

EPCglobal Ratifies E-Pedigree Standard

In releasing the standard, the organization seeks to help pharmaceutical companies meet the requirements of U.S. states that have passed drug-pedigree laws.

By Mary Catherine O'Connor

Jan. 11, 2007—[EPCglobal](#)'s board of governors has ratified the organization's electronic pedigree standard. The purpose of the new standard is to provide the pharmaceutical industry with a common format that supply chain partners can use to collect pedigree information, upon which providers of pedigree solutions can build their pedigree software offerings. While it addresses only electronic pedigrees (e-pedigrees), as opposed to paper-based ones, the standard does not specify RFID as the only technology that can automatically identify drugs products as they are shipped and received. An e-pedigree system based on the new standard could instead utilize bar coding or some other technology for automated data collection.

The main reason EPCglobal's board ratified the standard was to address the needs of companies involved in the manufacture, distribution and sale of prescription drugs sold in the handful of U.S. states that have passed legislation requiring drug pedigrees.

The states that have enacted pedigree laws (which include Florida, Indiana, Nevada and California) have all done so to deter counterfeit drugs from entering the supply chain. But not all laws require the same types of pedigrees—some allow paper-based pedigrees, while others ask for electronic versions—nor do they provide direction on how data relating to the drug products should be presented so it can be easily shared among trading partners.

"The regulators have not given us the form of the pedigree; they gave data elements and said who and under what conditions [they require them], but they left it to the industry to make the actual pedigree," explains Bob Celeste, who leads EPCglobal's Software Action Group (SAG) and was involved in the development of the standard by EPCglobal's Health and Life Sciences (HLS) Industry Action Group.

"We understand that not all companies are ready to use RFID, but without a standard, it would be much more difficult for the industry to create pedigrees," he says. "We're trying to meet the immediate need for the industry."

EPCglobal is also working on a track-and-trace platform standard for the pharmaceutical industry. Such a platform would use EPC RFID tags to monitor the movement of drugs through the supply chain. In addition, EPCglobal is developing an air-interface protocol based on high-frequency tags. Currently, a number of pharmaceutical companies are using HF tags on individual containers of drugs. However, those tags do not utilize EPC-based technology—rather, they are based on other air-interface protocols, such as ISO 15693.

The e-pedigree standard is comprised of instructions on how supply chain partners can create an electronic pedigree, add information to it and digitally sign it with a legally binding signature. It also describes how companies can send and receive data. Because the specification calls for all data to be XML-based, however, that data could be sent and received over a number of different systems—even e-mail.

Celeste says that six vendors of e-pedigree technology participated in writing and testing the standard, and that all six have based their current e-pedigree offerings on the standard. The standardization process took about one year, he says, and Florida's enactment last year of a pedigree law requiring electronic pedigrees was an incentive for EPCglobal to ratify it quickly.

Lucia Deus, vice president of product development for e-pedigree provider SupplyScape and EPCglobal's technical editor of the new spec, says, "Having a standard e-pedigree format is essential to pedigree interoperability across the network of trading partners." SupplyScape currently has approximately 45 customers using the company's e-pedigree software in their efforts to comply with state laws. The company was involved in the creation of the standard since its inception and contributed its own intellectual property, used in its e-pedigree platform, to the specification.

RELATED_ARTICLES It is important to note, Celeste says, that use of a system based on the standard does not imply compliance with any specific state law. To write the standard, the authors looked at various state requirements and authored the specification so it could comply with any and all of them. Still, each company that uses a system based on the standard protocol must ensure its compliance with whatever state laws it is obliged to meet.

EPCglobal will now begin working the new conformance requirements into a certification program to which e-pedigree solutions vendors can submit their products for testing to determine compliance to the new standard. This testing should begin during the next few quarters, says Celeste, and will be followed by interoperability certification testing to make sure EPCglobal standard-based software from different vendors can work together.

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