



**California State Board of Pharmacy**

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

## **Enforcement Committee Report**

Stan Goldenberg, RPh, Chair and Board Member  
Bill Powers, Board President  
Ruth Conroy, PharmD, Board Member  
Tim Dazé, Esq., Board Member  
Robert Swart, PharmD, Board Member

Including Report of the Meeting of June 20, 2007

A summary of the Enforcement Committee and Workgroup on E-Pedigree Meeting held June 20, 2007 is provided in **Attachment A**, near the back of this tab section.

### **ITEM 1: Report of the Workgroup on E-Pedigree:**

#### *1. Update of the Workgroup on E-Pedigree Meeting*

At the June 20<sup>th</sup> meeting, the workgroup had its largest meeting to date. Presentations were made by EPCglobal, Pfizer, Walgreens and PhRMA regarding progress to implement electronic pedigrees into the drug distribution channel for California. **Attachment A** holds the minutes of this meeting, and the PowerPoint presentations of the first three entities are provided as attachments to the minutes.

The FDA attended the meeting via telephone.

#### **EPCglobal**

Mike Rose, tri-chair of EPCglobal, provided a presentation of where EPCglobal is with respect to its standards setting project for electronic pedigrees. (For the PowerPoint presentation, see Attachment 1 of the minutes contained under **Attachment A.**)

In early January 2007, EPCglobal finalized the standard for electronic messaging. This was a major milestone for the implementation of electronic pedigree requirements. The new pedigree standard will support item level serialization, electronic signatures, RFID using non-line of sight identification of pallets, cases or items, and inference.

There are three companies currently certified:

- Axway
- Rfxcel
- SupplyScape

A brief summary of EPCglobal's progress (as reported at the June meeting) in seven areas is:

- Pedigree management use cases: objective: define all supply chain use cases, processes and information needs for use in creating pedigree messaging standards.  
Status: complete
- Pedigree messaging standards: objective: define a standard format for the pedigree-messaging standard that meets all federal and state requirements.  
Status: complete
- Item level tagging: objective: define requirements for tagging pharmaceuticals at the item level; this includes requirements for manufacturing lines, distribution environments, transportation and retail environments.  
Status: requirements complete. A high frequency technical work group was formed to define the standard. High frequency and ultra high frequency pilots are underway to provide uniform air interface protocol at the item level. The high frequency standard is expected to be completed in the 3<sup>rd</sup> quarter of 2007
- Serialization: objective: define requirements to be encoded on the electronic tag.  
Status: requirements completed. Two identifiers were identified for use (global trade item number (GTIN) and serialized shipping container number (SSCC)). The newly formed serialization group will address all remaining issues.
- Authenticating and Decommissioning: objective: define requirements for authenticating and decommissioning tags for optimizing tag utility and consumer privacy.  
Status: work to begin in March 2007, timeline is 6 months. The DEA is very interested in this. The solutions will span a mix of hardware, software and process responses.
- Track and trace: objective: define supply chain use cases, processes and information needs for sharing EPC-related data for forward and reverse logistics.  
Status: forward and reverse logistics processes and data exchanges completed, common vocabularies and location identifiers drafted, additional use cases to be addressed for 3<sup>rd</sup> party logistics and repackagers, product recall, data sharing strategy and guidelines, and pedigree on demand concepts are being developed.
- Tag Data Standards: objective: define additional memory requirements for tags (i.e., lot number expiration date)

Status: Work underway; defining common data structure that can be used by all industries.

The track and trace standard is expected to be complete in the third quarter of 2007.

### ***Pfizer***

Peggy Staver of Pfizer provided information about Pfizer's experience in electronically tagging Viagra. (A copy of this presentation is provided in Attachment 2 to the meeting minutes, provided under **Attachment A**.)

Ms. Staver indicated that Pfizer used a multifaceted approach to ward against counterfeiting of Viagra. They restricted sales so that Viagra can only be purchased from the manufacturer or from an authorized distributor. Pfizer also used technology, such as color shifting ink on the labels, RFID tags and 2-D bar codes.

In Pfizer's experience, the one-time costs of implementing serialization are about the same regardless of what type of tagging is used. The majority of the costs lie in the provision and commissioning of the serialized number and applying the tag. Although she noted that the implementation costs for Viagra were \$5 million, future costs for tagging Celebrex will be \$4 million.

Pfizer also has tagged Celebrex and Lipitor, and Pfizer has learned that each implementation is unique.

Pfizer indicated that they have 65 product lines at 21 manufacturing sites worldwide producing drugs for the US market. They estimate \$95 - \$100 million in costs to implement serialization throughout the system, and this does not include ongoing costs. Pfizer estimates that it will take five to seven years to implement serialization on all product lines and recommends a risk-based implementation for serialization, where the highest risk drugs are serialized first.

### ***Walgreens***

Sue Thoss, Walgreens Divisional Vice President, Logistics and Planning, provided a PowerPoint regarding Walgreens plans for item-level serialization (see Attachment 3 of the Meeting Minutes provided in **Attachment A**).

Walgreens expects to use tunnel and handheld readers for item-level barcode reading and an RFID tunnel for case reading at their distribution center. They expect item-level inference and validation. And they will do audit sampling.

Walgreens believes there will be one-time costs at its distribution center of \$700,000 to \$1 million, and ongoing costs of \$500,000 to \$1 million annually.

They expect to be fully integrated one year after the standards are in place, and expect it will take six months to “bleed out” the untagged inventory.

If inference is not allowed, the implementation costs will double to \$1 million to \$1.5 million, and ongoing costs of \$2.5 - \$3 million.

Walgreens also provided information on costs of implementation if other processes are used, which would not comply with California law (e.g., the wholesaler applies the serialization tags).

Walgreens suggested a phased-in implementation with certain drugs being tagged initially, and all drugs becoming tagged over a period of time. They suggested that controlled drugs and list 1 products be the first to be required to be RFID tagged.

Walgreens stated that they wanted the tagging on all drug products to be RFID tagged.

### ***PhRMA***

The Pharmaceutical Research and Manufacturers of America provided comments about California’s e-pedigree requirements. Written comments from PhRMA are provided in **Attachment 1**.

PhRMA encouraged the board to work with the end users of the pedigree systems as well as the manufacturers who are at the front end. Serialization should be first implemented for those drugs that have the greatest likelihood of being counterfeited, although PhRMA does not have a list of such drugs. PhRMA also states that the costs to serialize all item level packaging are significant with unproven safety benefits. Other non-electronic techniques used by some manufacturers to prevent counterfeiting, like color shifting inks on labels and threads through labels, were suggested as alternatives.

PhRMA supports phased-in use of serialization, although serialization will only protect packaging, not the medicine inside. Instead PhRMA suggests case level serialization with use of lot number control as a better method. PhRMA stated that it would take several years after all standards are in place for the tracking technology to be manufactured and put in use.

### ***Other Comments***

The HDMA stated that it fully supports the use of RFID tagging of all products at the manufacturer level. The HDMA seeks a track and trace system for serialized products. Also, HDMA noted that the costs projected by Walgreens are not necessarily those of other wholesalers.

The HDMA is not in favor of tracking by lot number, in part because of the burden placed on pharmacy for such systems, and principally because it is not possible to link transactions this way.

The CPhA stated its concerns with costs – if reimbursement is capped by insurance companies, pharmacies will have to absorb the costs of electronic tagging of products that are added to the price of the product by manufacturers. Pharmacies will not be reimbursed for these costs.

Two press clippings regarding electronic pedigrees are included in **Attachment 1**.

**2. Presentation to the Board on E-Pedigree Standards Development by EPCglobal**

Bob Celeste of EPCglobal will provide an update presentation to the board on the work of EPCglobal in developing e-pedigree standards.

**ITEM 2: For Discussion and Possible Action: Use of Average Manufacturers' Price as the Reimbursement Base for Medications for Medicaid Patients**

At the January 31, 2007 Board Meeting, the board voted to submit comments to CMS in response to their proposal to base Medicaid reimbursement upon average manufacturers price. The board's concern was that this policy could lead to pharmacies withdrawing from the program if reimbursement costs are less than their acquisition costs for the medicine. As a result, patient access to pharmacies and medicine, especially in inner city and rural locations may become imperiled.

The letter was written and mailed by the comment deadline. A copy of the letter is provided in **Attachment 2**.

Former Board Member John Tilley recently requested that the board continue discussion on this topic at this board meeting due to the serious impact such reimbursement will have on patient care in California. A copy of his comments are also included in **Attachment 2**.

The board's concern is access to pharmacies and medicine by Medi-Cal patients and patients in general if a number of pharmacies, especially in inner cities and rural areas, go out of business due to inadequate reimbursement or quit serving Medi-Cal patients.

### **ITEM 3: For Discussion: Requirement to Use Security Forms for All Medicaid Prescriptions**

Effective October 1, 2007, all Medicare-paid prescriptions, if written, will need to be on security prescription forms unless electronically sent.

The Centers for Medicare and Medicaid Services, in response to this federal legislation, is currently developing a "guidance document." In June, CMS contacted the board to learn about California's requirements for security prescription forms. Tentatively, CMS believes California's controlled substances security pads will fit their requirements (although the guidelines are not yet completed). There are about 30 million such prescriptions issued in California each year.

This item was added to the agenda for discussion. We currently have no additional information about these requirements.

### **ITEM 4: For Information: 2007 Pharmacy Self Assessment for Hospital and Community Pharmacy**

The 2007 hospital and community self-assessment forms have been completed and are available online. However, the 2007 version of the self-assessment forms cannot be required until regulation section 1715 is amended to reference the 2007 forms. While this regulation is being updated through a section 100 filing (rulemaking without regulatory effect), current regulation section 1715 requires the 2005 forms to be completed.

As such the board is advising pharmacies that a self-assessment must be performed by the PIC every odd-numbered year or within 30 days of a change in PIC. If either the 2005 or 2007 form is on file, the pharmacy is in compliance. The board will encourage completion of the 2007 form. If neither version of the self-assessment forms has been completed, the pharmacy is in violation of this regulation section and may be subject to citation and/or fine.

The 2007 self-assessment forms are available from the board's Web site.

### **ITEM 5: Presentation by the Nevada Board of Pharmacy on the Nevada Electronic Pedigree Program**

At the National Association of Boards of Pharmacy Meeting, the Nevada Board of Pharmacy made a presentation about their electronic pedigree requirements.

Nevada's requirements mandate wholesalers to provide certain data to the Nevada Board of Pharmacy each month.

Very recently, the Nevada Board of Pharmacy requested the opportunity to make a presentation to the California Board about adopting a similar program in California. Board President Powers agreed to schedule this presentation.

At this Board Meeting, Nevada Board Member Keith MacDonald, General Counsel Louis Ling and Executive Secretary Larry Pinson will make the presentation about Nevada's system. Nevada hopes to convince California to adopt these requirements until all details and technology for California's electronic pedigree system are in place by manufacturers, wholesalers and pharmacies.

A brief overview of the Nevada Board's Presentation is provided in **Attachment 3**.

### **ITEM 6: Presentation on the Pharmacists Recovery Program by Program Consultant Maximus**

California Business and Professions Code sections 4360-4373 establish the Pharmacists Recovery Program and parameters for its operation. This program was established in the mid-1980s as a program to:

“rehabilitate pharmacists and intern pharmacists whose competency may be impaired due to abuse of alcohol, drug use or mental illness. The intent of the pharmacists recovery program is to return these pharmacists and intern pharmacists to the practice of pharmacy in a manner that will not endanger the public health and safety. “

A pharmacist or intern may enter the program at the formal or informal direction of the board, or voluntarily (without the board's knowledge). Unlike other diversion programs operated by DCA healing arts board, our program continues any disciplinary action underway (although participation in the program is used in probation or as mitigation in settling cases). The key factor is that by joining the PRP, a pharmacist or intern is immediately monitored by the program for sobriety or abstinence, before the board's enforcement program can investigate and put in place other patient safeguards.

The provisions establishing the program are provided in **Attachment 4**.

During this meeting, Don Fensterman, LCSW, Program Director will provide information about the program.

We currently have 78 participants in the PRP. There are 54 board-referrals.

## **ITEM 7: Meeting Summary**

A summary of the June 20, 2007 Enforcement Committee and Workgroup on E-Pedigree is provided as **Attachment A**.

## **ITEM 8. Report on Enforcement Actions**

A report of enforcement actions taken during fiscal year 2006/07 is provided as **Attachment B**.

# Attachment 1

*Comments from PhRMA at the  
June 20, 2007 Enforcement  
Committee Meeting*

*General News Updates About  
E-Pedigree*

# CDW•G Fed Tech

[ feature - may 2007 ]

## Tag & Release

### Can the long-held promise of RFID help make pharmaceutical e-pedigrees a reality?

By Elizabeth Thompson Beckley



Illustration: Marcelle Faucher

The Fagan family of Long Island, N.Y., thought they were out of the woods when their 16-year-old son, Tim, came through a lifesaving liver transplant in 2002. Yes, he would need to take immune-suppressing drugs for the rest of his life, but his prognosis was good.

Among the drugs in Tim's regimen was Epogen, an anti-anemia medication prescribed to help boost his production of red blood cells. Tim's mother administered a weekly injection of the drug, bought from the local branch of a national pharmacy. But hours after the shot, Tim would wake up screaming in excruciating pain. His doctors had no explanation, and no one would have guessed the cause was fake pharmaceuticals.

"The first night I thought someone had broken into his room and was attacking him," says Tim's father, Kevin Fagan. "It was a very emotional and very painful thing to watch our son suffer. To find out two months later that he was taking counterfeit drugs just blew us out of the water. We couldn't believe counterfeit drugs even existed."

Indeed, counterfeit drugs pose an "increasingly sophisticated threat" in the United States, according to Dr. Andrew von Eschenbach, acting commissioner of the Food and Drug Administration, citing the 2006 update of the FDA's Counterfeit Drug Task Force Report.

"We have witnessed an increase in counterfeiting activities and a more sophisticated ability to introduce finished dosage-form counterfeits into legitimate drug distribution channels over the years," the report concludes.

To squash that threat, or at least suppress it, the FDA has championed the use of new technologies that would meet and surpass the goals of the Prescription Drug Marketing Act enacted in 1988 and updated in 1992. Among other things, the law established a pedigree requirement for the wholesale distribution of drugs to document the ownership history of a product.

54 Number of counterfeit drug cases opened by the FDA in 2006, compared with 9 in 1997.

Since 2004, the FDA's Counterfeit Task Force has supported widespread use of electronic track-and-trace technology to help secure drugs' integrity with accurate pedigrees in the supply chain. An e-pedigree is a legally binding document in electronic form that includes certain data elements required to populate the pedigree.

"We'd love to see companies continue to move toward an electronic pedigree," says Dr. Ilisa Bernstein, director of pharmacy affairs at the FDA. "The difficulty is that under the law there is no distinction between whether a pedigree is paper or electronic. In our view, if everyone moves toward some electronic pedigree and every product has its own serial number, we could track that product from manufacturer to pharmacy — that's a way we can further secure our supply chain."

Radio frequency identification is considered the most promising technology to achieve e-pedigrees, Bernstein says, with the primary advantage that it does not require direct line of sight to read — each item does not have to be scanned, as is the case with a bar code.

### Pinning Hopes on RFID Tag

An RFID tag, a small chip with a tiny antenna, can carry and transmit data. The tag goes under the label of each drug package. With RFID readers, supply-chain partners would gather information on the chip, so as the product moves out of the manufacturer's door, it is read, read again in the wholesaler's receiving dock and throughout the warehouse, and so on down the chain.

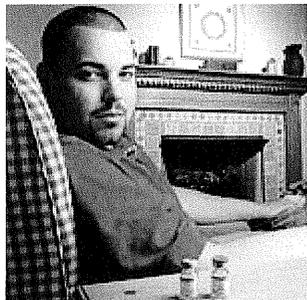


Photo: Andrew Kist  
Tim Fagan received counterfeit medication following a liver transplant. Now, he and his father have begun a campaign to find ways to keep such drugs out of legal supply chains.

"Companies can gain other benefits in addition to the supply-chain security that we're all looking for," Bernstein says. "Better inventory control, staff management and help in reducing some of the paperwork sometimes involved with the distribution of drugs, such as controlled substances."

Peggy Staver, director of trade product integrity for Pfizer, one of the few drug manufacturers pioneering the use of RFID technology, adds that the pharmaceutical industry is interested in potential operational benefits such as enhanced shipping and receiving efficiencies, accuracy, increased inventory management and availability, potential shelf-life applications, and recall possibilities.

"You can read an entire case of bottles in a fraction of a second ideally, when everything is working well, by passing a case through a portal or in the presence of a reader, as opposed to having to scan every individual item," Staver says.

But to date, only three drug makers have introduced serialized branded pharmaceutical products with RFID tags in the U.S. marketplace — Pfizer (see sidebar below), GlaxoSmithKline and Purdue Pharma. Each trading partner has to have the appropriate equipment, so an infrastructure is needed for RFID to work. But adoption across the industry has been slower than expected, and that infrastructure is not yet in place.

## Standards and Efficiencies

The industry could not move forward without standards, and the first pedigree standard was just published this January by EPCglobal North America, a nonprofit organization aimed at achieving mass adoption of electronic product code (EPC) and RFID technology.

"With one standard, vendors can be certified by us to be compliant and know that they are interoperable," says Bob Celeste, director of health care at EPCglobal North America.

### Counterfeit Drugs: FDA's Definition

Drugs sold under a product name without proper authorization and intentionally mislabeled in some way that suggests they are authentic, approved products.

This first standard builds on a document model and is essentially a one-way pedigree. Celeste describes it like a Russian doll or a snowball, in which more and more information is added to the previous information. Initially the manufacturer provides its data as well as information about the distributor, the drug itself and the transaction. That information moves in a parallel path with the drug.

With RFID, it is not necessarily on the chip, but a message that is sent to the distributor. The distributor receives that message, authenticates the shipment, and then wraps around it another message with information about the receiving part of the transaction. When the drug goes to the hospital or pharmacist, another layer is created about shipping, and it keeps going down the line, so everyone has knowledge of where that product has been and who has had it.

But the manufacturer or others at the beginning of a pedigree can't see into the future. So, according to Celeste, work is under way on a track-and-trace model where one could see up and down the supply chain. Today, if someone found a questionable drug or a drug in a place where it didn't belong, she would have to go to the manufacturer and walk her way up the supply chain to find the last place that bottle legally existed. With track-and-trace, she could go to anyone at any place on that supply chain and know the drug's entire history.

This offers additional business process benefits, such as more automated replenishment and vendor-managed inventory. For example, a distributor could have visibility of when a product is used by a customer and know when to replenish the drug and when to bill.

"The pedigree [standard] itself has taken a big step in that direction in at least identifying the information that needs to be passed, giving one standard that can comply with many regulations," Celeste says. "It's really giving the industry something to work with. So if you had paper and wanted to move to electronic, there are guidelines in the standard to do that."

## 25,000

Number of people believed to have injected a diluted version of Procrit, an anemia medication, during a counterfeit drug scare in 2001 and 2002.

SOURCE:

Turkewitz Law Firm

The pedigree is a messaging standard and does not require RFID, Celeste points out. He also notes one reason why widespread adoption has been slow: Each trading partner needs to understand the regulation in the jurisdiction with which it is trying to comply. If a company is shipping product in the United States, it has to understand the FDA's PDMA; in Florida, it needs to know PDMA, plus Florida's drug law; in California in 2009, it would have to understand the California law also.

The Florida law does not require an item to be serialized. The California law currently requires products to be serialized and numbers to be authenticated prior to receiving the drug. That's the niche where companies are starting to look at RFID from the compliance standpoint, Celeste says, offering a real-life example.

"If you're a distributor and receiving cases of drugs on a pallet, in 2009 in California you would have to verify each bottle in each case," Celeste says. "The manufacturer could mark the bottles with a 2-D bar code, meaning the distributor would have to open each case. Or, with RFID, the distributor can read right through the case. That is the link between pedigree and RFID."

Stakeholders are interested for a number of reasons, including brand protection. The proposition of having an RFID chip on a bottle and unique serialized numbers in a network could create a more secure environment in which a product is less likely to be diverted or counterfeited. At the end of the supply chain, in pharmacies and hospitals, the interest lies in the internal processes once those organizations receive drugs, Celeste says. As an example, he uses the ability to pull bottles off the shelf by their expiration dates.

EPCglobal North America has a group looking further into the future, connecting sensors with RFID. One would be able to get information on whether a drug has stayed in the appropriate temperature range, for example.

"Future work will be to get a sensor that does not require new hardware or software," Celeste says. "That's where RFID takes off. It's not just seen as a replacement for bar codes; it's seen as a highly mobile computer that can do many things during your processes."

## Hurdling Barriers

At some point, e-pedigrees will be commonplace, Bernstein predicts. "We were told in 2004 it would take three years. Here we are in 2007, and we're not there," she says.



Photo: Gary Landsman

"We were told in 2004 it would take three years. Here we are in 2007, and we're not there" on e-pedigrees for drugs, says the FDA's Dr. Ilisa Bernstein.

Among the reasons is concern about privacy. "People fear if someone is driving down the street with a reader, he could read what's in the medicine chest of a house he drives by. That's not the case," Bernstein says.

Both ultra-high-frequency near-field tags and high-frequency tags would require a reader to be within 4 to 5 inches of the tag to be able to read it, Celeste says. "And what you would read off there wouldn't necessarily tell you what drug it is," he explains. "Companies today are

masking the drug code on that tag and also working on decommissioning technology to make the tag active only if the consumer wanted it."

Another reason for pursuing the track-and-trace model is to split the security so it lies with both the tag and the bottle's unique number.

"The physical tag, yes, that may be counterfeited," Celeste says. "But the fact that the number on it is known to the network, if that number ever shows up again, it could alert the supply chain that there's an issue and both bottles could be quarantined until things are figured out."

Bernstein also acknowledges that cost can be a major barrier to early adoption of a new technology. The FDA is doing its part to try and make sure the costs of RFID or other technologies that will help achieve industrywide e-pedigrees don't add to the ever-increasing cost of drugs.

There are capital costs to retrofit packaging lines and enable unique serialization, Staver says. Depending on how many manufacturing lines a company has, there could be many lines that require hardware and software to tag items, cases and pallets. An ongoing cost is that of the tags, which are much more expensive than a printed bar code.

Pfizer spent nearly \$5 million implementing RFID on bottles, cases and pallets of Viagra, she says. "But we were early adopters, so our costs were higher back in 2005 than they would be today. Costs are coming down as the technology continues to mature."

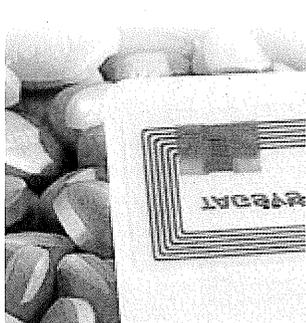
One thing drug manufacturers, regulators and consumers agree on is that technology alone will not prevent counterfeiting. Improved business practices, enhanced legislation, strengthened enforcement and the deployment of technology are all required, Staver says. "We need to do this in a way that doesn't undo the efficiencies built into current processes," she says.

Kevin Fagan and the lawyer representing his family, Eric Turkewitz, want to see the supply chain shortened, so that there are fewer opportunities for fake drugs to slip in. Manufacturers would be "foolish if they do not combine [RFID] with a very tight distribution system," Turkewitz says. "If they let their wholesalers buy drugs from secondary wholesalers, then they are inviting trouble."

Fagan says he supports a bill named for his son, "Tim Fagan's Law" (HR 2345), introduced by Rep. Steve Israel (D-N.Y.). The bill would increase criminal penalties for the sale or trade of counterfeit prescription drugs, modify requirements for maintaining drug pedigrees, establish recall authority for the FDA, and implement the safety measures recommended by the FDA's counterfeit drug task force, including the deployment of anti-counterfeiting technology.

"There has got to be a way to track where a drug has been. A pedigree system, whether paper or electronic, is a great step, but more important is to shut down the ways that [counterfeit] drugs can get into the supply chain," Fagan says. "Certainly track-and-trace is great, RFID is great, but we also need legislation that has a multipronged approach, and more people who become aware and get involved. If this could happen to us, it could happen to anyone."

### Tiny Tags for the Little Blue Pill: A Private Sector Pilot



In December 2005, Pfizer started shipping its erectile dysfunction medicine, Viagra (sildenafil), with radio frequency identification tags at the bottle, case and pallet level. With just over one year of experience and a \$5 million investment, Pfizer is on the leading edge of the high-tech track-and-trace wave that the Food and Drug Administration would like to see wash over the entire pharmaceutical industry.

The drug maker also is in the design phase of a pilot project that will add RFID to Celebrex (celecoxib, a nonsteroidal anti-inflammatory drug), with plans to introduce the RFID-tagged pain reliever at the case and pallet level late this year or early next, says Peggy Staver, Pfizer's director of trade product integrity.

"Our focus, and that of most of the pharmaceutical supply chain, has been on a safe and secure supply chain, looking at anti-counterfeiting," Staver says.

"This has been a patient safety initiative for us, but the reason [RFID] is preferred is for potential other benefits. You can track items with

bar codes, but they're just not as efficient as existing technology that may offer some additional benefits."

The issue becomes one of maturity and cost, she says. Bar codes have been around longer, are more reliable and more proven, and have lower costs. "That's why the industry is engaged in pilots, to better understand the cost benefits associated with implementation of RFID technology."

The Viagra project is still considered a pilot because it is one product family and only involves Viagra sold in the United States, but it is a commercial implementation from the standpoint that Pfizer is tagging all Viagra for all of its U.S. customers.

"Because of where we are with the maturity of the technology, Pfizer chose to incorporate a redundant 2-D bar code on the package label," Staver says. "The thought was that if the RFID tag could not be read, there would be a backup system that contains the same EPC, or electronic product code."

In January 2006, after Pfizer started shipping its RFID-tagged Viagra, the goal was for others in the supply chain to be able to read the unique EPC number found on each bottle, case or pallet of Viagra and confirm through Web authentication services that the number was a valid number issued by Pfizer. To date, more than 600,000 authentications have been performed using that authentication service, mostly by wholesale distributors and retail chains.

"We are only aware of 19 dead tags out of nearly 3 million units that have shipped in the market," she says. "That's a little misleading because all units have not been read. But based on the limited experience we've had, the technology appears to be performing very well as the product is moving through the supply chain."

Has the use of RFID cut the amount of fake Viagra? "We don't have a good baseline for what level of counterfeit there is in the U.S. market to say we've reduced counterfeiting by 'X,'" Staver says. "We can only look at overall FDA investigations of counterfeit drugs, and it's hard to understand some of the anomalies from one year to another."

#### As the Trailblazer, Pfizer Offers Lessons Learned

- RFID implementation is complex and costly.
- Standards are absolutely essential to guide industry efforts.
- Manufacturers need to work alongside industry stakeholders to identify and address issues.
- Privacy concerns are important and should be addressed, even though there are some misunderstandings.
- The RFID knowledge base needs to be expanded.
- Process redesign and training are critical.
- Data sharing and inventory visibility opportunities associated with RFID implementation need to be addressed.



*Subacute*

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## **CARDINAL HEALTH ANNOUNCES PLAN TO DEPLOY RFID TECHNOLOGY IN CALIFORNIA**

*Following Cardinal Health's industry-first, end-to-end RFID pilot, company leverages RFID technology to prepare for California pedigree legislation*

**DUBLIN, Ohio, May 3, 2007** — Cardinal Health announced today that it will integrate radio frequency identification (RFID) technology into the operations of its Sacramento, Calif. pharmaceutical distribution center by Fall 2007, to prepare for California's pedigree legislation that will require all drugs distributed within the state to be tracked and traced as they move throughout the supply chain.

The announcement, which was made at the RFID Journal Live! conference, hosted this week in Orlando, Fla., is part of Cardinal Health's ongoing efforts to protect the safety and efficiency of the nation's drug supply.

The announcement comes just months after Cardinal Health shared the results of its RFID pilot program, which was the health-care industry's first end-to-end test of RFID in a real-world setting. Data collected from the pilot confirmed that RFID technology using UHF as a single frequency is a feasible solution to track and trace the possession of pharmaceuticals at the unit, case and pallet levels. The pilot also confirmed that RFID technology offers significant promise to provide an added layer of safety within the pharmaceutical supply chain, by enabling item-level pedigrees to be tracked and traced as they pass from manufacturer to wholesaler to pharmacy.

The recently passed state legislation in California requires pharmaceutical manufacturers to originate item-level pedigrees for drugs distributed within the state's borders. This legislation also requires companies within the pharmaceutical supply chain (including companies that distribute drugs, like Cardinal Health) to update item-level drug pedigrees upon each change of ownership.

Cardinal Health operates dozens of pharmaceutical distribution centers nationwide. The company will start implementing RFID technology in its Sacramento, Calif. distribution center, as a means to receive and produce the electronic drug pedigrees needed to meet the requirements of the California legislation.

"While the Sacramento project is designed to support the pedigree legislation in California, it's also an extension of the end-to-end RFID pilot that we completed last year," said Steve Inacker, executive vice president of Global Supplier Services for Cardinal Health. "We look forward to leveraging this work to further validate the effectiveness and viability of RFID technology in real-world settings, should it be adopted as an industry standard."

As part of this effort, Cardinal Health will also leverage the new data, made available by RFID technology, to identify efficiency opportunities in key areas including returns and order accuracy, which can deliver value to the entire pharmaceutical supply chain.

### **Cardinal Health identifies next steps needed to facilitate industry-wide RFID adoption**

As Cardinal Health integrates RFID technology into its California operations, the company also said that industry standards and technology issues need to be addressed by the health-care industry as a whole, before RFID technology can be adopted industry-wide.

First, according to California law, product serialization must be initiated by the manufacturer, at the unit level, to allow tracking from the beginning to the end of the supply chain. For this to occur, Cardinal Health said the pharmaceutical supply chain industry must first agree on a standards-based approach and a single RFID protocol and technology. This will avoid the significant process and cost inefficiencies that would be created without such standards.

The company also said that technology and process improvements are needed to consistently achieve acceptable read rates at all packaging levels, and that industry acceptance is also needed for standard practices like accepting barcode technology as a complementary and redundant technology to RFID, and accepting unit-level "inference" when unit-level read rates are not possible.

### **About Cardinal Health**

Headquartered in Dublin, Ohio, Cardinal Health, Inc. (NYSE: CAH) is an \$80 billion, global company serving the health-care industry with products and services that help hospitals, physician offices and pharmacies reduce costs, improve safety, productivity and profitability, and deliver better care to patients. With a focus on making supply chains more efficient, reducing hospital-acquired infections and breaking the cycle of harmful medication errors, Cardinal Health develops market-leading technologies, including Alaris® IV pumps, Pyxis® automated dispensing systems, MedMined® data mining software and the CareFusion® patient identification system. The company also manufactures medical and surgical products and is one of the largest distributors of pharmaceuticals and medical supplies worldwide. Ranked No. 19 on the Fortune 500 and No. 1 in its sector on Fortune's ranking of Most Admired firms, Cardinal Health employs more than 40,000 people on five continents. More information about the company may be found at [www.cardinalhealth.com](http://www.cardinalhealth.com).

Except for historical information, all other information in this news release consists of forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. These forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially from those projected, anticipated or implied. The most significant of these uncertainties are described in Cardinal Health's Form 10-K, Form 10-Q and Form 8-K reports (including all amendments to those reports) and exhibits to those reports, and include (but are not limited to) the following: competitive pressures in its various lines of business; the loss of one or more key customer or supplier relationships or changes to the terms of those relationships; changes in the distribution patterns or reimbursement rates for health-care products and/or services; the results, consequences, effects or timing of any inquiry or investigation by any regulatory authority or any legal and administrative proceedings; difficulties, delays or additional costs in implementing the company's global restructuring program; and general economic and market conditions. Except to the extent required by applicable law, Cardinal Health undertakes no obligation to update or revise any forward-looking statement.

###

# SupplyScape

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## **SupplyScape Receives First-in-Industry Certification from EPCglobal Inc™**

*SupplyScape Achieves EPCglobal Drug Pedigree Messaging Standard Software Certification for its E-Pedigree™ Software*

**Woburn, Mass., June 7, 2007**— SupplyScape Corporation, the leading provider of value chain software to drive maximum business value and product security in the pharmaceutical supply chain, today announced that its E-Pedigree data management solution has been awarded EPCglobal Drug Pedigree Messaging Standard certification from GS1 EPCglobal Inc.

A long-standing member of EPCglobal, SupplyScape was recognized as one of the first companies to have its E-Pedigree software successfully pass rigorous testing and earn EPCglobal certified status. The certification mark was awarded at the EPCglobal Health and Life Sciences Meeting of the GS1 U Connect Conference on June 6 in Orlando, Florida.

“SupplyScape is dedicated to open and interoperable standards for the pharmaceutical industry,” noted Shabbir Dahod, president and CEO of SupplyScape. “It is gratifying that SupplyScape is one of the first in the industry to receive this certification for our E-Pedigree software. The widespread adoption of the EPCglobal Drug Pedigree Messaging Standard will enable the industry to exchange electronic pedigrees in a common and interoperable format, transforming the landscape of the pharmaceutical value chain.”

E-Pedigree’s certification acknowledges that the software performs according to defined EPCglobal standards criteria and has passed comprehensive testing by MET Laboratories, an independent, nationally recognized testing facility.

E-Pedigree’s certification also underscores the significant commitment the company has made to support the development and adoption of EPCglobal standards. SupplyScape was instrumental in developing the EPCglobal Drug Pedigree Messaging standard, contributing its electronic pedigree intellectual property toward the standard and working closely with the industry and EPCglobal over the past three years to secure introduction of the standard.

SupplyScape’s leadership within EPCglobal and the pharmaceutical industry is also reflected in its active participation in the Track & Trace, Supply Chain Integrity, EPCIS, Serialization, and RFID standards working groups. The company is also helping to educate the industry

## **Comments to the California Board of Pharmacy from the PhRMA Supply Chain Security Technical Group**

The Pharmaceutical Research and Manufacturers of America (PhRMA) is pleased to submit the following comments to the California Board of Pharmacy. PhRMA represents America's research based pharmaceutical and biotechnology companies, including many companies based in California. This communication continues the dialogue between PhRMA and the Board of Pharmacy regarding California's legislative and regulatory efforts to improve the security of the pharmaceutical supply chain. PhRMA commends both the State and the Board for your actions to prevent the introduction of counterfeit drugs, thus protecting Californians from unsafe medications.

PhRMA member companies are also working actively to protect patients from counterfeit medicines. We describe a number of steps below, including technology and process improvements that have led to a more secure pharmaceutical supply chain and reduced the possibility that a patient will receive counterfeit medicines through the legitimate prescription drug supply chain.

PhRMA is committed to working with the Board on effective and efficient supply chain security solutions. While we agree with the Board's ultimate objective of ensuring a secure supply chain, for several reasons the goal of serializing all packaged pharmaceuticals and implementing an interoperable track and trace system by 2009 is an unrealistic goal. PhRMA believes it worth exploring with the Board how implementation of a non-serialized electronic pedigree system can add an additional level of supply chain security.

PhRMA agrees with the Board that protecting patients and increasing the security of the supply chain is of paramount importance. To that end, we are currently examining the best methods to accomplish this. PhRMA would like to meet with the Board periodically as our work on this progresses.

### **Background**

A secure pharmaceutical supply chain is central to patient safety. PhRMA member companies have a strong interest in ensuring the supply chain that moves drugs from the manufacturer to the patient is safe and secure. Our members manufacture pharmaceutical products following exacting standards using extensive quality systems to assure that our innovative medicines provide consistent positive health outcomes for the patients who need them. Even the most innovative medicines cannot help the patients if those medicines are compromised by breakdowns in the distribution system, including diversion and counterfeiting. PhRMA member companies are committed to embracing new technologies as a means of protecting the integrity of the American prescription drug supply.

### **PhRMA Efforts to Increase Supply Chain Security**

Over the past eight years, PhRMA has engaged federal and state regulatory and policy makers to address critical issues related to supply chain security. PhRMA has an active Supply Chain Security Technical Group (SCSTG) that is helping define what additional steps should be taken by the pharmaceutical industry. We have testified about the need to shore up the Federal prescription drug pedigree requirements, strengthen wholesaler licensure requirements, and increase criminal penalties for persons convicted in trafficking of counterfeit drugs. We have worked with associations representing other companies in the distribution system to develop policies and legislation that will improve security throughout the distribution system.

## Security Technologies

Counterfeit resistant technologies serve two purposes: (1) they make it more difficult and costly for counterfeiters to produce a convincing copy of a drug's packaging and/or labeling; and (2) they provide companies with a means for determining whether a questionable product is authentic or counterfeit. Pharmaceutical companies are already employing a host of new packaging security technologies on higher risk medicines.

Current security advances include overt and covert features incorporated into the packaging and or labeling of a particular medicine and chemical taggants incorporated into the drug product itself. Overt features can include holographic images, special stickers, color shifting inks or threads in the container label, all of which can be used to verify that the container is authentic. Some of these approaches are similar to technologies used for currency authentication. Covert features include special inks, taggants, threads or materials that are known only to the manufacturer and require special equipment (e.g., UV light source) for identification.

Minute amounts of a chemical taggant are also used to authenticate medicines at a forensic level. At times such chemicals can be part of the bulk formulation of active ingredient or incorporated into the gel capsule or film coating of the pill. The taggant can be verified by chemical analysis by the company. Companies can also use the known analytical composition of the formulation for authentication purposes. For example, amounts of different inactive ingredients, defined impurity profiles, and dissolution patterns can be tested to determine a drug's authenticity.

## Security Processes

In addition to these product based security features, many companies have put in place integrated programs to protect their medicines. These processes often include:

- Full-time, dedicated staff to ensure company-wide vigilance in the fight against counterfeiting.
- Contractual requirements for distributors to buy directly and only from the manufacturer and to report any evidence of product diversion or counterfeiting.
- Audits of the supply chain.
- The use of secure distribution practices to prevent a drug shipment from being stolen, tampered or otherwise interfered with in transit.
- Verification of the authenticity and destruction of all returned products.
- Investigation of all complaints received from patients, health care providers, and others in the chain of distribution and use.
- Monitoring of criminal activities related to counterfeiting.
- Full cooperation with law enforcement and regulatory authorities.
- Active participation in industry anti-counterfeiting efforts.

## Technology Adoption Recommendations

Based on years of work on supply chain security as well as detailed knowledge of the level of development of multiple technologies, including their strengths and weaknesses, PhRMA has developed a series of recommendations.

### Phased Approach to Serialization

PhRMA believes that securing the supply chain can be accomplished most efficiently and effectively

through a phased approach. A phased approach can draw upon the strengths of existing technologies while it also encourages development of new technologies and adoption of standards for those technologies, so they can be implemented throughout the distribution system to ensure interoperability.

There has been much recent focus on the use of package serialization (whether by RFID or 2-D barcode technology). While serialization is a laudable and useful goal, by itself it will not fully solve the counterfeit problem. An RFID encoded package serial number only authenticates the packaging; it does not and cannot be used in the absence of other business practice changes throughout the supply chain to attest to the purity, potency, and safety of the medicine in the package.

### E-Pedigree

Our initial analysis indicates that the implementation of a non serialized e-pedigree is an achievable objective. Pedigree, originating from the Manufacturer with the first commercial sale, will tighten the chain of custody within the pharmaceutical supply chain by confirming the source and path of pharmaceuticals as well as minimizing the opportunity for counterfeit product to be introduced into the supply chain. In addition, this is one of the areas where a standard now exists, given the recent ratification of the e-pedigree messaging standard by EPCGlobal. Even with the ratification of this standard, there is much work to be done by supply chain partners and technology providers to ensure that this standard provides the necessary platform for interoperability. This work has already begun, primarily on the part of the companies that provide the technology, the companies that have the expertise to lead the effort.

### Case Level Serialization

PhRMA believes that serialization of case packaging accompanied by item level lot number control moves an additional step beyond the electronic pedigree described above. This will require greater coordination within the supply chain. A standard approach to expressing lot numbers on item level packaging will also be required. However, this approach will provide an additional level of supply chain security as well as an opportunity to learn about the complexities of implementing an additional security step throughout the supply chain.

### Item Level Serialization

Widespread introduction of item level serialized pharmaceutical packaging into the supply chain requires many process as well as technological changes. Manufacturers applying serial numbers, via bar codes or RFID tags, is only the first step. Each supply chain partner downstream from the manufacturer must be required to authenticate the serial number to ensure true electronic track and trace.

Standards must be developed and incorporated into the technical solutions used to secure the supply chain and insure interoperability across the various companies in the supply chain. These standards must be adopted by all supply chain parties before electronic track and trace can be fully implemented. This process of adopting mass serialization, authentication, and electronic track and trace, and the accompanying change in business practices, will be a very large, complex endeavor. A phased in approach will maximize the successful implementation of change of this magnitude. Sufficient time must be given to resolve many outstanding issues around privacy and the inclusion of product identifying information necessary to achieve the goal of improving supply chain security.

From an operational perspective, many manufacturers are piloting serialization with one drug using one partner, with plans to expand to additional drugs over a multi-year period. Such an approach to serialization enables manufacturers to gain experience, and then to develop a risk based model to phase in product serialization at the appropriate level (e.g., item, case, pallet) using various methods for

carrying product information (“data carriers”) (i.e., RFID or 2-D bar codes). Accordingly, multiple data carriers are likely to coexist for several years before all the companies in the distribution system make the capital investments required for complete adoption on an aligned distribution tracking system. However, even after serialization standards are finalized; it will take several years for the companies that make the tracking systems to update their products and for pharmaceutical manufacturers to make the necessary changes in equipment and processes to accomplish serialization. Some products may never be serialized beyond the lot and expiry dating currently found on our packaging.

Additionally, we believe that, for a variety of reasons, pharmaceutical manufacturers will move at different paces to implement serialization.

### Risk Based Approach

From a patient safety and supply chain security perspective, item level serialization of medicines at high risk of counterfeiting appears justifiable. Any risk assessment must take into account the best available, up to date counterfeiting information.

The costs to serialize all item level packaging are significant, with as-yet-unproven safety benefits. Of the estimated 10,000 distinct pharmaceutical products in the supply chain (this number includes generic drugs), only a very small percent have been subject to counterfeiting and/or diversion. In addition, the few documented cases of counterfeit prescription medicines found in the United States over the past 18 months have come from outside the normal distribution channels (e.g., foreign internet drug sellers, illegal importation, and repackagers). A prudent approach would be for all pharmaceutical manufacturers to focus investment of time as well as capital on those steps that most effectively advance patient safety, by focusing on medicines at the greatest risk of counterfeiting.

### Unresolved Serialization Issues

Even with this risk-based, phased approach, a number of significant issues remain to be resolved with Item level serialization:

1. The manufacturers must work with the FDA to resolve many issues to meet existing regulatory requirements, such as good manufacturing practices, labeling, and recall of mis-matched package units, or to modify those requirements to allow serialization without compromising the purity and potency of medicines.
2. Certain medicines may not be amenable to particular technologies for package serialization, for example RFIDs on biologics and 2-D bar codes on vials.
3. There is no industry-wide standard for either RFID or 2-D barcodes. A decision on an industry-wide standard will be needed before companies can develop systems to serialize packaging and manufacturers can invest in those systems with the knowledge that they will be accepted throughout the distribution chain.
4. Interoperable data management processes and systems will need to be developed, linking all of the companies in the distribution system.
5. All companies in the distribution system (wholesalers, retailers and manufacturers) will need to make significant infrastructure investments to be able to read and transmit data.

### **PhRMA Recommendations on a Pathway Forward**

1. The Board of Pharmacy should establish a technical advisory group of interested parties to offer advice and guidance on issues related to monitoring and improving supply chain security.
2. The Board should initiate discussions to implement a non-serialized e-pedigree standard and consider the necessary legislative and/or regulatory changes to make this possible.
3. The Board should work with the technical advisory group to develop a phased risk-based approach to serialization that moves beyond existing industry pilots. The Board should make the legislative and regulatory changes necessary to make this possible.
4. The Board should consider other options recommended by the technical advisory group identified in recommendation 1.

# Attachment 2

*Board Letter to the CMS Regarding  
Decreased Patient Access to  
Pharmacies if AMP is Used as the  
Reimbursement Base for  
Medicaid Patients*



**California State Board of Pharmacy**

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

February 16, 2007

Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-2238-P  
P.O. Box 8015  
Baltimore, MD 21244-8015

RE: File Code CMS-2238-P

Dear Sir or Madam:

The California State Board of Pharmacy (Board) appreciates this opportunity to submit comments on the proposed rulemaking in 42 CFR Part 447 (File Code CMS-2238-P), the purpose of which is to implement provisions of the Deficit Reduction Act of 2005 (DRA) pertaining to prescription drugs under the Medicaid program. While the Board is pleased that an attempt is being made to clarify this difficult subject area, and recognizes the constraints and mandates placed on CMS by the provisions of the DRA, the Board is concerned that the proposed rules, as written, may result in significant barriers to access necessary medication(s) by California residents who are recipients of Medicaid, particularly in rural and inner city locations.

The primary mandate of the Board is protection of the health and safety of the public in California. In the realm of drug distribution and treatment, this includes helping to ensure a safe, reliable, drug supply, and timely access to medications necessary for treatment.

When such access is impaired, particularly in vulnerable populations such as is often the case for recipients of Medicaid, public health and safety are also impacted. Furthermore, where the concern is overall health system cost savings, any such impairment of access to drugs, particularly among vulnerable populations, may lead to greater overall costs due to increased Emergency Room visits, hospitalizations, or aggravation of preexisting conditions due to an interruption of drug therapy.

We are concerned that the proposed rules may have this detrimental effect on access. We have heard from numerous stakeholders in the pharmaceutical industry, especially but not exclusively community pharmacies both large and small, that the proposed rules would make it economically infeasible for them to continue participating in Medicaid and/or providing drugs to Medicaid recipients in California. They have concluded that

the proposed rules would result in reimbursement and dispensing rates significantly below the lowest prices at which they can purchase the drugs to be dispensed.

Stakeholders in the industry will certainly express to CMS their specific concerns about the text of the proposed rulemaking more comprehensively than the Board, but as articulated to the Board, the difficulties with the current rules include: despite an acknowledgment of flaws in AMP data as a predictor of actual costs-to-dispense, CMS intends to rely on (and to publicly release) that data before resolving its uncertainties and unreliability; the given definition of AMP does not accurately reflect actual acquisition costs by pharmacies; the proposed rules for generics reimbursement will significantly undercount the actual costs of purchasing such drugs, by up to an average of 36 percent;<sup>1</sup> and without any direction to states to increase dispensing fees (particularly for generics), the average dispensing fee payment of \$4.50 is significantly below the actual costs-of-dispensing for pharmacies nationwide which has been cited to be between \$10.00 and \$12.00.<sup>2</sup> The overall message that has been delivered is that the new rules may very well result in a reduction or even elimination of the retail sites that are willing or fiscally able to dispense drugs to Medicaid recipients.

In his May 12, 2006 letter to Secretary Leavitt, Senator Charles Grassley also expressed a similar concern that states must be encouraged or required to reconsider their dispensing fees paid to pharmacies to compensate for presumably lowered drug costs under the new AMP-based calculation protocol. As Senator Grassley said:

*I expect states will very soon begin shifting to a pharmacy payment methodology based on the newly published interim AMP data. CMS should make clear to states that they should reconsider their dispensing fees paid to pharmacies under Medicaid particularly for generic drugs. States may have been working under an assumption borne out in numerous reports of the Office of the Inspector General that pharmacies were being reimbursed well beyond the acquisition cost of the drugs and so dispensing fees were set at levels below the actual cost of the dispensing of a drug. States should carefully consider data regarding the cost of dispensing in determining dispensing fees at the same time they change their reimbursements for acquisition cost to be more consistent with the actual cost of acquisition.*

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<sup>1</sup> See *Medicaid Outpatient Drugs: Estimated 2007 Federal Upper Limits for Reimbursement Compared with Retail Pharmacy Acquisition Costs*, GAO Report No. GAO-07-239R (December 22, 2006).

<sup>2</sup> See *National Study to Determine the Cost of Dispensing Prescriptions in Community Retail Pharmacies*, prepared by Grant Thornton LLP for The Coalition for Community Pharmacy Action (January 2007).

The Board agrees that in order to ensure appropriate access to prescription drugs for those residents of California who are recipients of Medicaid, the final result of this rulemaking must be that a combination of reimbursement and dispensing fees paid equals or exceeds the actual cost(s) of drug dispensing. Otherwise, access will be rapidly diminished.

Thank you for this opportunity to provide comments.

Sincerely,

A handwritten signature in cursive script that reads "William Powers".

WILLIAM POWERS  
Board President

Written Comments from John Tilley to Virginia Herold, 7/2/07

In 2005, Congress passed the Deficit Reduction Act of 2005. Attached to that bill was a piece that required CMS to reimburse pharmacies based upon AMP pricing as of July 1, 2007, on Medicaid Prescriptions only. AMP pricing is Average Manufacturers Price.

Thus, many classes of trade (with Independents being in the highest purchasing class) would now have their costs averaged with PBM's, rebates, chain prices, etc. Basically on the generic side, the General Accounting Office in Washington DC has figured that the average Independent pharmacy will now be reimbursed on Medicaid (Medi-Cal) prescriptions at 36% below their cost.

One of the provisions of the DRA of 2005, was that it stated that states should change their reimbursement of generics on Medicaid, but did not limit it to only generics.

In California, the state legislature in a conference committee decided to also attach branded products to the AMP pricing. Because of multi-tiered pricing by pharmaceutical manufacturers, rebates, etc., it is conceivable that a small pharmacy is paying \$400 for a branded product, and under the new formula may only get reimbursed based on a \$300 cost if the Average Manufacturers Price for that item was \$300.

There is obviously no way that a small pharmacy, or possibly any retail pharmacy would be able to fill Medi-Cal Rx's if we are losing \$50 or \$100 on that Rx. If it were limited to generic drugs, there would be the possibility of switching back to the more costly brand, and getting a Treatment Auth. Request. (TAR) A very perverse incentive to use the more expensive branded product, but possibly the only way that pharmacists would be able to dispense a product under Medicaid, and make a profit.

The Calif. State Legislature said in the committee report that they would try to hold Calif. pharmacies harmless for the branded product. The problem is that they have also given DHS the leeway to make the changes necessary. In conversations to DHS, I don't believe they are looking at the access issues, and are looking at straight cost savings.

I believe there are about 1200 Independent pharmacies in Calif. You probably have the more accurate count. If this stays as is, and is part of the Governor's Budget, we figure that 20 to 50% of the independents will go out of business. The only ones staying in business would be those with less than 10% Medi-Cal business, who can get by without this business. The average Independent pharmacy in Calif. does about 15-20% Medi-Cal, and Independents fill about 72% of the State's Medi-Cal Rx's. This is based upon NCPA's Digest numbers from 2 years ago.

I believe I was told the Governor wanted to save 40 Million from the AMP fix on Medi-Cal. If the brand name products are included, I believe the savings comes to over \$160 million. I'm not sure the Governor realizes that the extra savings will put many pharmacies out of business, and lose access for patients.

CMS was supposed to release the data on July 1st. They may be a little behind in getting everything ready. This is a good thing. The start date for the new reimbursement should be January 1st, 2008 in California. Through CPhA, and a Coalition of pharmacies including the chains, and Independents, we are working with the State Legislature to hopefully fix this before it is too late. We have about 5 months to hopefully get it fixed.

I realize the Board of Pharmacy does not get involved with monetary issues affecting pharmacy. But, this has to do with patient accessibility. If an Independent pharmacy is the only pharmacy in a small rural area, which we definitely have, and they go out of business, how do those patients receive their Medi-Cal Rx's? Also, for those pharmacies in the Urban areas, that speak the native language of the recipients in that area, if they close, does the local chain also speak that language? Many independents I know speak Vietnamese, Farsi, Spanish, Mandarin, Russian, or some other language. This does not include the many services that some Independent's offer over the chains, including Delivery to the Disabled, Long Term Care (Many in Skilled Nursing, or Assisted Living are on Medi-Cal) plus many other services that possibly the local chain doesn't offer. I believe this is why Independent's fill so many more Medicaid Rx's than the chains.

I guess I've gone on long enough. If I am mistaken about the state Legislature, or other issues in here, possibly Kathy can correct me. I know some pharmacies that are 95% Medi-Cal. We are all concerned about rising health care costs, and drug costs. But pharmacists are not the problem. We didn't create the Medi-Cal system. We are just trying to service our patients, and be there in our communities. Let me know if I can help.

Thanks, John Tilley  
President, National Community Pharmacists Association  
Pharmacy Owner, Downey, Ca.

cc.. Kathy Lynch, CPhA  
Jerry Shapiro, Los Angeles  
Charlie Sewell, NCPA  
Stan Goldenberg, Calif. State Board of Pharmacy

See what's free at [AOL.com](http://AOL.com).

# *Attachment 3*

*Nevada Board of Pharmacy's  
E-Pedigree Requirements*

NEVADA STATE BOARD OF PHARMACY  
OFFICE OF THE GENERAL COUNSEL

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## MEMORANDUM

**DATE:** July 5, 2007  
**TO:** Members of the California State Board of Pharmacy  
**FROM:** Larry L. Pinson, Pharm.D., Executive Secretary  
Louis Ling, General Counsel  
**SUBJECT:** Nevada's Electronic Pedigree Program

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Thank you for the invitation to present information regarding the Nevada Electronic Pedigree Program (NEPP). We are providing you the following information in a bulleted list to give you the most essential facts and information regarding the program as background for our fuller presentation to you on July 24. We hope you will become one of the first states to join us in the multi-state EPP.

### LEGAL BASIS FOR THE NEPP

- ❖ Nevada Revised Statutes (NRS) 639.540, which became effective October 1, 2005, required that pedigrees be in an electronic form after January 1, 2007.
- ❖ On March 23, 2006, Board held summit at which national leaders from all facets of drug supply chain met to discuss the present state-of-the-art regarding electronic pedigrees, RFID, and track-and-trace technology. The conclusion reached by the Board as a result of the summit was that a fully functioning and dependable track-and-trace system was the ultimate goal, but was still five to ten years in the future.
- ❖ On May 4, 2006, pursuant to the input received at the March 23, 2006 summit, the Board passed an amendment to Nevada Administrative Code (NAC) 639.603 requiring wholesalers to provide their pedigree information to the Board on a monthly basis beginning February 15, 2007.

### OPERATION OF THE NEPP

- ❖ Started January 1, 2007, as per NRS 639.540. First set of data were transmitted by February 15, 2007.

- ❖ By the 15<sup>th</sup> of each month, each wholesaler who engaged in prescription drug transactions into or through Nevada for which a pedigree would be required must send to the NEPP e-mail address an Excel file or .CSV file in a format established by the Board for the immediately preceding month.
- ❖ Upon receipt, the data is loaded into a database maintained in the Board's Reno office.
- ❖ Based upon the data received, the Board has been developing and refining tools to analyze the data for behavior that violates Nevada law or that creates concerns that merit further investigation. A more thorough iteration of the software toolkit will be completed within weeks.
- ❖ Board is also constructing a webcenter with separate secured portals for wholesalers and for state investigators. The wholesaler's portal will allow for one-button downloading of information and will generate a receipt demonstrating compliance. The state investigators' portal will allow for agents of various state agencies to gain secured access to the contents of the entire database. The state investigators' portal will contain the software toolkit being developed by the Board and will contain powerful searching tools, a useful set of standard reports, and an ability to create and save customized searches and reports set up by a particular using agency.
- ❖ Based upon input from the industry, the Board is migrating the data reporting format to the EPC Global Electronic Pedigree Format, meaning that the data will be reported in a nationally recognized and uniform format. We expect to be fully compliant with the EPC Global format by year's end.

#### EXPANSION OF NEPP TO A MULTI-STATE MODEL

- ❖ At NABP Annual Meeting in May in Portland, we made a presentation regarding the NEPP and asking other states to join the effort.
- ❖ When the software toolkit and webcenter are constructed and the migration to the EPC Global format is completed, we intend to make the software and webcenter available for all other states to use the database to direct their wholesalers to make similar reports into the database.
- ❖ Our intention is to keep the multi-state EPP implementation free to using states and contributing wholesalers. We are presently looking at several ways by which to minimize to cost of hosting and maintaining the ever-growing database.

#### ADVANTAGES OF MULTI-STATE MODEL

- ❖ Lessens effectiveness of prevalent practice of bad wholesalers of making all transactions cross state lines by allowing all states to have easy access to data regardless of whether transaction crossed state lines.

- ❖ Data should expose fraudulent pedigrees, potentially fraudulent or risky activity, and consistently bad wholesalers or clusters of bad wholesalers.
- ❖ Allows regulatory agencies to take action regarding bad wholesaling and bad drugs while the drugs may still be on pharmacy shelves. While the data may be as old as six weeks, some of it will be as fresh as a few days when received. Presently, most investigations do not occur until months or even years after the drugs have moved through the supply chain.
- ❖ Should foster easier and better communication among the states, thus making it increasingly difficult for bad wholesalers to survive.
- ❖ Because of flexibility of tools in toolkit software, each state can set up its own business rules for searches and reports, store them, and train an employee to run the customized searches and reports on a monthly basis to receive only those exceptions that would indicate unlawful or risky wholesaling behavior.
- ❖ May readily convert to a full track-and-trace model as the technology develops and allows. The differences between the multi-state EPP and a true track-and-trace are questions of scale, not design, and since the multi-state model will originate with a nationally recognized standard (the EPC Global format) that is already set up for track-and-trace type e-pedigrees, the transition ought to be manageable.

# *Attachment 4*

## *Pharmacists Recovery Program Statutory Mandates*

## Article 21 – Pharmacists Recovery Program

- 4360.** The board shall operate a pharmacists recovery program to rehabilitate pharmacists and intern pharmacists whose competency may be impaired due to abuse of alcohol, drug use, or mental illness. The intent of the pharmacists recovery program is to return these pharmacists and intern pharmacists to the practice of pharmacy in a manner that will not endanger the public health and safety.
- 4361.** (a) "Participant" means a pharmacist or intern pharmacist who has entered the pharmacists recovery program.
- (b) "Pharmacists recovery program" means the rehabilitation program created by this article for pharmacists and intern pharmacists.
- 4362.** (a) A pharmacist or intern pharmacist may enter the pharmacists recovery program if:
- (1) The pharmacist or intern pharmacist is referred by the board instead of, or in addition to, other means of disciplinary action.
  - (2) The pharmacist or intern pharmacist voluntarily elects to enter the pharmacists recovery program.
- (b) A pharmacist or intern pharmacist who enters the pharmacists recovery program pursuant to paragraph (2) of subdivision (a) shall not be subject to discipline or other enforcement action by the board solely on his or her entry into the pharmacists recovery program or on information obtained from the pharmacist or intern pharmacist while participating in the program unless the pharmacist or intern pharmacist would pose a threat to the health and safety of the public. However, if the board receives information regarding the conduct of the pharmacist or intern pharmacist, that information may serve as a basis for discipline or other enforcement by the board.
- 4364.** (a) The board shall establish criteria for the participation of pharmacists and intern pharmacists in the pharmacists recovery program.
- (b) The board may deny a pharmacist or intern pharmacist who fails to meet the criteria for participation entry into the pharmacists recovery program.
- (c) The establishment of criteria for participation in the pharmacists recovery program 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.
- 4365.** The board shall contract with one or more qualified contractors to administer the pharmacists recovery program.
- 4366.** The functions of the contractor administering the pharmacists recovery program shall include, but not be limited to, the following:
- (a) To evaluate those pharmacists and intern pharmacists who request participation in the program.
  - (b) To develop a treatment contract with each participant in the pharmacists recovery program.
  - (c) To monitor the compliance of each participant with their treatment contract.
  - (d) To prepare reports as required by the board.
  - (e) To inform each participant of the procedures followed in the program.
  - (f) To inform each participant of their rights and responsibilities in the program.
  - (g) To inform each participant of the possible consequences of noncompliance with the program.
- 4369.** (a) Any failure to comply with the treatment contract, determination that the participant is failing to derive benefit from the program, or other requirements of the pharmacists recovery program may result in the termination of the

pharmacist's or intern pharmacist's participation in the pharmacists recovery program. The name and license number of a pharmacist or intern pharmacist who is terminated from the pharmacists recovery program and the basis for the termination shall be reported to the board.

(b) Participation in the pharmacists recovery program shall not be a defense to any disciplinary action that may be taken by the board.

(c) No provision of this article shall preclude the board from commencing disciplinary action against a licensee who is terminated from the pharmacists recovery program.

**4371.** The board shall review the pharmacists recovery program on a quarterly basis. As part of this evaluation, the board shall review files of all participants in the pharmacists recovery program.

**4372.** All board records and records of the pharmacists recovery program pertaining to the treatment of a pharmacist or intern pharmacist in the program shall be kept confidential and are not subject to discovery, subpoena, or disclosure pursuant to Chapter 3.5 (commencing with Section 6250) of Division 7 of Title 1 of the Government Code. However, board records and records of the pharmacists recovery program may be disclosed and testimony provided in connection with participation in the pharmacists recovery program, but only to the extent those records or testimony are relevant to the conduct for which the pharmacist or intern pharmacist was terminated from the pharmacists recovery program.

**4373.** No member of the board shall be liable for any civil damages because of acts or omissions that may occur while acting in good faith pursuant to this article.

# Attachment A

*Meeting Summary of the  
Enforcement Committee and the  
Work Group on E-Pedigree  
June 20, 2007*



**California State Board of Pharmacy**  
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STATE AND CONSUMERS AFFAIRS AGENCY  
DEPARTMENT OF CONSUMER AFFAIRS  
ARNOLD SCHWARZENEGGER, GOVERNOR

## **Enforcement Committee Meeting and Work Group on E-Pedigree**

### **Minutes of the June 20, 2007 Meeting**

Red Lion Hotel  
1401 Arden Way  
Sacramento, CA 95815

9:30 a.m. -- 1:30 p.m.

Present: Stan Goldenberg, RPh, Chair  
Bill Powers, Board President  
Ruth Conroy, PharmD, Board Members  
Tim Dazé, Esq., Board Member  
Rob Swart, PharmD, Board Member

Virginia Herold, Executive Officer  
Karen Cates, Assistant Executive Officer  
Robert Ratcliff, Supervising Inspector  
Judi Nurse, Supervising Inspector  
Joan Coyne, Supervising Inspector  
Anne Sodergren, Legislative Coordinator  
Joshua Room, Liaison and Deputy Attorney General  
Spencer Walker, Staff Counsel

Chairperson Goldenberg called the meeting to order at 9:30 a.m.

Chairperson Goldenberg asked each individual present to introduce him or herself. He referred individuals to meeting materials that were available online in advance of the meeting.

#### **Workgroup on E-Pedigree**

*Amgen:*

Lew Kontnik of Amgen spoke about counterfeit drugs in worldwide markets. Mr. Kontnik stated modern pharmaceutical discoveries and patient health are being threatened and compromised by counterfeit drugs, which in some countries is running at 30 percent.

He stated there is a need for a pedigree system like California's to ward against the introduction of counterfeit medicine.

*EPCglobal:*

Mike Rose, TriChair-EPCglobal, provided an overview of the status of where EPCglobal is with respect to the development for standards for electronic pedigrees. He also walked through the adoption process of standards. A copy of his PowerPoint presentation is appended to these minutes (Attachment 1).

The Pedigree Messaging Standard was ratified in January 2007. There are three companies currently certified:

- Axway
- rfxcel
- SupplyScape

Item Level Tagging Standard: the purpose of this standard is for tagging pharmaceuticals at the item level. This will include requirements for manufacturing lines, distribution environments, transportation and retail environments. Current high frequency (HF) and ultra high frequency initiatives are underway to provide uniform air interface protocol at the item level. The ratification of the standard is expected in October 2007.

Serialization Standard: will define requirements for the EPC identified to be encoded on an RFID tag, and is nearing completion of prototype testing of the proposed specification.

Supply Chain Integrity: will define requirements and/or guidelines for authenticating and decommissioning tags. This component is still under development. An EPCglobal seminar is scheduled for July 2007.

Track and Trace Standard: to define supply chain use cases, processes and information needs for sharing EPC information related for sales and returns. This component is under development.

Tag Data Standards: focuses on defining additional user memory requirements for tags (lot number, expiration date). This is still under development.

The industry adoption task force is working to define a starting set of guidance for industry trade associations. They are working on two options to provide a pedigree: drug pedigree messaging standard (available now) or track and trace (under development).

EPCglobal is working to deal with other specific issues, like what is the manufacturer's smallest saleable unit, and how will repackagers forward the pedigree? Other issues

include receipt of partial shipments, drop shipments, resale of saleable drugs returned to manufacturer, intracompany transfers, voided pedigrees, and inference.

The Industry Adoption Task Force has a meeting every Wednesday morning. Interested entities may contact Bob Celeste of EPCglobal about attending a Web Seminar. Mr. Celeste can be reached at [rceleste@epcglobalna.org](mailto:rceleste@epcglobalna.org).

### *Pfizer*

Next, Peggy Staver of Pfizer provided information about Pfizer's experience in electronically tagging Viagra. A copy of this presentation is provided in Attachment 2.

Ms. Staver indicated that Pfizer used a multifaceted approach to ward against counterfeiting of Viagra. They restricted sales so that Viagra can only be purchased from the manufacturer or from an authorized distributor. Pfizer also used technology, such as color shifting ink on the labels, RFID tags and 2-D bar codes.

In Pfizer's experience, the one-time costs of implementing serialization are about the same regardless of what type of tagging is used. The majority of the costs lie in the provision and commissioning of the serialized number and applying the tag.

Although she noted that the implementation costs for Viagra were \$5 million, future costs for tagging Celebrex will be \$4 million.

Pfizer also has tagged Celebrex and Lipitor, and Pfizer has learned that each implementation is unique.

Currently underway at Pfizer in 2007 are e-pedigree testing, RFID tagging of Celebrex, and work on an industry pilot.

Pfizer indicated that they have 65 product lines at 21 manufacturing sites worldwide producing drugs for the US market. They estimate \$95 - \$100 million in costs to implement serialization throughout the system, and this does not include ongoing costs.

Pfizer estimates that it will take five to seven years to implement serialization on all product lines and recommends a risk-based implementation for serialization, where the highest risk drugs are serialized first.

### *Walgreens*

Sue Thoss, Walgreens Divisional Vice President, Logistics and Planning, provided a PowerPoint regarding Walgreens plans for item-level serialization. A copy of this presentation is attached to these minutes.

Ms. Thoss asked several questions, including in January 2009, what will happen to drugs in existence in the supply chain that are not tagged and serialized – will they be grandfathered in?

Ms. Thoss stated that item level serialization, starting at the manufacturer, would rely upon a manufacturer-applied RFID tag as well as an item level 2-D bar code as a back up to the RFID tag. They expect to use tunnel and handheld readers for item-level barcode reading and an RFID tunnel for case reading. They expect item-level inference and validation. They also will do audit sampling.

Walgreens believes there will be one-time costs at its distribution center of \$700,000 to \$1 million, and ongoing costs of \$500,000 to \$1 million annually.

They expect to be fully integrated one year after the standards are in place, and expect it will take six months to “bleed out” the untagged inventory.

If inference is not allowed, the implementation costs will double to \$1 million to \$1.5 million, and ongoing costs of \$2.5 - \$3 million.

Walgreens also provided information on costs of implementation if other processes are used, which would not comply with California law (e.g., the wholesaler applies the serialization tags).

Walgreens suggested a phased-in implementation with certain drugs being tagged initially, and all drugs becoming tagged over a period of time. They suggested that controlled drugs and list 1 products be the first to be required to be RFID tagged.

Walgreens stated that they wanted the tagging on all drug products to be RFID tagged.

### *PhRMA*

Marjorie from PhRMA provided comments regarding California’s electronic pedigree requirements. She encouraged the board to work with the end users of the pedigree systems as well as the manufacturers who are at the front end. She suggested that serialization should be first implemented for those drugs that have the greatest likelihood of being counterfeited, although PhRMA does not have a list of such drugs. Moreover, PhRMA states that the costs to serialize all item level packaging are significant with unproven safety benefits. She also spoke about some of the non-electronic techniques used by some manufacturers to prevent counterfeiting, like color shifting inks on labels and threads through labels.

She stated the PhRMA supports phased-in use of serialization, although serialization will only protect packaging, not the medicine inside. PhRMA suggests case level serialization with use of lot number control as a much better method.

She spoke about the complexities required throughout the supply chain to use serialization. She noted the pilot projects underway with tagging of one product from the manufacturer through the wholesaler. She stated it would take several years after all standards are in place for the tracking technology to be manufactured and put in use.

PhRMA suggests that the board initiate discussions to implement a nonserialized e-pedigree standard and consider legislation to make this possible.

### *HDMA*

Liz Gallenag of HDMA stated that this association supports the use of RFID tags on products to achieve serialization from pedigrees started by the manufacturers tagging the product. She noted that the costs projected by Walgreens are not necessarily those of other wholesalers.

The HDMA seeks a track and trace system. They are not in favor of tracking by lot number, in part because of the burden placed on pharmacy for such systems, and principally because it is not possible to link transactions this way.

### *Other Discussion:*

Following these presentations, several hospitals asked questions about how electronic pedigrees will be tracked into hospital pharmacies. Some of the questions included issues related to unit of use tracking versus unit of sale tracking.

The board will consider how to engage hospitals at a stronger level in the future.

## **Enforcement Committee**

### *1. Proposal to Develop an Ethics Course for Pharmacists*

Board Member Ravnan and Ms. Herold provided a brief update on where this project is currently headed. An ethicist met with Dr. Ravnan, Dr. Swart, Ms. Sodergren and Ms. Herold to discuss services he provides the Medical Board and Dental Board. A future meeting will be held with the course provider for the Medical Board's 22-hour course in the late summer. A full report will be provided at the October 2007 Board Meeting.

### *2. Proposed Amendments and Restructuring of the Disciplinary Guidelines*

Chairperson Goldenberg referred the committee to the draft version of the *Disciplinary Guidelines* contained in the packet. He noted that comments from Ron Marks have been received.

Mr. Room noted that staff has been updating the guidelines for several years. Staff have picked up terms used by other boards and is suggesting a slightly different format.

After some discussion, Mr. Goldenberg requested that the guidelines be brought back to the next Enforcement Committee Meeting for a longer, more detailed discussion.

Specific items for future discussion noted are:

- Posting a notice when on probation
- Requirements for the notice employers must sign
- Whether revocation based on nonpayment of cost recovery fees should be pursued.

### *3. Disposal of Drugs from Assisted Living Facilities*

Ms. Herold stated that at the last meeting, a question was raised about how patients can dispose of drugs from patients in assisted living facilities, where sometimes bag-loads of drugs are no longer needed and need to be disposed of. This year, SB 966 would establish take back drug programs in large retailers and supermarkets. However, the bill will not resolve the problems of assisted living facilities.

### *4. 2007 Pharmacy Self Assessment Process*

Ms. Herold noted that the 2007 hospital and community self-assessment forms have been completed and are available online. However, the 2007 version of the self-assessment forms cannot be required until regulation section 1715 is amended to reference the 2007 forms. While this regulation is being updated through a section 100 filing (rulemaking without regulatory effect), current regulation section 1715 requires the 2005 forms to be completed. As such the board is advising pharmacies that a self-assessment must be performed by the PIC every odd-numbered year or within 30 days of a change in PIC. If either the 2005 or 2007 form is on file, the pharmacy is in compliance. The board will encourage completion of the 2007 form. If neither version of the self-assessment forms has been completed, the pharmacy is in violation of this regulation section and may be subject to citation and/or fine.

### *5. Enforcement Statistics*

Chairperson Goldenberg referred the committee to the Enforcement Statistics provided in the packet.

### **Adjournment**

There being no additional business, Chairperson Goldenberg adjourned the meeting at 1:30 p.m.

# Attachment 1

*Presentation by EPCglobal*



# EPCglobal Update

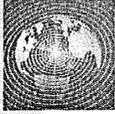
State of Pedigree and EPC/RFID Standards

## California Board of Pharmacy

June 20, 2007

Mike Rose, Tri-Chair, EPCglobal HLS IAG  
Ron Bone, Tri-Chair, EPCglobal HLS IAG

Bob Celeste, EPCglobal North America

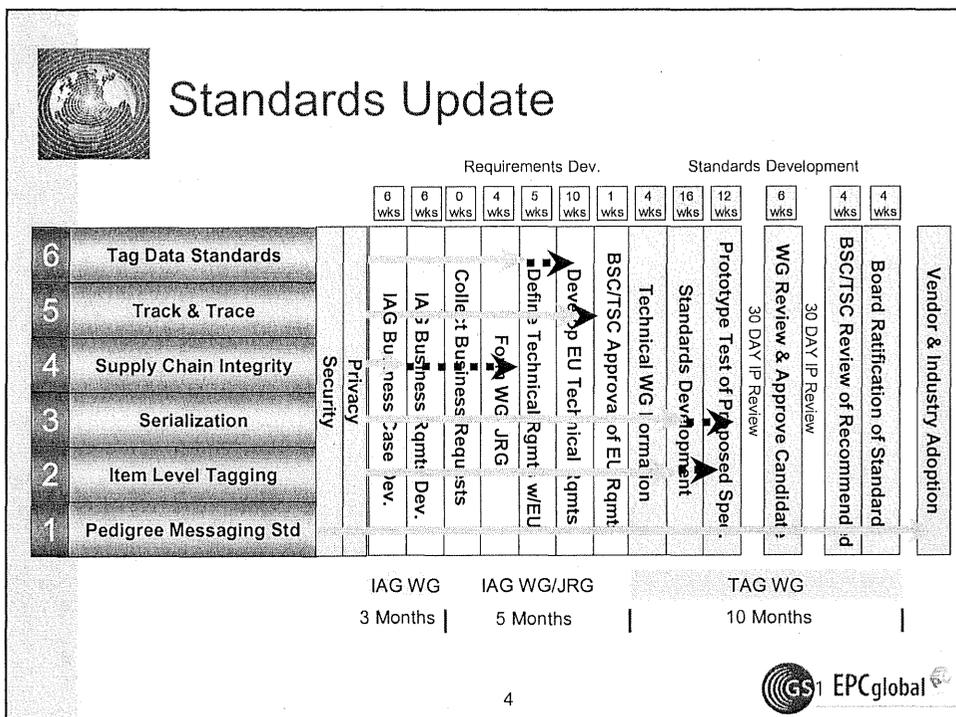
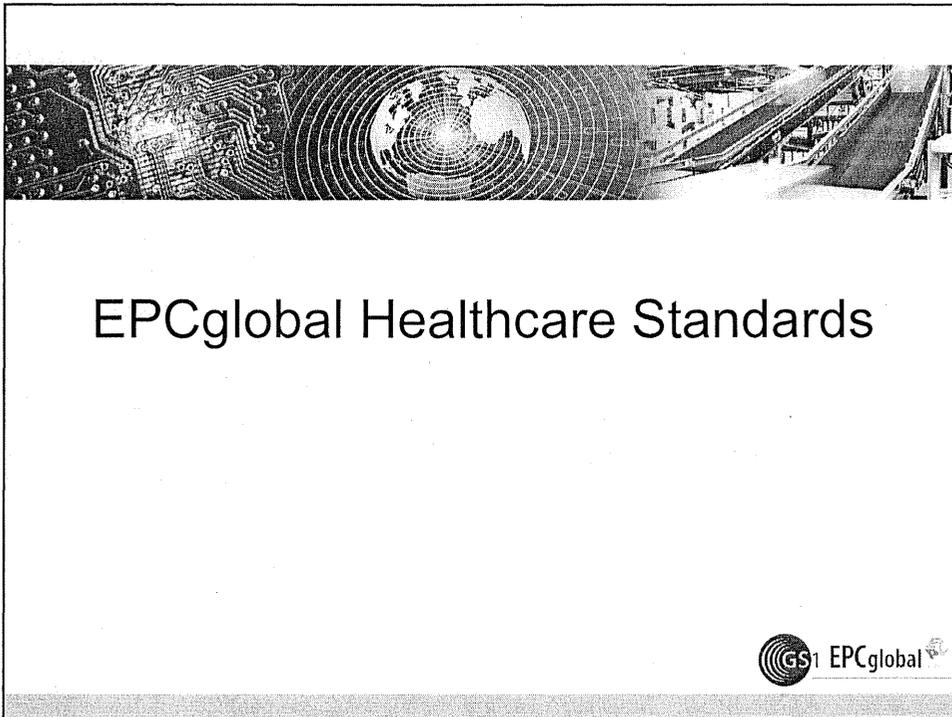


## Overview

- State of the Standards
- Follow Up Items from March 8, 2007 Workshop
- Next Steps

2







## Standards Update

6	Tag Data Standard
5	Track & Trace
4	Supply Chain Integrity
3	Serialization
2	Item Level Tagging
1	Pedigree Messaging Std

Define a standard format for a Pedigree Messaging standard that will meet all current Federal and State Pedigree requirements.

### Status:

- **Ratified standard – 01/2007**
- Certification Program - 3 companies certified
  - ✓ Axway
  - ✓ rfxcel
  - ✓ SupplyScape
- Education and awareness web seminars

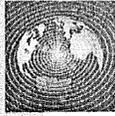
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# Pedigree Messaging Standard

Post-Ratification Activities



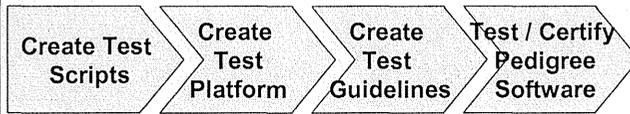


# Post Ratification Activities

## Pedigree Messaging Standard

Pedigree Standard Ratified January, 2007

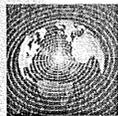
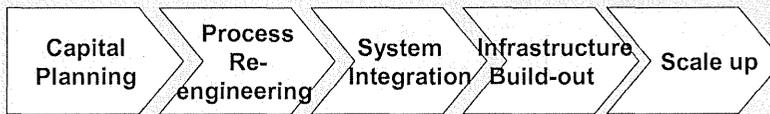
### EPCglobal



Pedigree Software

Completed 6/01/2007

### Industry



# Standards Update

6	Tag Data Standard
5	Track & Trace
4	Supply Chain Integrity
3	Serialization
2	Item Level Tagging
1	Pedigree Messaging Std

Define requirements for tagging pharmaceuticals at the item level. Include requirements for manufacturing lines, distribution environments, transportation and Retail environment.

**Status:**

- HF & UHF initiatives underway to provide uniform air interface protocol at item level.
- HF Standard expected '07.
- Completed vote for item level tagging requirements document
- Ratification of standard anticipated 10/07
- Anticipate silicon available for prototyping 2Q08



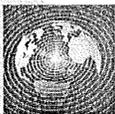
## Standards Update

6	Tag Data Standard
5	Track & Trace
4	Supply Chain Integrity
3	Serialization
2	Item Level Tagging
1	Pedigree Messaging Std

Define requirements for the EPC identifier to be encoded on an RFID tag.

### Status:

- Pharma Requirements complete. Identified 2 GS1 identifiers [Global Trade Item Number (GTIN) and Serialized Shipping Container Number (SSCC)] to be used.
- Collaborating with GS1/HUG via the "Global Healthcare Initiative" -- starting with Serialization.
  - Joint HUG/HLS Work Team
- Medical Devices, Biologics & other Business Requirements anticipate – 7/07



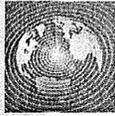
## Standards Update

6	Tag Data Standard
5	Track & Trace
4	Supply Chain Integrity
3	Serialization
2	Item Level Tagging
1	Pedigree Messaging Std

Define requirements and/or guidelines for authenticating and decommissioning tags consistent with optimizing tag utility and consumer/patient privacy.

### Status:

- Work Group formed
- Predominately HLS, however, cross industry work group expected
- Authentication and decommission alternative scenarios identified
- EPCglobal web seminar to be scheduled in July



## Standards Update

6	Tag Data Standard
5	Track & Trace
4	Supply Chain Integrity
3	Serialization
2	Item Level Tagging
1	Pedigree Messaging Std

Define supply chain use cases, processes and information needs for sharing EPC related data for forward and reverse logistics.

### Status:

- Forward & Reverse Logistics (Returns) processes and data exchanges completed
- Integrate with GS1 Traceability efforts
- Track & Trace to be interoperable with Pedigree Model
- Additional use cases addressed:
  - Repackers
  - To be done: 3rd Party Logistics Providers & Product Recall
- Sub-team within Supply Chain Integrity focused on security and pedigree integration
- Data Sharing Strategy & Guidelines will be addressed in Data Exchange JRG
- Common vocabularies and location identifiers incorporated into just ratified EPCIS Standard



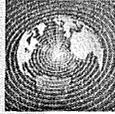
## Standards Update

6	Tag Data Standards
5	Track & Trace
4	Supply Chain Integrity
3	Serialization
2	Item Level Tagging
1	Pedigree Messaging Std

Tag Data JRG focused on defining additional user memory requirements for tags (ie. Lot Number, Expiration Date).

### Status:

- Work underway. Defining common data structure that can be used by all industries.
- Captured business requirements
- Comment phase for approval



## Industry Adoption Task Force

### Executive Summary

- **Mission:**
  - Define a 'starting set' of guidance for industry trade associations
  - Work closely with EPCglobal and GS1.
  - Educate and hand-off the Roadmap to industry trade associations.
- **Objectives:**
  - Guidance on: Unique Identification based on Serialization.
  - Guidance on: Carrier and Auto-Identification Alternatives
  - Guidance on: Two Options to provide a Pedigree:
    - Option 1 – Drug Pedigree Standard (Available Now)
    - Option 2 – Track and Trace (Under Development)
  - Guidance on: Trading Partner Action Steps for Adoption
- **Timeline:**
  - Communications program underway
  - Anticipate completion by 8/2007

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## EPCglobal HLS Update

### State of Pedigree and EPC/RFID Standards Status Update

Follow Up Items  
From  
March 8, 2007 Pedigree Workshop  
with  
Subset of California Board of Pharmacy





# Standards - Follow Up Items Summary Update

Current Status

Weekly conference calls to work on follow up items

		Assign Responsibility	Document & Identify Item	Status
1	Unit Dose Serialization	Individual company	Business Practice	On going
2	Receipt of Partial Shipments	Pedigree WG	Supported by Current Standard	Completed
3	Drop Shipments	Pedigree WG	Supported by Current Standard	Completed
4	Sign & Cert. Inbound	Industry Assoc	Supported by Current Standard	Completed
5	Resale of Returned Product	Pedigree WG	Supported by Current Standard	Completed
6	Intra-Company Transfers	Individual company	Business Practice	
7	Voided Pedigrees	Industry Pedigree WG	Standard enhancement	In Progress
8	Inference	Industry Adoption WG	Guidance on use of standard	In Progress



## 1. Unit Dose Serialization Update

**Scenario:** Mfgs sellable unit may be "broken down" and sold as eaches.

**Issues:**

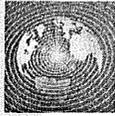
1. How are the eaches serialized
2. What is the impact to Repackers
3. How will Repackers continue the pedigree

**Assignment:** Individual Company

**Status:**

- Business process issue for Supply Chain stakeholders to address level of serialization

1	Unit Dose Serialization
2	Receipt of Partial Shipments
3	Drop Shipments
4	Sign & Cert. Inbound
5	Resale of Returned Product
6	Intra-Company Transfers
7	Voided Pedigrees
8	Inference



## 2. Receipt of Partial Shipments Update

1	Unit Dose Serialization
2	Receipt of Partial Shipments
3	Drop Shipments
4	Sign & Cert. Inbound
5	Resale of Returned Product
6	Intra-Company Transfers
7	Voided Pedigrees
8	Inference

**Scenario:** Orders are not always received complete, having likely pedigree implications.

**Issues:**

1. How often does this occur
2. What pedigree or business process changes may be required

**Assignment:** Pedigree Workgroup

**Status:**

- Current Pedigree standard addresses partials receipts



## 3. Drop Shipments Update

1	Unit Dose Serialization
2	Receipt of Partial Shipments
3	Drop Shipments
4	Sign & Cert. Inbound
5	Resale of Returned Product
6	Intra-Company Transfers
7	Voided Pedigrees
8	Inference

**Scenario:** Mfgs ship certain products to end-customers, while billing goes through wholesalers.

**Issues:**

1. Where should the pedigree be sent
2. What transaction information should it reflect

**Assignment:** Pedigree Workgroup

**Status:**

- Current Pedigree std addresses drop shipments



## 4. Sign & Certify Inbound Update

1	Unit Dose Serialization
2	Receipt of Partial Shipments
3	Drop Shipments
4	Sign & Cert. Inbound
5	Resale of Returned Product
6	Intra-Company Transfers
7	Voided Pedigrees
8	Inference

**Scenario:** Signature and certification of in-bound shipments, as well as out-bound.

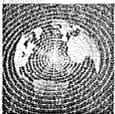
**Issues:**

1. Evaluate the implications of not using inference

**Assignment:** Industry Associations

**Status:**

- Standard supports signing requirements for in-bound and out-bound



## 5. Resale of Returned Product Update

1	Unit Dose Serialization
2	Receipt of Partial Shipments
3	Drop Shipments
4	Sign & Cert. Inbound
5	Resale of Returned Product
6	Intra-Company Transfers
7	Voided Pedigrees
8	Inference

**Scenario:** There are times when saleable product is returned by the Whsr to the Mfgr and may be resold by the Mfgr.

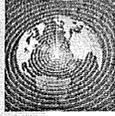
**Issues:**

1. Customers may not want returned product if the pedigree must reflect the previous distribution of the product.
2. How should a pedigree treat this transaction – reflect all previous movement of the product, or start anew when sold by the Mfgr
3. What documents, processes, controls and enforcement would be required

**Assignment:** Pedigree WG

**Status:**

- Pedigree standard addresses Resale of Returns



## 6. Intra-Company Transfers Update

1	Unit Dose Serialization
2	Receipt of Partial Shipments
3	Drop Shipments
4	Sign & Cert. Inbound
5	Resale of Returned Product
6	Intra-Company Transfers
7	Voided Pedigrees
8	Inference

**Scenario:** Pedigree Status for intra-company transfers into CA.

**Issues:**

1. Product sold to a Whlstr to an out-of-state location that does not require a Mfgr originated pedigree may be intra-company transferred to CA.
2. What are the CA pedigree implications

**Assignment:** Individual Company

**Status:**

- Standard supports manufacturer and/or wholesaler originated pedigrees



## 7. Voided Pedigrees Update

1	Unit Dose Serialization
2	Receipt of Partial Shipments
3	Drop Shipments
4	Sign & Cert. Inbound
5	Resale of Returned Product
6	Intra-Company Transfers
7	Voided Pedigrees
8	Inference

**Scenario:** Pedigree needs to be updated or changed to correct simple administrative errors such as shipping wrong product or incorrect serial number.

**Issues:**

1. What is the process of voiding pedigrees where an error has occurred, or a product has been returned
2. How are pedigrees for products marked for destruction managed

**Assignment:** Industry & Pedigree WG

**Status:**

- Identified as a pedigree management issue
- Initiating Work Group to address issue, in the interim, Standard provides guidelines & best practices





## 8. Inference Update

1	Unit Dose Serialization
2	Receipt of Partial Shipments
3	Drop Shipments
4	Sign & Cert. Inbound
5	Resale of Returned Product
6	Intra-Company Transfers
7	Voided Pedigrees
8	Inference

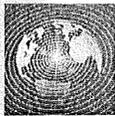
**Scenario:** Whether inference will be allowed at any step requiring "certification of the receipt", meaning that the receipt is positively affirming that they received all of the products specified in the pedigree without physically verifying all serial numbers.

**Issues:**

1. Does the pedigree std allow two separate signature events for one receipt step (one to receive, one to certify at a later date).
2. What is the Industry's view on inference and it's application
3. Is there a time limit from inbound receipt inference until all unique ID numbers have been certified

**Assignment:** Industry Adoption Workgroup  
**Status:**

- Establishing a set of inference recommendations

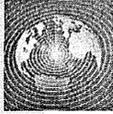


## Communication Activities

- Planned Web Seminars:
  - Pedigree Messaging Standard -Manufacturers outside US
  - Supply Chain Integrity – authentication, decommissioning use cases
  - EPCIS – What does it mean to healthcare?
  - Hospital Forums – every other month

To register for a Web Seminar, please contact Bob Celeste at:

[rceleste@epcglobalna.org](mailto:rceleste@epcglobalna.org)



## Next Step

- In process of scheduling another pedigree workshop with the following recommended objectives:
  1. Review status of the work on the follow up items in detail,
  2. Discuss impact to standards, and
  3. Review work of the Industry Adoption workgroup

25



## Questions?



# Attachment 2

*Presentation by Pfizer*



# Patient Safety and Channel Security

California Enforcement  
Committee  
June 20, 2007



## Discussion Points

- Background
- Actions to date
- Work in Progress
- Item-level Serialization
- Future Vision
- Summary

Page 2



## Background

- Pfizer shares the California Board of Pharmacy's concern for patient safety and is committed to addressing issues that impact the safety of our US pharmaceutical distribution system
- As a result of Pfizer's experience with counterfeit product (Viagra, Lipitor, etc) it is clear there is no easy or single solution to the counterfeiting problem
- A multi-faceted approach involving business practices, legislation/regulation, enforcement and technology is necessary to address this issue
  - ◆ Cross-industry collaboration and cooperation is essential

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## Actions to Date

- Business Practices
  - ◆ Required Pfizer-authorized wholesale customers (ADR's) to purchase Pfizer products directly from Pfizer or other Pfizer-authorized wholesalers
  - ◆ Steps have been taken to discourage repackaging of Pfizer products
  - ◆ Distributor audits have been implemented
  - ◆ Resources have been dedicated to product integrity work teams and initiatives

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## Actions to Date



### ■ Legislation and Regulation

- ◆ Pfizer has been very active in promoting public policy at both the federal and state level to deter counterfeiting
- ◆ At the state level, Pfizer has called for stricter laws regarding the licensing of wholesale distributors and greater oversight of repackaging operations
- ◆ Pfizer has supported the implementation of a pedigree process
- ◆ At the federal level, Pfizer has played an instrumental role in raising awareness of the risk importation poses to our supply chain, has supported implementation of PDMA, and the need for a uniform set of pedigree requirements

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## Actions To Date



### ■ Enforcement

- ◆ Increased investment in Global Security anti-counterfeiting resources and lab (analytical testing) capabilities
- ◆ Developing and providing leads to global enforcement agencies, FBI, FDA (OCI), etc on an ongoing basis
- ◆ Supporting investigative efforts
- ◆ Monitoring the market and internet for suspicious activity
- ◆ Aggressively pursuing criminal enterprises suspected of counterfeiting our products and cooperating with law enforcement to successfully prosecute those involved

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## Actions to Date

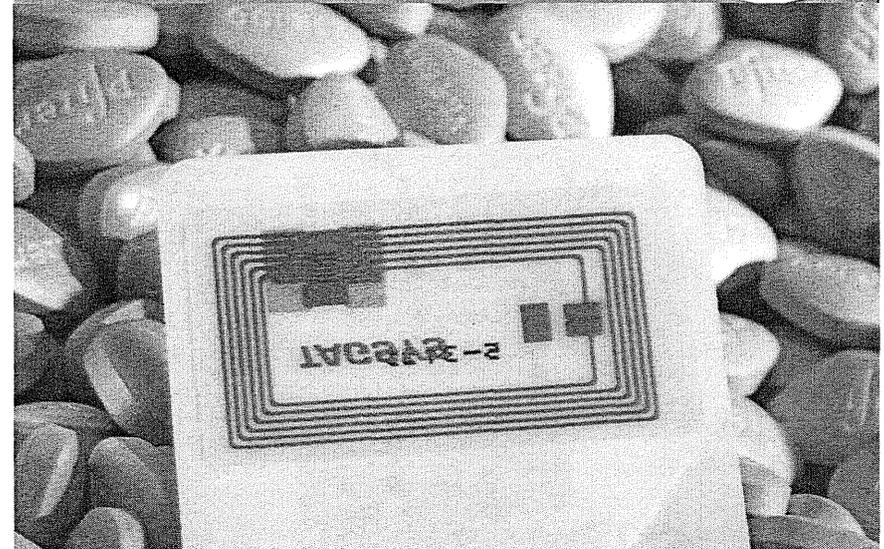


### ■ Technology

- ◆ Overt anti-counterfeiting technology (color-shifting ink) has been incorporated into the packaging of “at risk” items
- ◆ Covert technologies are also used on a select basis on packaging and products
- ◆ RFID technology (and serialization) has been incorporated into the packaging of our US Viagra bottles, cases, and pallets
  - One year to implement at a cost of approximately \$5 million (initial implementation costs)
- ◆ Viagra authentication service implemented– allowing others in the supply chain to verify the authenticity of the serialized number found on Viagra packaging.

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## RFID and Viagra



## RFID Tagged Viagra



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## Viagra Label



Store at 25°C (77°F);  
excursions permitted to  
15-30°C (59-86°F)  
[see USP Controlled  
Room Temperature].  
Dispense in tight  
containers (USP).

**DOSAGE AND USE**  
See accompanying  
prescribing information.

\*Each tablet contains  
sildenafil citrate  
equivalent to 100 mg sildenafil.



This package contains  
a radio frequency device.

05-5487-30-5

NDC 0069-4220-30

30 Tablets

Rx only

**Viagra®**  
(sildenafil citrate) tablets

**100 mg\***

Distributed by



**Pfizer Labs**

Division of Pfizer Inc, NY, NY 10017



N3 0069-4220-30  
8709245

4009

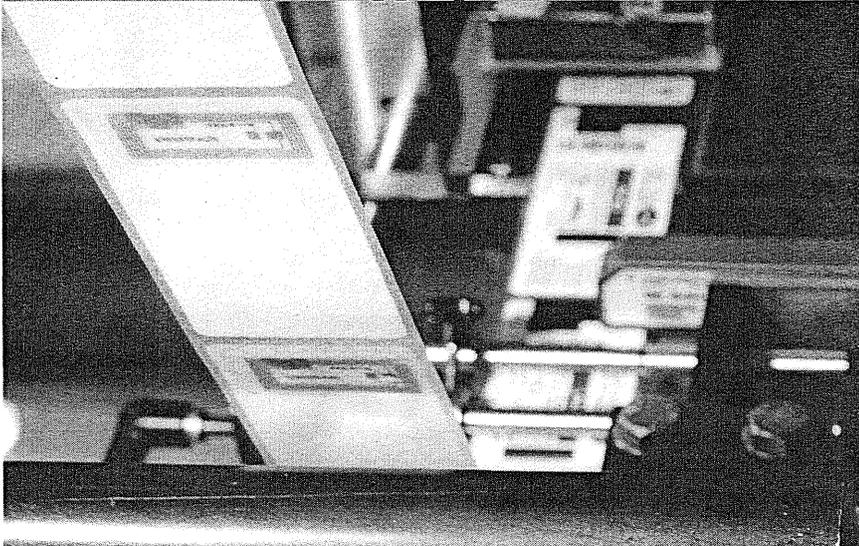


PROD003  
EXP 1 APR 04

Viagra® (sildenafil citrate) tablets

Page 10

## RFID Item-Level Tagging



## Serialization Lessons Learned



- As a result of our experience with Viagra and our current efforts with Celebrex, this is what we know:
  - Serialization is complex and costly
    - During a one-year period as many as 75 Pfizer colleagues and several external consultants were involved with the Viagra implementation
  - The one-time serialization implementation costs do not vary significantly regardless of the chosen data carrier (RFID or 2D)
  - The majority of the cost incurred lies in the provisioning and commissioning of the unique serialized number and applying this serial number to packages moving at speed on packaging lines
  - Effective process controls are essential to ensure the accuracy and integrity of the serialization process
  - Significant modifications are also required at distribution points to capture and associate serialized information with outbound customer shipments
  - Enhanced order assembly and shipping accuracy will be required in a serialized and pedigree environment to minimize disruption and returns
  - Each implementation is unique

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## Work in Progress



### Significant 2007 Initiatives:

- E-pedigree implementation & testing – Viagra
- RFID implementation – Celebrex case-level
- On Track – industry pilots
- PhRMA Supply Chain Security Technical Group
- Rx SafeTrack – track and trace vision
- Standards Development and Industry Adoption “Roadmap”

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## Work in Progress



### ■ E-pedigree Implementation and Testing – Viagra

- ◆ Our solution provider has been selected and funding secured for Viagra pedigree testing and implementation
- ◆ Interested trading partners have been identified and we are working with their solution providers to address data requirements
- ◆ An electronic signature capability is being implemented at each of our US logistics centers
- ◆ Testing of Viagra e-pedigrees to begin by end of June
- ◆ Systems interoperability to be tested with solution providers chosen by trading partners

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## Work in Progress



### ■ RFID Implementation – Celebrex case-level

- ◆ 4 packaging lines involved at one site in Caguas, PR
- ◆ Different line automation and floor space options than Viagra
- ◆ Faster line speed and greater case volume than Viagra
- ◆ Many competing priorities for line time; must not disrupt supply
- ◆ Effort to implement projected at 1 year and a cost of approximately \$4 million (initial implementation cost)

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## Work in Progress



### ■ On Track

- ◆ Pilot work to address various issues including RFID implementation, end-to-end e-pedigree testing, 2D bar code serialization and utilization, cost/benefit
- ◆ Participation from Manufacturers, Wholesale Distributors, and Retailers (chains and others), and solution providers

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## Work in Progress



- PhRMA Supply Chain Security Technical Group
  - ◆ Technology, Business Process and Legislative teams
  - ◆ Discussion Topics
    - Serialization
    - Data Carriers
    - Electronic Pedigree
    - Track and Trace
    - Authentication
    - Other Good Distribution Practices
    - Cost/Benefit
  - ◆ White Paper Due in Fall

## Work in Progress



- Rx SafeTrack (formerly Call to Action)
  - ◆ Cross-industry group tasked with defining a vision for track and trace and a possible date when a track and trace process could be implemented
  - ◆ Leadership and commitment being provided by an Executive Council comprised of 9 industry CEO's.
  - ◆ Recommendations due October 2007

## Work in Progress



- Standards Development and Industry Adoption
  - ◆ Significant effort underway with EPCglobal members defining user requirements for critical areas necessary to support serialization
    - Serialization standard
    - Item-level tagging
    - Track and Trace
    - Decommissioning, etc
  - ◆ Industry Adoption Roadmap currently being shared with industry trade associations as a starting point for discussions surrounding serialization and e-pedigree

## Pfizer Item-level Serialization



The magnitude of the effort.....

- 65 packaging lines at 21 sites (including 10 contract manufacturers) supplying product to the U.S. market
- Over 600 individual SKU's sold in the U.S.
- \$95 – 100 Million estimated cost to implement serialization capability on packaging lines and in logistics centers (RFID or 2D); ongoing cost not included
- Each implementation is unique and complex due to varying line speeds, line automation equipment, floor space availability, and the competing priorities for line time; must not disrupt supply to patients
- Best estimate of time required to implement item-level serialization for ALL products (5 -7 years) once funding and resources are secured; unclear business value (for ALL items)
- Today we have 1 product (5 SKU's) serialized at the item-level and we are an "early adopter"

## Item-level Serialization and Pedigree



- Open Issues
  - ◆ Need for ratified standards, conformance testing, certification, etc.
  - ◆ Need for guidance from the FDA regarding
    - Validation and process controls required to manage uniquely identified items
    - Recall conditions (if any) when serialization “exceptions” occur
    - Acceptable symbology and text to be used on product labeling and packaging
    - Use of RFID to serialize products such as biologics
  - ◆ Need a uniform and consistent set of requirements; varying pedigree requirements at the state and federal level
  - ◆ Implementing regulations are necessary to guide implementations and minimize rework
  - ◆ Need for industry to agree on a path forward and move together to implement

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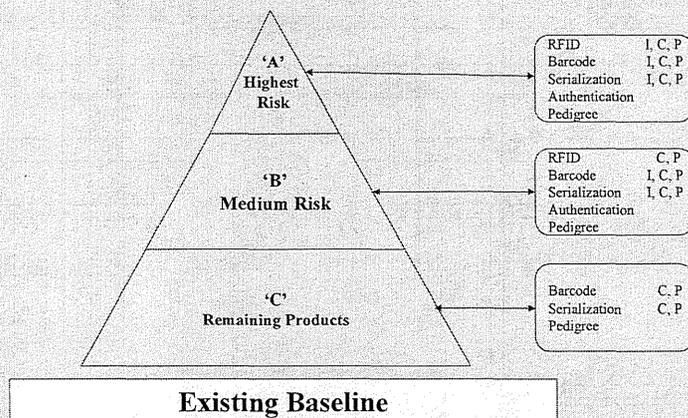
## Future Vision



- A risk-based and phased approach to the deployment of e-pedigree, serialization, RFID and 2D technology
- E-pedigree deployment by 2009
  - ◆ Begins to build much of the infrastructure necessary to support serialization and a future track and trace capability
- Robust (and interoperable) pedigree and track and trace systems would be deployed to support the inclusion of serialized information once serialized product is available.
- Pharmaceutical manufacturers would implement their serialization strategies beginning with an assessment of their product portfolio against various risk factors
- Level of technology application would be driven by risk

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## A Risk-based Approach



Key : I – Item Level, C – Case, P – Pallet

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## E-Pedigree and Patient Safety



### How does electronic pedigree enhance patient safety?

- Electronic pedigree information can be secured in a way that makes it less susceptible to falsification than today's paper-based documents
- The requirement to “certify” information found on the pedigree is accurate (before passing product in the supply chain) should heighten due diligence regarding the source and previous ownership of the product
- Electronic information regarding who has taken ownership of specific products provides an audit trail to facilitate investigations
- Electronic pedigrees add a barrier for counterfeiters who must not only counterfeit the product but now must also breach the secure exchange of electronic information about the movement of that product
- Electronic pedigree information is theoretically more readily retrievable when needed to support investigations, etc.
- Electronic pedigree requirements that begin with the manufacturer and require the participation of all segments of the supply chain close many of the gaps that exist in today's process
- Electronic pedigrees may enable (at a minimum) lot level tracking of product shipments that does not exist today for many

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## Summary



- Many steps have been taken during the past 4 years to enhance patient safety by further securing the supply channel
- Significant industry-wide efforts are underway today to further address channel security and the role serialization will play going forward
- Item-level serialization is complex, requires extensive investment and collaboration, and will take many years to implement for all products
- Electronic-pedigree implementation offers additional channel security benefits and can be implemented in the near-term
- A risk-based approach to serialization applies enhancements to products where higher risk exists and focuses resources

# Attachment 3

*Presentation by Walgreens*



**Sue Thoss**  
**Divisional Vice President, Logistics and**  
**Planning**  
**[Sue.Thoss@walgreens.com](mailto:Sue.Thoss@walgreens.com)**

## Agenda

- Discuss impact on Walgreens from:
  - Item-level serialization starting at manufacturer
  - Case-level serialization starting at manufacturer
  - No serialization by manufacturer
- Q&A

3

*Walgreens*

## Accelerators

- Standards
- Inference
- Pooling
- "Grandfather" existing inventory
- Phased implementation

4

*Walgreens*

## General Assumptions

- Authentication of pedigree at point of entry in into California required for intra-company shipments
- Accurate flow of standardized data from manufacturers and wholesalers
- Costs include California DC impact only
- Store costs presented in future meeting

5

*Walgreens*

## Item-level serialization starting at manufacturer - RFID

### Assumptions

Manufacturer applies Item-level serialization using RFID  
Item-level 2D barcode provided as backup to RFID

### Walgreens Costs (DC costs)

One-time: \$700K - \$1M  
Ongoing: \$500K - \$1M/yr

### Implementation

12 months (after standards are in place)  
DC process and technology re-engineering  
6 months to bleed out inventory

### Method

RFID tunnel/handheld readers for case and Item-level tag reading  
Item-level validation  
Audit sampling

6

*Walgreens*

## Item-level serialization starting at manufacturer – 2D Barcode with inference

### Assumptions

Manufacturer applies item-level serialization using 2D barcode  
Cases serialized using RFID  
Inference allowed

### Walgreens Costs (DC costs)

One-time: \$700K - \$1M  
Ongoing: \$500K - \$1M/yr

### Implementation

12 months (after standards are in place)  
DC process and technology re-engineering  
6 months to bleed out inventory

### Method

2D barcode tunnel/handheld readers for item-level barcode reading  
RFID tunnel for case reading  
Item-level inference  
Item-level validation  
Audit sampling

7

*Walgreens*

## Item-level serialization starting at manufacturer – 2D Barcode without inference

### Assumptions

Manufacturer applies item-level serialization using 2D barcode  
Cases serialized using RFID  
No inference allowed

### Walgreens Costs (DC costs)

One-time: \$1M - \$1.5M  
Ongoing: \$2.5M - \$3M/yr

### Implementation

12 months (after standards are in place)  
DC process and technology re-engineering  
6 months to bleed out inventory

### Method

RFID tunnel/handheld readers for case reading  
Tunnel/handheld 2D barcode readers for item-level barcode reading  
Item-level validation  
Audit sampling

8

*Walgreens*

## Case-level serialization by manufacturer – all types

### Assumptions

Manufacturer apply case-level serialization using RFID, 2D, or SSCC-18 barcode  
Walgreens DC would apply item-level serialization and add to Pedigree  
FDA will approve altering of packaging for item-level serialization

### Walgreens Costs (DC costs)

One-time: \$1.2M - \$1.7M  
Ongoing: \$7M - \$8M/yr

### Implementation

18 months (after standards are in place)  
DC process and technology re-engineering  
6 months to bleed out inventory

### Method

Serialization of every item will be done upon arrival at DC  
Limited product may require 2D barcode  
RFID tunnel/handheld readers for case reading  
Case-level validation  
Audit sampling

9

*Walgreens*

## No serialization by manufacturer (Pooling allowed)

### Assumptions

Manufacturer or Wholesaler would pass pedigree with lot and expiration date  
Pooling concept allowed

### Walgreens Costs (DC costs)

One-time: \$400K - \$500K  
Ongoing: \$500K - \$750K/yr

### Implementation

6 months (after standards are in place)  
DC process and technology re-engineering  
6 months to bleed out inventory

### Method

Items can be tracked by identifying the batch they came in using NDC, lot, and expiration date (pooling)  
Lot and expiration date validation at receiving  
Audit sampling

10

*Walgreens*

# No serialization by manufacturer

## Assumptions

Manufacturer or Wholesaler would pass pedigree with lot and expiration date

Pooling concept not allowed

FDA will approve altering of packaging for item-level serialization

## Walgreens Costs (DC costs)

One-time: \$1.2M - \$1.7M

Ongoing: \$7M - \$8M/yr

## Implementation

18 months (after standards are in place)

DC process and technology re-engineering

6 months prior to bleed out inventory

## Method

Walgreens provides serialization of every item using RFID

Limited product may require 2D barcode

Lot and expiration date validation at receiving

Audit sampling

11

*Walgreens*

# Q & A

## Thanks for your time

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*Walgreens*

# Attachment B

*Enforcement Statistics 2006-07*

# Board of Pharmacy Enforcement Statistics

## Fiscal Year 2006/2007

**Workload Statistics**                      **July-Sept**   **Oct-Dec**   **Jan-Mar**   **Apr-June**   **Total 06/07**

**Complaints/Investigations**

Initiated	378	373	377	304	1432
Closed	412	266	553	446	1677
Pending (at the end of quarter)	671	922	815	815	815

**Cases Assigned & Pending (by Team)**

Compliance Team	103	85	81	94	94
Drug Diversion/Fraud	106	125	118	82	82
Mediation Team	85	57	127	136	136
Probation/PRP	56	65	61	61	61
Enforcement	94	186	172	186	186

**Application Investigations**

Initiated	68	97	75	58	298
Closed					
Approved	3	14	73	16	106
Denied	2	3	1	7	13
Total*	6	17	80	44	147
Pending (at the end of quarter)	98	178	174	186	186

**Citation & Fine**

Issued	141	121	343	130	735
Citations Closed	172	124	120	241	657
Total Fines Collected	\$75,815.00	\$90,701.70	\$131,910.00	\$138,285.00	\$436,711.70

\* This figure includes withdrawn applications.

\*\* Fines collected and reports in previous fiscal year.

# Board of Pharmacy Enforcement Statistics

## Fiscal Year 2006/2007

**Workload Statistics**                      **July-Sept**   **Oct-Dec**   **Jan-Mar**   **Apr-June**   **Total 06/07**

**Administrative Cases** (by effective date of decision)

Referred to AG's Office*	35	20	44	35	99
Pleadings Filed	24	22	24	16	70
Pending					
Pre-accusation	59	52	46	62	62
Post Accusation	86	69	64	56	56
Total	149	128	143	147	147
Closed**	23	38	30	26	117
Revocation					
Pharmacist	1	4	6	2	13
Pharmacy	1	3	0	1	5
Other	9	14	12	0	35
Revocation, stayed; suspension/probation					
Pharmacist	1	2	1	2	6
Pharmacy	0	0	0	0	0
Other	0	0	1	0	1
Revocation, stayed; probation					
Pharmacist	1	1	4	3	9
Pharmacy	0	0	0	0	0
Other	0	0	1	1	2
Suspension, stayed; probation					
Pharmacist	0	0	0	0	0
Pharmacy	0	0	0	0	0
Other	0	0	0	0	0
Surrender/Voluntary Surrender					
Pharmacist	3	7	6	0	16
Pharmacy	0	5	0	0	5
Other	1	4	2	4	11
Public Reprival/Reprimand					
Pharmacist	0	0	0	0	0
Pharmacy	0	0	0	0	0
Other	0	0	1	0	1
Cost Recovery Requested	\$40,239.00	\$142,128.75	\$53,344.75	\$140,603.25	\$376,315.75
Cost Recovery Collected	\$21,104.66	\$39,650.49	\$29,020.38	\$40,501.78	\$130,277.31

\* This figure includes Citation Appeals

\*\* This figure includes cases withdrawn

# Board of Pharmacy Enforcement Statistics

## Fiscal Year 2006/2007

**Workload Statistics**                      **July-Sept**   **Oct-Dec**   **Jan-Mar**   **Apr-June**   **Total 06/07**

### Probation Statistics

Licenses on Probation

Pharmacist	93	100	102	104	104
Pharmacy	5	6	6	5	5
Other	14	13	15	15	15
Probation Office Conferences	9	7	5	10	31
Probation Site Inspections	92	41	66	45	244
Probationers Referred to AG for non-compliance	3	0	0	1	4

As part of probation monitoring, the board requires licensees to appear before the supervising inspector at probation office conferences. These conferences are used as 1) an orientation to probation and the specific requirements of probation at the onset, 2) to address areas of non-compliance when other efforts such as letters have failed, and 3) when a licensee is scheduled to end probation.

### Pharmacists Recovery Program (as of 6/30/07)

Program Statistics

In lieu of discipline	0	0	0	2	2
In addition to probation	2	4	2	4	12
Closed, successful	1	4	1	2	8
Closed, non-compliant	1	0	1	3	5
Closed, other	0	1	2	2	5
Total Board mandated Participants	50	54	53	53	54
Total Self-Referred Participants*	26	30	23	24	24
Treatment Contracts Reviewed	43	46	45	44	178

Monthly the board meets with the clinical case manager to review treatment contracts for scheduled board mandated participants. During these monthly meetings, treatment contracts and participant compliance is reviewed by the PRP case manager, diversion program manager and supervising inspector and appropriate changes are made at that time and approved by the executive officer. Additionally, non-compliance is also addressed on a needed basis e.g., all positive urines screens are reported to the board immediately and appropriate action is taken.

\* By law, no other data is reported to the board other than the fact that the pharmacists and interns are enrolled in the program.

As of June 30, 2007.

# California State Board of Pharmacy

## Citation and Fine Statistics

### July 1, 2006 – June 30, 2007

**777 citations have been issued so far this fiscal year**

Total dollar amount of fines issued this fiscal year  
\$ 1,271,550.00

Total dollar amount of fines collected  
\$436,711.70\*

\*This amount also reflects payment of the citations issued before July 1, 2006.

The average number of days from date case is  
opened until a citation is issued is **158**

Average number of days from date citation is  
issued to date citation is closed is **45**

#### Citation Breakdown by license type

Total issued	RPH with fine	RPH no fine	PHY with fine	PHY no fine	PIC with fine	PIC no fine	TCH with fine	TCH no fine
777	134	39	177	104	103	26	24	5

#### Citation Breakdown by Miscellaneous license type

Wholesalers	Exemptee's	Clinics	Drug room	Exempt Hosp.	Hosp. pharmacy	Misc.	Unlicensed Premises	Unlicensed person
37	24	2	1	5	8	61	24	3

\*Licensed Correctional Facilities, Exempt Pharmacies, Non-Resident Pharmacies, and Vet Retailers

## Top Ten Violations for the fourth quarter of 2006/2007 by license type

Pharmacists	%	Pharmacies	%	Pharmacists in charge	%
1716 - Variation from prescription	46%	1716 - Variation from prescription	28%	1716 - Variation from prescription	10%
1716/1761(a) – Variation from prescription/No pharmacist shall compound or dispense any prescription, which contains any significant error or omission...	9%	1714(b)- Operational standards and security; pharmacy responsible for pharmacy security	18%	1715 – Self-assessment of a pharmacy by the pharmacist-in-charge	9%
1714(d)- Operational standards and security; pharmacist responsible for pharmacy security	9%	1716/1761(a) – Variation from prescription/No pharmacist shall compound or dispense any prescription, which contains any significant error or omission...	7%	1714(d)- Operational standards and security; pharmacist responsible for pharmacy security	9%
4339 - Non-pharmacist acting as manager, compounding, dispensing, or furnishing drugs	4%	4342 - Actions by board to prevent sales of preparations or drugs lacking quality or strength; Penalties for knowing or willful violation of regulations governing those sales	5%	4342 - Actions by board to prevent sales of preparations or drugs lacking quality or strength; Penalties for knowing or willful violation of regulations governing those sales	8%
4342 - Actions by board to prevent sales of preparations or drugs lacking quality or strength; Penalties for knowing or willful violation of regulations governing those sales	3%	1764/56.10et seq.- Unauthorized disclosure of prescription and medical information	4%	1716/1761(a) – Variation from prescription/No pharmacist shall compound or dispense any prescription, which contains any significant error or omission...	6%
1707.3 – Duty to review drug therapy	3%	1714(c)- Operational standards and security; the pharmacy must be maintained in a sanitary condition	3%	4063 - Refill of prescription for dangerous drug or device; prescriber authorization	5%
4322 - Misdemeanor or infraction: false representation to secure license for self or others; false representation of licensure	3%	1716/1761 - Variation from Rx / Erroneous Rx	3%	1714(b)- Operational standards and security; pharmacy responsible for pharmacy security	5%
4059(a)- Furnishing dangerous drugs without a prescription	3%	4063 - Refill of prescription for dangerous drug or device; prescriber authorization	2%	1304.11- Inventory requirements	4%
1764/56.10et seq.- Unauthorized disclosure of prescription and medical information	2%	4081(a)- Records of dangerous drugs kept open for inspection	2%	1707.2- Duty to consult	4%
4081(a)- Records of dangerous drugs kept open for inspection	2%	4115(e) - Pharmacy technician license required	2%	1711- Quality assurance programs	3%

# Contested Citations Office Conference

(These statistics also include contested Letters of Admonishment)

There were twenty office conferences held this fiscal year

Number of requests	255
--------------------	-----

Number scheduled	255
------------------	-----

Number appeared	148*
-----------------	------

Number Postponed	64**
------------------	------

\*Please note on three occasions unscheduled citations were heard with a related case at office conference.

\*\*Please note these are added back into the number of requests and scheduled case totals above.

Total number of requests withdrawn	31
Failed to appear	3

## Office Conference between July 1, 2006 and June 30, 2007

Total number of citations affirmed	87
------------------------------------	----

Decision	Total citations	Total dollar amount reduced
Modified	30	\$10,375.00
Dismissed	30	\$4,000.00
Reduced to Letter of Admonishment	1	\$0.00

Please note due to additional investigation being required,  
Seven cases are pending a decision

# GOALS, OUTCOMES, OBJECTIVES, AND MEASURES

## ENFORCEMENT COMMITTEE

Goal 1: Exercise oversight on all pharmacy activities.

Outcome: Improve consumer protection.

Objective 1.1	Achieve 100 percent closure on all cases within 6 months.						
Measure:	Percentage of cases closed.						
Tasks:	1. Mediate all complaints within 90 days (for cases closed during quarter).						
		<u>N</u>	< 90 days	< 120 days	< 180 days	Longer	<u>Average Days</u>
	Qtr 1	141	113 (81%)	5 (3%)	11 (8%)	12 (8%)	50
	Qtr 2	72	67 (94%)	0 (0%)	4 (5%)	1 (1%)	17
	Qtr 3	113	100 (89%)	3 (3%)	4 (3%)	6 (5%)	32
	Qtr 4	172	157 (92%)	2 (1%)	4 (2%)	9 (5%)	22
	2. Investigate all cases within 120 days (for cases closed during quarter).						
		<u>N</u>	< 120 days	< 180 days	< 270 days	Longer	<u>Average Days</u>
	Qtr 1	271	195 (72%)	49 (18%)	25 (9%)	2 (1%)	87
	Qtr 2	173	146 (84%)	15 (9%)	12 (7%)	0 (0%)	79
	Qtr 3	438	290 (66%)	107 (24%)	29 (7%)	12 (3%)	82
	Qtr 4	268	189 (70%)	47 (18%)	21 (8%)	11 (4%)	96

3. Close (e.g., no violation, issue citation and fine, refer to the AG's Office) all board investigations and mediations within 180 days.

<b>Qtr 1</b>	<b><u>N</u></b>	<b>&lt; 180</b>	<b>&lt; 270</b>	<b>&lt; 365</b>	<b>&gt; 365</b>
Closed, no additional action	210	166	14	15	15
Cite and/or fine letter of admonishment	167	82	50	25	10
Attorney General's Office	35	11	7	10	7
<b>Qtr 2</b>	<b><u>N</u></b>	<b>&lt; 180</b>	<b>&lt; 270</b>	<b>&lt; 365</b>	<b>&gt; 365</b>
Closed, no additional action	104	94	6	3	1
Cite and/or fine letter of admonishment	128	33	84	6	5
Attorney General's Office	12	2	4	3	3
<b>Qtr 3</b>	<b><u>N</u></b>	<b>&lt; 180</b>	<b>&lt; 270</b>	<b>&lt; 365</b>	<b>&gt; 365</b>
Closed, no additional action	172	157	12	3	0
Cite and/or fine letter of admonishment	631	337	16	7	1
Attorney General's Office	18	10	6	2	0
<b>Qtr 4</b>	<b><u>N</u></b>	<b>&lt; 180</b>	<b>&lt; 270</b>	<b>&lt; 365</b>	<b>&gt; 365</b>
Closed, no additional action	252	238	10	4	0
Cite and/or fine letter of admonishment	161	142	13	6	0
Attorney General's Office	28	20	6	1	1

<p>Objective 1.2</p> <p>Measure:</p> <p>Tasks:</p>	<p>Manage enforcement activities for achievement of performance expectations.</p> <p>Percentage compliance with program requirements.</p> <p>1. Administer the Pharmacists Recovery Program.</p> <table border="1" data-bbox="359 217 1508 497"> <thead> <tr> <th></th> <th>Voluntary Participants</th> <th>Participants Mandated Into Program</th> <th>Noncompliant, Terminated From Program</th> <th>Successfully Completed Program</th> </tr> </thead> <tbody> <tr> <td>Qtr 1</td> <td>26</td> <td>50</td> <td>1</td> <td>1</td> </tr> <tr> <td>Qtr 2</td> <td>30</td> <td>54</td> <td>0</td> <td>4</td> </tr> <tr> <td>Qtr 3</td> <td>23</td> <td>53</td> <td>1</td> <td>1</td> </tr> <tr> <td>Qtr 4</td> <td>24</td> <td>53</td> <td>3</td> <td>0</td> </tr> </tbody> </table> <p>2. Administer the Probation Monitoring Program.</p> <table border="1" data-bbox="359 569 1228 880"> <thead> <tr> <th></th> <th>Qtr 1</th> <th>Qtr 2</th> <th>Qtr 3</th> <th>Qtr 4</th> </tr> </thead> <tbody> <tr> <td>Individuals</td> <td>107</td> <td>100</td> <td>116</td> <td>105</td> </tr> <tr> <td>Sites</td> <td>5</td> <td>6</td> <td>7</td> <td>6</td> </tr> <tr> <td>Tolled</td> <td>27</td> <td>27</td> <td>20</td> <td>20</td> </tr> <tr> <td>Inspections Conducted</td> <td>92</td> <td>41</td> <td>66</td> <td>45</td> </tr> <tr> <td>Successfully Completed</td> <td>1</td> <td>1</td> <td>1</td> <td>2</td> </tr> <tr> <td>Petitions to Revoke Filed</td> <td>3</td> <td>0</td> <td>0</td> <td>0</td> </tr> </tbody> </table> <p>3. Issue all citations and fines within 30 days.</p> <table border="1" data-bbox="359 942 1412 1336"> <thead> <tr> <th></th> <th><u>N</u></th> <th>30 days</th> <th>60 days</th> <th>90 days</th> <th>&gt; 90 days</th> <th><u>Average Days</u></th> </tr> </thead> <tbody> <tr> <td>Qtr 1</td> <td>140</td> <td>41 (29%)</td> <td>61 (43%)</td> <td>21 (15%)</td> <td>17 (12%)</td> <td>51</td> </tr> <tr> <td>Qtr 2</td> <td>118</td> <td>14 (12%)</td> <td>22 (18%)</td> <td>41 (35%)</td> <td>41 (35%)</td> <td>84</td> </tr> <tr> <td>Qtr 3</td> <td>340</td> <td>73 (21%)</td> <td>77 (23%)</td> <td>123 (36%)</td> <td>67 (20%)</td> <td>70</td> </tr> <tr> <td>Qtr 4</td> <td>130</td> <td>18 (14%)</td> <td>92 (71%)</td> <td>17 (13%)</td> <td>2 (2%)</td> <td>50</td> </tr> </tbody> </table> <p>4. Issue letters of admonishment within 30 days.</p> <table border="1" data-bbox="359 1419 1396 1802"> <thead> <tr> <th></th> <th><u>N</u></th> <th>30 days</th> <th>60 days</th> <th>90 days</th> <th>&gt; 90 days</th> <th><u>Average</u></th> </tr> </thead> <tbody> <tr> <td>Qtr 1</td> <td>33</td> <td>30 (91%)</td> <td>1 (3%)</td> <td>2 (6%)</td> <td>0 (0%)</td> <td>12</td> </tr> <tr> <td>Qtr 2</td> <td>4</td> <td>4 (100%)</td> <td>0 (0%)</td> <td>0 (0%)</td> <td>0 (0%)</td> <td>18</td> </tr> <tr> <td>Qtr 3</td> <td>9</td> <td>3 (33%)</td> <td>0 (0%)</td> <td>4 (44%)</td> <td>2 (22%)</td> <td>62</td> </tr> <tr> <td>Qtr 4</td> <td>22</td> <td>3 (14%)</td> <td>18 (82%)</td> <td>1 (4%)</td> <td>0 (0%)</td> <td>40</td> </tr> </tbody> </table>		Voluntary Participants	Participants Mandated Into Program	Noncompliant, Terminated From Program	Successfully Completed Program	Qtr 1	26	50	1	1	Qtr 2	30	54	0	4	Qtr 3	23	53	1	1	Qtr 4	24	53	3	0		Qtr 1	Qtr 2	Qtr 3	Qtr 4	Individuals	107	100	116	105	Sites	5	6	7	6	Tolled	27	27	20	20	Inspections Conducted	92	41	66	45	Successfully Completed	1	1	1	2	Petitions to Revoke Filed	3	0	0	0		<u>N</u>	30 days	60 days	90 days	> 90 days	<u>Average Days</u>	Qtr 1	140	41 (29%)	61 (43%)	21 (15%)	17 (12%)	51	Qtr 2	118	14 (12%)	22 (18%)	41 (35%)	41 (35%)	84	Qtr 3	340	73 (21%)	77 (23%)	123 (36%)	67 (20%)	70	Qtr 4	130	18 (14%)	92 (71%)	17 (13%)	2 (2%)	50		<u>N</u>	30 days	60 days	90 days	> 90 days	<u>Average</u>	Qtr 1	33	30 (91%)	1 (3%)	2 (6%)	0 (0%)	12	Qtr 2	4	4 (100%)	0 (0%)	0 (0%)	0 (0%)	18	Qtr 3	9	3 (33%)	0 (0%)	4 (44%)	2 (22%)	62	Qtr 4	22	3 (14%)	18 (82%)	1 (4%)	0 (0%)	40
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5. Obtain immediate public protection sanctions for egregious violations.

	Interim Suspension Orders	Automatic Suspension Based on Conviction	Penal Code 23 Restriction
Qtr 1	0	0	2
Qtr 2	0	0	1
Qtr 3	0	0	0
Qtr 4	0	0	0

6. Submit petitions to revoke probation within 30 days for noncompliance with terms of probation.

	30 days	60 days	> 60 days	<u>N</u>
Qtr 1	1	0	2	3
Qtr 2	0	0	0	0
Qtr 3	0	0	0	0
Qtr 4	0	0	0	0

Objective 1.3

Achieve 100 percent closure on all administrative cases within 1 year.

Measure:

Percentage of administrative cases closed within 1 year.

	<u>N</u>	1 Year	1.5 Year	2 Year	2.5 Year	>2.5 Years	<u>Average</u>
Qtr 1	22	6 (27.3 %)	11 (50 %)	3 (13.6%)	1 (4.6%)	1 (4.6%)	456 days
Qtr 2	37	13 (35.1%)	11 (29.7%)	7 (18.9%)	2 (5.4%)	4 (10.8%)	568 days
Qtr 3	29	16 (55.2%)	7 (24.1%)	2 (6.9%)	2 (6.9%)	2 (6.9%)	444 days
Qtr 4	27	13 48.2%	6 22.2%	6 22.2%	1 3.7%	1 3.7%	448 days

Objective 1.4	Inspect 100 percent of all facilities once every 3 year inspection cycle ending 6/30/08.																				
Measure:	Percentage of licensed facilities inspected once every 3 year cycle.																				
Tasks:	1. Inspect licensed premises to educate licensees proactively about legal requirements and practice standards to prevent serious violations that could harm the public.																				
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	2. Inspect sterile compounding pharmacies initially before licensure and annually before renewal.																				
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3. Initiate investigations based upon violations discovered during routine inspections.																					
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Objective 1.5	Initiate policy review of 25 emerging enforcement issues by June 30, 2011.
Measure:	The number of issues.
Tasks:	<p>1.1. Monitor the implementation of e-pedigree on all prescription medications sold in California.</p> <p><i>Sept. 28, 2006: Board convenes third Workgroup on Implementation of E-Pedigree Meeting. Presentations provided by EPCglobal, McKesson, Supervising Inspector Nurse and Johnson and Johnson.</i></p> <p><i>Sept. 30, 2006: Governor signs SB 1476 which delays implementation of e-pedigree requirements until 2009, requires serialization and interoperability and notification to the board whenever counterfeit drugs are discovered.</i></p> <p><i>Oct. 6, 2006: FDA provides presentation on federal pedigree requirements at board-hosted NABP District 7 &amp; 8 Meeting.</i></p> <p><i>Dec. 2006: Board convenes fourth Workgroup on Implementation of E-Pedigree Meeting. Presentations made by EPCglobal, McKesson, AmerisourceBergen and Cardinal. Pilot testing e-pedigree systems underway at each of the three large wholesalers. Standards for electronic pedigree to be finalized by January 2007 by EPCglobal.</i></p> <p><i>Jan. 2007: EPCglobal finalizes electronic messaging standards for electronic pedigrees.</i></p> <p><i>Feb. 2007: EPCglobal convenes regional meeting with hospitals to discuss implementation issues of e-pedigree in these facilities. Hospitals are encouraged to join the board's Workgroup on Implementation of E-Pedigree Meetings.</i></p> <p><i>March 2007: Two Board members and executive staff meet with nine EPCglobal representatives to walk through EPCglobal's messaging standards and business scenarios. The standard complies with California's e-pedigree requirements although some questions remain about situation-specific criteria.</i></p> <p><i>Board convenes fifth Workgroup on Implementation of E-pedigree Meeting. Presentations are made by EPCglobal, AmerisourceBergen and SupplyScope.</i></p> <p><i>May 2007: Board presents information at the National Association of Boards of Pharmacy annual meeting on California's electronic pedigree requirements in both a poster session and a full presentation to the full assembly.</i></p> <p><i>June 2007: Board convenes sixth Workgroup on E-pedigree Meeting, with the largest attendance of any prior meeting. Presentations were made by EPCglobal, Pfizer, Walgreens and PhRMA. Hospital pharmacies were specifically invited to attend this meeting.</i></p> <p>2. Implement federal restrictions on ephedrine, pseudoephedrine or phenylpropanolamine products.</p> <p><i>Sept. 2006: Final phase-in of federal requirements takes effect on September 30. Board newsletter provides information for licensees.</i></p> <p><i>Oct. 2006: Board adds Consumer friendly materials regarding sales of these drugs to its Website.</i></p>

3. **Monitor the efforts of the DEA and DHHS to implement electronic prescribing for controlled substances.**
  - Sept. 2006: DEA releases proposed rule to allow prescribers to issue 90 days' worth of Schedule II prescriptions at one time.*
  - Oct. 2006: Board considers proposed rule.*
  - Nov. 2006: Board submits letter supporting change in DEA policy allowing prescribers to write multiple prescriptions for Schedule II drugs with "Do not fill before (date)" at one time, eliminating the need for patients to revisit prescribers merely to obtain prescriptions.*
4. **Evaluate establishment of an ethics course as an enforcement option.**
  - June 2007: Subcommittee meets with ethicist trainer for Dental Board.*
5. **Participate in emerging issues at the national level affecting the health of Californians regarding their prescription medicine.**
  - May 2007: Board staff provides presentation at National Association of Boards of Pharmacy annual meeting on California's pedigree requirements.*
  - June 2007: Board works with Center for Medicare and Medicaid Services on security prescription forms that will be required in only four months for all written Medicaid and Medicare prescriptions.*