



Enforcement Committee and E-Pedigree Public Meeting MINUTES

Date: Tuesday, December 4, 2012

Location: Hilton Los Angeles Airport
5711 West Century Blvd.
Los Angeles, CA 90045

Committee Members Present: Randy Kajioka, PharmD, Committee Chair
Rosalyn Hackworth, Public Member
Shirley Wheat, Public Member
Tappan Zee, Public Member

Committee Members Absent: Amy Gutierrez, PharmD, Professional Member

Staff Present: Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Carolyn Klein, Manager
Joshua A. Room, Deputy Attorney General
Kristy Shellans, Sr. Staff Counsel

Note: The webcast for this meeting is available at *YouTube* Channel: California DCA

http://www.youtube.com/watch?v=0TDC_FXOi7M

Call to Order

Committee Chair Randy Kajioka called the meeting to order at 9:52 a.m. and roll call was conducted. Mr. Zee, Ms. Hackworth and Dr. Kajioka were present at Roll Call. Public Member Shirley Wheat arrived after the first presentation began.

Board Members Stan Weisser, Greg Lippe, and Victor Law were in attendance in the audience.

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

(a) Presentation on the Track-and-Trace Pilot by the US Veterans Administration

Presenters included Lloyd Mager, Abbot Laboratories; Kevan MacKenzie, McKesson; Ms. Chris Chandler, PharmD, VA Health Care Administration; and Margot Drees, Global Healthcare Exchange (GHX) via teleconference.

The presenters provided background on each of their respective entities. Mr. Mager noted that Abbot will be splitting into two companies and that in the future he will be representing AbVie. A copy of the PowerPoint presented is appended to these minutes describing the pilot project that was conducted by the Veterans Administration for 60 cases of a 'cold chain' product, Humira.

Ms. Drees noted that approximately \$50 billion spent in medical health care flows through GHX annually. She provided an overview of the track and trace system that was utilized in the pilot, describing business processes the track and trace system. Mr. Mager described the serialization of the products using GS1 standards and the bar codes used. He reviewed the scope, objectives and goals of the pilot. He discussed the process overview of serializing the products, how the product moved through the system, and the chain of custody of the product at the case level. Mr. Mager discussed the types of barcodes used on the cases and the information contained in each, as well as the types of events that were recorded for the transactions, adding that HDMA guidelines were used for the bar codes. Mr. MacKenzie spoke of the data received in advance of product receipt (by McKesson), noting that McKesson inferred the contents of each case. He described the systems in place to record, scan and match data, purchase orders and products. Mr. MacKenzie described how data was recorded in McKesson's EPCIS system. Mr. Mager added that EPCIS is a communication standard. Mr. Mager spoke about the interfaces of systems; the ownership, sharing and visibility of data; and verification of products. The presenters described a mock recall event of one of the cases of product in the pilot; and discussed issues related to the reading and recording of product NDC numbers.

The presenters reviewed findings and limitations of the pilot project, commenting on what is available through the GHX system. He spoke of data consistency and use of 10- and 11-digit NDC numbers.

Dr. Chandler provided an overview of the VA facilities, populations they serve, and the VA's Consolidated Medical Outpatient Pharmacy (CMOP). The VA's seven CMOP facilities ship more than 100 million prescriptions each year, and she described some of the VA's business processes in receipt and distribution of prescriptions. She spoke of the pilot partners, use of the GHX network, and the authentication process (safety check) of the medications. She described the barcodes used, the GLNs used for purposes of the pilot, and of the mock recall that was conducted during the pilot. Dr. Chandler spoke of 'next steps' and ways of further securing the drug supply chain.

Ms. Wheat asked about use of the GHX system, asking if the pilot participants would have to joint such a network or system. Ms. Drees responded that the GHX model is a subscription based system. Ms. Wheat asked about visibility of the data and what type of information each of the pilot partners had access to. Mr. Mager indicated that a trade partner would be able to see an event that involves that trade partner (who you got the product from; where you sent the product). When asked about the use of specific software, Mr. Mager added that he supported the use of a model (not a specific system) that could host data and connect systems together. He said that each participant needed to have a common link with the other. Ms. Drees added that each trading partner was registered with GHX and they used GHX to capture data. The presenters spoke of how each trade partner was able to use their existing systems, yet trade data via GHX.

Mr. Room asked about the process steps and capabilities. He asked how the certification requirement of the accuracy of the drug was conducted and trading that information. Mr. Mager said the accuracy was dependent on the model used, noting that technology plays a part, as well as the process that is used.

Ms. Shellans reflected Mr. Mager's comment that the certification be of a business process used. Mr. Room asked about the central repository of data and how information is certified. Mr. Room spoke to the provision of data that is the 'source' of information, in lieu of data that is modified or amended. Mr. Kajioka asked about the inference process and how data is validated when cases are opened.

Ms. Herold asked about the documentation of the 'eaches' and the decommissioning of a pedigree. Dr. Chandler responded that in the pilot they did not look at decommissioning. Ms. Herold spoke of the pedigree data is passed and the beneficial byproduct that could be created for purposes of third-party payers. Dr. Chandler indicated that decommissioning (end of life for the serial number) is a conversation that trade partners need to have. Mr. Room asked about an event that might suggest the drug is ready for dispensing and wouldn't further be distributed except for recall or return. Ms. Herold asked if data was received on products in advance of receipt of serialized product. Mr. MacKenzie indicated that during the pilot they received data in advance of receipt, once the ship event was recorded.

Dr. Kajioka recessed for lunch, and the meeting reconvened at 12:15 p.m.

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

Presentation by HP Labs

Mr. Steve Simski with HP Labs, an HP Fellow and a Director of HP Labs. (A copy of the .ppt presentation is appended to these minutes.) Mr. Simski spoke of an HP software system that he states would couple nicely with the needs of the pharmaceutical industry. He described it as a global product authentication service. Mr. Simski provided a demonstration using his phone to read a barcode on a piece of paper, and accessing the HP global system. He discussed how the system has been used to facilitate a recall and provided an example of a food recall, and discussed some of the outcomes of HP's efforts in their system.

Dr. Kajioka asked about the number of products tagged by this product, and Mr. Simski advised HP's system can be applied to tens of millions of pieces, asserting the system is robust enough to meet the needs of the pharmaceutical industry. Dr. Kajioka asked about the interoperability of the HP system to other systems, noting he did not see any response from HP on the board's request for information related to inference. At that time, Ms. Herold invited all interested parties to submit information and comments to the board regarding inference. Ms. Herold referenced the authentication as demonstrated by the phone read. She asked if the existing software out there is sufficient to append the pedigree when the drug is received at the pharmacy. Mr. Simski spoke to the security needed between sender and recipient. He indicated EPCIS is sufficient and is standard based. He said HP would work on the security analytics, as a way of people to interrogate the EPCIS data. Mr. Simski asked if the board is considering different levels of authentication for higher dollar pharmaceuticals than for lower cost products.

An audience member identified himself with AMGEN and asked if the system works with a 2-D bar code. Mr. Simski stated it does.

Presentation by Intelliflex

Presenters were Mr. Peter Norton from Intelliflex; Mr. Scott Pugh Verify Brand, and Mr. Kaley Parkinson with Rehrig Pacific Company. (A copy of the .ppt presentation is appended to these minutes.) Each presented information on their respective backgrounds. Mr. Norton noted that Intelliflex is a RFID battery assisted passive tag provider, one that is well known in the food chain industry. The tags can hold way points, temperature data, serial numbers, etc. He spoke of the battery and shelf life of the tags, and the ability to send data collected by the tags.

Mr. Norton stated this is a partnership of three companies to provide a consolidated, integrated solution to provide international traceability of the drug supply chain. Mr. Pugh provided that Verify Brand is dedicated to serialization and traceability utilizing GS1 standards. He said the software is used all over the world – nearly 80 countries. Mr. Parkinson expanded on Rehrig's history and how they service clients.

Mr. Norton spoke to the benefits of using RFID tags and provided information on the cost of the tags and readers and the re-use of tags that have reached the end of life. Mr. Pugh spoke to the value of using random serialized number instead of sequential. He advocated the use of tools and services that would integrate a broad range of data sets. He spoke of mobile solutions, integration with logistic carriers, and of pulling data in from those carriers. He noted that various types of events can be captured and maintained. They have a reverse logistics component that would allow for recalls and – from an investigatory perspective – provide data as to why the reverse component was utilized. Mr. Parkinson spoke of the reusable transport items that are available through Intelliflex. He asserted these reusable components can result in significant cost savings by reusing the assets. Such an investment in these types of items can offset the cost of the intelligence that is used alongside the reusable tag.

There was discussion on the ownership of the tags, the battery life of the tags, costs of the tags and readers, the period of time in which the data from the tags could be read, and the types of products to which the tags can be applied.

Ms. Shellans asked if there were limitations to the types of drug products to which the tags are applied – such as all products or just biologics. Mr. Room asked for clarification on the transfer of EPCIS data.

Presentation by SmartRmeds for Life

Presenter was Mr. Walter Berghahn, President, SmartRmeds for Life, a consultant working in pharmaceutical packaging. Mr. Berghahn spoke about existing systems and processes currently in the market place that would create a robust item-to-case aggregation. (A copy of the .ppt presentation is appended to these minutes.) He spoke of fully- or semi-automated systems or manually solutions. He spoke of some of the industry players who are providing the solutions currently and in limiting the potential for human interaction to eliminate errors. He stated he would like to see California's e-Pedigree law implemented on the Federal level, not superseded by federal requirements.

Mr. Room said the models presented utilized standard sized packaging, and he asked about challenges that may be realized for different sizes and shapes of packaging. For the types of containers that are not easily automated, Mr. Room asked about the level of human interaction to serialize the product. (i.e., aggregating the product after it is packed).

There were no additional presentations.

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

Dr. Kajioka indicated the committee did not want to try to formulate language in this setting. He stated he would want board staff to draft language for presentation to the full board, first vetted by the Committee.

Mr. Room asked if it is the committee or the board's desire – based on the limited information received from industry – that a draft should be prepared. Dr. Kajioka indicated he would like to see industry provide additional information for the board's consideration, adding he would like to see information provided on liability, and again encouraged industry partners to submit comments to the board regarding inference.

Mr. Room said he doesn't feel like he has the information necessary to draft regulation language on information based on the limited comments received. He said he would like additional comments on the types of inference that need to be identified (i.e., what inferences are appropriate).

Mr. Zee suggested moving forward with what information we have received so as to not delay the issue further, and Ms. Wheat agreed with Mr. Zee's recommendation. Ms. Wheat thinks we should draft something so that we can get additional input.

Mr. Room added that California statute sets out the requirements of pedigree are that every trade partner is to verify at the unit level. In the absence of action by the board to allow for inference, verification is required at the unit level. One of the things Josh is asking is at what level is inference needed, or what types of inference industry wants. Kristy asked if the committee would like a summary of the comments received to date. She stated the board is establishing a general performance standard. Ms. Wheat said such a summary would be helpful. Ms. Shellans recommended that a concept paper be brought back to be vetted by the committee. It was the consensus of the committee that a summary or framework be brought back as a starting point for the committee's consideration. Ms. Hackworth agreed with the suggestion to have a concept paper outlining the issues. Ms. Herold summarized upcoming meeting dates on which such a concept could be discussed. She added that every time inference is used, you have created an exception to the integrity of the pedigree attached to the drug. Ms. Wheat suggested that a summary of comments be provided for the February 2013 meeting and draft language be brought to the March 2013 meeting.

(d) Discussion on the Use of Drop Shipments in an E-Pedigree System

The committee discussed some of the issues associating with drop shipments. Mr. Room said one of them main problems with drop shipments is the timing because the wholesaler doesn't become aware of the transaction until after a shipment is received – where the paperwork is generated after the fact. He invited Mr. Ron Bone, McKesson to address the committee.

Mr. Bone described situations (usually urgent needs) where a manufacturer prepares a product and ships it directly to a pharmacy. In these situations, the manufacturer doesn't usually generate a billing when a drug is shipped – sometimes a wholesaler will be billed. Mr. Bone stated his believe that a drop

shipment has the least risk of any transaction because it's a direct connection between the manufacturer and the pharmacy.

Ms. Wheat inquired why the board is addressing the drop shipment issue and the committee discussed the recording of a pedigree in these instances. Mr. Bone spoke to the certification of a pedigree by a wholesaler, where the wholesaler never had possession of the drug. Mr. Room added that the law requires all changes in ownership be tracked, and you have to receive the data at or before receipt of the drug. So in this example, the pharmacy will not have received any data to which it will validate the pedigree information for the drug it received from the manufacturer. There was discussion of authentication receipt versus the chain of custody information required for pedigree validation.

The participants addressed challenges associated with drop shipments and the timing of the reconciliation of data for these transactions. Mr. Room added that the problem with exempting drop shipments is that you will have a product with an SNI on it that does not have corresponding data in the database. Mr. Room asked Mr. Mike Ventura of Glaxo Smith Kline if there is something that can be done at the manufacturer level to speed up the transmission of the pedigree data in the circumstance described.

Ms. Herold asked partners to lay out scenarios to help the board better understand these processes – to visually show how drop shipments move ... how they move, the timelines and the paperwork. Mr. Room asked for additional information on two areas of potential regulation. One, for trading partners to suggest language to deal with the temporality of the documents. Two, what do industry partners want to do with the fact that the wholesalers are certifying receipt of product that it never has possession of. How do they envision as a good way to deal with that.

Mr. Mike Ventura commented that from a manufacturer perspective, they understand serialization. He said that when it comes to compliance with California requirements, they short of becoming compliant. Mr. Room clarified that to be compliant with pedigree, you are not required to provide DPMS. Mr. Room spoke of the record of receipt and ownership is what is required. Mr. Room stated that the board was not going to 'bless' one particular system.

Mr. Lloyd Mager questioned the board about grandfathering. He provided an example of a product with a long shelf life, asking if – for the board's proposed regulation – it could be grandfathered. Mr. Room explained that the whole point of Pedigree is to create a system that, moving forward, works.

(e) General Discussion

There was no additional general discussion.

(f) 2013 Future Meetings

Ms. Herold said the future meeting dates are on the board's website, suggesting the March Enforcement Committee meeting be moved. Ms. Herold said that she will coordinate a date with the President of the board and all the committee members. Future committee meetings will be held September __ and December 3.

(g) Closing Comments

II. Public Comment on Items Not on the Agenda/Agenda Items For Future Meetings

There was no public comment.

Dr. Kajioka adjourned the meeting at 2:42 p.m.