

licensing fee, and the ICCBBA uses the fees to revise, enhance, extend, and maintain the ISBT 128 system and associated databases (Ref. 45). The ISBT Council accepted an application specification for ISBT 128 in July, 1994, and approved a resolution that all bar coded blood products collected after July 4, 1998, be labeled using ISBT 128. However, the use of ISBT 128 in the United States has been slow, and the ISBT 128 system has not been implemented in accordance with the ISBT Council's resolution.

Despite the international convention and guidance document, comments submitted in response to the public meeting suggest that § 606.121(c)(13) has not resulted in a uniform, international bar coding system for blood in the United States. While some comments described ISBT 128 in favorable terms, stating, for example, that it allows more information to be encoded or is more accurate than Codabar or that ISBT 128 represents an internationally-accepted standard for blood, at least one comment indicated that licensing fees associated with ISBT 128 may deter hospitals from using the ICCBBA system. Comments were also divided as to whether to require the use of ISBT 128 or simply require the use of "machine readable" symbols.

We considered whether the proposal should specify the use of ABC Codabar, ISBT 128, a different symbology or standard, or simply require the use of "machine-readable information" approved by the CBER Director. Each approach has its advantages and disadvantages. For example, requiring the use of ISBT 128 would help ensure a uniform bar coding standard for blood and blood components and be consistent with the international standard, but requiring ISBT 128 would mean that we would have to institute new rulemaking if a new symbology, standard, or technology was adopted. Requiring "machine-readable" information approved by the Director of CBER would allow CBER to consider new technologies in the future, but could result in some blood establishments adopting one system and others using a different system, thereby defeating the goal of creating a uniform system for identifying blood and blood components. Therefore, we invite comment as to whether we should require the use of ISBT 128, require the use of a symbology consistent with that required for drugs in proposed § 201.25, or require "machine-readable information" as approved by the Director of CBER or some other standard or symbology.

In developing this proposal, we recognize that the blood industry currently uses a machine-readable code that does not meet UCC/EAN standards. Some comments at the public meeting stated that the scanners are capable of reading multiple systems (e.g., UCC/EAN and ISBT). Based on our understanding of the state of the industry and the ability of scanners to read more than one symbology, we decided to propose a rule that would permit the existing coding to continue. We invite comments on whether this proposal is feasible or whether we should require the use of UCC/EAN standards for blood and blood components.

The proposal would require that the machine-readable information meet certain minimum requirements and be approved by the Director of CBER. These minimum requirements would move us closer to the goal of increasing patient safety. We anticipate that the industry will standardize encoded machine-readable information and readers, using our minimum requirements to minimize, to the greatest extent possible, the need for "country-specific" software and the high cost associated with software development and maintenance.

Thus, we propose to amend § 606.121(c)(13) to require the use of "machine-readable information" approved by the Director of CBER. The Director will review the machine-readable information technology to ensure that the minimum requirements are met regarding the accuracy of the required labeling information, spacing, and conditions of use.

Proposed § 606.121(c)(13) also would:

- Explain that all blood establishments that manufacture, process, repackage, or relabel blood or blood components intended for transfusion and regulated under the act or the Public Health Service Act are subject to the machine-readable information requirement. This would be consistent with the pre-existing requirement at § 606.121(a) and (b).

- State that blood and blood components intended for transfusion are subject to the machine-readable information requirement. This would be consistent with the pre-existing requirement at § 606.121(a) that describes the purpose behind container label requirements.

- Describe the minimum contents of the machine-readable information as a unique facility identifier, lot number relating to the donor, product code, and the donor's ABO blood group and Rh type. This would reflect the pre-existing

requirement at § 606.121(c)(1), (c)(2), (c)(3), (c)(10), and (c)(12).

- Specify that the machine-readable information must be unique to the blood or blood component, be surrounded by sufficient blank space so that the machine-readable information can be read correctly, and remain intact under normal conditions of use. This would be consistent with the pre-existing requirement at § 606.120(c) that requires labeling to be clear and legible.

- State that the machine-readable information must appear on the label of the blood or blood component which is or can be transfused to a patient or from which the blood or blood component can be taken and transfused to a patient. The proposal would not specify where the machine-readable information must appear on the label. To illustrate how this would work, the proposal's reference to any blood or blood component would include a unit of whole blood, packed red blood cells, plasma, platelets, and cryoprecipitate AHF. The unit of blood or blood component label would contain the machine-readable information if the blood or blood component has any possibility of being transfused to a patient, whether or not the unit is actually transfused. Additionally, the phrase, "from which the blood or blood component can be taken and transfused to a patient" would include the circumstance where blood or a blood component is extracted or aspirated with a syringe from the container of blood or blood component in order to transfuse to a patient. This technique might be used when transfusing neonates or under other medically necessitated circumstances. In this case, the blood or blood component from which the aspirate is taken must have affixed to it a label containing the required machine-readable information. This would be consistent with the pre-existing requirement at § 606.121(c)(8)(iii) that requires specific statements if a product is intended for transfusion.

We also invite comment on how the proposed rule might affect hospitals where patients receive blood or blood components. Specifically, we want to hear how the proposal might affect a hospital's decision to purchase a machine reader (e.g., scanner) that properly identifies the intended recipient of the blood or blood component. To prevent medical errors, this machine reader would need to be compatible with the machine readable information encoded on the blood or blood component label, yet a hospital's purchasing decision might also be influenced by the bar codes appearing