

The Far-Reaching Effects of California's Drug Tracking Legislation

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Patients, employers, manufacturers, and legislators often influence policies regarding the practice of pharmacy. Legislation that requires changes in the practice of pharmacy are usually the hardest to comply with because the law is most often intentionally vague, and the pharmacists are left with the daunting task of trying to integrate the new laws into their practices. Recently, such legislation has been passed in California, and some are fearful that it will be adopted federally and pharmacists will be left with the huge task of compliance.

In California, a law was passed to improve the process of insuring that the medication shipped from a manufacturer is the same medication that is delivered to the pharmacy. The intent of the law is to avoid tampering and misplacement of drug shipments, thereby improving patient safety. The legislation requires all pharmaceutical manufacturers to create an e-pedigree by 2015, which will allow every item-level package to be traced back through the shipping steps to its origin. In addition, every pharmacy must be able to accept these e-pedigrees by 2017.

The e-pedigree is an improvement over current requirements. In fact, the closest system that is in place is found overseas. In Turkey and France, drug packages are labeled with a two-dimensional data matrix code, and this code is scanned when leaving the plant and again when delivered to the pharmacy. The e-pedigree system that California requires is a step up from the 2D matrix code. The e-pedigree system requires that each manufacturer assign a Standard Numerical Identifier, or SNI, to each box of items. Each item in that box will be given its own SNI, but the two will complement each other. As the package makes its way to the end user, ownership changes, and each owner's e-pedigree is added onto a digital shipment order according to Global Standard One. GS1 is a nonprofit organization that has worked to improve efficacy and visibility of supply chains across the world. This digital shipment order is called the Drug Pedigree Messaging Standard.

Another technique, known as Track-and-Trace, is very similar to the e-pedigree system except that, when the shipment changes hands, the previous owner is given a copy of any new information. This step allows an inquirer, such as a government entity, to trace the package back through its shipments or confirm delivery of packages.

Almost all participants in the drug manufacturing, shipping, and wholesaling have concerns with the legislation. Not all drugs ordered in California are made in that state, so for the e-pedigree system to work there, all states would have to enact an e-pedigree system. Therefore, even though legislation for the e-pedigree system is only found in California at this time, all states should be wary of changes that may occur locally. Steve Drucker, the Director of Global Pharmaceutical Commercialization in Packaging Technologies and Compliance at Merck, believes that implementation of a full Track-and-Trace system would cost almost 100 million dollars. Robert Bepko Jr., a Director of Professional Services at Norwalk Hospital in Connecticut, is concerned because his hospital already has an inventory system recently purchased from McKesson and, with the new requirements on the horizon, his system may be obsolete. In 2010 the FDA got involved by issuing a guidance document for SNI formation. It is identified as a

guidance document rather than a law, but it is still suggested to be as strong as a legal requirement. Because the guidance document suggests that an SNI add 20 additional numbers to the NDC code, the National Council for Prescription Drug Programs (NCPDP) would have to change how information technology systems identify drugs packages and reformat software to accommodate the extra numerals. Many retail chains, as well as the American Society of Health-System Pharmacists, have become so concerned that they have formed a work group known as the NCPDP Work Group 17 to track the outcomes and benefits of the California Project.

The future of legislation related to drug tracking is not set in stone. It is important for hospital pharmacists and administrators to understand what is being explored so that they can prepare for changes and be able to adapt to them in a timely manner.

Abstracted from "Track-and-Trace Drug Verification FDA Plans New National Standards, Pharmacies Tread With Trepidation" Written By Stephen Barlas. P&T Vol. 36. No 4, April 2011.