HANYS

HEALTHCARE ASSOCIATION OF NEW YORK STATE

Representing New York State's Not-For-Profit Hospitals, Health Systems, and Continuing Care Providers

Daniel Sisto, President

June 12, 2003

Ms. Jennie Butler
Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, Maryland 20852

Dear Ms. Butler:

The Healthcare Association of New York State (HANYS) serves as the key advocate for more than 550 non-profit and public hospitals, nursing facilities, home care agencies, and other health care providers throughout New York State. HANYS thanks you for the opportunity to discuss member concerns regarding patient safety and medication errors.

Specifically, we are writing to share our comments regarding the Department of Health and Human Services, Food and Drug Administration's (FDA) proposal to require certain human drug product labels and biological product labels to have bar codes (21 CFR Parts 201, 606, and 610). HANYS' recommendations are highlighted in bold throughout this letter.

In preparing our comments, HANYS sought the advice of clinical and administrative representatives from member acute care hospitals and other health care settings. Our comments reflect input from these individuals and organizations. HANYS and its member organizations remain committed to providing high quality care to the patients and communities that we serve. **HANYS, like many other professional and member associations and organizations, supports the concept of bar coding and scanning as another step in reducing medication error risks and improving patient safety. We specifically endorse the recommendations contained in the comment letter from the American Hospital Association.** We have concerns, however, about the ease or difficulty with which our members will be able to comply with this new mandate.

Manufacturer and Pharmaceutical Issues

Some health care organizations have employed barcode-enabled point-of-care (BPOC) systems as a way of combating errors—a process that has resulted in significant decreases. Many more, however, have not because of staffing challenges,

Main Headquarters
One Empire Drive, Rensselaer, New York 12144
phone (518) 431-7600 / *fax* (518) 431-7915
www.hanys.org
Washington, D.C. Office
499 South Capitol Street SW, Suite 410, Washington, D.C. 20003
(202) 639-1502 / *fax* (202) 639-9542

02N-0204

C106

capital costs for equipment, and wide variations in pharmaceutical manufacturers' practices.

Now, the FDA is considering an extension of this BPOC effort, through a rule that would require that all human drugs and biological products be packaged and bar coded in single dosages. Manufacturers are reasonably apprehensive about the retooling costs required in fulfilling its requirements.

Because of printing-space constraints, labeling of immediate containers (i.e., single tablet, pill, or capsule packages, pre-filled syringes, and ampules) may necessitate modifications in label strategies and design, production line retooling, or increased package size. The FDA has allowed three years from the date of approval of its proposal for all of the crucial reprocessing and retooling to take place. The government expects that conformity will cost the pharmaceutical industry between $500 million and $1.4 billion over a ten-year period. The FDA has recognized that some manufacturers and repackagers might do away with their unit-dose packaged drugs rather than incur the retooling expenditures.

Successful and useful bar coding requires the use of standardized data, data movers, and data capture technologies. The established EAN.UCC system and HIBCC health care standards are the foundation of unit-dose bar coding today and any possible FDA-mandated bar coding regulation is expected to build on one or both of these standards. **HANYS recommends that manufacturers and suppliers of drugs and biologicals provide 100% of their products with bar coding.** This will reduce the workload of not only nurses, but also pharmacists, both of whom are in short supply in this current and anticipated future work force.

HANYS has received several comments from its members regarding their concern that the pharmaceutical industry has already cut back on the unit-dose packaging that is currently available and that this requirement may give them another reason to reduce the number of items available. Several members commented that the "FDA must be specific in its proposal indicating the need and requirement for unit-dose packaging with bar coding."

Health Care Organization Issues

If unit-dose packaging and labeling does decline, our members are concerned that the onus would shift to end-users (especially hospital pharmacies) to repackage medications into a unit-dose, bar-coded package or to use a third-party packager at a cost of seven to eight cents per unit. These technologies are available but the cost is more than what was estimated by the FDA. Hospitals cannot afford another unfunded mandate and, with an already limited pharmacy employment pool, this could make staffing even more difficult.

FDA delays, manufacturer hesitation, and possible variations in product accessibility are likely to slow advancement but should not impede health systems from choosing BPOC technology to realize advances in patient safety. At present, only about 35% of medications in a typical hospital have labels containing a bar code at the unit-dose level. Since not all medications are

dispensed in prescribed unit-dose packaging, further preparation by the nurse at the bedside or medication station is usual.

Patient Safety Issues

Patient safety is best achieved when essentially all medications are bar coded. The inadequacy of manufacturer-applied bar codes on immediate containers (unit doses) requires the pharmacy to attach bar-code labels on up to 65% of doses.

There are certain aspects of the implementation of the unit-dose bar-coding technology that require additional thought and deliberation. Areas demanding particular attention include, but are not limited to, different patient populations, standardization, compatibility, reliability, financial considerations, and affordability.

Children and infants are at particular risk for medication errors. Many pediatric doses are not standard and are prepared internally by the pharmacy or on the unit by a nurse. A device for adding a bar-code label to institution-specific medications may increase the cost of dose preparation, as well as additional time. Infant identification also represents challenges to bar coding because of the small size of the ID band. Methods that associate mother to baby may have bar coding for the mother, but only manual identification for the infant.

For these reasons, **HANYS supports the FDA's effort to require a bar code on the label of human drug products down to the unit-dose packaging.** HANYS is pleased with the proposal that the bar code will contain, at a minimum, the drug's National Drug Code (NDC) number and that FDA intends to "redefine the NDC number and to make the NDC number unique and more useful to informational databases, whether the databases are created for purposes of preventing medication errors, obtaining the latest information about a specific drug, or tracking drug use or distribution." **We would advocate that the NDC number also contain the expiration date. Additionally, HANYS would propose that bar coding of drugs should also be required for non-standard items, at minimal cost, to the dispensing pharmacy, whether at the health facility or a community drug store.** This would include such preparations as ointments, lipids, crash cart supplies, total parenteral nutrition (TPN), etc.

Point-of-care medication validation products have been on the market for about three years. However, some systems are still burdensome and may cause an unnecessary increase in the time needed to administer medications. Internal bar coding efforts require that pertinent policies, procedures, checks, and controls be in place to reduce the chance for error to be introduced into the medication use system.

The ability of scanners to read the bar code is critical to its successful adoption by health care. Some bar scanners cannot read curved surfaces. Since almost all identification bracelets are on a patient's wrist, or infant's leg, valuable time can be wasted flattening out the identification band

to allow the scanner to read it, often requiring as much time as would be spent administering a medication without benefit of technology.

Nurses must have a trustworthy, correct, and speedy system that reduces workload and is more efficient and quicker than current manual ones. **HANYS urges that staff be involved and adequately trained in all bar-coding processes.**

Cost

HANYS feels compelled to raise the issue of affordability and investment in BPOC technology. Obviously, the cost of implementation and performance in practice settings will vary for each facility and the structural and process alterations essential in administering point-of-care systems. Both manufacturers and suppliers must contribute to the production of materials that both respond to the mandate for safety and address workload burden in this time of shortages of health care professionals. **It is also imperative that some method of reimbursement for these expenses be available to purchase the applicable technology or to make system alterations.**

In conclusion, we applaud the FDA's efforts to improve patient safety, and reduce the number of adverse drug events due to medication errors. Bar-code labeling for human drug and biologic products is one approach of employing technology to a broad spectrum of potentially high-risk processes and achieve a considerable safety effect. **Bar coding patient identification bands, caregiver badges, and unit-dose medications, can help health systems significantly augment patient safety during drug administration.**

Thank you again for the opportunity to provide comments on this proposed rule. If you have any questions about these comments, please feel free to contact Trish McBreen, Quality and Research Initiatives at (518) 431-7811.

Sincerely,

Raymond Sweeney

Raymond D. Sweeney
Executive Vice President

RDS:tm:ays