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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

Red Lion Hotel
1401 Arden Way
Sacramento, CA 95815

Present: William Powers, Chair, and Board Member
Stan Goldenberg, R.Ph.. Board President and Member
Dave Fong, PharmD., Board Member

Staff: Patricia Harris, Executive Officer
Virginia Herold, Assistant Executive Officer
Robert Ratcliff, Supervising Inspector
Judi Nurse, Supervising Inspector
Dennis Ming, Supervising Inspector
Joan Coyne, Supervising Inspector
Board of Pharmacy Inspectors
Joshua Room, Liaison Counsel, Deputy Attorney General
LaVonne Powell, Staff Counsel

Call to Order

Chair William Powers called to the meeting to order at 9:30 a.m. He welcomed the many participants and explained that the purpose of the Workgroup on E-Pedigree was to bring all the stakeholders together to discuss the implementation of the electronic pedigree requirement that will take effect on January 1, 2007.

Presentation on California's Requirements

Supervising Inspector Judi Nurse gave a brief overview of California law regarding the electronic pedigree requirement. She explained that in 2004, the Board of Pharmacy sponsored legislation, SB 1307 (Chapter 857, Statutes of 2004) that became law in 2005. The bill made various changes to license requirements of wholesalers and the distribution of dangerous drugs in California. Most of the licensing requirements became effective in 2006 and the pedigree requirement becomes effective January 1, 2007

Ms. Nurse reported that the law authorizes the Board of Pharmacy to delay implementation of the pedigree requirement until January 1, 2008, if the board determines that manufacturers or wholesalers require additional time to implement electronic technologies to track the distribution of the prescription drug within the state. The California legislature may extend the date for compliance with requirement for a pedigree for pharmacies if it determines that it is not yet economically and technically feasible for pharmacies to implement electronic technologies to track the distribution of prescription drugs within California. She presented the definition and requirements for an electronic pedigree and the prescription drug information that must be tracked.

She gave an overview of the transaction source and information that must be recorded on the pedigree each time a prescription drug changes ownership and the requirement that the information on the pedigree must be certified as true and correct.

Ms. Nurse explained that the other provisions of law as it relate wholesalers and pharmacies. All wholesale distributors selling prescription drugs into California must be licensed in California as of January 1, 2005. As of January 1, 2006, all licensed wholesale distributors must have a surety bond. Beginning January 1, 2007, a wholesale distributor or pharmacy may not purchase, sell, trade or transfer a prescription drug without receiving or issuing a pedigree. In addition, pharmacies may only furnish prescription drugs to: wholesale or manufacturer from whom drugs are acquired, a licensed wholesale reverse distributor (as defined in B & P § 4040.5), to a pharmacy or wholesale distributor in sufficient quantity to alleviate a specific shortage, a patient or pharmacy pursuant to a prescription, health care provider authorized to purchase prescription drugs and to a pharmacy under common control.

Ms. Nurse provided the restrictions that are limited to manufacturers and wholesale distributors in that they can only furnish prescription drugs to a licensed business or prescriber, can only acquire prescription drugs from manufacturer or licensed wholesaler, and starting January 1, 2007, a wholesaler or pharmacy may not sell, trade or transfer a prescription drug without a pedigree.

State of E-Pedigree and EPC/Radio Frequency Identification (RFID) Standards

Mike Rose from Johnson and Johnson and Ron Bon from McKesson as Co-Chairs of the EPCglobal Healthcare and Life Sciences Business and Action Group presented on the state of electronic pedigree and RFID standards.

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 EPC Global Network and related technology. The EPCglobal network combines radio frequency identification (RFID) technology, existing communications network infrastructure, the Electronic Product Code™ (EPC, which is a number for uniquely identifying an item) to enable accurate, cost-efficient visibility of information in the supply chain. EPCglobal community represents 30 of the top 40 pharmaceutical manufacturers, which includes 16 of the top 20 US manufactures, 3 of the 4 top retail pharmacies and 4 of the top 6 supermarket pharmacies (20,000 locations in total) and 4 of the top 5 medical device companies.

In 2004, the EPCglobal Healthcare Action Group was formed to address the following critical needs: pedigree management (including a pedigree messaging standard), air interface standard for item level tagging, serialization (the format of the EPC on the tag), decommissioning of tags and network security. EPCglobal also helped form and supports the Unified Pedigree Coalition.

While the presentation focused on Radio Frequency Identification technology (RFID) technology, it was explained that the standards that were developed are for any electronic pedigree. However, EPC/RFID was chosen because shipments can be read and authenticated with no "line of sight" needed. It is anticipated that RFID will the method used to track a drug's pedigree. The manufacturer would tag the drug with a small chip and antenna. When the tag is in close proximity of a reader, it would receive a low-powered radio signal and interact with a reader exchanging identification data and other information. Once the reader receives data, it would be sent to a computer for processing.

Wholesale distributors and pharmacies can confirm inbound receipts of item level products, expired items can be identified without handling each item, pallets and cases can be received without disassembly and there is a reduction in physical handling which equates to a reduction in risk and increased security. EPC also takes advantage of best practices for data sharing in that the owner holds the distributed data and there is a lower cost to the supply chain. It was noted that current EPC implementations by global leaders indicate a long-term commitment. RFID has the capability to solve critical regulatory issues. However, not all products are RFID candidates such as biologics, proteins, metal and glass. The tag and reader prices are coming down and there are pilots underway that will contribute to the efforts to establish standards.

The E-Pedigree standard addresses two key challenges in the pharmaceutical industry in that it provides a universal interchange format to express pedigree requirements of varied state regulations as drug products flow from one state to another and it enables trading partners to send and receive pedigrees in a secure and interoperable manner that leverages business to business technologies and processes. The E-Pedigree standards process requires that each party engaged in the wholesale distribution of prescription drugs must provide a pedigree to the recipient for sales, returns, and transfers of prescription drugs, pedigrees must contain a certification (via signature) by the sender that the information is true and accurate, pedigrees must be authenticated by the recipient prior to receipt of the drugs, recipient must add receipt and authentication to the pedigree, and a pedigree received by or provided by an organization is subject to recordkeeping requirements for record retention and availability.

The E-Pedigree interchange standards establish a format that meets federal PDMA standards and state requirements; it also has an extensible format that supports future state requirements. The standards also support regulatory and business requirements in that it tracks serialized items, repackaged products, sales, transfers, and return transactions. It can create an electronic pedigree from paper pedigree and it supports digital signatures and electronic authentication. It also enables interoperability among trading partners in that there is representation of pedigrees in a common portable format and there is an exchange of data using existing business data transfer

mechanisms. It also supports standard security protocols such as public key infrastructure.

The E-pedigree standards establish the requirements for the process, format, data elements, interchange, signatures and authentication. The E-pedigree interchange standards have been completed that meets the federal and state needs, addresses regulatory and business requirements, and enables interoperability among trading partners

The challenges to industry included data sharing issues, non-serialized items, patient privacy, public policy, regulatory considerations, cost/benefits differences by stakeholder, end-to-end supply chain implementation which is essential for mass adoption, and a lack of an universal pedigree agreement. The technology challenges were serialization, tag frequency, performance, package size, physical characteristics and event vocabulary.

E-Pedigree Pilot Programs
Viagra RFID Pilot Program

Walt Slijepcevich, Director of Pharmacy Development for Pfizer presented Pfizer's Viagra RFID pilot program. He stated that it is a pilot program aimed at shipping RFID/EPC tagged Viagra and creating an authentication capability by the end of 2005. Viagra was selected because it is Pfizer's most frequently counterfeited product and now all Viagra produced for sale in the U.S. has an RFID/EPC tag. The key objective of the pilot program was to learn more about mass serialization and RFID technology and the business processes that are required. He explained the capabilities that RFID created and the key decisions that needed to be made. The next phase of the pilot project is to determine how to handle data and exception reporting, learn more about wholesaler and pharmacy needs, understand the business process implementations and determine ongoing costs.

To implement RFID, there must be a commitment of others in the distribution channel, continued collaboration to obtain real world experience with RFID and mass serialization throughout the distribution channel (which is a significant investment), feedback on performance and utility of RFID-tagged product under normal day-to-day use, understanding of benefit and effect of targeted or total employment of mass serialization/RFID, resolution of data access and sharing, feasibility of tagging all pharmaceuticals and standards decisions and cost effective, robust tags.

The timetable provided indicated that there are numerous issues that must be addressed before a specific timetable for widespread adoption can be adopted. The key questions that need to be answered are: How will data be shared and who will have access? Do all pharmaceuticals need to be serialized and tagged for anti-counterfeiting purposes? How does the technology perform? Can costs be reduced? For an implementation timetable, it is Pfizer's position that there be two phases. Phase 1 would require tag only for "high-risk" products for adoption in the near future. Phase 2 would require a RFID tag on all items, which would be several years away and would be involve a substantial investment.

Pfizer supports the process used by EPCglobal in that the established standards are driven by business requirements and specific to the pharmaceutical industry. However, broader participation is needed from community and hospital pharmacy and while standards are under

development, guidelines on issues of privacy, EPC numbering schemes, and frequencies need to be developed.

Concern was expressed that an electronic solution may not be an immediate fix and the implementation of an electronic pedigree involving mass serialization may be many years off. However, to address immediate needs of securing the distribution system would be to require a pedigree when the chain of custody of a drug product does not go through the "normal distribution channel," which means the prescription drug goes from the manufacturer to a wholesale distributor to a pharmacy.

Mr. Slijepcevich concluded his presentation by stating that Pfizer is committed to the following initiatives in 2006, which are: McKesson On Track project and working with trading partners to address RFID implementation, Healthcare Distribution Management Association (HDMA) data management/sharing project, EPCglobal standards setting activities, developing Pfizer's own internal pedigree compliance solution, and Viagra RFID assessment and sharing lessons learned with the industry.

Use of RFID

Bob Dufour, Director of Pharmacy, Professional Services and Government Relations for Wal-Mart Stores presented its experience with RFID, which began in 1999 with trials in general merchandise and food products. In April 2004, the initial pilot began with 8 suppliers and one distribution center. By 2007, the pilot will include over 100 Wal-Mart stores and clubs, 5 distribution centers and 300 suppliers. To date, Wal-Mart has received 230,000-tagged pallets, 9 million tagged cases and over 90 million EPC reads.

Mr. Dufour presented slides of the pharmacy RFID program that showed the readers and scanning process. He stated that the milestones needed to expedite adoption included: the development of a single industry direction, developed business plans to simplify implementation, unified frequency standard and universal pedigree requirements.

Implementation of E-Pedigree

At the Enforcement Committee meeting of December 2005, a question and answer document was prepared and provided to all interested parties. Based on the discussion at that meeting and other questions that were submitted, the document was revised. Questions with a shaded background identified those questions that were new or that had been revised from the original December document. The document was marked "draft" because it is a work in progress and is intended for discussion purposes as the Board of Pharmacy is seeking input from all stakeholders.

Deputy Attorney General Joshua Room, Liaison Counsel for the board, commented that many of the subsequent questions that the board received addressed the issue of "change of ownership." He answered that in the sample questions and answers, the board provided examples of transactions that do or may constitute a "change of ownership." It 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. He stated that "possession and risk" are strong indicators of ownership.

Mr. Room also explained that 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.

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.

It is not the board's intent to answer hypothetical questions or determine how licensed entities must comply with the law.

It was asked whether prescription drugs that have expired and are not resalable require a pedigree when returned to a wholesaler, reverse distributor or manufacturer. A pedigree is required as part of the records of acquisition and/or disposition of any prescription drug by a wholesaler and pharmacy. If the transaction is considered a "change of ownership" then the transaction must be recorded on the pedigree. It was also asked about situations where a pharmacy purchases another pharmacy and its prescription drug inventory or a pharmacy purchases the inventory of a pharmacy that is closing. The purchase of the inventory may be considered a change of ownership and may require that it be recorded on the prescription drug pedigree.

Implementation Date of E-Pedigree – 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.

In addition, the board has received letters from the Food Marketing Institute (FMI), National Association of Chain Drug Stores (NACDS), Biogen Idec seeking a delay in implementation to January 1, 2008, because of concerns that it is an unrealistic compliance date for the entire pharmaceutical supply chain, from manufacturers to pharmacies to implement and comply with the requirements of an electronic pedigree.

It was expressed that twelve states, including California, have adopted legislation requiring pedigrees for prescription drugs. However, no state has imposed requirements as broad and far-reaching as California. It was suggested that California consider as the other states have a provision that recognizes a "normal distribution channel." "Normal distribution channel" means a chain of custody during distribution of a prescription drug that goes from a manufacturer to a wholesaler 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 intercompany pharmacy to a patient. Direct sales of a prescription drugs by a manufacturer to a pharmacy or a chain pharmacy warehouse are within the normal distribution channel. Therefore, a prescription drug that is distributed through the "normal distribution channel" would not be required to have a pedigree.

It was noted that the "normal distribution channel" concept was considered during the legislative process, but was not accepted by the board. The problems with a "normal distribution channel" or "authorized distributor" approach include the difficulty of monitoring and enforcing such relationships. Whereas it is possible for board inspectors and staff to identify and verify an e-pedigree, they are not experts in contract law and able to reliably analyze contractual relationships between manufacturers, wholesalers, and pharmacies, such as would be necessary to verify claimed exemptions from e-pedigree requirements based on "normal distribution channel" or "authorized distributor" relationships. Moreover, where status as a "normal distribution channel" or "authorized distributor" depends on private-party designations as such, the board lacks the ability to effectively monitor such designations. These relationships can change without notice, and often out of the view of the board. And furthermore, adopting a "normal distribution channel" or "authorized distributor" approach would presumably exempt a huge number of transactions from being part of the e-pedigree tracking system, which is inimical to the intent of the statute. This would take those transactions out of the verifiable e-pedigree domain, and increase the temptation for individuals, including even the employees of those "authorized distributors," to take advantage of this lack of oversight. The risk is too great. The e-pedigree is a far more reliable method of tracking the flow of drugs.

Concern was also expressed regarding the impact of the pedigree requirement may have on 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 in the next few months.

Other alternatives included establishing a list of the most susceptible prescription drugs and require a pedigree for only those drugs on the list. Provide exemptions to wholesalers that distribute incidental shipments of prescription drugs into California and exempt Third Party Logistics Providers from licensure as wholesalers.

It was also noted that the delay on the effective date of the pedigree provisions in the federal Prescription Drug Marketing Act (PDMA) expires December 2006. The federal Food and Drug Administration (FDA) held a Counterfeit Drug Task Force Public Workshop in February 2006 to receive comments. It was reported that the task force for the Anti-Counterfeiting initiative plans to issue its final report to the Commissioner in May. During this meeting it was suggested to the FDA that it create uniform standards for pedigree implementation so that an interoperable system could be created to assist the states. A delay by the board would give the FDA time to create additional guidance for states and/or modify the PDMA.

The Enforcement Committee acknowledge the tremendous amount work that the industry has done nationwide to implement the electronic pedigree requirement and while much of the discussion focused on why compliance could not be met by January 1, 2007, the committee asked the stakeholders to set forth how compliance will be achieved and the milestones that will be used to reach this goal. The delay of implementation will be on the board's April agenda as an action item and stakeholders were requested to submit extension requests with implementation milestones to the executive officer by April 1, 2006. Many stakeholders expressed their commitment to implementing the E-pedigree requirement but noted the difficulty of meeting the 2007 compliance date and would present milestones to demonstrate their efforts, however, it was noted that some milestones might be difficult to achieve because they are dependent upon the actions of others in the distribution chain.

Adjournment

Chair Powers adjourned the Enforcement Committee – Workgroup on E-Pedigree at 2:45 p.m. He noted that the next meeting is scheduled for June 20, 2006, in Sacramento.