

All Eyes on FDA for Drug E-Pedigree

Now that California has extended its electronic-pedigree deadline to 2011, the U.S. Food and Drug Administration could become the first governing body to issue e-pedigree requirements for protecting the pharma supply chain—assuming it meets its goal.

By Claire Swedberg

April 10, 2008—With the deadline for California's electronic-pedigree (e-pedigree) requirement for pharmaceuticals moved from Jan. 1, 2009, to Jan. 1, 2011, the push for a drug-authenticating e-pedigree system now seems to have shifted to the federal rather than state level. The U.S. Food and Drug Administration (FDA) has set a deadline of January 2010 to put in place a pedigree system that would protect the pharmaceutical supply chain "against counterfeit, diverted, subpotent, substandard, adulterated, misbranded or expired drugs." While the FDA is not considering only electronic solutions—other paper-based identification systems that do not use RFID or bar coding are being discussed as well—the agency has shown an interest in RFID technology, which would make the pedigree solution electronic.

An e-pedigree is an electronic record for tracking the movement of prescription drugs through the supply chain to combat counterfeit or adulterated prescription drugs. California was the first state to set a deadline for e-pedigree compliance that could include a \$5,000 fine for every violation (each sellable unit found not in compliance).

Nevada and Virginia also have e-pedigree systems on a limited scale. In Nevada, a pharmaceutical wholesaler must create e-pedigrees for any pharmaceutical items it ships, then send all of the electronic records once a month to the Nevada State Board of Pharmacy.

Both California's and the FDA's pedigree system are comprehensive, and would begin with tracking items earlier, at the point of manufacture, and then follow them to the point of sale. The state of Florida issued its own pedigree requirement in 2006, but that is document-based, with participants manually recording data about pharmaceutical shipments. In addition, the California e-pedigree system calls for tracking additional details, such as product volume and dosage.

But on March 25, the California State Board of Pharmacy issued a decision to delay implementation of its e-pedigree law. After the board set the 2009 deadline two years ago, some industry members have since been more successful than others in putting their own e-pedigree systems in place. In its March 25 decision, however, the board wrote that a large percentage of industry members have indicated they will be unable to meet the deadline by 2009, but could do so by 2011.

Because the implementation delays among some industry members would affect the efficacy of systems that other members already set in operation, the board determined the industry as a whole would not be able to meet the 2009 deadline. An imperfect or non-uniform implementation of an e-pedigree system, the board wrote, could cause unnecessary delays in the supply chain, or unneeded expenses.

In 2004, the California State Board of Pharmacy first issued a pending e-pedigree requirement for the

prescription drug industry operating in the state, with a deadline of Jan. 1, 2007. In 2006, the board moved that deadline back to 2009 to allow the industry more time to implement technologies. An e-pedigree, the board ruled, can be accomplished using bar codes or RFID technology. In January 2008, the board asked for industry input prior to its March 25 meeting in San Diego, and as a result of those responses, issued the 2011 extension of the requirement.

The new deadline is one year later than the FDA's intended implementation of e-pedigrees on a federal level. In summer 2007, Congress gave the agency 30 months to develop a pedigree requirement that would be federally mandated. If the FDA meets that deadline, the requirement will take effect in January 2010. In the meantime, the FDA is seeking comments from drug manufacturers, pharmacies, distributors and other industry stakeholders.

A federally mandated program may be a better solution for the pharmaceutical industry than a state-mandated one, says Doug Farry, director of government relations practice at McKenna Long & Aldridge and chairman of the firm's RFID practice group. If California's mandate were different than another state's or the FDA's, he points out, the pharmaceutical industry would have a problem complying with multiple requirements.

With the FDA now the only governing body looking closely at an e-pedigree requirement by 2010, the federal agency has the opportunity to set a nationwide standard for an e-pedigree system, as well as which technology should be used and what policies should be in place for enforcement. However, Farry says, the resolution of policy issues, such as enforcement and liability, may be the greatest obstacle, and was very likely one reason California issued a delay of two more years. Those yet-to-be-determined policies include spelling out who will be held liable if a product is found to be counterfeit after the e-pedigree system is put in place, as well as clarifying which parties will be responsible for what happens in specific parts of the supply chain.

"My belief," Farry says, "is that regardless of what [technology] standards they—either California or the FDA—still have, the challenge is, How is this enforced?" He notes that overseeing and enforcing rules for the entire pharmaceutical supply chain, from manufacturer to retailer, would be a difficult task for the FDA. "What enforcement mechanism will they have in place? That is going to remain a challenge," he states. The prescription drug industry, he adds, may be balking not only at implementing technology by 2009 (as per California's former deadline), but also at the fact that enforcement and liability policies have not yet been established.

"I would argue that it is the difficulty in resolving policy questions that is more the issue than the technology," Farry says. "I believe policy issues are slowing this down. Those who are being asked to implement the technology are hesitant to invest money in a system without knowing what the rules are going to be—what's my liability if I put this into place?" Farry, however, believes the FDA can still answer such policy questions by the federal agency's deadline. "Can they be resolved? Sure, there is certainly time. It depends on the different players feeling incentivized to come to the table to come up with win-win solutions."

The FDA has testified to Congress that RFID is the most promising technology for a drug-pedigree system, but Congress has also recommended considering holograms and microdots, similar to those found on U.S. currency, as well as bar codes. What's more, the federal agency is also reviewing the standardization of serial numbers—the unique numerical identifier for use with RFID or bar-coding technology.

An e-pedigree system would require a unique serial number be placed on each item being tracked, but there is no current standard specific to the serial numbers used. "I think serialization is the biggest problem," says Ronald E. Quirk, Jr., counsel at Washington, D.C., law office Venable LLP. Quirk indicates that until a serialization standard is determined at the FDA, it is prudent for the state of California to delay any regulations specific to an e-pedigree.

Some pharmaceutical companies, including Cardinal Health (see [Cardinal Health Deploying Drug E-Pedigree System](#)) and [Purdue Pharmaceutical](#), have already implemented an electronic tracking system using RFID in their supply chain. Purdue began investigating electronic tracking in 2002, and started piloting an RFID-based system in 2005 (see [Purdue Pharma to Run Pedigree Pilot](#)).

RELATED_ARTICLES At present, Purdue Pharma tags every bottle of OxyContin it ships with an EPC Gen 2 RFID tag. "When we first implemented the system, there was no legislation on the horizon," says Aaron Graham, the company's VP and chief security officer. Independently, Purdue was seeking ways to ensure the safety of the supply chain, and discussed 2-D bar codes before opting for RFID technology. With bar coding, he points out, "You need line of sight—and when you're moving thousands of units, that is not efficient."

Purdue's early start in RFID gave it an advantage others in the industry don't have, Graham says. "People are seriously concerned about public health," he states, "but it's not a simple solution—we got a running start at it." Graham says he doubts the industry could have met the 2009 deadline, and that the additional time will enable both the pharmaceutical company and RFID vendors to catch up. "I think if every drug manufacturer was held accountable [by 2009], there would be a problem with the supply of tags," he says, adding that currently, "there aren't enough available tags in the world economy." The new deadline extension, he says, is "realistic and viable."

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