HEALTHCARE
LEADERSHIP
COUNCIL

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Dear Madam or Sir:

The Healthcare Leadership Council (HLC) appreciates this opportunity to submit the following comments in regard to the Food and Drug Administration's proposed rule on bar code labeling for human drug products and blood. We commend the FDA for the extensive research and consultation conducted in developing this proposed rule.

HLC is a coalition of chief executives representing all disciplines within the healthcare system. Our members jointly develop policies, plans and programs to achieve our vision of an effective 21st century healthcare system. HLC is unique in that it represents all sectors of the health care industry affected by the FDA's bar code rulemaking, including hospitals and hospital systems, pharmacies, pharmaceutical companies, pharmaceutical distributors, and medical device manufacturers.

The safety of the nation's health care system is a top priority for HLC. Our Chief Executive Task Force on Patient Safety and Quality was created so that the various sectors of the healthcare industry could work together to help elevate public confidence in the safety of the healthcare system. The Task Force collaborates on specific, evidence-based, pragmatic solutions and innovations that have the potential to substantially improve quality and reduce patient errors. HLC believes that by focusing on measurable and achievable solutions as our core priority, the public will be assured of a health system dedicated to safety and continual improvement.

Additionally, HLC is an active member of the National Alliance for Health Information Technology. We participated in drafting the consensus proposed bar code rule comments of that organization and are in general agreement with the majority of the NAHIT recommendations.

General Comments

HLC members have long been active in seeking to improve safety, and their efforts represent a broad range of ongoing programs. Several of our hospital and pharmaceutical members, as well as our medical device and technology manufacturers, have extensive experience with automated identification of medical products using bar codes. HLC believes the prevention of medication errors requires the cooperation of numerous parties along the drug supply chain, from the creators of the bar code printing equipment to the nurse administering the dose at the patient bedside. In developing HLC's comments on this proposed rule, and earlier comments delivered at the July 26, 2002 FDA hearing on this issue, HLC members focused on the importance of the "usability" and ultimate acceptance of any new standard.

HLC believes a pragmatic bar coding rule should support the highest level of patient safety possible through the most feasible and cost efficient approach that can be implemented in the shortest period of time. Further, a new bar code requirement should build upon, but not disrupt, current market forces and self-initiated bar coding activities. New standards should aim to reduce, rather than increase, the labor needs of health care organizations. Finally, HLC believes the FDA should allow for a flexible environment that can accommodate new, more effective technologies as they become available.

In developing the proposed rule, we believe FDA sought to meet many of these same goals. However, HLC members would urge the FDA to reconsider the fact that single dose containers come in various shapes and sizes - and some are more easily bar coded than others. Examples of such various unit dose forms include oral solids, oral liquids, topical creams, pre-packaged unit-dose syringes, vials and ampules. Because of their very small size or irregular shape, some of these unit dose drug containers are more difficult to print with bar codes than others - especially in an automated printing system. Consideration should be given to the difficulty of printing and scanning bar codes onto these very small and oddly-shaped containers through establishment of a fast-track review process for waiver applications.

In addition, although not addressed in this proposed rule, HLC believes the FDA should re-evaluate the annual label approval process with respect to label changes that may be necessary to accommodate bar codes. FDA may also need to consider eliminating some label information which currently is required, especially for very small products and packaging, as discussed above, for which the FDA has currently declined to provide an exemption.

While not directly related to this rule, HLC is strongly concerned with the FDA's intent expressed in this rule to *"revise [FDA's] drug establishment registration and listing*

regulations to redefine the NDC number and to make the NDC number unique and more useful to informational databases, whether those databases are created for purposes of preventing medication errors, obtaining the latest information about a specific drug, or tracking drug use or distribution".

A few of our varied concerns related to the FDA's stated intention include the labeling and information system changes necessary to accommodate new NDC numbers and/or a revised NDC format, the ability of the FDA to issue NDC numbers (now issued by individual companies) without delays, and the FDA's oversight of a new electronic database of NDC numbers for the user community which may result in lagging formulary updates or other interference between manufacturers and purchasers. Various information systems that have been built upon the NDC numbering system must be considered as well. For example, controlled drugs (regulated by the Drug Enforcement Agency) use the NDC number as the basis for identification and for DEA-required reporting. Changes to the NDC numbering system must take into account the needs of the DEA and DEA registrants that are required to report to this system.

HLC strongly suggests that the FDA consult with numerous affected organizations before issuing a new NDC rule.

Comments on Specific Issues Identified in Proposed Rule

The FDA, in addition to requesting general comments, sought comments on the following specific issues identified in the description of the proposed rule. HLC is pleased to offer the following responses to these issues.

1. Should the FDA require bar codes on prescription drug samples, and the costs and benefits associated with such bar codes.

What the FDA said:

> *"We recognize that the vast majority of prescription drug samples are usually given to patients at physicians' offices and are not administered in hospitals. Because we have no evidence to suggest that physicians' offices are likely to be equipped with bar code scanners in the immediate future, the benefits associated with preventing medication errors through bar codes on prescription drug samples are unlikely to be realized in this health care setting. We also recognize that it is unlikely that charitable institutions, such as free clinics, would have the resources to buy bar code scanners to prevent medication errors. As a result, we have decided to omit prescription drug samples from the rule at this time."*

We commend the FDA's practical recommendation to exclude sample packages since they are most likely to be used in settings where bar codes will not be used for patient safety purposes. The FDA is correct that it is very uncommon for hospitals to administer sample medications, and some hospitals even prohibit use of samples.

We believe that FDA's bar code requirements should be limited initially to unit dose drugs and biologics used in the institutional environment, including both prescription and OTC medications. HLC agrees with the FDA that bar coding of samples should remain voluntary, although HLC and other similar organizations will continue to encourage manufacturers to bar code all single-dose drugs packaged for institutional use, even those made voluntary by FDA. Typically, manufacturers do not like to introduce variability into their packaging and printing lines, and therefore many will most likely bar code their sample packages. However, short term, unusually packaged samples – which are often packaged as such to assist in educating new care givers and patients – may be more difficult to bar code than standard packages.

2. The risks and benefits of including vaccines in a bar code rule.

What the FDA said:

> *"A bar code on vaccines could help ensure the accuracy of those* [medical] *records insofar as identification of the vaccine, its manufacturer, and date of administration are concerned, and, for those vaccines administered in health care facilities, help ensure that the right vaccine is administered to the right patient at the right time. However, we are sensitive to the vaccine manufacturers' concerns, particularly as they relate to possible adverse impacts on vaccine production or availability . . ."*

HLC agrees that bar codes should be included on vaccines. While vaccines are primarily administered in an outpatient setting, national accreditors and national Quality Review Organizations are urging more administration of certain vaccines in an inpatient setting. The FDA should consider, however, the unique challenges of bar coding very small packages, including single-dose vaccines. For further discussion on this, please see question number 8.

3. What terms should be used to describe OTC drugs that should be subject to the bar code requirement?

What the FDA said:

> *"We propose to require bar codes on OTC drugs that are dispensed pursuant to an order and are commonly used in health care facilities."*
> *"The proposal would apply to any manufacturer, repacker, relabeler, or private*

label distributor who sells a specific package of an OTC drug product."
"We would interpret "commonly used in hospitals" to include OTC drugs that are sold to hospitals, packaged for institutional use, labeled for institutional use, or marketed, promoted, or sold to hospitals through drug purchasing contracts or catalogues."
"Some products in hospitals that are traditional types of OTC drugs, such as aspirin or acetaminophen, are dispensed pursuant to a physician's order."
"FDA considered requiring bar codes for OTC drugs "sold directly to hospitals" or "labeled for use in an institutional setting" but deemed these alternatives too difficult to administer and easily circumvented by selling the OTC drugs to distributors or other third parties for resale or relabeling".

As noted in our initial comments during the FDA's public hearing, HLC agrees with the FDA's intent to capture in this bar coding rule critical OTC drugs used in a setting where a patient safety bar code system could likely be employed. However, because of the massive number of OTC drugs, HLC believes that the current FDA language requires some clarification to eliminate confusion and thus potential barriers to full implementation of the rule. We suggest the language *"Over-the-counter drugs are excluded from bar coding requirements except for those OTC therapeutic drugs that are packaged for institutional use or specifically marketed for use in an institution for therapeutic purposes."*

4. Information on the costs and benefits associated with putting lot number and expiration date information in the bar code.

What the FDA said:

"We neither found nor received data to show that the benefits of bar coding lot number and expiration date information would exceed the costs of putting that information in the bar code. There is, however, limited information on the extent to which patient safety is affected by and medication errors occur as a result of taking expired or recalled drugs."

HLC believes that, for the sake of swift implementation, bar code data element requirements should be limited initially to the NDC number. The NDC number contains the necessary information to ensure that the right patient is being administered the right drug in the right dosage. The addition of lot number and expiration date can be considered when the technology is developed and research is conducted showing that patient safety is enhanced with this additional information proportional to the cost of implementation. The FDA already requires lot number and expiration date to be included in human readable form on the drug package. This information should continue to be sufficient for recall purposes and for determining if a drug is still within the effective date.

Additional information in the bar code will require the use of more printing space or a more complex bar code. In either case, the cost of bar coding is increased because of the need for larger packaging, the reduced speed of processing, and the increased cost of new printing equipment. Because of this increased cost, HLC is strongly concerned that requiring the inclusion of lot number and expiration date in the bar code would dramatically reduce the incentive for single-dose packaging.

5. Whether the rule should refer instead to linear bar codes without mentioning any particular standard or refer to UCC/EAN and HIBCC standards.

What the FDA said:

> *"Healthcare companies have sponsored two organizations that have each developed different bar code symbologies: the Uniform Code Council's Universal Product Code (UPC) and the Health Industry Bar Code Council's Health Industry Bar Code (HIBCC). UPC codes are more widely used in retail stores while HIBCC is specially designed to safeguard against errors. However, although the HIBCC code has been more effectively used by medical device manufacturers, it has not won wide acceptance within the pharmaceutical markets. Within these symbologies, the groups have defined acceptable linear (or one-dimensional) codes, two-dimensional codes, and composite codes (a combination of one- and two-dimensional symbology). The advantage of two-dimensional and composite codes is that they can include additional information in the same area. Potential disadvantages of two-dimensional and composite symbologies are the higher costs for readers and scanners and the additional risk of uncertain data recovery by misinterpreting coded information."*
>
> The rule *"...would require the bar code for drugs and biological products (other than blood and blood products) to be any linear bar code in the UCC/EAN standard."*
>
> *"Adopting a linear bar code in the UCC/EAN standard, as opposed to a specific bar code symbology, should give firms some flexibility in selecting the bar code symbology that best fits their needs and should also give the rule some flexibility as linear bar code symbologies change, are added, or are phased out."*
>
> *"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."*

HLC acknowledges that this is one of the most critical issues to ensure that this rule accomplishes its intended goal. Of primary importance is the need to use a standard that

ensures the ability of all institutions to implement the requirements of the rule without incurring significant costs.

UCC/EAN and HIBCC. HIBCC standards have been more widely used for medical devices. UCC/EAN has been the traditional standard setting organization for the pharmaceutical industry and HLC supports its retainment. Using the UCC/EAN system of standards allows the flexibility of bar coding the NDC number separately, or within a Universal Product Code (UPC), an International Article Number (EAN) or Global Trade Item Number (GTIN).

Linear bar codes and "complex" bar codes. HLC strongly believes in supporting emerging technologies and we do not advocate prohibiting future use of two-dimensional, Reduced Space Symbology (RSS), or other types of more advanced bar codes. We recommend that the FDA drop the reference to "linear" in describing the required bar code standard.

Since linear bar codes are included within the widely accepted UCC/EAN standard set, referring to "UCC/EAN standards" will allow for the use of linear bar codes but not prevent the development and use of newer types of codes. A concern of the FDA's may be that without specifying a "linear" bar code, manufacturers may choose to use multi-dimensional codes that hospital scanning equipment will be unable to read. However, the fact that customer demand has already resulted in a substantial number of single-dose drugs already being bar coded is evidence that manufacturers will choose to use a bar code symbology that is most desired and readable by their customers.

6. Additional information regarding bar code scanning technology and the ability of bar code scanners to read different symbologies.

What the FDA said:

> *"Our position presumes that, by the time any final bar code rule becomes effective (assuming that we do issue a final rule), bar code scanners will be able to read different UCC/EAN linear bar code symbologies reliably and efficiently. This is a critical consideration because the proposed rule's benefits are realized only if hospitals invest in bar code scanners, and we reiterate that their willingness to make that investment may depend on the number of different bar code symbologies that will be used and the ability of bar code scanners (particularly those scanners already in use at the hospitals) to read different symbologies."*

Virtually all bedside bar code scanners currently employed in hospitals can read – or can be programmed to read – any linear bar code, and some can read more complex codes. It is our belief that manufacturers will initially use linear bar codes on their packages, given

the greater prevalence of linear bar code readers in hospitals. The incentive for manufacturers to use more complex bar codes largely relates to the space on the package, which may be too small for a linear bar code, thus requiring an RSS or two-dimensional bar code. If certain FDA allowances are made for especially small or otherwise difficult-to-bar-code packages, it is less likely that manufacturers will need to resort to more complex bar codes that may require hospitals to purchase new bar code scanning equipment.

7. Whether the rule should adopt a different format (whether that format is a symbology, standard, or other technology), considering 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?
- Will hospitals be able to read or use the symbol, standard, or technology, either with existing equipment or equipment under development?

What the FDA said:

"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."
"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."

(See comments to question 5.)

8. Whether any specific product or class of products should be exempt from a bar code requirement and the reasons why an exemption is considered to be necessary. In addition, how could we create a waiver provision that would minimize the potential for misusing the waiver?

What the FDA said:

"We decline to create an exemption provision because we believe that almost all products are capable of bearing a bar code. In addition, exemption provisions sometimes create unintended administrative problems and consume agency resources as some individuals or firms may be tempted to submit exemptions requests notwithstanding their ability to comply with a particularly regulatory requirement."

The major concern among HLC members is the ability to place bar codes, leaving the required amount of white space, on very small vials and other single-dose containers. The lack of available flat surface area in which to print on these small and odd-shaped packages will result in either (1) eliminating the production of these packages, or (2) redeveloping larger packaging for these single doses, increasing costs for consumers. We believe that the FDA should consider reducing the currently required human readable label information on small packages to allow space for a bar code plus the surrounding white space required by this rule. We also believe that, in lieu of a waiver provision, the FDA should develop a fast-track review process for reviewing bar code requirements, on a case-by-case basis, for very small packages, and other packages or drugs for which bar coding is especially difficult.

9. Whether the implementation period for a final rule can and should be shortened from three years to some other specific time period.

What the FDA said:

> *"We decided on the 3-year implementation date to give affected firms time to redesign their labels and exhaust pre-existing label stocks and to give hospitals time to decide which scanning devices or systems to develop or purchase. Additionally, . . . we want to give hospitals more time to decide whether they would be willing to work with pharmaceutical firms to have other information (such as lot number and expiration date) encoded."*

HLC believes the proposed implementation timeline for a new bar code requirement is sufficient. Any new regulation should take into consideration the time and expense required to re-tool packaging operations, including purchasing new printing and verification equipment, redesigning package artwork, and re-filing for new label approvals. Additionally, it is important to remember that printing bar codes on drug labels will not be effective unless medical facilities implement the equipment and systems necessary to use the bar codes for safety purposes. Hospitals need to be assured that sustainable bar coding equipment and software compatible with their existing information technology is available. A feasible phase-in schedule, such as the one proposed by FDA, will help ensure that the regulation will be effective for improving patient safety.

10. Whether we should require the use of ISBT 128 for blood products, a specific symbology that is consistent with that required for drugs in proposed Sec. 201.25, or "machine-readable symbols" as approved by the Director of CBER.

What the FDA said:

> *"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 standards, 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 the CBER would allow CBER to consider new technologies in the future, but could result in some blood establishments adopting one system and other using a different system, thereby defeating the goal of creating a uniform system for identifying blood and blood components."*

(Note: Answer to question 10 is combined with answer to question 11.)

11. How the proposed rule might affect hospitals where patients receive blood or blood components, particularly with respect to a hospital's decision to purchase a machine reader (e.g., scanner) that can properly identify the intended recipient of the blood or blood component, the machine readable information encoded on the blood or blood component label, and perhaps the linear bar codes appearing on drugs and OTC drugs that are dispensed pursuant to an order and commonly used in the hospital.

HLC strongly encourages widespread application of new technologies aimed at ensuring the right patient gets the right unit of blood or blood product. Some hospitals are already using bar coding technologies but there has been only limited application of existing technology to reduce blood use errors in hospitals. We believe that the FDA should encourage the development and use of blood identification systems for blood products. Such blood identification systems should be compatible with the same systems hospitals employ for bedside pharmaceutical identification. It is our understanding the FDA-endorsed ISBT Code 128 includes a linear format and is capable of being implemented compatibly with the pharmaceutical bar codes supported by the FDA and in this organization's comments.

12. Whether any of the alternatives discussed in the economic analysis have merit.

The FDA considered several alternatives to the proposed rule, including:

(a) do nothing;
(b) requiring variable information;
(c) covering all OTC drug products;
(d) exemption for small entities;
(e) FDA selecting a specific symbology.

HLC believes that automated drug identification has the potential to greatly reduce the incidence of medication errors by ensuring that the right patient receives the right dosage at the right time. As such, HLC members support the FDA's efforts to develop a new bar code system for prescription and certain OTC drugs, vaccines and blood products used in institutional settings. This new system, however, should allow for flexibility and the development of new technologies for use in future bar coding efforts. As we have noted above, HLC urges the FDA to consider an expedited process for reviewing special case packages for which bar coding is especially difficult.

Conclusion

HLC supports the FDA's efforts to develop and implement regulations requiring automated drug identification to improve patient safety. We believe this effort is an important step towards reducing medication-related errors. We appreciate this opportunity to provide comment and we look forward to working with the FDA to finalize and implement the proposed rule.

Sincerely,

Mary R. Grealy
President