere with the most efficient response to those affected. The Board encourages its licensees to assist, and follow directions from, local, state, and national health officials. The Board expects licensees to apply their judgment and training to providing medication to patients in the best interests of the patients, with circumstances on the ground dictating the extent to which regulatory requirements can be met in affected areas. The Board further expects that during such emergency, the highest standard of care possible will be provided, and that once the emergency has dissipated, its licensees will return to practices conforming to state and federal requirements.

Q48 Is the board planning to seek legislation to revise or delay the pedigree law?

Though it is possible that legislation may develop during 2008 addressing pedigree requirements, including some of the topics and questions raised by these Q&As, the board is not planning any substantial legislative revision of the pedigree law, nor is any legislative delay anticipated.

Q49 Has the board promulgated regulations under the pedigree law? Are any planned?

The board has not yet promulgated any regulations pertaining to the pedigree law, and there are no regulations currently pending or in review which pertain to the pedigree requirements.

It is possible that the board may promulgate regulations in 2008 clarifying or specifying pedigree requirements, including some of the topics and questions raised by these Q&As, and the board is open to suggestions regarding perceived needs for regulation. However, at this time there are no specific plans for any implementing regulations, as the legislation largely speaks for itself.

Manufacturer/Wholesaler Questions

Q50 What are California’s definitions of “manufacturer” and “wholesaler”?

For the purposes of prescription drugs or devices, California law defines a “manufacturer” as any person who prepares, derives, produces, compounds, or repackages any drug or device except a pharmacy that manufactures on the immediate premises where the drug or device is sold to the ultimate consumer. (B&P § 4033(a), (b), (c); see also H&S § 109970.) A “wholesaler” is any person who acts as a wholesale merchant, broker, jobber, customs broker, reverse distributor, agent, or a nonresident wholesaler, who sells for resale, or negotiates for distribution, or takes possession of, any dangerous drug or device. (B&P § 4043(a).)

Q51 We have heard numerous references to “third party logistics providers” or “3PLs” in the context of compliance with pedigree requirements. What are they, how do they differ from common carriers, and how are they relevant to the pedigree law?

A third party logistics provider is required to be licensed as a resident or non-resident wholesaler in California. A common carrier is not. Whereas a common carrier (e.g., UPS, Federal Express) takes possession of prescription drugs only for however long it may take to deliver them to their destination, a third party logistics provider typically acquires and stores drugs for some period of time. Similarly, a third party logistics provider could commonly receive multiple cases or pallets of a particular drug and may deliver just a case, or an individual unit, to a purchaser, whereas a common carrier does not manipulate the product in any way before delivery.

The board is not aware of any statutory/regulatory definition of “third party logistics providers” or “3PLs,” and does not claim any particular expertise on these entities or the role(s) they play in the economy more generally. As a general matter, “third party logistics provider” seems to be a descriptive term referring to some “provider” of “logistics” that is external (i.e., a “third party”) to one or more “primary” entities in any given industry or transaction. “Logistics” that might be contracted out to a “third party logistics provider” could include storage, transportation (e.g., air freight or trucking), IT infrastructure, personnel management, or other “logistics” functions.

Within the prescription drug distribution infrastructure, the board has some understanding of the role typically (though perhaps not exclusively) played by these entities: the working definition of “third party logistics providers” or “3PLs” employed by the board is a provider that keeps and stores a stock of prescription drugs on behalf of a manufacturer, and then delivers some or all of those drugs at some time in the future at the direction of the manufacturer. The “logistics” that are being provided in this instance include the storage of the drugs (reducing the need for storage space held by the manufacturer), and the transportation of those drugs to the eventual purchaser.

Third party logistics providers are relevant to the pedigree law for reasons including (a) that they must provide, acquire, and retain pedigrees, and (b) that it has been reported to the board that in at least some cases, these entities do not take ownership of the drugs they store on behalf of their manufacturer clients, which introduces some uncertainty about their recordation on the pedigree.

Q52 If a third party logistics provider/3PL does not take ownership of drugs that it has stored on behalf of a manufacturer, what are the respective parties' responsibilities with regard to the information on, provision of, receipt and retention of a pedigree?

The board cannot offer legal advice, and cannot comment in advance on application of the law to any particular set of factual circumstances. The board offers only the following observations, but these observations do not have the force of law and are not binding on the board.

If it is established that there is no change of ownership between the manufacturer and the 3PL, so that the only change of ownership is between the manufacturer and the purchaser to whom drugs are transferred by the 3PL, then it may not be required that the transfer between the manufacturer and the 3PL be recorded on the pedigree. The pedigree may only be required to record mandated data elements pertaining to the final sales transaction between the manufacturer and purchaser.

However, as discussed in response to Q28 above, the 3PL is nonetheless required to receive the pedigree with its acquisition of the drugs, and to provide the pedigree with its transfer thereof, and the pedigree is part of the records of acquisition and/or disposition of the drug that must be retained for inspection wherever the prescription drug may travel or be stored.

For example, if manufacturer M transfers drugs to third party logistics provider W, which then at the behest of the manufacturer transfers those drugs to pharmacy P, and it is established that the only change of ownership is that between M and P, the pedigree record showing ownership by the manufacturer must nonetheless transfer to W with the drugs, and a pedigree record with this information plus the change of ownership to P must be transferred to P by W with the drugs, and must be retained by both W and P for a period of at least three years for purposes of inspection.

The general rule is that if a particular transfer does not result in a change 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 pedigree and record-keeping purposes. In those circumstances where there is a change of ownership between manufacturer and 3PL, the pedigree record obviously must be updated and passed as usual with each transfer of the drug.

Q53 We have heard numerous references to “drop shipments” with regard to pedigree requirements. What are they, and how are they relevant to the pedigree law?

The board is not aware of any statutory/regulatory definition of “drop shipments,” and does not claim any particular expertise on the role(s) of these shipments in the economy more generally. Within the prescription drug distribution infrastructure, the board has some understanding of the typical (though perhaps not exclusive) use of “drop shipments”: the working definition of “drop shipment” employed by the board is that a manufacturer ships drugs directly to an end purchaser (e.g., a pharmacy), but the purchase and sale transaction, billing, and customer relationship(s) for the shipment, are handled by a wholesaler. In other words, the order is received and shipped by the manufacturer, but all moneys pass through the wholesaler. The wholesaler is both the buyer and seller of the drugs, and thus ownership but not possession passes through the wholesaler.

By this definition, “drop shipments” are in effect the converse of the 3PL transactions discussed in response to Q50 above: a 3PL wholesaler may allegedly have possession without ownership, whereas a drop shipment wholesaler may allegedly have ownership without possession, of drugs.

Drop shipments are relevant to the pedigree law for reasons including (a) that the pedigree must pass with every transfer of possession of the drugs, and must record every change of ownership of the drugs, and (b) that it has been reported to the board that in at least some cases, these drop shipment wholesalers do not take possession of the drugs they buy and sell on paper on behalf of their manufacturer and end purchaser clients, which introduces some uncertainty about timing of the acquisition and provision of the pedigree, and the data that must be recorded on the pedigree.

Q54 If a manufacturer makes a “drop shipment” to an end purchaser whereby it passes ownership but not possession to an intervening wholesaler, what are the respective parties’ responsibilities with regard to the pedigree law?

The board cannot offer legal advice, and cannot comment in advance on application of the law to any particular set of factual circumstances. The board offers only the following observations, but these observations do not have the force of law and are not binding on the board.

If a “drop shipment” as described above results in ownership (and the requisite sales paperwork) but not possession passing through the hands of a wholesaler, this will most directly be reflected in the shipping information contained in the pedigree record, which will reflect that the drugs did not go to the wholesaler, but instead were shipped directly **from** the manufacturer and **to** the end purchaser (e.g., the pharmacy or prescriber). Passage of the pedigree will otherwise be the same.

In other words, if manufacturer M receives a “drop shipment” order from pharmacy P, which is to be routed through wholesaler W for billing, ownership, and paperwork purposes, M initiates a pedigree record documenting the sales transaction from M to W with shipping information that shows the direct shipment to the pharmacy P. This pedigree then passes to W and to P, and W appends the second part of the drop ship transaction documenting the sales transaction from W to P. The complete pedigree must be retained by W and P for a period of at least three years.

Q55 Can you clarify the level of drug product serialization required by the law, and/or use of the term “saleable unit” versus “smallest package or immediate container”?

The term “saleable unit” does not appear in the law, and is merely a terminology employed as an explanatory device to clarify and explain “smallest package or immediate container distributed by the manufacturer, received and distributed by the wholesaler, and received by the pharmacy or another person furnishing, administering, or dispensing” the drug, and/or the requirement of a “unique identifier” established on each such package at point of manufacture. “Saleable unit” is helpful to explain the required serialization of the smallest package made available for wholesale or retail sale by a manufacturer or wholesaler, i.e., the smallest package or immediate container (e.g., each bottle in a case of 48 bottles) saleable to a pharmacy, prescriber, hospital, etc.

Q56 If a manufacturer sells a particular drug in cases (e.g., with 48 bottles inside), which cases are then both sold as whole cases and broken into mixed cases, mixed totes, or individual bottle sales by wholesalers or other distributors, is the case sold by the manufacturer the “smallest package or immediate container”?

No. The “smallest package or immediate container” is the smallest unit in which the product is saleable, and/or the smallest unit which can be acquired by a pharmacy, prescriber, hospital, etc. So in this case the “smallest package or immediate container” (onto which a unique identifier is to be placed and at which level the pedigree must track the drug) is each of the 48 bottles.

Q57 If one manufacturer owns the rights to manufacture a prescription drug (e.g., is the holder of an approved New Drug Application (NDA)), but contracts out the actual manufacture of the drug to a contract manufacturer, and/or the packaging/labeling of the drug to a second contractor, and then contracts out some or all of storage and delivery of the drug to a 3PL, which then transfers the drug to a wholesaler or to an end purchaser, which of these transactions needs to be recorded on the pedigree?

The preceding is a sample paraphrase and amalgam of numerous questions the board received on the topic of manufacturer “ownership” of prescription drugs before they are the subjects of their first wholesale or retail “sale,” wherein the questions involved numerous hypotheticals regarding domestic and international transfers of drugs within and between various contractors.

The board cannot offer legal advice, and cannot comment in advance on application of the law to any particular set of factual circumstances. The board offers only the following observations, but these observations do not have the force of law and are not binding on the board.

In general, the obligations of the pedigree law require that any transaction resulting in change of ownership of a dangerous drug be recorded on the pedigree, and this requirement may apply to pre-distribution as well as post-distribution transactions. If any of the above-described transfers constitutes a change of ownership, the obligation may apply equally to these transfers as well.

On the other hand, the board had not fully anticipated the possibility that more than one company might constitute the “manufacturer” of a particular drug, and/or that there may be (even multiple) transfers of a drug (constituting changes of ownership) prior to wholesale or retail sale.

The board requires further data and information on the topic of contract manufacturing, labeling, and other transfers of prescription drugs (or rights thereto) before it can provide clarity, and takes this opportunity to invite manufacturers whose operations would raise these questions to submit further information to the board. The board is also consulting with or seeking guidance from the federal Food and Drug Administration (FDA) on these issues of definition and ownership.

The board is also interested in hearing from industry about what solution(s) to these issues might exist or might be created, and whether these proposed solutions would require statutory change, a promulgation of regulations, or are a matter of enforcement discretion.

Q58 What is the role of a repackager with regard to receipt and generation of pedigrees?

In California, an entity that repackages prescription drugs is licensed as a manufacturer. (B&P § 4033(a); H&S § 109970.) When a drug is repackaged, it may typically (but not always) acquire a new National Drug Code (NDC) number, a new lot number and perhaps a new expiration date.

The pedigree law mandates that a single pedigree shall include every change of ownership of a given dangerous drug from its initial manufacture through to its final transaction to a pharmacy or other person for furnishing, administering, or dispensing the drug, regardless of repackaging or assignment of another NDC number. (B&P § 4034(c).)

Accordingly, the repackager must receive (from the manufacturer, wholesaler, or other source of the drug) a pedigree with the prescription drug documenting all transactions resulting in a change of ownership up through receipt by the repackager, and all of the new pedigree information (e.g., new NDC number, etc.) must be documented on the original pedigree, certified under penalty of perjury, and passed on/continue with the newly repackaged prescription drug.

The board is interested in further data and information on the repackaging industry, particularly on the topic of compliance with the requirement of maintenance of a single pedigree.

Q59 Are kit assemblers considered manufacturers? Do they pass pedigrees?

Yes to both. Kit assembly is a form of repackaging, and pursuant to California law any person engaged in repackaging is a manufacturer. (B&P § 4033(a)); H&S § 109970.)

Q60 If a dangerous drug is purchased in cases of 100, and individual items from that 100 are then combined (1 per kit) with another drug or one or more device(s) into “kits” (e.g., for sale to hospitals), which are sold only as in kit form, does the pedigree need to reflect the serialization of the individual drugs, the kits, or both?

The preceding is a sample paraphrase and amalgam of numerous questions and hypotheticals the board received on the topic of “kitting” of prescription drugs (i.e., combining drugs into “kits”).

The board cannot offer legal advice, and cannot comment in advance on application of the law to any particular set of factual circumstances. The board offers only the following observations, but these observations do not have the force of law and are not binding on the board.

Each of the 100 items in the case(s) described (and/or each of the prescription drugs with which it is combined in the kit) should be received with a pedigree which tracks to the item level. That pedigree will continue with the drug(s) when the drug(s) is/are passed to another recipient.

In addition, by combining in a kit two or more drugs, or a drug with a device, a kit manufacturer creates a new “saleable unit” which, unlike a traditional repackaging of a single drug where the existing pedigree still captures all of the pertinent drug information, creates new information.

That saleable unit (e.g., the surgical tray) will be separately serialized and will be the subject of a pedigree initiated by the kit manufacturer, linked to/associated with the existing drug pedigree(s).

An exception to this latter requirement for a kit pedigree may arise where the assembled “kit,” as a unit, is deemed a dangerous (prescription) device rather than a dangerous (prescription) drug. The California pedigree requirement only applies to transfers of prescription drugs.

Q61 Does the pedigree law have any exemption to serialization or pedigree requirements for generic drugs or drugs with lower cost or profit margins?

No. The serialization and pedigree requirements apply to all dangerous (prescription) drugs.

Q62 Is an out-of-state manufacturer that only distributes its own product required to be licensed by the board as a nonresident wholesaler?

Not if it is appropriately licensed as a manufacturer. A drug manufacturer licensed by the FDA or pursuant to Health and Safety Code section 111615 (by California) that only distributes drugs and devices of its own manufacture is exempt from the requirement of licensure as a wholesaler, whether it is located within or outside of California. (B&P § 4160(e).) If, however, the drugs or devices are stored after manufacture at a location other than the licensed manufacturing site, that location would require a wholesaler or nonresident wholesaler license issued by the board.

Q63 If a prescription drug is returned to a wholesaler or manufacturer in another state by a California pharmacy, is a pedigree required to accompany that return?

Yes. A California wholesaler or pharmacy may not sell, trade or transfer a prescription drug without providing a pedigree, and a single pedigree must include any drug return(s).

Pharmacy Questions

Q64 Is a pharmacy required to obtain a pedigree when buying a prescription drug?

Yes. As of the effective date of the pedigree law, a pharmacy may not acquire a dangerous drug without receiving a certified pedigree from the source of the dangerous drug. (B&P § 4163(d).)

Q65 To whom/what entities can a pharmacy furnish prescription drugs?

California law (B&P § 4126.5) specifies that a pharmacy may furnish dangerous drugs only to:

- A wholesaler owned or under common control by the wholesaler from whom the prescription drug was acquired.
- The pharmaceutical manufacturer from whom 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 is authorized to purchase dangerous drugs.
- Another pharmacy under common control.

Q66 What does “common control” mean?

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. (B&P § 4126.5(d).)

Q67 Is a pharmacy ever required to provide a pedigree?

Yes. As of the effective date of the pedigree law, no pharmacy may sell, trade, or transfer a drug at wholesale without providing a pedigree. (B&P § 4163(c).) Any transaction that results in a change of ownership of the drug must be recorded on the pedigree and the pedigree certified as true and accurate before it is sent. This might include returns, sales/transfers to other pharmacies to alleviate shortages or pursuant to prescriptions, sales/transfers to authorized providers, and/or sales/transfers to another pharmacy under common control, among other possible transactions.

Remember that even if the transaction in question does not result in a change of ownership of the prescription drug, so that it need not be recorded on the pedigree, as was discussed in response to Q28 above the existing pedigree must still be provided to any subsequent recipient of the drug(s), and the pedigree is part of the records of acquisition and/or disposition of the drug(s) that must be retained for inspection wherever the prescription drug(s) may travel or be stored.

Technology Questions

Q68 Does the pedigree law mandate the type(s) of technology that must be employed?

Not yet, at least not with specificity. The general approach taken by the law, and by the board, is to state the elements and requirements of serialization and pedigree, to place some parameters on those elements and requirements (e.g., that the pedigree be an electronic record, that it be created and maintained in an interoperable electronic system, that the pedigree track at smallest package or immediate container and be combined with serialization by a unique identifier, and that there be only one pedigree for all transactions of a given dangerous drug), and to otherwise permit the affected industries and their individual members to decide and develop necessary infrastructure and information technology that best meets the needs of the affected parties.

The industry, its associations, and standards-setting bodies (e.g., GS1/EPCglobal), along with a variety of technology vendors, consultants, and the like, have responded with rapid development of standards, technology, and infrastructure necessary to the tasks of serialization and pedigree.

The board has not ruled out the possibility of mandating particular technologies or approaches if agreement cannot be reached or if necessary technologies are not uniformly deployed. And there are certain technologies that may seem best-suited to the requirements set forth by the law. For instance, at passage of the bill (SB 1307) which in 2004 first enacted a pedigree requirement into California law, the author of that bill (Senator Liz Figueroa) placed into the record (Senate Daily Journal for the 2003-2004 Regular Session, pages 5404-5405) a letter addressed to the President Pro Tempore of the Senate which stated that the intent of SB 1307 included that the requirement for electronic pedigrees be met by a system employing Radio Frequency Identification (RFID) tags, that such a system was then in development and was expected to be available to meet the January 1, 2007 deadline set by SB 1307, and that the bill did not specify RFID tags so that any future technological innovations could be implemented without a change in statute.

The board has not yet provided specific directions or technological requirements regarding how to ensure interoperability, authenticity, integrity and non-repudiation of electronic pedigrees. It is the responsibility of the involved parties to meet these requirements. The board has observed and to some degree helped to guide the development of the necessary technologies, and has when appropriate stated whether certain developments would seem to satisfy requirements of the law. But it has not yet mandated particular technologies or approaches to pedigree or serialization.

The board expects that the trading partners will be sufficiently motivated by their shared interest with the board in security of the drug supply and protection of the public, as well as by their own responsibilities under the law to certify accurate delivery or receipt of drug products and the truth and accuracy of the pedigree data exchanged, that mandates on technology to ensure drug or data security, accuracy, integrity, interoperability and non-repudiation may not prove necessary. The board expects that industry best practices will develop optimal technology (or other) standards to control collection, transmission, and sharing of data independent of legal mandates. If this is not the case, the board reserves to itself the authority to step in as necessary to secure cooperation.

Q69 Is Radio Frequency Identification (RFID) technology required by law?

No, not currently, although the intent of the original law was that RFID tags be employed. All that the law currently requires is that drug products be serialized with a “unique” identifier. An RFID tag may serve as one such “unique” identifier, as may, for instance, a 2D barcode.

RFID has the clear advantage of being a non-line-of-sight technology, permitting validation by reading of individual items within a case, tote, etc., without having to open every such package.

Q70 Does the law mandate a certain kind of data carrier/tag (e.g., UHF vs. HF RFID vs. 2D barcode), alone or in combination, or protocols for the use of such carrier(s)?

No. The board expects that these standards for use will be developed by the industry. The board does note that the data available to the board suggests the greatest serialization/pedigree utility is available through applications of RFID tags (most likely UHF Gen 2) at the unit and case levels, alone or in combination with 2D Data Matrix barcode tags at these levels for backup. The board notes that requirements of this kind of tagging are already being circulated in the industry. If it proves necessary, the board has not ruled out the possibility of such technology mandate(s).

Q71 Does the law mandate a certain serialization scheme or data format and/or mandate requirements for the type or amount of data capacity that must be available?

Not currently. The law does require that the identification number used to serialize drug product at the item level be “unique,” which may be further specified if necessary but which is generally understood to effectively eliminate the likelihood of repetition. The board notes that 96-bit data standards such as the SGTIN-96 have been developed to ensure sufficiently unique serialization. If it proves necessary, the board has not ruled out the possibility of such technology mandate(s).

Q72 Does the law set forth specific requirements for those digital signatures that may be employed to certify delivery or receipt, to validate deliveries against pedigree data, and to attest to the truth and accuracy of the pedigree data upon transmission?

Not currently. The board expects that these standards for use will be developed by the industry, and/or that digital signature standards are fairly well settled. If it proves necessary, the board has not ruled out the possibility of such technology mandate(s).

The board notes, for instance, the various references in California law to accepted standards for utilization of digital signatures, including in Government Code section 16.5, which states that a digital signature to a public entity shall have the same force and effect as a manual signature if: it is unique to the person using it; it is capable of verification; it is under the sole control of the person using it; it is linked to data in such a manner that if the data are changed, the signature is invalidated; and it conforms to the regulations at California Code of Regulations, title 2, sections 22000-22005. (See also the FAQs on use and standards for of acceptable digital signatures on the California Secretary of State’s website <http://www.sos.ca.gov/digsig/digsigfaq.htm>).

Q73 Does the law designate a certification authority for digital signature certificates?

Not currently. The board expects that certification authorities may be designated by the industry, and/or that standards for signature certification will become clear. Pursuant to Government Code section 16.5 and California Code of Regulations, title 2, section 22003, the California Secretary of State has published a list of certification authorities approved for digital signature certification (for use or acceptance by public entities) at <http://www.sos.ca.gov/digsig/digsig.htm>. If it proves necessary, the board may rely on this list or formulate its own list of approved authorities.

Q74 Does the board have or plan any regulations pertaining to such topic areas as item-level tag use, tag data standards, pedigree record formats, data exchange standards?

No such regulations have yet been promulgated, and the board has thus far preferred to permit an organic development of the technology and standards, with board guidance but not mandates. If it proves necessary, the board has not ruled out the possibility of such technology mandate(s).

Q75 Can a pedigree database contain more information than is required by California as long as the electronic pedigree requirements for California are part of the data?

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

Q76 Is there a clearinghouse for the transaction data for electronic pedigrees?

The law does not mandate the creation or maintenance of a clearinghouse for this data. At the present time, the board is not aware that there is any central clearinghouse for pedigree data.

Q77 Is there a hotline to verify pedigree data provided in a pedigree?

The law does not mandate the creation or maintenance of a hotline to verify the authenticity of pedigree data. At the present time, the board is not aware that there is any such hotline.

Q78 Can a wholesaler or pharmacy maintain/store the pedigree record electronically?

Yes. 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 immediately be produced (B&P § 4105.)

COMMON STRATEGIES YOU MAY EMPLOY TO AVOID COUNTERFEIT, MISBRANDED OR ADULTERATED DRUGS

1. Know your supplier. Deal only with trustworthy, reputable suppliers. Just because your supplier has a license does not necessarily mean that 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 labels.
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 <http://www.fda.gov/medwatch> or 1-800-FDA-1088, contact the manufacturer, and contact the Board of Pharmacy.

EXCERPTS OF STATUTES PERTINENT TO PEDIGREE

Business and Professions Code section 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 one or more wholesalers, manufacturers, or pharmacies, until final sale to a pharmacy or other person furnishing, administering, or dispensing the dangerous drug. The pedigree shall be created and maintained in an interoperable electronic system, ensuring compatibility throughout all stages of distribution.

(b) A pedigree shall include all of the following information:

(1) The source of the dangerous drug, including the name, the federal manufacturer's registration number or a state license number as determined by the board, and principal address of the source.

(2) The trade or generic name of the drug, 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 the federal manufacturer's registration number or a state license number as determined by the board, 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) A single pedigree shall include every change of ownership of a given dangerous drug from its initial manufacture through to its final transaction to a pharmacy or other person for furnishing, administering, or dispensing the drug, regardless of repackaging or assignment of another National Drug Code (NDC) Directory number.

(d) A pedigree shall track each dangerous drug at the smallest package or immediate container distributed by the manufacturer, received and distributed by the wholesaler, and received by the pharmacy or another person furnishing, administering, or dispensing the dangerous drug.

(e) Any return of a dangerous drug to a wholesaler or manufacturer shall be documented on the same pedigree as the transaction that resulted in the receipt of the drug by the party returning it.

(f) 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.

(g) The following transactions are not required to be recorded on a pedigree:

(1) The provision of samples of dangerous drugs by a manufacturer's employee to an authorized prescriber, provided the samples are dispensed to a patient of the prescriber without charge.

(2) An injectable dangerous drug that is delivered by the manufacturer directly to an authorized prescriber or other entity directly responsible for administration of the injectable dangerous drug, only for an injectable dangerous drug that by law may only be administered under the professional supervision of the prescriber or other entity directly responsible for administration of the drug. Injectable dangerous drugs exempted from the pedigree requirement by this paragraph may not be dispensed to a patient or a patient's agent for self-administration, and shall only be administered to the patient, as defined in Section 4016, by the prescriber or other authorized entity that received the drug directly from the manufacturer.

(3) The exemption in paragraph (2) shall expire and be inoperative on January 1, 2010, unless prior to that date the board receives, at a public hearing, evidence that entities involved in the distribution of the injectable dangerous drugs subject to that paragraph are not able to provide a pedigree in compliance with all of the provisions of California law, and the board votes to extend the expiration date for the exemption until January 1, 2011. The decision as to whether to extend the expiration date shall be within the sole discretion of the board, and shall not be subject to the requirements of Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of the Government Code.

(h) If a manufacturer, wholesaler, or pharmacy has reasonable cause to believe that a dangerous drug in, or having been in, its possession is counterfeit or the subject of a fraudulent transaction, the manufacturer, wholesaler, or pharmacy shall notify the board within 72 hours of obtaining that knowledge. This subdivision shall apply to any dangerous drug that has been sold or distributed in or through this state.

(i) "Interoperable electronic system" as used in this chapter means an electronic track and trace system for dangerous drugs that uses a unique identification number, established at the point of manufacture, contained within a standardized nonproprietary data format and architecture, that is uniformly used by manufacturers, wholesalers, and pharmacies for the pedigree of a dangerous drug.

(j) 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.

(k) This section shall become operative on January 1, 2009. However, the board may extend the date for compliance with this section and Section 4163 until January 1, 2011, in accordance with Section 4163.5.

Business and Professions Code section 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.

Business and Professions Code section 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) Except as otherwise provided in Section 4163.5, commencing on January 1, 2009, a wholesaler or pharmacy may not sell, trade, or transfer a dangerous drug at wholesale without providing a pedigree.

(d) Except as otherwise provided in Section 4163.5, commencing on January 1, 2009, a wholesaler or pharmacy may not acquire a dangerous drug without receiving a pedigree.

Business and Professions Code section 4163.1

It is the intent of the Legislature that commencing on January 1, 2007, and continuing through the full implementation of the pedigree requirements specified by Section 4163, manufacturers and wholesalers shall use best efforts to provide in the most readily accessible form possible, information regarding the manufacturer's specific relationships in the distribution of dangerous drugs with wholesalers.

Business and Professions Code section 4163.5

The board may extend the date for compliance with the requirement for a pedigree set forth in Sections 4034 and 4163 until January 1, 2011, 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.