

numbers, and hospitals that already have or intend to buy linear bar code scanners might not have to upgrade those scanners or purchase new devices if the proposed rule would require the use of linear bar codes only. In contrast, if we were to allow for other technologies such as RFID or even two-dimensional symbols such as DataMatrix, hospitals might have to buy RFID readers, optical scanning equipment, or other equipment because linear bar code scanners may be incapable of reading other technologies and, depending on the particular scanner, may be incapable of being upgraded. However, we invite comment on whether the rule should adopt a different format (whether that format is a symbology, standard, or other technology), and recommend that any comments advocating the use of a different model consider and discuss the following issues:

- What other symbol, standard, or technology should we consider, either in place of a linear bar code or in addition to it? How accepted is that symbol, standard, or technology among firms that would have to affix or use that symbol, standard, or technology? For example, we know that RFID technology has great potential for encoding a lot of data and for identifying individual products, but the technology is not yet widely accepted in the pharmaceutical industry due to its novelty and costs.
- Will hospitals be able to read or use the symbol, standard, or technology, either with existing equipment or equipment under development? We reiterate that hospitals might not have the financial resources to buy multiple pieces of equipment to read multiple, incompatible formats, so hospitals must be able to make equipment purchasing decisions confidently, knowing that they will recapture their investment costs.

Insofar as drug products are concerned, we also decline to have the proposal refer to the use of machine-readable codes or symbologies that can be read by machines "currently" used. Although a reference to "machine-readable" symbols or to "current" technology might seem to make a rule more accommodating to future technological developments, words such as "machine-readable" and "current," when used in a regulation, can create several practical difficulties. For example, in the absence of an accepted standard or process, disputes could arise as to how we or any other person or group determines what is "current." A manufacturer who wants to use a novel bar code or symbol could get

different answers depending on whom it consulted; a hospital using linear bar code readers might find the novel code incapable of being read by its "current" scanners, whereas the firm marketing a new machine to read the novel code would argue that the novel code is "machine-readable" by "current" machines. Similarly, if only a fraction of the machines used in hospitals can read a new code, a hospital might argue that the new code cannot be read by "current" machines, yet, if machines were or could be upgraded or modified, a firm that marketed the machines or upgrade service might argue that the new code can, indeed, be read by current machines, provided that upgrades or modifications are made. These and other potential problems associated with a reference to "current" machines or "machine-readable" technology lead us to avoid using such terms in this proposal. (Different considerations apply for blood and blood products, and we discuss the proposed requirement for machine-readable symbols for blood and blood product containers at section II. H of this document.)

Furthermore, we decline to establish committees or other bodies to study the issue further or to decide technological issues. Given the comments we have received thus far, we have no assurance that a committee or other body would arrive at a consensus.

Nevertheless, if a group comprised of the affected industries and persons who would use the bar code could agree on a standard, symbology, or technology, we would be interested in learning about such standard, symbology, or technology and its costs and benefits. We would carefully review the information and consider the information when drafting a final rule.

## 2. Are There Any Specific Requirements for the Bar Code?

Proposed § 201.25(c)(1)(i) and (c)(1)(ii) would require the bar code to be surrounded by sufficient blank space so that the bar code can be scanned correctly and to remain intact under normal conditions of use. These requirements would help ensure that the bar code can be read easily and accurately so that its safety benefits may be realized. We note that today some manufacturers have bar codes at locations where the bar codes are destroyed, damaged, or otherwise rendered useless. For example, some manufacturers have put bar codes on individual foil-wrapped packets, but the bar code overlaps the folds or perforations that separate the foil-wrapped packets. When one packet is

separated from the others, the bar code is split into pieces, and the resulting bar code fragments can provide misleading or nonsensical information to the bar code scanner or might not be read at all by the scanner. So, the proposed rule would require the bar code to be placed in a manner so that it remains intact during normal conditions of use. For the foil-wrapped packet example, this would mean that the bar code would be placed away from folds or perforations so that each packet, when separated from the others, has its own intact and easily scanned bar code.

Note, too, that the proposal would include the phrase "under normal conditions of use." Depending on the packaging and container used, the "normal conditions of use" may or may not require the bar code to remain intact at all times. For example, assume that you have a tablet in a blister package and that the bar code is printed on the flat side of the blister package. If the bar code is scanned before the tablet is pushed through the flat side, the bar code would not remain "intact" after the tablet has been dispensed, and this would be acceptable because, under "normal conditions of use," the bar code would have already served its purpose by being scanned before the drug was dispensed. In contrast, assume that you have a bottle that contains multiple tablets. The bar code on the bottle, under proposed § 201.25(c)(1)(ii), would have to remain intact throughout the bottle's use so that the bar code could be scanned each time a tablet is dispensed from that bottle.

One comment said we should audit bar code quality, help industry build a bar code information infrastructure, publish our results, and support mandatory testing and verification of bar codes.

We decline to adopt the comment's suggestions. The bar code would be part of the drug's label, so issues concerning its quality and verification would be subject to current good manufacturing practices (GMP's). In general, persons who would be subject to the bar code requirement would be responsible for having written procedures for the receipt, identification, storage, handling, sampling, examination, and/or testing of labeling and packaging materials, for exercising control over labeling materials and label operations, and for ensuring that correct labels are used (see 21 CFR 211.122, 211.125, 211.130). Failure to meet GMP's will cause a drug to be considered adulterated under section 502(a)(2)(B) of the act.

We also note that there are various standards relating to bar codes already. For example, the American Society for