

bar codes to meet individual needs. (We discuss issues relating to the choice of a bar code symbology, standard, or other machine-readable format, and the potential impact on innovation, in detail in section II.D of this document.)

B. What Products Would Have to Have a Bar Code? (Proposed § 201.25(b))

1. What Did We Hear at the Public Meeting?

In the June 18, 2002, **Federal Register** notice (67 FR 41360 at 41361) announcing the public meeting on bar coding, we asked which medical products should have a bar code. We specifically invited comment on whether all prescription and OTC drugs should be bar coded, and we asked about blood products, vaccines, and medical devices (id.). We wanted our request for comments to help us decide which products should be covered by the proposal. For example, we sought information about OTC drugs because we did not know the costs and benefits of requiring all OTC drugs to have a bar code. For blood, we knew that an international bar coding standard (ISBT 128) existed, but did not know whether a rule requiring blood to have a bar code was necessary given that international standard. For vaccines, we were concerned that bar coding costs could have an adverse impact on vaccine manufacturers and vaccine supplies. For devices, our request for information was prompted by several letters to Secretary of DHHS Thompson, asking him to include devices in any bar coding rule (Refs. 31, 32, and 33).

The public comments we received reflected a variety of different positions. For example, almost all comments agreed that prescription drugs should have a bar code and that the bar code should extend to products at the unit dose level. However, comments from the pharmaceutical industry indicated that some products, such as samples, should not fall within a bar code regulation or that we should allow for exemptions. The USP also supported an exemption for certain containers, such as ampules or vials under 5 milliliters (mL).

For OTC drugs, many health care professionals supported bar codes on all OTC drugs, but other comments, including a comment from a trade association representing the OTC drug industry, disagreed, stating most OTC drugs are used in consumer settings where bar codes would not add value. The trade association also stated that all OTC drug products intended for retail sale have the universal product code (UPC) on the outer container and that

there could be “significant potential negative impact” if we modified the UPC bar code system on OTC drug products. In contrast, one manufacturer of OTC drugs supported requiring bar codes on the outer container, but did not favor requiring bar codes for certain categories of products that carry little or no risk of causing adverse drug events in an institutional setting. CHPA and other companies repeated their concerns about bar codes for OTC drug products during a meeting with FDA on September 17, 2002, and emphasized the potential adverse impact on retailers if we required the UPC code to contain the NDC number. Some comments supported bar codes on OTC drugs used in hospitals or in “institutional settings” or OTC drugs packaged and sold for use in institutions.

A split between health care professionals and industry also existed for vaccines. For example, the Centers for Disease Control and Prevention, which coordinates the VISI program, recommended that vaccines have bar codes so that information on vaccines could be readily captured into medical records and other forms, thereby enhancing the monitoring of immunization programs and surveillance of adverse effects. Vaccine manufacturers, including VISI members, expressed a different view, stating that even small bar codes may be difficult to place on vaccines. One industry comment added that requiring bar codes on vaccines would “increase the potential for disrupting vaccine production lines, particularly if there is a need for in-line printing” and that “[g]iven the fragile nature of vaccine supply and recent shortages of a number of vaccines, there is concern that any additional disruptions could exacerbate this situation.”

For blood, the comments generally agreed that we should require bar codes. Most comments acknowledged that an internationally standardized bar code symbology (ISBT 128) for blood exists and that the bar codes describe the blood’s identification number, blood group and Rh type, product number, expiration date and time, and special testing results. However, while some comments recommended that we require blood containers to have bar codes using the ISBT 128 symbology, one comment, representing thousands of blood collection centers, blood banks, and transfusion services, opposed requiring the use of ISBT 128 through a regulation. Instead, the comment wanted us to require adoption of a United States Industry Consensus Standard for the Uniform Labeling of Blood and Blood Components or “focus

on requiring electronic data interchange and the definition and use of standard data structures.”

For devices, the comments suggested another split between health care professionals and the regulated industry. Many health care professionals and hospital groups supported requiring bar codes on devices, although some would defer action on medical devices so that progress on a rule to require bar codes on drugs would not be slowed down. Others would defer action on medical devices because different device classes present different levels of risk. Device manufacturers generally opposed the inclusion of medical devices in a bar coding proposal. The device industry noted, as we did in our June 18, 2002, **Federal Register** notice (67 FR 41360) announcing the public meeting, that medical devices present different issues compared to drugs, biological products, and blood. For example, there are different classes of medical devices, and each class represents a different degree of risk, so, for a low-risk device (such as a bandage), a bar code might not have an impact on patient safety (67 FR 41360 at 41361). As another example, some medical devices may be reconditioned by parties other than the original manufacturer; in such situations, the original manufacturer might want to ensure that its bar code is removed or eliminated if the device is reconditioned, because the device no longer comes directly from the original manufacturer. Comments from device industry interests recommended further study and a separate rulemaking for devices or the voluntary use of “automatic identifiers.” However, one device manufacturer indicated that it already uses bar codes on its devices, but it uses the bar code for reimbursement purposes and for logistical reasons rather than for safety concerns. The manufacturer also recommended that, if we wanted bar codes on devices, we should issue guidelines instead of a rule.

2. What Products Would the Rule Cover?

After careful consideration of the comments, we propose to require the following products to carry a bar code:

- All prescription drug products, including biological products (including vaccines), but excluding physician samples; and
- Over-the-counter (OTC) drugs that are dispensed pursuant to an order and are commonly used in hospitals; and

For blood and blood components, the proposal would require the use of machine-readable information.