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**Statement of the  
Healthcare Information and Management Systems Society  
Presented to the  
Food and Drug Administration of the  
Department of Health and Human Services  
On  
Bar Code Label Requirements for Human Drug Products**

**July 26, 2002**

*The following statement is provided by Joyce Sensmeier, MS, RN, BC, CPHIMS, Director of Professional Services, Healthcare Information and Management Systems Society*

I am here on behalf of the Healthcare Information and Management Systems Society (HIMSS), a non-profit association focused on advancing the best use of information and management systems for the betterment of human health. Based in Chicago with an office in Ann Arbor, Michigan, HIMSS has 39 chapters and more than 13,000 individual members working in healthcare organizations throughout the world. Individual members include healthcare professionals in hospitals, corporate healthcare systems, clinical practice groups, Healthcare Information Technology supplier organizations, healthcare consulting firms, and government settings in professional levels ranging from senior staff to CIOs and CEOs. HIMSS also serves over 80 corporate members, which include suppliers and consultants in the health information and management systems industry.

HIMSS strongly supports industry cooperation in achieving viable point-of-care, unit-of-use bar coding to reduce medical errors and improve productivity. HIMSS members represent all aspects of the supply chain impacted by unit-of-use bar code technology. By means of the advocacy process as implemented by the Advocacy Committee, HIMSS is working to accelerate adoption of bar coding at the point of care through initiatives in the following areas:

- Publication of a White Paper on Bar Coding for Patient Safety and other related articles in a variety of HIMSS publication venues.
- Formation of a Supply Chain Special Interest Group. This group provides a forum within HIMSS to create, share, review and advocate for information and management systems issues related to the healthcare supply chain from manufacture to point of use and disposal. This forum focuses on issues that add value to patient care through greater efficiency and cost savings as well as patient safety.
- Formation of a Bar Coding Task Force whose mandate by HIMSS Board of Directors is to facilitate industry cooperation in achieving viable point-of care, unit-of-use bar coding to reduce medical errors and improve productivity.
- Development of a flow chart describing the effect of bar code technology on the continuum of care (see exhibit A)

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Healthcare Information and Management Systems Society

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- Informal one-on-one discussions with key Industry and Congressional leaders and staff on the importance of bar coding technology to the overall improvement of patient safety
- Development of a HIMSS position statement on point-of-care unit-of-use bar coding technology which follows:

### **Position Statement**

With the goal of moving towards a fully electronic health record system, the Healthcare Information and Management Systems Society (HIMSS) advocates the comprehensive use of standards-based<sup>1</sup> bar coding technology in the healthcare environment. The Society recognizes the significant benefits this technology can bring forward in the following areas:

- Patient registration and/or admission processes
- Patient safety, clinical care delivery, and patient tracking
- Product/supply logistics and material management coordination
- Patient accounting and billing

### **Methodology**

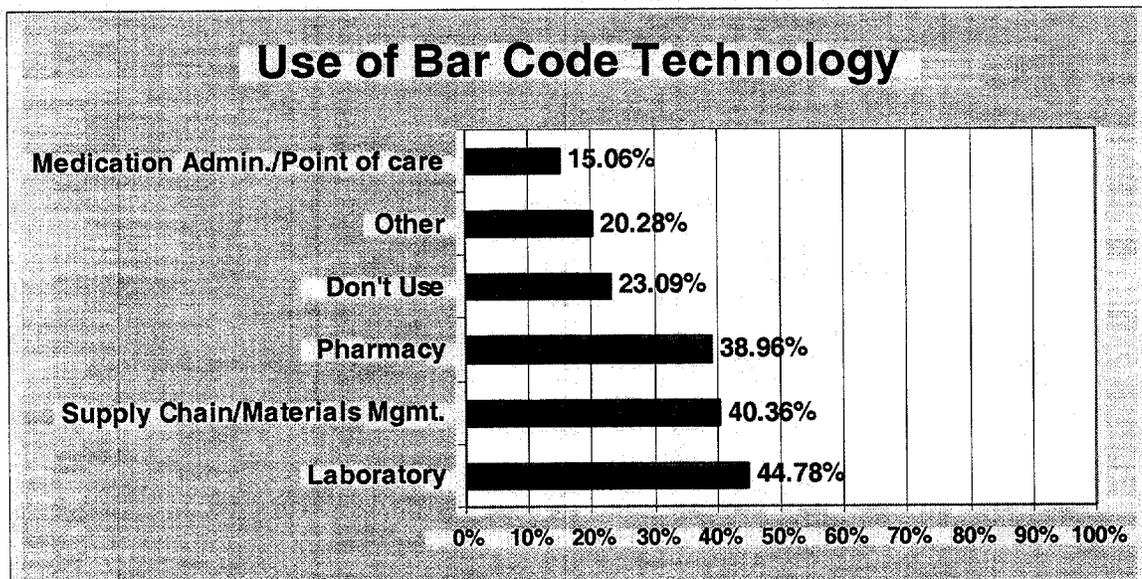
- Improvements in the patient registration and/or admission processes can be achieved by use of bar codes on patient:
  - forms
  - labels and wrist bands
  - records (including face sheets)
- Improvements in patient safety, clinical care delivery, and patient tracking can be achieved by use of:
  - bar codes on unit-of-use medications
  - bar codes on medical devices
  - bar codes on medical/surgical supplies
  - bar codes to identify care givers, clinicians and patients
  - bar codes on order requisitions, test results, and patient charts/medical records
  - bar coding scanners at the point of care
- Improvements in product, supply, and material management coordination can be achieved by use of bar codes on:
  - unit-of-use items for inventory control/tracking
  - bulk items to assist in materials tracking and logistics
  - tracking of reusable/refurbished equipment and supplies, product recalls, and warnings
- Improvement in patient accounting and billing can be achieved by use of bar codes on:
  - supply items to capture charges
  - patient statements for identification of remittance advice

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<sup>1</sup> HIMSS endorses the bar coding standards of UCC/EAN and the HIBC Supplier Labeling Standard and Provider Standard.

### Current Statistics

Nearly 77 percent of the 619 respondents of the HIMSS 2002 Hot Topics survey reported that their organization uses bar coding technology. The survey, conducted at the 2002 Annual HIMSS Conference and Exhibition in January, addressed key topics influencing the healthcare IT industry, including the issue of patient safety. The two areas in which bar coding was reported to be most prevalent were laboratory (45 percent) and Supply chain/materials management (40 percent). However, only 15 percent of respondents indicated that their organization uses bar coding technology for medication administration at the point of care.



### Final Statement

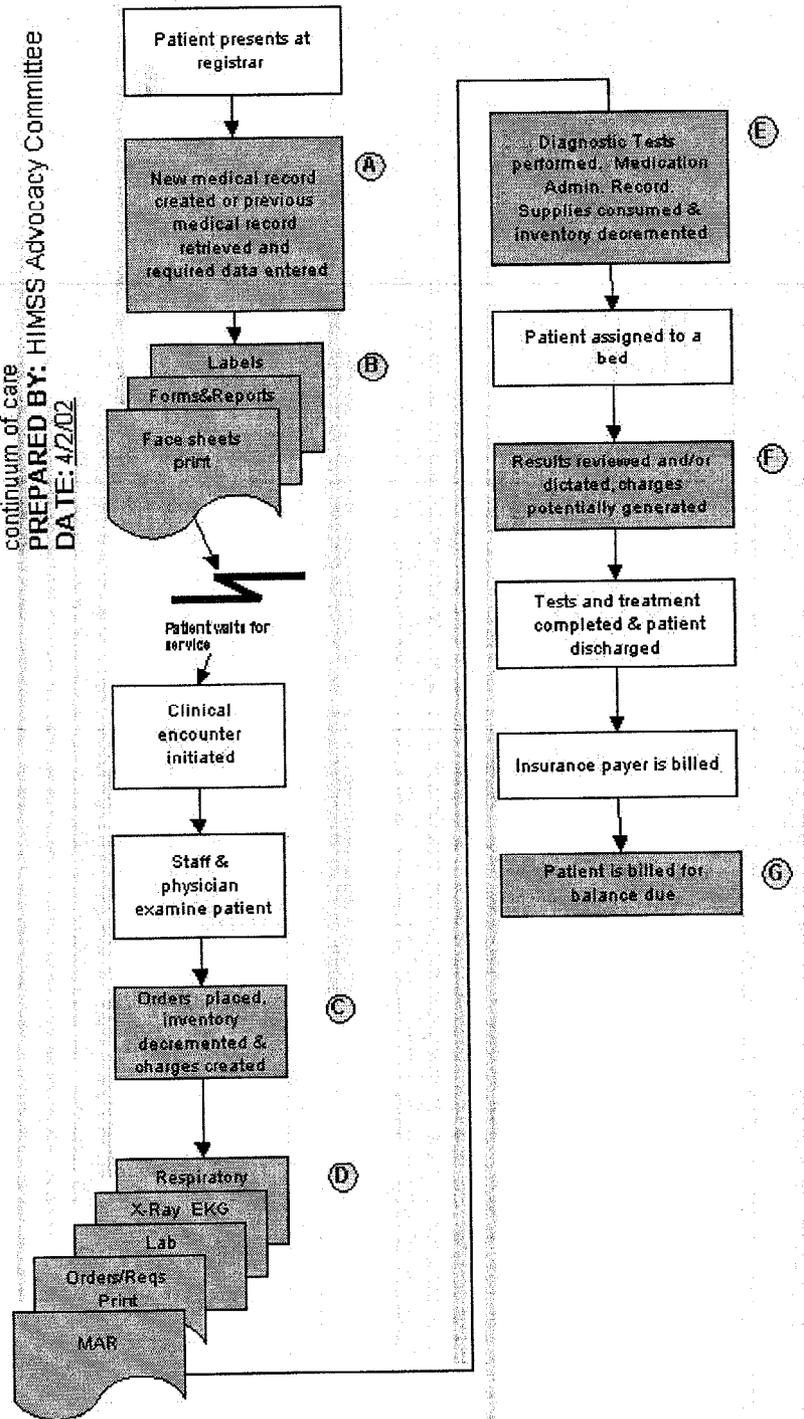
HIMSS strongly supports industry cooperation in achieving viable point-of-care, unit-of-use bar coding to reduce medical errors and improve productivity, and stands ready to work with the industry towards its implementation. It is our recommendation that bar coding be applied immediately to the medication administration process. Use of this technology along with embedded decision support, will provide the nurse with a mechanism for automatically checking the 5 rights of medication administration, including verifying the right patient, drug, dose, route, and time. This mechanism will go far to enhance patient safety at the point of care, and provide the nurse with support in administering timely, accurate and effective medication therapy. HIMSS recognizes that implementation of comprehensive use of standards-based bar coding technology is dependent upon multiple components, including organizational readiness and the existing IT infrastructure. A healthcare organization may choose to start at any point in this methodology and still achieve significant benefits. To assist organizations with assessing readiness and understanding the complexities of implementing this technology, HIMSS has developed a compendium of materials, which are available at: <http://www.himss.org/ASP/advocacy.asp>.

## 1 Attachment: Exhibit A – Conceptual Flowchart

### **About the Healthcare Information and Management Systems Society (HIMSS)**

The Healthcare Information and Management Systems Society (HIMSS) provides leadership in healthcare for the management of technology, information, and change through member services, education and networking opportunities, and publications. Members are kept abreast of the latest industry information and research, as well as legislative and policy issues. Based in Chicago with an office in Ann Arbor, Mich, HIMSS has 39 chapters and more than 13,000 individual members working in healthcare organizations throughout the world. Individual members include healthcare professionals in hospitals, corporate healthcare systems, clinical practice groups, HIT supplier organizations, healthcare consulting firms, and government settings in professional levels ranging from senior staff to CIOs and CEOs. HIMSS also serves over 80 corporate members, which include suppliers and consultants in the health information and management systems industry. HIMSS' Web site is [www.himss.org](http://www.himss.org)

CONCEPTUAL FLOWCHART  
 PROCESS: Effects of bar code technology on the  
 continuum of care  
 PREPARED BY: HIMSS Advocacy Committee  
 DATE: 4/2/02



## Exhibit A

Each shaded box and corresponding letter indicates when bar code technology impacts a patient during a hospital visit. Further explanation of each instance is included on the second page of this document.

Bar code technology impacts:

- Patient registration
- Order entry
- Patient identification
- Administering of Rx and Medication Administration Record
- Utilization of supplies
- Patient tracking
- Patient billing

- Ⓐ Once a patient presents for admission, bar code technology may be utilized to scan a patient ID card previously issued by the healthcare system assisting in the elimination of duplicate medical record creation.
- Ⓑ Labels (for patient arm bands and misc. forms), insurance forms and face sheets are generated upon registration and contain a patient identifying bar code.
- Ⓒ When orders are placed, the patient wrist band is scanned to ensure that orders are entered for the correct patient and on the correct account.
- Ⓓ Order requisitions are printed in various departments for the diagnostic tests ordered. Medication Administration Records (MAR) may be updated as meds are administered. Each item or med has an identifying bar code so that patient & clinician matching/tracking can be automated.
- Ⓔ As tests are performed, supplies are consumed (gauze, needles, dye, prep. materials). These items should be scanned before utilizing them, thereby assisting in tracking of inventory and charge creation. MAR may also be updated again.
- Ⓕ Bar codes should be placed on charts, films, lab reports, and specimens to facilitate proper patient identification for dictation and results delivery.
- Ⓖ Bar codes should be placed on the remittance portion of the patient bill to increase accuracy when posting patient payments in the patient accounting department.