Congress Moves on Drug Track-and-Trace Bill
Hospital Pharmacies Will Need to Read 2D Bar Codes

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Congress is apparently finally serious about passing a bill establishing a federal mandate related to tracking pharmaceuticals through the distribution system. Similar bills passed the House on June 3 and a Senate committee in late May. A bill could be on President Barack Obama’s desk before the August recess—that is, unless one or more players in the drug chain find the final wording (to be established by a House–Senate conference committee) unacceptable and are successful in stopping the bill from reaching the President.

The House bill is called the Safeguarding America’s Pharmaceuticals Act (H.R. 1919). The Senate bill is the Drug Supply Chain Security Act (S. 957). Both have bipartisan support, which is a good sign. The bills would require pharmacies of all stripes, called “dispensers” in the bill’s language, to obtain a transaction record (paper or electronic) for each drug arriving in the pharmacy starting in 2015.

Once the manufacturers have to place unique product identifiers on each package starting in 2018 or 2019, pharmacies will probably have to buy two-dimensional (2D) bar-code readers in order, at a minimum, to automatically read the National Drug Code (NDC) on each package. The product identifiers will also have to contain a Standardized Numerical Identifier (SNI), the lot number, and the expiration date. An NDC/SNI cannot be placed in a linear bar code. Most pharmacies have linear readers today.

The bills are supposed to prevent counterfeit drugs from getting into the distribution system, but neither bill requires tracking and tracing of the SNIs that manufacturers will be printing on drug labels.

Deborah Templeton, RPh, MHA, Vice President of Supply Chain Services at Geisinger Health System, says:

While both are supportive of starting down the path of safer track and trace, both have time lines that are very protracted and do not get to the patient level straightaway. There will be additional work for both dispensers and repackagers, allowing for manual as well as electronic record keeping. However, if done correctly and set up efficiently, it should be worth the value in making the drug supply chain safer.

As January 1, 2015, draws closer, the pressure is mounting on Congress to act. On this date, manufacturers that sell drug packages in California must serialize half of those packages; the other half are required a year later. In 2017, all retail and hospital pharmacies must be able to “read” these serialized labels (“e-pedigrees”). With serialization, an NDC/SNI will be required to appear on the package label.

The two congressional bills would preempt California’s law and would establish a new deadline for product tagging at 5 years or more after passage of the bill. That would delay California’s deadline by 3 years or more. Further, packages would be tracked at the lot level (i.e., via transaction information), not at the unit level, which is what California would require.

These two diminutions of the California requirements don’t sit well with the California Board of Pharmacy, whose president, Stanley C. Weisser, RPh, wrote to the Senate committee. His letter said in part,

We are by no means satisfied with the current form that the draft proposal takes and believe it represents a significant step backward from the California model for electronic pedigree/track-and-trace.

However, his letter stopped short of opposing the bill. It is not clear whether his comments might turn California’s two Democratic senators against the bill and, if so, whether they could rally enough support in the Democrat-controlled Senate to stop the bill there.

Nor is it clear where the drug manufacturers stand. Mark Grayson, a spokesman for the Pharmaceutical Manufacturers of America, says the first priority for his members is pre-empting the California deadline of January 1, 2015, and getting a national standard in place. He adds that there will be time to address the bill’s requirements when the House and Senate bills arrive in a conference committee, where the final version will be worked out.

Yet even a 2018 deadline for putting unique NDC/SNI tags on drug packages will be tough for many drug manufacturers to meet. In April, Michael Rose, Vice President of Supply Chain Visibility at Johnson and Johnson Health Care Systems, Inc., testified to the Health Subcommittee of the House Energy & Commerce Committee that the company had just serialized its first product for the U.S. market, Janssen’s Prezista (darunavir). Few companies selling within the U.S. are applying an SNI to the bar code on the package label for this drug. All companies are putting NDCs in either linear or 2D bar codes and are printing NDCs along with both lot numbers and expiration dates in hard copy on the label too.

Aside from having to verify paper or electronic transaction statements and histories starting in 2015, pharmacies would be given 8 years after the House bill passes to begin verifying that the product identifier of at least three packages (or 10% of suspected prescription drug products, whichever is greater) or of all packages (if there are fewer than three) corresponds with the prescription drug product identifier for such products.

Many hospitals also repackagers. The bill, which has verification provisions and other rules that apply to repackagers, exempts repackaging by hospitals. That is the good news, but the real story is (if and when the bill’s final language is set) how much bad news there will be, in terms of technology requirements, for hospital pharmacies.

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