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Document Managements Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane (Room 1061)
Rockville, MD 20852
Docket No. 02N-0204
<http://www.fda.gov/dockets/ecomments>

In response to the request for comments from the FDA on the document published in the **Federal Register** on March 14, 2003 and titled, Bar Code Label Requirement for Human Drug Products and Blood, we offer the attached comments for your consideration.

AmeriNet believes that the proposed rule has the potential to have a significant positive impact on patient care and medication safety and we commend the FDA for your efforts to move this issue to the forefront. From our perspective, the proposed rule as published in the Federal Register is a very well constructed document and we propose only minor suggestions for revisions.

In general, we support the decision by the FDA to require the bar coding of only the NDC# for medications and blood products and to not require bar coding of medical devices. We would, however, encourage the FDA to consider the inclusion of standards for bar coding of the lot# and expiration date. This could be accomplished rather simply with a couple of statements that would require that the same standards used for the NDC number should apply to the lot# and expiration date if a manufacturer or repackager elects to include those two data elements on the label. We would also encourage the FDA to monitor the adoption of bar code capability by software and hardware suppliers to scan and record lot # and expiration date information. As the availability of the systems and the viability of including this information in an electronic medical record, the FDA should reconsider its position regarding the requirement to bar code these two pieces of information.

We also believe that it is critical to clarify the timeline for adoption of the rule. From our interpretation, it appears that there is a three year deadline for adoption but adoption, itself, is not defined. It is our recommendation that this term be defined to mean that labels for all affected products must include a bar code for at least the NDC# and that the new labeling must be available in the supply chain for purchase by institutions by the deadline. We suggest that the deadline should not be defined to mean a time period by which manufacturers must be ready to produce labels. We would even encourage the FDA to consider a shorter implementation timeline of two years.

The attached document provides additional comments on various aspects of the proposed rule. We thank you for the efforts of the Agency and for the opportunity to provide comment and are available for additional comment, clarification or assistance.

Founded in 1986, St. Louis-based AmeriNet, Inc. operates through its three shareholder health care organizations: AmeriNet Central, Intermountain Health Care, Inc. and Vector. AmeriNet is GPO of choice for a diverse industry including over 1,800 hospitals and over 16,000 non-acute members, creating value and purchasing strength through an array of programs and services.

Sincerely,



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Vice President, Pharmacy

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AmeriNet Comments to FDA Bar Code Label Requirement
for Human Drug Products and Blood (Docket No. 02N-0204)

Submitted via Email to:
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Page 1 Summary:

Right dose cannot be unequivocally validated using a bar code since the actual dose may be a partial or multiples of the strength contained within the bar code. There is no specific solution to this but rather an awareness of the limitation in this area. Since bar code placement is not required for hospitals that might repackage products using their own technology, it might be important, however, to state that facilities that do perform such practices must use a bar code that is consistent with the labeling of the product. For example, a facility might split a 20mg furosemide tablet and prepackage that half tablet in a package labeled as 10mg furosemide. Perhaps, the FDA should consider some guidance on this issue due to the potential for error. If a hospital chose to create a “dummy” NDC to facilitate bar coding of non-standard strengths, it would be important to place the burden on the hospital packager for maintenance of a database to identify those products.

Page 9 Section D:

Same caution as stated above

Page 16:

Same caution as stated above to the effect that it may be necessary to either create special guidelines or require hospitals to adhere to the same guidelines as manufacturers, etc. if the hospital elects to perform onsite bar code labeling.

Page 19:

Regarding which OTC products should be required to have bar coded labels, one way to identify a large proportion of these products is to define the requirement by stating that all OTC products which are intended to be dispensed, intact and in the original container as provided by the manufacturer, for use by inpatients must have a bar code on the label. Such items would include topical products (ointments, creams, etc.), ophthalmics, otics, etc.

Page 44:

The final rule should at least suggest that the bar code be oriented on the label in such a way as to promote the visual reading of the drug, strength, etc. while scanning the bar code. For example, placing the bar code on the opposite side of a vial from the label might mean that a caregiver would depend upon the scanning process to recognize the appropriate drug, strength, etc rather than actually reading the label. The only exception to this should be when the “real estate” on the label does not support this format, with the burden on the manufacturer to justify the decision to not orient the label contents in this fashion.

Page 56:

Since blood products such as albumin and IGIV are often distributed by pharmacy and administered by nursing, the bar code standards for these products should be the same as for other prescription and OTC medications.

Page 64:

We suggest that the reporting of bar code status and any label changes affecting bar codes should be a part of the standard reporting requirements. However, it is important to understand that annual reporting would not be sufficient to provide the maximum benefit to the users. Perhaps, databases such as Medispan, First Data Bank, etc. could be encouraged to create a data field for each product to identify the bar code status for that specific NDC. Today, these systems supply information relating to medication and packaging characteristics on a very frequent basis to the supply chain and should therefore be capable of tracking this data provided that manufacturers supplied this info to those companies.

Page 75:

Regarding the ability to use the bar code to screen for appropriate doses, it should be understood that the ability to check strength by use of a bar code is not free of potential errors. An order for 10mg of furosemide orally would be generally result in the pharmacist dispensing a 20mg tablet with directions to take one-half tablet. In some cases, an institution may decide to split the tablets so that the 10mg dose is available in a unit dose package as $\frac{1}{2}$ of a 20mg tablet to eliminate the need for the nurse to split a dose. Software systems to document administration should have to provide the functionality to issue a warning in this case and require manual intervention to validate the appropriate dose. The FDA should consider the appropriateness of providing guidance regarding a recommended process for applying bar codes to institutions that perform such repackaging on site where the dose of the packaged product does not match the dose associated with the NDC.

Page 86 Section 4:

NDA should be changed to NDC

Page 87:

We recommend that the FDA consider using language such as “patient care areas” to better describe the areas and to provide a more generic term that might apply to both inpatient and outpatient treatment settings. The term, “wards”, is also used in subsequent sections (page 99, etc.)

Page 101:

Since most inpatient reimbursement today involves a high proportion of Medicare and Medicaid patients under either a prospective payment or per diem basis, increased accuracy of charge capture does not necessarily result in increased revenue. Therefore, costs to the facility associated with implementation of bar code scanning capability will not likely be offset by this increased reimbursement.

Page 113:

It is important to create a system that will provide bar codes as part of the manufacturing process for as close to 100% of the products as possible. Anything less than this will continue to require facilities to repackage medications that are not available in bar coding

and risk the potential for labeling mistakes already identified in the proposed rule. The other alternative is to run both a bar code scanning and a manual system for documentation of medication administration. This then creates potential problems for the nurse that has to deal with two systems and eliminates the benefits already identified with bar code scanning of medications for those medications that do not have bar coding incorporated into the label. Therefore, it is essential to include specific language in the requirement to ensure that the labels of OTC packages used at the bedside include a bar code.

Page 115 VIII(1):

Why not require bar coding on sample packages as well with the exception that the bar code can be limited to the package rather than the specific unit of use tablet or capsule package since the outer sample package is usually given intact to a patient. This will facilitate system development to automate the tracking of medication samples and would not create a significant burden for manufacturers.

Page 115 VIIIe:

It will likely be difficult to establish and maintain a specific list of OTC products that are used in hospitals. It might be more appropriate to state that all OTC products intended to be dispensed in the original container for administration to or use by the patient require bar codes. Examples of such products include but are not limited to tubes of ointment, creams, etc, ophthalmic and otic dropper bottles, as well as all unit dose packages of oral solids and liquids. "Dispensed pursuant to an order" may not be sufficient to cover the intent since some facilities may treat OTC medications differently than prescription medications. For example, some OTC medications may be considered "comfort medications" that can be requested by a nurse without a physician's order.

Page 115 VIII2:

Although systems are routinely not available today to scan and record lot number and expiration date information, the final rule should include the provision for a second phase which would require that lot number and expiration date be included as part of the bar code. This will provide for more complete documentation in the medical record and also support the documentation of this information in the retail environment. At the very least, the final rule should provide guidance on how to include lot# and expiration date if a manufacturer elects to include this information in the bar code.

Page 116 VIII6:

We suggest that the final rule should provide a list of attributes that need to be met by the bar code methodology. In so doing, the rule can meet the necessary flexibility but still ensure that a minimum standard will be met. In any case, the standard should not be of a type that would require hospitals to spend significant additional amounts to replace scanning equipment that would otherwise meet the need.

Page 116 VIII8:

We do not recommend that the FDA establish a waiver process. Instead, we recommend that the rule simply require a bar code on all packages as listed in the rule. Manufacturers would then be required to develop packaging that supports the rule rather than expending resources in an effort to avoid compliance.

Page 116 VIII9:

Regarding the 3 year implementation period, what is required by the 3 year time line? Does it mean that all packages must be available in distribution by that 3 year period or does it mean that all labeling changes must have been approved by the FDA by the end of the 3 year implementation period with actual availability of the bar coded product to occur within some timeline after the 3 year period? We recommend that the final rule should require all manufacturers to have completed the process of obtaining FDA approval for all label revisions to include bar code by no later than 2 years following the effective date of the rule with a requirement that all product packaging being shipped by the manufacturer must meet the requirements of this rule no later than 3 years following the effective date of the final rule. Additional consideration should be given to shortening these timelines to 18 and 30 months, respectively, if comments from other responders, including manufacturers, support this change.

Page 117 VIII11:

By definition, do the “blood components” include IVIG and albumin? If so, ISBT code 128 technology would not be beneficial as these products are usually distributed by the pharmacy rather than lab. In fact, an expectation that blood products would be scanned prior to administration by the nurse would seem to dictate that the bar code format should be the same as for pharmaceuticals in general. Today, the use of the ISBT code 128 technology generally only has application within the blood bank. Scanning of blood components at the bedside prior to administration is not routine so it would seem reasonable to make sure that the bar code methodology can be supported by the pharmacy and bedside scanning systems.

End of Comments

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