FDA’s New Guidelines On Serialized Numerical Identifiers Are Not Helpful to Pharmacies

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Hospital and non-hospital pharmacies will undoubtedly be facing some major challenges in connection with authenticating drug packages, and this task isn’t being made any easier by the guidance that the FDA issued at the end of March. Those guidelines, intended for the use of serialized numerical identifiers (SNIs), simply bless a standard that had previously been adopted by a standards group called GS1. In doing that, the FDA pushed aside a request from hospitals and their pharmacies to specify an SNI that would provide more information about drug packages. Taking a step to fulfill this request would have helped to ensure that patients in the hospital receive the appropriate drug, dose, and formulation.

The American Society of Health-System Pharmacists (ASHP) had urged the FDA to modify the National Drug Code (NDC) number so that its components would include the RxNorm concept unique identifier (CUI) as the drug, form, and dose component of the code. RxNorm, produced by the National Library of Medicine, is a standardized nomenclature for clinical drugs.

Justine Coffey, JD, LLM, Director of Federal Regulatory Affairs at ASHP, says, “Currently, ASHP members are struggling with inconsistencies relating to the National Drug Code and its application to barcode point-of-care, clinical information systems, and hospital financial systems.”

The SNI, a unique combination of two numbers, is printed on a package label to identify the drug inside. The FDA’s final guidance says that one-half of the SNI is the NDC, which is specific to each drug made by each manufacturer, plus an exclusive serial number, generated by the manufacturer or repackager for each individual package. Serial numbers should be numeric or alphanumeric (including letters, numbers, or both) and should have no more than 20 characters. The FDA “guidance” is simply that; drug manufacturers are not required to follow it or to place an SNI on a drug package.

The FDA guidance parallels the serialization format adopted by GS1. GS1 has published two standards: one standard is applied to a two-dimensional (2D) bar code (called GT10); the other is applied to a radiofrequency identification (RFID) tag called G10.

GS1 standards are used by all U.S. manufacturers who have been conducting pilot projects on serialization with the intent of complying with a California law. This law mandates that manufacturers serialize 50% of their products by January 1, 2015, as part of a broader e-pedigree requirement, which involves tracking a unit-level package from its manufacture to its dispensation. Under the California law, pharmacies must be able to “read” the serial numbers by July 1, 2017. The pharmacies will be able to do that by (1) installing bar-code readers that can automatically capture the serial number and scan it into a software system or (2) “eyeballing” the human-readable number on the package and manually entering the data on the keyboard. (Human-readable text is often encoded as ASCII or Unicode.)

Ruby Raley, Director of Healthcare Solutions at Axway, which is working with some drug manufacturers and their future purchasers on e-pedigree implementations, notes that hospitals are particularly concerned about avoiding medication errors, especially given the passage of the health care reform bill (the Patient Protection and Affordable Care Act), which mandates several new payment models based on reducing hospital errors of all kinds. She explains that many drugs come in multiple formulations and doses, but this information cannot be gleaned from the SNI, as endorsed by the FDA. Hospitals are particularly sensitive to this issue, she says, given the publicity generated by the misadministration of heparin to twins born in November 2007 to actor Dennis Quaid and his wife.

Preventing inadvertent medication errors is only one perceived benefit of drug package serialization; the FDA has promoted the SNI primarily as a way of preventing drug counterfeiting. Thefts of high-value prescription medications continue to occur. In March, thieves broke into an Eli Lilly warehouse in Enfield, Connecticut, and stole $75 million worth of prescription drugs. The criminals took pallets of the anti-cancer drugs gemcitabine (Gemzar) and pemetrexed (Alimta), the schizophrenia drug olanzapine (Zyprexa), the antidepressant duloxetine (Cymbalta), and other prescription agents.

Theoretically, those stolen drugs would not be able to re-enter the legal distribution chain if they had SNIs printed on 2D bar codes or RFID tags on each package label. Concern about counterfeit products was what prompted Section 505 of the FDA Amendments Act (FDAAA), which Congress passed in October 2007. One provision required the FDA to establish a format for an SNI; the other provision required the agency to approve technology that could be used to read those SNIs. This second rule-making on technology has not been finalized, but it is eagerly awaited.

Ilisa Bernstein, PharmD, JD, Director of Pharmacy Affairs in the Office of the Commissioner at the FDA, has been leading the agency’s efforts on anti-counterfeiting issues. At this time, however, she has not offered to comment on the FDA’s future intentions.

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In addition to concerns about the insufficiency of the SNI prescribed by the FDA, hospitals and their pharmacies—and pharmacies in general for that matter—are worried about technology requirements and costs. Almost all manufacturers involved in pilot projects are using 2D bar codes for unit-level serialization, according to Bob Celeste, Director of Health Care at GS1. Axway’s Ms. Raley says that the FDA’s SNI greatly favors serialization with 2D bar codes.

The California law is likely to give way to a national requirement that pharmacies everywhere in the U.S. will have to start considering how to “read” what they will be viewing as an imperfect SNI.