Pharmacy Product Tracing Likely to Go National

Costs to Pharmacies Worrisome

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On November 17, 2008, Mark Kinney, Vice President of Government Affairs for the Independent Pharmacy Cooperative, was trying unsuccessfully to get cell phone service in the lobby of the Hyatt Crystal City in Arlington, Virginia. He was attending the Radiofrequency Identification (RFID) Track and Trace Healthcare Summit, sponsored by the Healthcare Distribution Management Association (HDMA) and the National Association of Chain Drug Stores (NACDS). At that particular moment, however, the lack of cell phone service was not his biggest concern; he was more worried about the congressional session scheduled for January 2009 and whether Congress would be passing the latest version of a drug-packing tracking bill. This bill would dictate when both retail and hospital pharmacies across the country must install software and hardware to authenticate the identity of drug packages they receive.

The bill is called the Safeguarding America’s Pharmaceuticals Act, and its revision, to be addressed by the 2009 Congress, was one of the main topics at the RFID conference. Sponsored by Representatives Steve Buyer (R-Ind.) and Jim Matheson (D-Utah), the bill essentially mandates an “electronic pedigree” for drug packages traveling down the distribution chain to the pharmacy. The bill would require pharmacies, wholesalers, and manufacturers to do nationally what they will have to do in California, based on legislation that state passed some years ago.

Manufacturers must place a unique number on a small bar code or an RFID tag on the label of each drug product package; they must then send that number, along with other details, to the wholesaler, in the form of an e-pedigree. The e-pedigree is then kept in a database that allows everyone in the distribution chain to track and trace the package as it is checked in, down the chain via either a bar code reader or an RFID reader. If the FDA orders a recall, the manufacturer would know exactly which pharmacy had a bad lot, thereby speeding that recall and making life easier for the distribution chain.

California has pushed back the date for implementation twice already and did so a third time, much to the industry’s relief, when Governor Arnold Schwarzenegger signed a Senate bill (SB 1307) on September 30, 2008. Instead of having to comply on January 1, 2011, this new bill substantially postpones the deadlines for compliance. Manufacturers doing business in California must comply with half of their packages by January 1, 2015, and with the remaining half one year later. For distributors to be able to “read” e-pedigrees, the deadline is July 2016. Pharmacies must be able to authenticate those pedigrees by July 2017.

The Buyer–Matheson bill will make the California e-pedigree requirements and the implementation schedule a national fiat, which is why pharmacy types were holding their breath waiting for the bill’s newest iteration during the HDMA/NACDS conference. However, the two congressmen ended up releasing not a full-blown revision of their 2008 bill but a “discussion draft.” Unfortunately, according to Mr. Kinney, the draft was a step backward in some respects. Its key shortcoming: it drops an important provision from the 2008 bill—that non-chain pharmacies would receive $1 for every $3 they spend on hardware and software to implement an authentication system. That would be important, given that Accenture, a consulting firm, estimates that pharmacies will have to spend up to $80,000 to comply with the California requirement.

“We are all in favor of a solution that secures the drug supply,” said Mr. Kinney, whose trade group represents 3,300 pharmacies. “But the hardware expense is a big concern for us.”

However, the 2009 discussion draft drops that grant program, probably because of the expected, severe federal budget deficit.

Mr. Kinney stated, “The discussion draft steps back from what was agreed to last year and kind of starts the discussion all over again. Two or three things we thought were pretty important are no longer in the discussion draft.”

In addition to the disappearance of the $3-to-$1 grants, the discussion draft, as the bill last year would have it, requires wholesalers to be registered in each of the 50 states. This means that wholesalers and distributors would have to comply with 50 sets of regulations dealing with background checks, fingerprinting, surety bonds, inspections, and the like. Pharmacy groups are hoping that the bill endorses one national program.

Even though the Buyer–Matheson bill would, in effect, nationalize the California program, the FDA is already moving forward on one aspect of a national program, as dictated by the FDA Amendments Act (FDAAA) of 2007. That act required the FDA to create a national standard for identification, validation, authentication, and tracking and tracing of prescription drugs via a standardized numeral identifier on each drug package. That must be accomplished by March 2010. Unlike the California and Buyer–Matheson bills, the FDAAA did not mandate an implementation schedule, which is why Buyer–Matheson is so important, in the view of drug companies and pharmacies.

Jeffrey Shuren, Associate Commissioner for Policy and Planning at the FDA, spoke at the conference, and a standing room-only audience of 200-plus hung on his every word. He predicted that Congress would pass a broad FDA reform bill in 2009 and that the Safeguarding America’s Pharmaceuticals Act would be attached as an amendment to that bill.