Hospital pharmacies got a lot less than they had hoped for with regard to the Food and Drug Administration’s (FDA’s) “final rule” on pharmaceutical package bar coding. First, there is no requirement for manufacturers of brand-name, generic, and over-the-counter drugs to put all hospital pharmaceuticals in unit-dose packages. Second, the bar code, which must appear on all bulk and unit-dose drugs and blood and vaccine products that are “commonly used in hospitals and dispensed pursuant to an order,” need not include a lot number or an expiration date; only the National Drug Code (NDC) number is required in the bar code.

It is true that most of the drugs currently arriving in hospital pharmacies are in unit-dose packages; however, only 30% to 35% of them have bar codes. Doug Scheckelhoff, director of pharmacy practice sections at the American Society of Health-System Pharmacists (ASHP), hopes that this rate will approach nearly 100% as a result of the FDA’s final rule, with which companies must comply within two years.

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Although the whole point of the ability of hospital pharmacies to dispense bar-coded, unit-dose packages is to reduce the chance of patients receiving the wrong medication at the bedside, the bar codes, unfortunately, don’t help there—unless, of course, the hospital has pursued scanners, which nurses can use before dispensing the packages.

So here are a couple of questions raised by the FDA’s final rule.

1. Will manufacturers pull back on the number of hospital unit-dose (HUD) packages that they sell to hospitals because of the added cost of applying bar codes?

   This is a major concern. Certainly, over the past decade, the number of unit-dose packages sold to hospitals has declined.

   “I talked with a brand-name executive a year ago, and he told me that he had reduced by 60% the number of products packaged in HUD,” stated Peter Mayberry, executive director of the Healthcare Compliance Packaging Council.

2. Will the FDA approve a number of exemptions from the bar code dictate?

   The final rule contains both blanket and general exemptions, neither of which was part of the proposed rule. Obviously, therefore, the FDA felt considerable pressure to give drug companies “a way out.”

   For example, companies can ask for a general exemption if they can prove that “compliance with the bar code requirement would adversely affect the drug’s safety, effectiveness, purity, or potency or not be technologically feasible.” The request must also explain why the problem cannot be reasonably remedied by measures such as package redesign or the use of overwraps. Companies can also earn a general exemption by arguing that “an alternative regulatory program or method of product use renders the bar code unnecessary for patient safety.”

If the FDA final rule encourages drug manufacturers to drop unit-dose stock-keeping units (SKUs) or if it leads to a flood of approved exemptions, pressure on hospital pharmacies will grow. Pharmacies already do a substantial amount of repackaging, and they may have to do even more, which would not be a positive development. The rule does not require hospital pharmacies to put bulk drugs in unit-dose packages or to add a bar code to them. However, most hospital pharmacies do repackage bulk drugs into unit-dose portions because the Joint Commission on Accreditation of Healthcare Organizations demands “safe” operations from hospital pharmacies. The term “safe” is understood to imply that all drugs would be sent to patients in unit-dose packages.

Some pharmacies even add bar codes to the unit doses that they package, but given that only 10% to 15% of hospitals have scanners, clearly not a lot of in-hospital bar coding is occurring now. Furthermore, the FDA final rule is not requiring hospitals to buy scanners. That is really the $64 million question: Will hospitals take the plunge and buy bedside scanners?

Hospitals, of course, want to do the right thing, but budgets are tight and scanners not only are expensive but also are “finicky,” in the sense that not all scanners read all bar codes.

It is frustrating and unfortunate that pharmacists are essentially powerless. They find themselves right in the middle of the equation set up by the FDA: they cannot convince manufacturers to sell in unit doses, and they cannot force hospitals to buy bedside scanners.