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

Dear Sir/Madam:

I write on behalf of Trinity Health, a Catholic-sponsored multi-state healthcare provider, regarding the proposed *Bar Code Label Requirements for Human Drug Products and Blood"* (*Federal Register*, vol. 68, no 50, pp. 12500-12534).

Our hospitals and other healthcare facilities span large inner city to small remote rural areas and provide a continuum from acute inpatient hospital to home health services. Our primary service areas include:

- California (Fresno);
- Idaho (Boise);
- Indiana (Mishawaka, Plymouth and South Bend);
- Iowa (Clinton, Dubuque, Mason City, New Hampton, and Sioux City);
- Maryland (Silver Spring);
- Michigan (Ann Arbor, Battle Creek, Cadillac, Grand Rapids, Grayling, Howell, Livonia, Macomb County, Muskegon, Oakland County, Port Huron and Saline); and
- Ohio (Columbus).

It is within this context that I provide our comments.

First, I want to commend the Food and Drug Administration (FDA) for its systematic (December 3, 2001 announcement that bar code regulations would be addressed) and collaborative (July, 2002 public meeting) approach to the development of these proposed regulations. We were pleased to have had the opportunity to participate in last summer's public meeting and provide written input (Docket No. 02N-0204) on elements to be included in bar codes and on what products they should be placed. Additionally, we are gratified that the features of the proposed regulations manifest provisions derived from research inquiries that conclusively show the quantum improvement in patient safety when bar codes are utilized on human drug and other products.

Much has been written about the "modernization" of Medicare, usually in the context of incorporating outpatient prescription drugs and preventive services in the Medicare benefits package. Less discussed but just as critical an element of modernization is the adoption of new technology to enhance patient safety and improve the quality of care. Trinity Health, through its "Project Genesis," is implementing several new computer systems to implement, among other things, best practices in clinical functions, an electronic medical record and a clinical data repository.

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Already Trinity Health's patients are benefiting from the computerized physician order entry (CPOE) technology that has been implemented in fourteen of our hospitals. The CPOE system triggered 65,000 alerts between July and December, 2002, which required over 7,000 interventions. This experience speaks for itself in the added patient safety provided to Trinity Health's patients from the CPOE technology. As such, the bar code label regulations that have been proposed are a necessary patient-safety-enhancing complement to our own investment in patient-safety-improving technology. Our comments on some of the specific features of the regulations follow:

- **Lot, serial number and expiration date**. These items are not proposed to be required on bar codes. We recommend that the lot, serial number, and expiration date be included on the bar code.
  →RATIONALE: Notwithstanding the fact that adverse drug events (ADEs) from expired medications are identified in the preamble to the regulations as being minimal (90 and 21 ADEs in which a patient received an expired and recalled drug, respectively, from 71,546 adverse events, Federal Register, p. 12507), the opportunity to avoid an ADE from an expired medication should be addressed by requiring the lot and serial number on the bar code. Lot and serial numbers are integral to knowing whether the drugs and devices being used by the health care provider meet all required specifications. Additionally, they are necessary elements for health care providers to know when a drug or device is recalled.

- **Placement of the bar code on the unit of dose**. We agree with the proposed regulatory requirement that the bar code be placed on the dosage unit.
  →RATIONALE: This requirement will, per the statement in the preamble, enable "health care professionals to check whether they are giving the right drug via the right dose and right route of administration to the right patient at the right time" (Federal Register, p. 12501). Put another way, placement of the bar code on the dosage unit is a necessary element of the bar coding if the improved patient safety goals of the regulations are to be met.

- **Bar codes for over-the-counter drugs dispensed pursuant to an order**. We agree with the decision to require bar codes on such over-the-counter (OTC) drugs, including on the unit of use packaging.
  →RATIONALE: As the rationale in the preamble indicates, OTC drugs have the potential to interact with prescription drugs and thus should be part of the bar coding requirement. Additionally, they are commonly used in hospitals (tylenol, aspirin, Motrin, etc.). Hence, if we are to implement bar coding, they also must have barcodes.

- **Three-year implementation time period**. We do not object to the three-year implementation period once the regulations become final. However, this significant duration time period argues for the making the regulations final at the earliest possible date.
  →RATIONALE: While there are start-up requirements for the "manufacturers, repackers, relabelers and private-label distributors of human prescription drug products," the organizations subject to the regulations, the evidence of improved

patient safety argues for standardization and wider acceptance as soon as practicable.

- **Bar codes for devices**. The proposed regulations do not mandate bar codes for devices. We believe that it is essential that the final regulations require such codes and request that the FDA reject the device industry's request for "further study" (*Federal Register, p. 12504).* Bar-code mandates for devices are especially important in light of the three-year time period from the date the regulations are final to their implementation date.
  →RATIONALE: Implantable devices are made to detailed specifications, are generally costly, frequently complex, and sometimes fail. Hence, it can be presumed that the manufacturer will recall devices when after-the-fact reviews detect defects that are harmful to patients in whom they have been implanted. Devices need to have bar codes that are able to be incorporated in a patient's medical record and quickly searchable from that record. It is to state the obvious to note that this information is required so that we are able to determine the appropriate clinical protocol when a patient has received an implantable device that has been recalled. Many of these medical devices cost several thousand dollars. Hence, the added cost to the manufacturer of the bar code is minimal when compared to the cost of the device and almost nonexistent when compared to the added patient safety that would accrue from the incorporation of a bar code on such devices.

- **Standardization and readability of bar codes**. We agree with the preamble's statement that "the private market's failure to develop standardized bar codes has impeded the growth of the technological investment necessary to reduce the number of ADEs in the nation's hospitals...and that a regulatory intervention to establish a standardized system of bar codes is needed to address this market failure" (*Federal Register*, p. 12518). We concur with this conclusion and believe that it also argues for movement away from proprietary to nationally-accepted bar codes that are both "human" and machine-readable.
  →RATIONALE: Standardization in and of itself will encourage health care providers to purchase the necessary bar code reading technology that will bring about the desired enhancement of patient safety. Additionally, bar codes with appropriate numbering will further widen their acceptability and use.

- **Bar code quality**. We strongly concur with the requirement that the bar code's machine-readable identifier must "[r]emain intact under normal conditions of use." Additionally, the bar codes should be placed in a location and in such a manner that the full code is maintained when the product is disaggregated into unit dosage packets.
  →RATIONALE: Our own use of manufacturers' bar codes suggests that bar codes sometime fail to maintain their integrity (e.g., the linear lines becomes jagged, the bar code markings degrade on the medium they are placed, the bar code is placed in such a manner that it becomes unusable at the unit dosage level, etc.). Further, it has been our experience that that the bar code does not always agree with the written description of the product.

- **Bar code auditing and compliance**. We recommend that the FDA conduct, in addition to traditional enforcement, audits of the bar code quality utilized by those subject to the requirements. In addition, we recommend that entities subject to the bar-coding requirements be required to do self-audits.
  →RATIONALE: These requirements will both speed standardization and enable patient-safety improvements to be implemented more quickly.

Thank you for your consideration of my views.

Sincerely,

Bruce L. Van Cleave, MD
Executive Vice President
Clinical and Physician Services

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