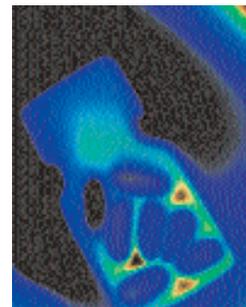


Prepare for Bar Coding

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With a few obvious exceptions, drug makers and their suppliers appear to be ill-equipped to meet new requirements in regard to bar coding packages for drug products used in hospitals.

FDA announced its intention to require bar codes on prescription (Rx) and over-the-counter (OTC) drugs and certain biological products used in hospitals more than one year ago. The final rule was published on 26 February 2004 (www.fda.gov/OHRMS/DOCKETS/98fr/04-4249.htm).

Yet drug makers and their suppliers seem to be largely in the dark about the regulation's requirements. In fact, at the Interphex show in New York City in March, misinformation about the requirements of the final regulation was rampant.

The rule requires a linear bar code representing the product's national drug code (NDC) to be placed on the immediate container label and outer wrapper that appears on most Rx and certain OTC drugs that are commonly used in hospitals, or about 75% of OTC products. The lot number and expiration date information do not have to be encoded, but drug makers may do so, if desired.

The rule also requires machine-readable information on container labels of blood and blood components intended for transfusion. FDA-approved symbology on these labels identifies the collecting facility, the lot number relating to the donor, the product code, and the donor's blood group/type. However, most establishments that collect blood already put this information on labels, therefore, the new rule is expected to have minimal impact on blood-related products.

The goal is to reduce medication errors, which caused more than 7000 deaths in 1993 (1). The rule also is intended to encourage the adoption of advanced information systems in hospitals. "Bar codes can help doctors, nurses, and hospitals make sure that they give their patients the right drugs at the appropriate dosage," explains Tommy G. Thompson, secretary of the United States Department of Health and Human Services (Washington, DC), which oversees FDA.

In use, the bar code would be scanned at the point of administration to confirm the right drug is being given to the right patient at the right time. This process also might include scanning a patient's bar-coded wrist band or an employee's identification badge.

Although only a few hospitals currently have bar code systems installed, early adopters have found that the systems can reduce medication errors by about two-thirds. This translates into preventing nearly 500,000 adverse events and transfusion errors during the next two decades and eliminating an estimated \$93 billion in costs related to patient pain and suffering and lost work time. Reducing errors also can reduce insurance costs.

"For hospitals, bar coding reduces errors and equals instant billing," says Jeanne Taborsky, a consultant with SciRegs Consulting (Columbia, MD) in a presentation in February 2004 at a Pharmaceutical Bar Coding seminar in Philadelphia, Pennsylvania (which was organized by Barnett International, Media, PA). Because scanning occurs as drugs are dispensed, data needed for billing are automatically captured in the system. "Scanning a bar code documents an action," explains Karen Longe, a consultant at Karen Longe & Associates, Inc. (Lake Bluff, IL), another speaker at the conference.

The linear bar code must meet the standards of the Uniform Code Council (UCC)/EAN International (Lawrenceville, NJ/Brussels, Belgium). This means that any UCC/EAN linear bar code capable of accommodating the NDC is acceptable. The rule does not limit the choice to reduced space symbology (RSS), a family of linear bar codes, including some stacked configurations which compress data into a compact space. However, space constraints may make an RSS the only practical choice.

Another conference speaker, Laurie Hernandez, general manager, Hospital Products Division, Abbott Laboratories (Abbott Park, IL), says, "RSS played a key role in our ability to bar code all of our products." Abbott's hospital products division uses RSS for the NDC on small vials and ampules, and plans to use RSS composite for secondary data such as lot and expiration date. However, printing RSS composite at 300/min currently poses a challenge because of print speed limitations.

At present, data matrix and other two-dimensional (2D) codes are not permitted for the NDC

Real world bar coding

Abbott's hospital products division, which will soon be spun-off as an independent company called Hospira, decided to make bar coding a priority about four years ago and bar coded its entire product line shortly before FDA issued its proposed rule.

One of the initial steps was to organize two teams—a corporate task force and a multifunctional team. The goal was to implement bar codes at all levels of packaging, ranging from ampules to large, flat containers, and involved more than 1200 different drugs and 5800 packages.

Early on, the team committed to a standard UCC.EAN-128 symbology. Work began with corrugate in seven plants. "It would have been simpler if we had done one plant or one packaging type at a time," admits Laurie Hernandez, who will head the strategic marketing department for the new company.

Hernandez quickly discovered one of the biggest challenges is differentiating among package sizes. For example, "If a wholesaler can break a case of 60 into six inner packs of 10, then the 10-pack needs a separate code, or you don't even get paid right," she explains.

As the project progressed, it quickly became clear that the standard UCC.EAN-128 symbology was too large for 300 unit-of-use containers involving some of the company's most critical products. The solution proved to be an RSS. However, as the first healthcare company to commercially use RSS to bar code hospital injectables and intravenous solution products, there were some hurdles to overcome. After a trial run in 2001 at St. Alexius Medical Center (Bismarck, ND) demonstrated readability at bedside, Abbott started designing labels incorporating RSS for its products in 1- and 2-mL vials and other small containers (e.g., ampules).

As the bar coding initiative proceeded, each label was reviewed so that any other necessary changes could be done at the same time. "We wanted to touch the label only once, to minimize costs," explains Hernandez.

The transition to bar codes "requires a tremendous amount of change," says Hernandez, adding that some resistance is inevitable. Nevertheless, "Quality healthcare is going to require bar codes in the future," she concludes.

bar code. However, the agency left the door open to possibly revising the rule to allow 2D codes or even radio frequency identification (RFID) technology at some point in the future.

Publication of the rule means approximately 153,500 packaging units of Rx and OTC drugs must be changed to accommodate the bar code information. The transition could cost manufacturers as much as \$60.8 million in artwork redesign expenses and capital equipment costs. If new equipment is involved, the transition also will cause considerable downtime and related costs because it typically takes about one week to install coding equipment and train personnel. Once installed, the coder must be validated—a process that can take days or even weeks.

The final rule applies to most drug manufacturers, as well as repackers, re-labelers, private label distributors, and blood establishments. The rule states that packaging for new medications must carry bar codes within 60 days of approval. Most previously approved medi-

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cines and all blood and blood products have two years from the effective date of 26 April 2004 to bring labels into compliance. Label changes for drugs already on the market do not require FDA approval, and may simply be included in an annual report to the agency. However, because the transition to bar coding is quite complex, drug makers must start the process immediately.

Line upgrades

Adding a bar-coded NDC will necessitate a redesign of packaging graphics to provide space for the bar code, and may require a change in package size or material. Packaging material must be chosen very carefully to ensure good print quality. Adequate contrast between bar code lines and spaces is essential for high read rates. Substrates that will carry the code also must be carefully

chosen. It may be necessary to avoid recycled paper (which tends to allow ink to bleed, blurring bar code edges) or to print a background color on foil lidstock to provide sufficient contrast for the printed code.

“Bar code printing also needs to be correlated to the reader that the end user will be using to ensure the bar code will be readable at the point of use,” says Taborsky.

However, it should not be too difficult to upgrade lines to produce bar-coded packaging by adding or upgrading platen printers, flexo printers, laser coders, thermal-transfer printers, or inkjet units. Most coding equipment is relatively compact and should mount easily on existing lines. In addition, today’s coders generally are designed to handle a variety of codes, including RSS, if package real estate dictates the use of one of these compact codes. On older units, it may be possible to upgrade software to print RSS.

For companies that prefer not to invest in new coding equipment, using preprinted packaging materials is an option. Whether printed on- or off-line, bar code print quality should meet ISO 15416 standards. Verification ensures that codes meet print quality specifications and therefore will be readable downstream in the supply chain regardless of the scanner used. Code verification is extremely important because it is the only way to ensure efficient data collection and avoid recalls sparked by unreadable codes.

To read codes downstream on the packaging line or in a healthcare setting, stationary or handheld laser scanners typically do the job. However, it might be smarter to invest in camera-based imagers that are capable of decoding 2D as well as linear symbologies. Installing 2D-compatible scanners will provide flexibility if a need for a 2D code arises or FDA decides to revise the rule to allow 2D codes for the NDC.

Because laser scanners are so widely used in the existing infrastructure, printing bar codes in red should be avoided as this color is invisible to the units. Red can be an acceptable background color, however.

Complying with the new regulations should be seen as an opportunity to achieve other efficiencies. Because labels must be redesigned, now is the time to make other changes. Some changes might include adding a second or third language to allow the same packaging to be used



globally, updating graphics or product information, and standardizing label sizes.

Implementation

Longe recommends that a bar code implementation program begin with organizing a project team drawn from shipping, receiving, finance, sales, customer service, regulatory, package engineering, marketing, quality, purchasing, manufacturing, information technology (IT), and distribution. The team also needs a leader who has upper management support and authority, and good communication skills. If technical expertise is needed, additional project team members should be drawn from the ranks of pharmaceutical industry-savvy bar code consultants, equipment vendors, and software suppliers.

After developing a long-term strategy that provides a business benefit beyond regulatory compliance and allows for future technology developments such as RFID, the team should plan a phased implementation. In all but the smallest companies, it is virtually impossible to bar code

all products simultaneously; therefore, Longe suggests starting with one level of packaging or one product.

Perhaps most importantly, Longe recommends drug makers take the time to understand their operation. This includes creating flow charts diagramming material flow, process flow, and information flow. To do this successfully, "talk to the people on the line, so they can tell you how things really work," says Longe. "Spend a lot of time on this step. This is not a week-long process—it's months," she warns.

There also are numerous IT considerations, including the question of what happens between the computers and scanners. What data will be collected? How will the data be collected? Where will the data come from? How will the bar code system interface with existing systems? And finally, how will the data be backed up?

Other technical requirements include writing detailed specifications for printers, scanners, and labels, developing a way to confirm labels have the correct information, and crafting a bar code quality

verification program. In addition, Longe predicts the healthcare industry will follow the lead of the retail sector by penalizing drug manufacturers that ship product with codes that do not scan by levying huge fines and canceling orders.

Training also is vital in the transition to bar codes. "Start early and include everyone remotely involved," says Longe. She also recommends a combination of informal and formal training. The former should provide opportunities simply to "play" with the equipment, and the latter includes presenting written documents that explain various roles and responsibilities to delineate procedures for various events. These events may include what an employee should do if the printer were to run out of labels, how one would adjust print darkness, and/or detail maintenance-related issues.

Longe segments implementation into several steps.

- To prevent duplication and coding problems, limit code numbering responsibility to a single expert who understands how to differentiate packaging levels and other technical considerations.
- Address all connectivity issues.
- Install hardware and software.
- Validate data from the new system against the old system.
- Develop good documentation (standard operating procedures) and test procedures.
- Test the system for worst-case scenarios.
- Run parallel systems to avoid downtime.
- Plan to tweak the system daily during initial implementation based on user input.
- Have a contingency plan.
- Validate software.

An audit follows implementation to identify how operations have changed, and what has been learned. This also is the time to "look for additional changes and improvements," says Longe. If goals are accomplished, the system can be rolled out to other products or package levels. "This is where the benefits come," says Longe.

References

1. FDA, "Bar Code Label Requirements for Human Drug Products and Blood, Proposed Rule," (Docket No. 02N-0204, 13 March 2003, Washington, DC), pp. 5-6. **PT**