

# THE NATIONAL QUALITY FORUM

June 5, 2003

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

To Whom it May Concern:

The National Quality Forum (NQF) commends the Food and Drug Administration (FDA) for preparing to amend its pre- and post-marketing safety reporting regulations for human drug and biological products to include bar-coding and for recognizing the need to develop definitions, reporting formats and standards for bar-coding. The NQF offers its assistance in vetting, reviewing and harmonizing proposed changes.

The NQF has followed with interest the FDA's growing interest in bar coding as a way to improve patient safety. For this initiative to be successful, the practices and standards related to bar coding will need to undergo public review and debate and gain "buy in" throughout the healthcare community. Given the controversy attendant to any change in the healthcare system, a prominent public vetting of the proposed improvements will be important, and especially for Medicare and other public programs.

The National Quality Forum (NQF), a unique public-private collaboration of approximately 180 organizations, would be pleased to assist the FDA in undertaking a public review of issues attendant to bar coding drugs and devices. The NQF was established to standardize performance measures and otherwise develop consensus on healthcare quality issues across all stakeholders, including consumers, purchasers, providers and researchers, in both the public and private sectors. You are probably familiar with some of our work, so I won't say more here in the way of background. I did want to emphasize to you that we have a keen interest in helping to standardize technologies that measurably improve patient safety and in working towards public agreement on how to focus quality improvement efforts in the arena of medication safety.

A list of NQF member organizations is attached as well as a letter that was sent to William Hubbard in October 2002, when I learned that the FDA was drafting proposed rules on bar coding for medication use in hospitals. Please let me know if the NQF can be of assistance to you in making bar coding a success.

Sincerely,

Kenneth W. Kizer, M.D., M.P.H.  
President and CEO

Attachments: Roster of National Quality Forum member organizations  
Letter to William Hubbard, FDA, October 18, 2002

# THE NATIONAL QUALITY FORUM

## Members

AAAHC-Institute for Quality Improvement  
AARP  
AFL-CIO  
Agency for Healthcare Research and Quality  
Alexian Brothers Medical Center  
Alliance for Quality Nursing Home Care, Inc.  
Alliance of Community Health Plans  
American Academy of Family Physicians  
American Academy of Orthopaedic Surgeons  
American Academy of Physician Assistants  
American Association of Health Plans  
American Association of Homes and Services for the Aging  
American Association of Nurse Anesthetists  
American Board for Certification in Orthotics and Prosthetics  
American Board of Internal Medicine Foundation  
American Board of Medical Specialties  
ACC/AHA Performance Measurement Task Force  
American College of Cardiology  
American College of Medical Quality  
American College of Obstetricians and Gynecologists  
Am. College of Physicians–Am. Society of Internal Medicine  
American College of Radiology  
American College of Surgeons  
American Federation of Teachers Healthcare  
American Health Care Association  
American Health Quality Association  
American Heart Association  
American Hospice Foundation  
American Hospital Association  
American Medical Association  
American Nurses Association  
American Optometric Association  
American Osteopathic Association  
American Pharmacists Association Foundation  
American Society for Quality–Health Care Division  
American Society for Therapeutic Radiology and Oncology  
American Society of Clinical Oncology  
American Society of Health-System Pharmacists  
Anesthesia Patient Safety Foundation  
Ascension Health  
Aspect Medical Systems, Inc.  
Association of American Medical Colleges  
Aventis Pharmaceuticals  
Battelle Memorial Institute  
Beacon Health Strategies  
Blue Cross Blue Shield of Michigan  
Buyers Health Care Action Group  
California Health Decisions  
California HealthCare Foundation  
Cardinal Health, Inc.  
Catholic Health Initiatives  
Catholic Healthcare Partners  
Centers for Disease Control and Prevention  
Centers for Medicare & Medicaid Services  
Center to Advance Palliative Care  
Central Florida Health Care Coalition  
Cleveland Clinic Foundation  
CHRISTUS Health  
CIGNA Healthcare  
CMRI  
College of American Pathologists  
Commonwealth Fund  
Community Hospital of the Monterey Peninsula  
Consumer Coalition for Quality Health Care  
Coral Initiative, LLC  
Council of Medical Specialty Societies  
CRG Medical  
Delaware Health Care Commission  
Delmarva Foundation  
Duke University-Health Sector Management Program  
eHealth Initiative  
Empire Blue Cross/Blue Shield  
Employer Health Care Alliance Cooperative (The Alliance)  
Federation of American Hospitals  
First Health, Inc.  
Ford Motor Company  
Forum of End Stage Renal Disease Networks  
Foundation for Accountability (FACCT)  
General Motors  
GlaxoSmithKline  
Greater Detroit Area Health Council  
Greater New York Hospital Association  
HCA  
Health Care Excel, Inc.  
HealthCare 21  
HealthHelp Inc.  
Healthcare Leadership Council  
Health Resources and Services Administration

# THE NATIONAL QUALITY FORUM

## Members

Health Grades, Inc.  
Hudson Health Plan  
Henry Ford Health System  
Hoag Hospital  
Horizon Blue Cross and Blue Shield of New Jersey  
Illinois Department of Public Health  
Institute for Safe Medication Practices  
Integrated Healthcare Association  
INTEGRIS Health  
IPRO  
The Jackson Organization  
Jefferson Health, Office. of Health Policy & Clinical Outcomes  
Joint Comm. on Accreditation of Healthcare Organizations  
Kaiser Permanente  
Leapfrog Group  
Long Term Care Institute, Inc.  
Los Angeles County - Department of Health Services  
Loyola University Health System-Ctr for Clinical Effectiveness  
Maine Health Management Coalition  
March of Dimes  
Mayo Foundation  
Medical Review of North Carolina, Inc.  
Memorial Health University Medical Center  
Memorial Sloan-Kettering Cancer Center.  
Midwest Business Group on Health  
National Association for Healthcare Quality  
National Association of Chain Drug Stores  
Nat'l. Assoc. of Children's Hospitals and Related Institutions  
National Association Medical Staff Services  
National Association of Public Hospitals and Health Systems  
National Association of State Medicaid Directors  
National Business Coalition on Health  
National Citizens Coalition for Nursing Home Reform  
National Committee for Quality Assurance  
National Committee for Quality Health Care  
National Hospice and Palliative Care Organization  
National Institutes of Health  
National Partnership for Women and Families  
National Patient Safety Foundation  
National Pharmaceutical Council  
National Research Corporation  
Nemours Foundation  
New Jersey Health Care Quality Institute, Inc.  
New York Presbyterian Hospital and Health System  
North Shore-Long Island Jewish Health System  
Northeast Health Care Quality Foundation  
Ohio KePRO  
Pacific Business Group on Health  
PacifiCare  
Partners Healthcare System, Inc.  
Physician Consortium for Performance Improvement  
Premier, Inc.  
Professional Research Consultants, Inc.  
Qualidigm  
Rhode Island and Providence Plantations, Dept. of Health  
Robert Wood Johnson University Hospital – New Brunswick  
Robert Wood Johnson University Hospital - Hamilton  
Service Employees International Union  
Schaller Anderson, Inc.  
Sisters of Mercy Health System  
South Nassau Communities Hospital  
Spartanburg Regional Healthcare System  
Spectrum Health  
State University of New York, College of Optometry  
Stratis Health  
Substance Abuse and Mental Health Services Administration  
Sutter Health  
Tenet Healthcare  
Texas Medical Institute of Technology  
Trinity Health  
Uniform Data System for Medical Rehabilitation  
UnitedHealth Group  
United Hospital Fund  
University of Michigan Hospitals and Health Centers  
University of North Carolina-Program on Health Outcomes  
URAC  
US Department of Defense-Health Affairs  
US Food and Drug Administration  
US Office of Personnel Management  
US Pharmacopeia  
Veterans Health Administration  
VHA, Inc.  
Virginia Health Quality Center  
Washington Business Group on Health  
West Virginia Medical Institute  
Yale-New Haven Health System

# THE NATIONAL QUALITY FORUM

October 16, 2002

Mr. William K. Hubbard  
Senior Associate Commissioner  
for Policy, Planning and Legislation  
Food and Drug Administration  
5600 Fishers Lane  
Room 14101  
Rockville, MD 20857

Dear Mr. Hubbard:

I am aware that your office is currently drafting proposed rules on bar coding for medication use in hospitals, and I want to offer assistance in two ways.

First, in determining which standards should apply for bar coding (e.g., for data encryption, etc.) I ask that you consider working with the National Quality Forum (NQF) for this specific task. Determining which bar code standards should be used seems like it would lend itself nicely to the voluntary consensus standards setting process.

As you probably know, FDA is one of the nearly 160 NQF member organizations. Other federal members include CMS, AHRQ, NCI, CDC, NIH, VA and DOD. The NQF is a public-private entity that comports with the National Technology Transfer and Advancement Act of 1995 and OMB Circular A-119 as a voluntary consensus standards setting body. The use of voluntary consensus standards is new to healthcare, but certainly is not new in other industries. It seems to me that getting agreement, or consensus, on standards for bar coding is exactly the type of work that the NQF was created to do, and I can see several advantages to FDA in using voluntary consensus standards for bar coding, instead of FDA having to determine which standards to use. I would be happy to provide you with further information about current work that we are doing for CMS, AHRQ and NCI, if that would be helpful in your consideration.

Second, it was under my direction as Under Secretary for Health that VA launched its award winning bar code medication administration (BCMA) system. I suspect that you already have had substantial dialogue with VA about its BCMA, but if I can provide any additional perspective from my former vantage point as the CEO of the veterans healthcare system, I hope that you will not hesitate to contact me.

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Please feel free to call me (202.783.1300) at any time if I or the NQF can be helpful to your efforts.

Sincerely,

Kenneth W. Kizer, M.D., M.P.H.  
President and Chief Executive Officer

cc: Steven Galson, M.D., M.P.H.  
Deputy Director, Center for Drug Evaluation and Research  
Food and Drug Administration  
1451 Rockville Pike, HFD-001  
Rockville, MD 20852