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

Enforcement Committee and Workgroup on E-Pedigree
MEETING SUMMARY

Date: March 21, 2007

Location: Red Lion Hotel
1401 Arden Way
Sacramento, California 95815

Board Members Present:
Bill Powers, Board President and Chairperson
Ruth Conroy, PharmD, Board Member
Stanley Goldenberg, RPh, Board Member
Rob Swart, PharmD, Board Member

Staff Present:
Virginia Herold, Executive Officer
Robert Ratcliff, Supervising Inspector
Judi Nurse, Supervising Inspector
Joan Coyne, Supervising Inspector
Joshua Room, Deputy Attorney General
Anne Sodergren, Legislation and Regulation Manager
Karen Abbe, Public and Licensee Education Analyst

Call to Order

Chairperson Powers called the meeting to order at 9:35 a.m.

Mr. Powers advised that there was a change to Agenda Item 1c. The Proposed Modified Disciplinary Guidelines for the Board of Pharmacy would not be discussed at this meeting due to a printing error. This item will be placed on the agenda for the next Enforcement Committee meeting.

1. Enforcement Committee

a. Letter of Concern to CMS regarding the Federal Deficit Reduction Act's Use of Average Manufacturers' Cost as Reimbursement Base for Medications for Medicaid Patients

At the January 31, 2007 Board Meeting, the board voted to submit written comments to the Centers for Medicare & Medicaid Services (CMS) regarding their proposal to based Medicaid reimbursement on average manufacturer price. The board's concern was that this policy would lead to limited patient access due to pharmacies withdrawing from the Medicaid program if reimbursement costs are less than pharmacy costs to buy the medications.

Mr. Powers stated that a copy of the letter sent from the board to CMS dated February 16, 2007 was included in the committee meeting materials packet.

b. Proposal to Develop an Ethics Course for Pharmacists, Modeled After the Experiences of the Medical Board of California In Establishing an Ethics Course for Physicians

At the January 31, 2007 Board Meeting, the board directed that a small work group be formed to perform an in-depth review of a proposal to develop an ethics course for pharmacists which could be used as a term in disciplinary decisions. Some of the topics the board directed this work group to review included recommendations of the types of violations that could warrant a probation condition of completing an ethics course, consideration of the experiences of the Medical Board, and generally, to look at the proposal and components more fully.

The board directed that a report of this review be provided at the June 20 and September 20 Enforcement Committee meetings, and at the October 2007 Board Meeting.

Mr. Powers stated that one board member, Susan Ravnan, had volunteered to serve on the work group. At today's meeting, board member Robert Swart volunteered as well, so there are now two board members on the subcommittee. Mr. Powers asked if there was any discussion on the matter, and there was none.

c. Proposed Modified Disciplinary Guidelines for the Board of Pharmacy

Mr. Powers restated that Agenda Item 1c would not be discussed today due to a printing error. This item will be placed on the agenda for the next Enforcement Committee meeting.

d. Enforcement Committee Strategic Plan Update for 2007-08

In July 2006, the board finalized its strategic plan for 2006-2011. Each year in the spring, the board revises the strategic plan to keep it current.

Ms. Herold stated that at the April 2007 Board Meeting, the board will review any modifications to the strategic plan recommended by each committee for the development of the 2007-08 strategic plan. At this time, the Enforcement Committee has the opportunity to revise its strategic plan, and the materials in the committee

packet reflect the last committee update provided at January 31, 2007 Board Meeting. She suggested that the plan be updated to add activities underway or completed by the committee: analysis of an enforcement option of an ethics course, and a letter to CMS and DEA encouraging them to alter the process by which prescriptions are written or reimbursed. With the three changes, all activities will be included in the strategic plan.

Mr. Powers asked if there was any discussion on the matter. There were no comments from the board or from the public. Dr. Swart made a motion to accept the three suggested changes.

MOTION: That the Board of Pharmacy update the Enforcement Committee's Strategic Plan for 2007-08 to add the option of an ethics course, and a letter to CMS and DEA.

M/S: SWART/CONROY

SUPPORT: 4 OPPOSE: 0

2. Comments by the FDA on the Implementation of the Prescription Drug Marketing Act (PDMA) Provisions Involving Pedigrees

In June 2006, the FDA indicated it would implement PDMA pedigree requirements for medicine sales that occur outside the authorized distribution channel. The requirements would be in force beginning December 2006. However, just prior to December 2006, a U.S. District Court Judge in the Eastern District of New York issued a written order granting a preliminary injunction enjoining the FDA from implementing one section – 21 CFR 203.50(a). Section (a) specifies the type of information that must appear in the pedigree.

The committee's meeting materials for this meeting included the ADDENDUM to FDA's Guidance for Industry: PDMA Pedigree Requirements – Questions and Answers Related to the Preliminary Injunction ordered 12/5/06 in RXUSA Wholesalers, Inc. v. HHS (dated 12/15/06).

Ilisa Bernstein, PharmD, JD, Director of Pharmacy Affairs, FDA, Office of the Commissioner/Office of Policy, provided an update via speakerphone regarding the FDA's pedigree requirements. She also spoke about FDA studies underway with respect to RFID tagging on liquid products.

Dr. Bernstein thanked the committee for inviting her to speak. She said she last spoke with the committee before the regulations went into effect. The FDA was sued on some of the regulation provisions resulting in the court issuing a preliminary injunction until December 8, 2007, when all the regulations will go into effect. The injunction prohibits the FDA from implementing 21 CFR 203.50(a) at this time.

In summary, 21 CFR 203.50(a) says that each sales transaction must be included on the pedigree; that provision and others are subject to the preliminary injunction. The FDA intends to send the regulations and notice of appeal to court so that pedigrees must include information going back to the manufacturer. Though the injunction was from the Eastern District of New York, drugs pass through interstate commerce. The preliminary injunction does not affect the requirement that pedigrees must go back to the last authorized distributor of record (ADR).

Dr. Bernstein stated that the bulk of the policy guide she spoke of in December is still in effect until December 1, 2007 (i.e., who is an ADR). Those regulations should be undertaken as well as 203.50(b), (c), and (d), which are part of PDMA and are still in effect. Under the injunction, pedigrees must only go back to the last ADR, but it's in the best interest for pedigrees to go back to the manufacturer.

Dr. Bernstein said she was limited in what she could talk about regarding the lawsuit, but could talk about the studies initiated by the FDA several years ago regarding RFID. The FDA asked manufacturers what affect radio frequency had on the integrity and stability of drug products. The FDA heard back about some theoretical effects, but no hard data was presented. The FDA's Center for Devices (along with the Center for Drugs) subsequently asked their lab to look at identified products and packaging. They developed an exposure system using RFID technology in order to determine whether there is any effect. Data was gathered, and an analysis of that data will be prepared. The FDA's labs have competing priorities for their resources, but the analysis will be forthcoming. At this time, the FDA cannot predict what the data will reveal.

Mr. Goldenberg asked what would the FDA require (regarding pedigrees) during an inspection of a pharmacy.

Dr. Bernstein replied that the enforcement of pharmacies is usually deferred to states, unless something comes to the FDA's attention.

Mr. Goldenberg asked whether small and large biotechnical proteins were part of the represented samples tested, and if so, which products were tested.

Ms. Bernstein replied that biotechnic proteins were part of the samples tested, but she did not have details to share about the samples taken.

Mr. Powers asked whether the FDA is auditing implementation of the new law and if an enforcement report would be issued.

Dr. Bernstein replied that enforcement and auditing are two different things. The FDA does have an enforcement program. The law and the regulations are in effect and enforcement is underway, but she couldn't specifically target where enforcement activities are being prioritized. She stated that the FDA issues enforcement

statistics, which talk about the numbers of inspections. The information is posted on their website.

Mr. Powers asked if there were any comments from the public. There were none. Dr. Bernstein was invited to stay on speakerphone to participate in the remainder of the committee meeting.

3. Workgroup on E-Pedigree

a. Status of the Progress of the EPCglobal Workgroup and Standards for Electronic Pedigrees

Since the last Enforcement Committee meeting, EPCglobal released its Ratified Pedigree Standard (January 2007). A copy of the press release was included in the committee meeting materials. The press release included a link to the website where the standard (138 pages) can be downloaded. Ratification of the standard is a major milestone for E-Pedigree.

Bob Celeste, EPCglobal, gave a presentation on the state of E-Pedigree and EPCglobal RFID Standards. Mr. Celeste stated that new information and some updates had been added to his presentation including pedigree requirements, supply chain registry, and tag decommissioning. A copy of the PowerPoint presentation is attached to this meeting summary.

Mr. Celeste spoke on several issues including work streams, item level tagging, serialization, drug expiration dates, lot numbers, track and trace, and high-frequency vs. ultra high-frequency. He stated that RFID is not required in order to produce E-pedigree. He emphasized that when referring to pedigree, you must look at:

1) the standard
2) the law you are trying to comply with

EPCglobal is now working on developing a standard for electronic track and trace; this standard is expected to be complete in the third quarter of 2007. Additional work is underway in the area of authenticating and decommissioning tags.

Mr. Goldenberg invited stakeholders to present their ideas and concerns to EPCglobal while the standards are being developed.

Dr. Swart requested that when updates are made to the EPCglobal charts, that arrows would show whether progress had stalled out in particular areas.

Mr. Celeste replied that most areas of development are in the 10-20 week stage, so he didn't show progress on the charts.

Mr. Powers asked for comments from any of the stakeholders and the public.

George Pennebaker stated that he was concerned that the pedigree tracking must be capable of capturing events that don't happen "often." He stressed that we must take care of problem issues, no matter how infrequently they happen, for example, what happens to the pedigree information when a wholesaler goes out of business. He also asked if the EPCglobal standard considers NCPDP standards. Mr. Celeste stated yes.

b. Summary of Meeting with EPCglobal on March 8, 2007

Mr. Goldenberg stated that he, President Powers, Virginia Herold, Judi Nurse, and Joshua Room met earlier in March with the nine representatives of EPCglobal. They walked through the messaging standard and various scenarios. A copy of the meeting summary is available in the meeting materials for this meeting. Information was provided including the fact that manufacturers destroy any drugs returned to them. He believes they are looking at minutia of detail, and they are also looking at "frequency of actions" to see how best to handle those infrequent occurrences.

The messaging standard developed by EPCglobal meets California's pedigree requirements.

Mr. Room stated that terminology must be agreed upon as they relate to E-Pedigree.

Dr. Swart asked how pedigree will be tracked into a new location when pharmacies consolidate.

Mr. Celeste replied that that will fall into the realm of due diligence when purchasing a company, including the products owned by those companies.

Mr. Room stated that it is important to determine whether pedigree will reflect change of ownership transactions, and whether it can be added onto pedigree.

John Valencia, representing a variety of pharmaceutical manufacturers, stated that the EPCglobal presentation was interesting, but asked if the board will move to adopt formal standards now that the law is revised and instituted. He stated that while interesting, the information is not binding.

Mr. Room clarified that there is no requirement for the board to adopt the standard. The board met with EPCglobal and indicated its interest in the standard, and it appears to include California's legal requirements. The standard itself is the industry's way to comply with the law.

Mr. Powers asked the FDA (via speakerphone) if they had any questions at this time; they had none.

c. Update by Manufacturers, Wholesalers and Pharmacies on Implementation of Electronic Pedigrees

Mr. Goldenberg stated that the board holds these quarterly public meetings as outreach programs to clarify the law and implementation strategies to licensees. If any stakeholders or anyone else that is interested has suggestions or wants to participate, they should contact Executive Officer Herold.

Mr. Powers called on Heather Zenk, a licensed pharmacist from Amerisource Bergen, to make a presentation on E-Pedigree.

Dr. Zenk stated that AmerisourceBergen is one of the three largest wholesalers. AmerisourceBergen gave a full presentation at the last work group on its electronic pedigree pilot project, and she would provide an update regarding what they had done since that meeting. A copy of this presentation is attached to this meeting summary.

Since the last meeting, Amerisource Bergen conducted a series of webinars, sharing data. They want to provide the pharmaceutical industry with data in order to avoid misconceptions, particularly about the manufacturing perspective.

Dr. Zenk stated that AmerisourceBergen wants the webinars to be just another vehicle to engage partners. She expects that probably by the third quarter of 2007, they will have data to give back to the industry and users. They are still in the phase of determining how data will move efficiently. They have solutions, and a pilot should be up and running by May 2007, which will be rolled out to end users in the third quarter of 2007. It's a step by step process, and they want to be sure it's compliant.

Mr. Powers asked if there were any questions for Dr. Zenk from the public. There were none.

Mr. Powers called on SupplyScape for their presentation.

Lucy Deus, Vice President of Product Development at SupplyScape, stated that she would share information about their interim drug pedigree messaging standard during the 2006 timeframe. She used that information as a basis for how things went, what they learned, and how things must be different to comply with California's requirements. She stated that they leverage pedigree data into their other business operations. A copy of her presentation is attached to this meeting summary.

She commented that there are substantial business opportunities for companies to gain a return on their investment in adopting pedigrees, and a major retail pharmacy participated in tracking and storing pedigree dates for one year. The memory storage requirements turned out to be quite small for 50 million items: it required

700 MB of storage, which on new computers 100 times this amount of memory is about $50.

Ms. Deus emphasized that all benefits of electronic pedigree are not automatic. Companies need to look to their business operations and recognize how data generated from electronic tracking can benefit their operations.

She added that there are about six vendors working on interoperability issues, plus some additional "home grown" solutions developed by individual entities. She stated that businesses need to integrate pedigree software into "critical touch" points in business practices, which will aid companies in gathering data in other business operations. For example, physical and financial information regarding inventory, returns reconciliation, shelf life management, and facilitated identification of lots subject to recalls. She stated that companies need to test systems internally to make certain they work, then coordinate details with trading partners.

President Powers emphasized that the board is a consumer protection agency. E-pedigree is the law in California and 2009 is the implementation date. The board encourages all stakeholders to participate in development of the standards, making certain their operational needs are considered.

d. Question and Answer Session and General Discussion

There were a few comments from attendees on different enforcement issues. Greg Light, from Omnicare stated that his company primarily serves patients in long-term care and residential care facilities. Regulations are strict on skilled nursing facilities, however, for those residents in assisted-living facilities, the pharmacy is being asked to handle returned medications from patients. He is concerned that there are no regulations in place regarding how pharmacies handle those returned medications. There are two or three possibilities each time for drug diversions to occur. Drugs are returned in grocery bags, coffee cans, some are labeled, some are not; some are outdated. It puts pharmacies in the position of being medical waste haulers, but their primary concern is diversion.

Mr. Light asked the board for further instructions on how to deal with this effectively. He saw that *The Script* addressed returning drugs for credit from assisted-living care.

Mr. Goldenberg asked if the board should put the issue of guidelines on a future agenda.

Mr. Powers said that there were some attempts in the past to deal with the issue legislatively. He stated that the matter will be placed on a future agenda.

Mr. Goldenberg clarified that skilled nursing facilities are regulated by the Department of Social Services. He said they should look at whether the board

should be meeting with the Department of Social Services or the Department of Health Services.

Ms. Herold stated that because of the diversion issue, the Enforcement Committee is the right committee for this issue. She said that the board should discuss possible resolutions. Under consideration in the California Legislature is a bill (Simitian) that would mandate pharmacies to take back returned medications.

Mr. Powers asked if there were any further questions or comments.

Drew Harrison, from Baxter Care, stated that he wanted to underscore business processes. He would like clarification from the board regarding granularity – how low does electronic tagging need to go. The law says pedigree must track from the smallest manufacturer's container level. For Baxter, the lowest level may be a shelf pack or case – the item is never broken down, shipped or sold in smaller units. He asked for guidance. Mr. Harrison stated that the consequences of tagging at the unit level, especially for some products, could defeat the intent of the law. Baxter requested the board's interpretation of law.

Mr. Room stated that the board wants to hear industry-level feedback as to whether tracking back to granularity would be a challenge. The law requires tracking down to an individual container, but if that provides challenges and if exceptions are needed by way of regulation, the board can provide that if we know that business processes are hampered by that. The board wants to know is being experienced by the industry.

Mr. Harrison asked if the board wants documentation as to the challenges created by unit dosages.

Mr. Room responded that yes, the board welcomes that feedback, and that Executive Officer Herold will accept that information.

Adjournment

There being no additional business, Chairperson Powers adjourned the meeting at 11:58 a.m.