DocuSys
Digital Medical Solutions

June 2, 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: **COMMENT REGARDING REQUIREMENT FOR DRUG BARCODE LABELING**

Dear FDA:

DocuSys is a company specializing in the computerized monitoring of injectable medications utilizing barcodes. A considerable amount of information about the drug about to be administered to a patient is relayed to an information management system for anesthesia and critical care. This allows comparison with patient information like drug allergies, medical history, physical conditions; and clinicians can be given feedback at the point of care, prior to delivery. DocuSys strongly endorses the placement of standardized barcodes on medication containers from the original manufacturer. We wish to alert the FDA to a potential gap in the safety net resulting from repackaging at the local level.

Point of Care Electronic Checking

In order for electronic checking to exist at the point of care, the barcode must be checked immediately prior to the administration to the patient. Removal of the product from its original packaging and re-labeling, removes the ability to scan the medicine unless an identical or equivalent barcode is placed on the repackaged container.

Hospitals Repackage Drugs

Hospitals and health care workers must inevitably repackage medications prior to delivery to patients. While many medicines are supplied in sizes appropriate for a single patient use (unit dosing), many other instances involve preparing individual patient doses from the original container or bulk supplies. If the final delivery vessel is a syringe, the medicine must be transferred into a different container (syringe) from the original manufacturer's vial or ampoule, even if a unit dose amount is supplied. These final dosage preparations, which are actually delivering the medication to the patient, should also have appropriate electronic safeguards. If the medicine is repackaged locally, hospitals must apply barcodes to the final container label, if the electronic safety net is to work. Errors occurring during the administration phase of drug delivery are caught only two percent of the time before reaching the patient[1]. If the final vessel has no barcode, then the electronic drug delivery monitoring or safety net goes blind, right where it is needed the most – at the point of administration.

It is therefore inevitable that healthcare providing institutions will need to properly label (including bar-coding) of final doses of therapeutic agents. Electronic safety systems cannot help if vital information included on the original package label (required by FDA) is not part of the electronic label. If errors are to be avoided when medicines are transferred from supply containers to final delivery containers, the automatic electronic label on the original manufacturer's product must include the same vital information as exists on the marketed product packaging.

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Having certain information electronically verifiable at the time of unit dose preparation can greatly enhance patient safety!

While it may be impractical to ask manufacturers to include on a standardized barcode everything found on the package insert, it would be of considerable value to at least require certain key elements important in the prevention of adverse drug events. These should include (aside from the drug identifier number):

1. The concentration and amount of medication dispensed in the original container. (To enable concentration error or overdosing error prevention).
2. The expected route of administration. For example, certain medications must not be given intravenously or as major nerve anesthetics. (See example below from The Institute of Safe Medication Practice's website.) The FDA already requires special labeling of original containers to avoid these types of errors!
3. The drug expiration date. Expiration date needs to be automatically checked at the point of care. Having the original drug's expiration date be a part of the barcode allows an automatic electronic expiration check during the process of preparing individual drug doses or when medicines are being transferred from original containers. Including the expiration date on original packaging would allow out of date drugs to be quickly and reliably removed from clinical stocks.

When these basic elements are included in electronically readable form, they can be automatically incorporated into point of care systems. All of these items will substantially improve the safety net against drug errors.

DocuSys Focuses on the Final Yard of Medication Delivery

DocuSys provides a system for labeling and tracking medications given by bolus injection or infusion using barcodes. See figure 2. The DocuSys technology provides much more information about the expected drug delivery in the barcode applied to the syringe for individual patient use. This includes:

- The expiration date
- The concentration of the drug (it may need dilution from it's original supply)
- The size of syringe to be used
- The technician preparing the syringe (when prepared by a pharmacist or pharmacy technician)
- The amount of drug dispensed
- A unique tracking number for monitoring which patient got what drug. Once a particular preparation of medication has been associated with a patient, it becomes possible to warn clinicians if that syringe is accidentally introduced into another patient's intravenous tubing.

The electronic safety net must extend to the point of care. See figure 3. Having standardized barcodes on the original manufacturer's containers including route, concentration and expiration date will allow further technological safeguards against accidental mislabeling of syringes or other preparations (like infusions) for patients. The transfer of vital route, requirement for dilution, expiration date and other information to the final delivery vessel must not be a manual process. The original manufacturer's barcode is the appropriate means to convey this data.

The FDA has the opportunity to substantially reduce drug errors by including a few key elements in the required barcode labels on marketed pharmaceuticals. The name of the medication or NDC number alone is not sufficient to maximally improve patient safety.

Sincerely,

Robert Evans, DO
Medical Director
DocuSys, Inc.
http://docusys.net/

Attachments

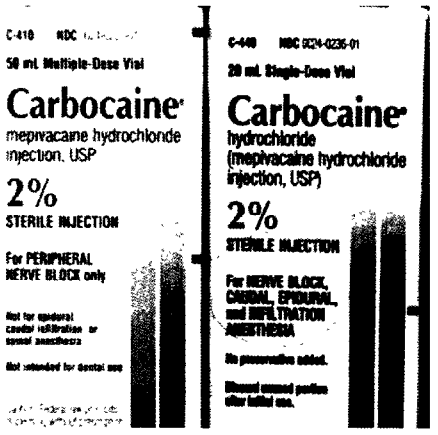

Figure 1 From ISMP showing the labeling of important route, amount and concentration information on supplied medication packaging.

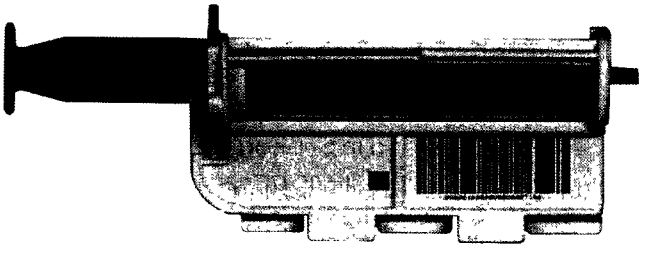

Figure 2. Syringe mounted on a syringe - label - cradle (SLC) showing attached barcode.

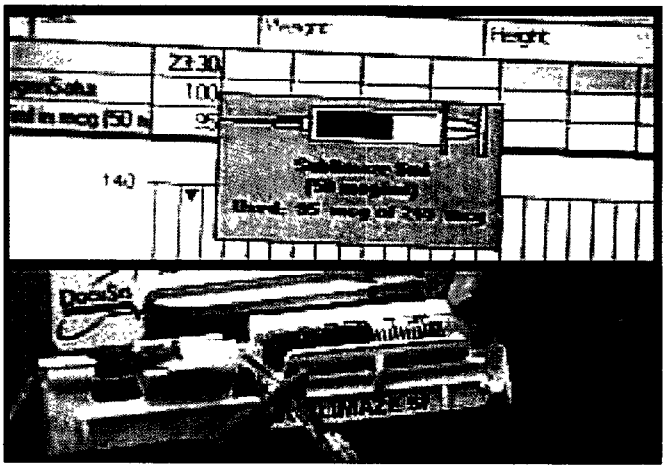

Figure 3. Syringe inserted into intravenous tubing. Computer display shows monitoring of what and how much is being injected.

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[1] **Leape, Bates, Cullen, et al.** "Systems Analysis of Adverse Drug Events" JAMA 1995