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## California Not Ready for Drug Pedigrees – Is RFID?

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April 8, 2008—The California State Board of Pharmacy recently issued a decision to delay implementation of the state's drug pedigree law until 2011. The law does not require the use of

RFID to carry drug pedigrees, but the technology is widely seen as a potentially effective component for pharmaceutical pedigree and other track-and-trace systems.

California's law requires pharmaceuticals to be identified with a unique serial number at the unit level and to be tracked from the time they are produced to the time they are distributed to consumers. The law was originally scheduled to take effect January 1, 2009, but last month the California Board of Pharmacy moved the compliance deadline to January 1, 2011. The extension was made after numerous pharmaceutical companies and industry associations said they needed more time to prepare.

"The California Board of Pharmacy really had no choice but to delay implementation. Most companies in the pharmaceutical supply chain were not ready for the rule, and the Board itself wasn't ready to enforce it," Dr. Adam J. Fein, PhD, an expert in pharmaceutical economics and supply chain issues, told RFID Update. Fein is founder and president of Pembroke Consulting, a pharmaceutical industry consultancy in Philadelphia, and also authors Drug Channels, a blog that follows pedigree activity and other industry developments. This post provides a good summary of California pedigree developments. The state pharmacy board has its own Q&A about the law here.

In its decision, the California Board of Pharmacy said RFID and other technology solutions for pedigrees *"...would benefit greatly from more time to mature."* However, technology readiness was not the issue according to Fein and Mark O'Connell, CEO of SupplyScape, a pedigree solutions provider headquartered in Boston.

"Our belief is the technology is ready," O'Connell told RFID Update. "There are companies who took a serious approach to California requirements and were ready to comply. They didn't start six months ago, they started three years ago."

“Existing technology is certainly capable of meeting the requirements,” Fein said, though he noted he has some doubts about RFID. One of Fein’s clients has developed a pedigree solution that uses two-dimensional (2D) bar codes to identify each unit-of-use, and Fein favors the bar code approach.

“The amount of data required by unit-level serialization is enormous. Most companies in the pharmaceutical industry use ERP systems. The data from serialization will be the equivalent of adding an entire ERP system every year,” Fein said. “RFID has not been tested at that level and is not suitable for that scale.”

O’Connell, who was interviewed separately, disagrees. “The belief is that RFID technology is ready. It’s really a cost issue. How expensive will it be to put RFID labels on drugs, and what will that do to the cost of drugs?” he said.

Neither O’Connell nor Fein felt technology readiness were a major reason the California requirements were delayed. They, along with the California Board of Pharmacy itself, cited industry readiness and the complexity of deploying pedigree systems as the key factors for the decision.

“The California law requires something that has never been done before,” said Fein. “First, it applies to every transaction. Most pedigree requirements begin when drugs are transferred by a wholesaler, but California requires a pedigree from the point of production. The second issue that’s new is unit-of-use level serialization. Most other laws require pedigrees at the case or other packaging level. Third, companies are required to do all this using an electronic system to exchange data...In one sense they’re requiring companies in the pharmaceutical supply chain to create their own Internet, from scratch.”

O’Connell said several SupplyScape customers have California compliance systems in place, but the fastest any company has

implemented one is 100 weeks. He expects it to become somewhat easier to comply as requirements clarify and companies gain more experience with the regulations, but he does not expect the process to become easy. Both O'Connell and Fein believe the two-year extension gives companies adequate time to prepare.

The delay could have a domino effect on other pedigree programs. The US Food and Drug Administration (FDA) plans to have national pedigree requirements in place by 2010, which now falls ahead of the California deadline. The FDA recently issued a request for comments for its program.

“California is a potential roadmap that could be used nationwide – if it works,” said Fein. “There’s a lot riding on California.”

Several vendors and analysts have cited pedigree requirements in California and elsewhere as a potential catalyst for RFID adoption. It is unclear how the delay will effect RFID implementation efforts. O'Connell does not expect the market to slow because most companies can't afford to take off from their compliance efforts to still meet the later deadline. For related coverage, see:

- *RFID Solution Announced for California e-Pedigree Reqs*
- *Disagreement Awaits Imminent HF Gen2 RFID Standard*
- *Impinj Demos New Approach for Pharma RFID Tagging*



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