



MINUTES

Enforcement Committee and E-Pedigree Public Meeting

September 11, 2012

COMMITTEE MEMBERS PRESENT:

Randy Kajioka, Vice-President, Chair
Tappan Zee, Public Member
Rosalyn Hackworth, Public Member
Amy Gutierrez, PharmD
Shirley Wheat, Public Member

LOCATION:

Hyatt Regency San Francisco Airport
1333 Bayshore Highway
Burlingame, CA 94010

STAFF MEMBERS PRESENT:

Virginia Herold, Executive Officer
Anne Sodergren, Assistance Executive Officer
Carolyn Klein, Legislation and Regulations Manager
Susan Cappello, Enforcement Manager
Kristy Shellans, DCA Senior Counsel
Joshua Room, Deputy Attorney General

The meeting was Webcast at http://www.pharmacy.ca.gov/meetings/current_webcasts.shtml

The meeting was called to order at 9:37 and called for a moment of silence in respect for the September 11 events. Roll call taken and quorum established.

I. Enforcement Committee Issues:

(a) Discussion Regarding the Process under Which the Board May Accept the Surrender of a License from a Licensee on Probation with the Board.

Ms. Cappello provided an overview of the voluntary surrender requirements and the benefits of having a document by which a licensee could submit to the board as well as an implementation strategy. Once the surrender is approved, the signed form would be attached as an addendum to the disciplinary order.

Ms. Shellans provided the committee with additional information on how the proposal would work and what action can or cannot be taken.

Dr. Gutierrez asked if the forms would also apply to wholesalers and non-resident pharmacies. Ms. Shellans indicated that it would.

Motion: (Wheat /Hackworth) – Motion to move to accept the forms as presented and delegate the acceptance of the surrender to the Executive Officer.

Vote: 5-0

(b) Discussion Regarding Electronic Prescribing of Controlled Substances in California, Including a Request for Proposals by the California HealthCare Foundation for a Pilot Study in Ambulatory Provider Settings.

Ms. Herold provided an overview of the issues with e-prescribing. One principal impediment is that the DEA is unable to provide a list of certified and authenticated pharmacies to post on the board's Website. Ms. Herold advised the committee that board inspectors have been instructed to request a copy of the auditing certification approval when inspecting pharmacies that are using e-prescribing for controlled substances.

Public Comment: Al Carver, representing Walgreens, advised the committee that a copy of the certification with DEA auditing requirements can be provided when requested by an inspector. Mr. Carver stated that Walgreens has difficulty confirming if the prescriber is also certified and indicated that currently Walgreens is relying on SureScripts to identify whether the prescriber's system meets the requirements because SureScripts will not transmit an e-prescription from an uncertified system. Those scripts sent from a non-authorized prescriber are returned back to the prescriber with a notice indicating that the prescription cannot be filled.

Dr. Kajioka requested clarification of information that Walgreens received from SureScripts about the number of prescribers that have been approved consistent with the rule.

Mr. Carver advised the committee that Walgreen's does have such a list and will provide it to the board for information purposes.

Ms. Herold also advised the committee about funding for pilot projects available through the California HealthCare Foundation and referred to materials in the committee meeting's packet.

(c) Request for Clarification Regarding 16 California Code of Regulations Section 1707.5(d) Involving Availability of Interpreters for Patients with Limited English Speaking Skills in a Nuclear Pharmacy.

Dr. Kajioka provided a brief overview of the issues involving patient-centered label regulations and if the translation requirement would apply to a nuclear pharmacy.

Ms. Shellans advised the committee that the requirement does not apply because the medicine is not dispensed to the patient.

No public comment was provided.

II. Discussion on the Implementation of California's Electronic Pedigree Requirements for Prescription Medication

(a) Presentations and Questions from the Pharmaceutical Supply Chain on Their Readiness to Meet California's Staggered E-Pedigree Implementation Schedule.

Dr. Kajioka welcomed those who had traveled to attend the meeting. Dr. Kajioka noted that Brazil now has electronic serialization requirements.

No public or board comment was provided.

(b) Update on the Status of Proposed Regulations to Specify a Unique Identification Number for Prescription Medication, and “Grandfathering” Provisions for Non-Pedigreed Dangerous Drugs.

Ms. Herold stated that the regulation specifying the requirements for serialized numbers as well as the grandfathering provisions were finalized at the July Board Meeting and that the proposed regulations had been released for the required 45-day comment period. Ms. Herold provided a brief timeline for the regulation and advised all present the process to request a regulation hearing if one is requested.

No public or board comment was provided.

(c) Discussion Concerning Elements for Possible Regulation Requirements to Permit Inference as Provided by California Business and Professions Code Section 4163.3.

Dr. Kajioka provided an overview of the board’s desire to document the need for inference. In July the board released a request for comments on inference seeking specific elements from industry. Dr. Kajioka underscored that consumer protection cannot be compromised with the use of inference but that board recognizes the requests of the supply chain to use inference. Dr. Kajioka provided a brief synopsis of the comments provided.

Dr. Gutierrez also spoke in favor of the comments and encouraged everyone to submit their comments.

Mr. Room indicated that the comments received were very general in nature and did not provide the board with sufficient information to develop regulations at this point. He requested that more detailed information be provided. Mr. Room also highlighted that one submission indicated that the cost of aggregation was too high to implement. Mr. Room pointed out that inference cannot be achieved unless aggregation occurs.

Mr. Room also indicated that some of the comments included statements that industry is looking to the board or FDA to identify who will manage the data, and what type of solutions should be employed. These topics are outside the scope of this information request.

Ms. Herold advised the committee that comments submitted from two organizations seemingly did not make it to the board’s office. Ms. Herold advised all present that if comments were not included in the meeting materials packets that they can be sent via scanned letter attached to an e-mail to Ms. Herold.

PUBLIC COMMENT/PRESENTATIONS:

Bill Fletcher - Pharmacy Logistics Solutions. (PowerPoint presentation provided at the end of these minutes) Mr. Fletcher indicated that he was presenting to the board to share some of the lessons learned as well as a reminder to all present why the law is on the books. Mr. Fletcher commented that by complicating the issue, it just delays the implementation and provided some examples. Mr. Fletcher indicated that the cost for implementation of the electronic pedigree is primarily on the manufacturer. Mr. Fletcher highlighted several other industries that serialize products and infer serialized products moving through the supply chain including auto parts distributors, electronic component distributors as well as consumer electronics.

Mr. Fletcher advised the committee that inference is widely used. Mr. Fletcher indicated that nonconformance issues are detected at the point of sale, when the detected saleable item is removed from the container and scanned at checkout. Mr. Fletcher noted that if a drug serial number is checked against trade documents like a pedigree when the item is removed from the case, bad products would never move through the supply chain.

Mr. Fletcher provided an overview of the Good Manufacturing Practices (GMP) as it relates to determining the confidants of the contents of a sealed box. GMPs used in the pharmacy industry validate requirements and ensure consistent procedures are followed.

Mr. Fletcher highlighted some of the problems experienced with implementation as well as some of the risks of a limited solution. Mr. Fletcher indicated that some manufacturers have made the integration of the serialized product more complicated than necessary and indicated that tracking of the serialized number should not begin until the point of aggregation.

Mr. Fletcher discussed some of the other technologies used including electronic data interchange (EDI) advanced shipping notices (ASN) as well as GS1 identifiers.

Mr. Fletcher provided examples of advanced shipping notices offered for automotive parts. Mr. Fletcher underscored that the concept is not new and provided a chart documenting that 50% of the pharmacy supply chain are already using ASNs.

Mr. Fletcher indicated that EDI can comply with the "certification" requirement provided for in the law and provided the committee with the basic premise upon how that is done.

No public or committee comments were provided.

Bob Celeste - GS1 (PowerPoint presentation provided at the end of these minutes)

Mr. Celeste provided the committee with an update on the progress of the standards setting work being done by his organization. Mr. Celeste provided an overview of the standards in healthcare used to identify, capture and share information with trading partners. Mr. Celeste indicated that the GS1 standards ensure barcode quality to ensure it can be read at the end of the supply chain through all of the processing shipping and handling.

Mr. Celeste discussed the development of an implementation guide done through the Secure Supply Chain Task Force. Mr. Celeste discussed the current status of the development and the timeline for finalization of the guideline. Mr. Celeste highlighted the areas that will be covered in the guideline document.

Mr. Celeste discussed standards activities with respect to inference and advised the committee that GS1 worked with Stanford University to develop a statistical sampling paper. Mr. Celeste indicated that the inference paper may be revised to include the statistical sampling information developed by Stanford University after further vetting. A copy of this document is in the meeting materials.

Mr. Celeste advised the board that GS1 continues to hold conference calls to discuss physical vs. virtual accountability. Mr. Celeste highlighted what is happening next including traceability adoption.

Dr. Kajioka asked for clarification on the inference document, specifically to clarify at what point a sealed case should be opened and read. Mr. Celeste indicated that when a case unit is naturally opened that is when the item should be read. This ensures that an item is not unnecessarily opened.

There was no additional committee or public comment.

Lynn Paulson - speaking on behalf of CSHP.

Dr. Paulson asked the board to provide some guidance on what it is expected for a hospital to comply. Dr. Paulson indicated that a hospital could receive up to 80 totes a day that are mixed lots. Hospitals need a workable system that includes just one reader irrespective of the company providing the totes. In addition, Dr. Paulson indicated that a hospital needs to maintain the box intact as a way to reduce diversion. Dr. Paulson advised the committee that there are a lot of challenges to implementing the e-pedigree requirements and getting some of these requirements to work in a real world scenario. Dr. Paulson suggested a two-day collaborative meeting to develop solutions to these changes.

Mr. Room asked Dr. Paulson about the inference requirements and was advised by Dr. Paulson that the cases would be scanned when received and inventoried. Mr. Room clarified that hospitals are requesting inference when a case is involved - - that the item can be inferred until the case is opened.

Ms. Herold asked if Dr. Paulson was interested in engaging in a pilot project and was advised that yes Dr. Paulson is interested in pilot projects with wholesalers.

There was no additional committee or public comment.

Liz Gallenagh – HDMA (PowerPoint presentation provided at the end of these minutes)

Ms. Gallenagh indicated that inference is key to the implementation strategy of e-pedigree. Ms. Gallenagh provided a brief overview of the HDMA organization and its members. In addition she provided an overview of the suppliers they receive products from as well as the types of settings that they provide products to. Ms. Gallenagh stated that the need for inference of serialized products is needed due to use of 2D barcode because such a barcode requires “line of sight” technology to read the information.

Ms. Gallenagh provided a scenario of how inference would be used including the use of an ASN as well as what factors would be present. Ms. Gallenagh indicated that without inference, technologies and processes will be difficult or impossible to successfully deploy. Ms. Gallenagh spoke of the benefits to the use of inference including increased security of the supply chain by limiting the number of open cases in a warehouse.

Mr. Room asked for clarification on what HDMA is requesting - - inbound inference only and if so, is it time-based? Mr. Room asked what percentage of a wholesaler’s shipment is homogenous and was advised that it depends on the size of the wholesalers, but indicated that it could be 75-85 percent of the shipments received by the large wholesalers, but would likely be a smaller percentage for smaller wholesalers.

General discussion indicated that about 2 percent of cases are never opened by a wholesaler and remain intact through the supply chain to the pharmacy.

Ms. Gallenagh indicated that the comments she provided were specific to inbound shipments. She requested flexibility on the elements that must be included in company SOPs to allow for the different ways business is conducted by large wholesalers and suggested that perhaps the board should identify the factors that must be addressed in the SOPs rather than prescribing the SOPs themselves.

Ms. Herold asked about what happens if a package is inferred inbound and outbound, what is the role of the wholesaler if a problem is identified at the end of the chain at a pharmacy. Julie Kuhn of Cardinal Health responded with a real world scenario when a case was received by the manufacturer without any record of the shipment. Ms. Kuhn indicated that exception processing needs to be undertaken but indicated that the general process would be expected that the pharmacy would work with the wholesaler to resolve the issue.

Ms. Herold asked about information surrounding the use of the advanced shipping notice and asked what the process is now if a shipment is received without an ASN. Ms. Gallenagh advised that the shipment is always in response to the wholesaler placing an order and as such there is always a PO or other sort of documentation. The committee was advised that such a scenario needs to be vetted through the exception process and that work is just beginning in this area.

Dr. Gutierrez asked for clarification on how drop shipments are being handled. Dr. Gutierrez was advised that the issue of drop shipments needs to be further discussed because of the unique scenario where the wholesaler takes ownership but never takes possession of the products.

No additional public or committee comment was provided.

Steve Gray – Representing Kaiser Permanente and as an individual

Dr. Gray stated that many of the board members are new to the issue and underscored that the intent of e-pedigree is patient protection. Dr. Gray asked the board to focus on the top priority – protection of the public via enforcement against the bad players. Dr. Gray stated that if a true track and trace model is being employed, then inference is essential given technology limitations. Dr. Gray indicated that inference must then be done at the pallet level and case level as well as the need to have inference for a shelf packet as well (especially for hospitals and wholesalers). Dr. Gray discussed the complexity of the supply chain and various business settings and suggested that multiple solutions may be necessary when defining inference.

Dr. Gray advised the board that the use of EDI has occurred for at least a decade and indicated that the EDI needs to be incorporated into the pedigree. Dr. Gray indicated that the issue of drop shipment needs to be discussed and the solution will require some flexibility. Dr. Gray also advised the committee that one of the SOPs needed are to address the scenario where the receiver is on site at the shipping site and accepts ownership of the product immediately.

No public or committee comments were provided.

Ruby Raley - Axway

Ms. Raley spoke to the needs of independent pharmacies and the fact that many wholesalers act as the warehouse for such pharmacies and this must be considered when developing the inference rules. Ms. Raley also indicated that information technology should not drive implementation but it should be driven by the regulators and industry. Ms. Raley indicated that the committee needs to discuss the forensics and what tools are needed by the regulator or QA personnel to identify what went wrong and where the hole in the process occurred. Also, what type of recording is sufficient to meet the forensic needs and that the exceptions need to be vetted and how that should be included in the SOPs.

Dr. Gray recommended to the committee that the database of information should be maintained by a quasi-government organization to protect the proprietary information. Kaiser is opposed to making such information public and indicated that this needs to be considered by the board.

Steve Drucker - Merck

Mr. Drucker thanked the committee for the work in the area of e-pedigree. Mr. Drucker indicated that costs of the solution must be considered to ensure that the costs are associated with value. Mr. Drucker spoke in support of e-pedigree and indicated that Merck is interested in moving forward. Items that should be included in the inference discussion are the level of accuracy, what can industry commit to, what is the risk involved -- what is acceptable risk, and last, what is the impact to the supply chain. Mr. Drucker referenced

the PDSA efforts and the areas that all supply chain members could agree with including barcoding lot leveling tracking first.

No public or committee comments were provided.

(d) General Discussion

There was no additional discussion

(e) 2013 Future Meetings

Dr. Kajioka confirmed the next enforcement committee meeting is December 4, 2012.

Dr. Kajioka discussed future Enforcement Committee dates.

March 5 - Bay Area

June 4 – possibly southern CA

September 10 -

December 3

(f) Closing Comments

Dr. Kajioka summarized some of the comments from the public speakers.

III. Public Comment on Items Not on the Agenda/Agenda Items for Future Meetings

No public comment was provided.

Dr. Kajioka adjourned the meeting at approximately 2:00 p.m.