

**STATEMENT OF
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TO THE
SUBCOMMITTEE ON HEALTH,
COMMITTEE ON ENERGY AND COMMERCE,
U.S. HOUSE OF REPRESENTATIVES
ON
PATIENT SAFETY AND QUALITY INITIATIVES**

June 9, 2005

On behalf of the National Quality Forum's (NQF) more than 260 member organizations (please see attached membership list), I am pleased to offer this brief statement for the record. I commend the Subcommittee for holding this hearing, as the need for improvement in healthcare quality and safety measures is urgent and great synergism can be achieved through guided collaboration of the public and private sectors and federal and state governments.

Background

Healthcare quality, including safety, in the United States presents a paradox. In some ways American healthcare is the envy of the world, offering millions of patients ready access to highly skilled, committed professionals working in state-of-the-art healthcare institutions, having all the advantages of the latest innovations in biomedical research, technology, and treatment. At the same time, the "system" is fragmented and uncoordinated, often difficult to access, very expensive, and suffers from serious and pervasive deficiencies in quality. Five years ago, in a landmark study, the Institute of Medicine (IOM)

reported that 44,000 to 98,000 deaths each year are directly attributable to medical errors that occur in hospitals alone. Despite much activity since then, I am unaware of any evidence showing that we have truly succeeded in reducing this medical carnage.

The absence of a national electronic health information management system to support coordinated, comprehensive, patient-centered healthcare contributes to the occurrence of medical errors; hinders efforts to measure and improve health system performance; and makes improvements in efficiency extremely difficult.

NQF and Patient Safety

I would like to briefly describe the role of NQF as it relates to the subject of this hearing, and describe some of the activities we have both pursued and spawned that may be of interest to the Subcommittee as it moves this very important agenda forward.

NQF is a not-for-profit membership organization created in 1999 to standardize national performance measures and quality indicators for healthcare; to develop a national strategy for healthcare quality measurement and reporting; to serve as an “honest broker” for convening multidisciplinary, multi-stakeholder groups to work on healthcare quality issues; and to do other things, as needed, to improve healthcare quality. It was established pursuant to a recommendation of the President’s Advisory Commission on Consumer Protection and Quality in the Health Care Industry. The Commission felt that a Forum needed to exist where healthcare stakeholders from both the private and public sectors could come together to achieve accord about a coherent way to improve the quality of American healthcare.

NQF is a *voluntary consensus standards setting body* as specified by the National Technology and Transfer Advancement Act of 1995 and OMB Circular A-119 (1998). NQF uses a formal Consensus Development Process that resembles federal rulemaking in a number of ways, and is more explicit than many other consensus processes used by voluntary consensus standards setting bodies – e.g., that used by the American National Standards Institute (ANSI). The performance measures endorsed via the CDP can be used for both public reporting and accountability purposes or for internal quality improvement activities.

Among the work the NQF has done to date has been to endorse performance measures in the areas of acute hospital care, nursing homes, and home health, as well as measures addressing such high priority concerns as diabetes, cardiac surgery, and nursing-sensitive care. Other projects are underway to address cancer, deep vein thrombosis, and ambulatory care, among other things. In addition, and of particular relevance to this hearing, we have endorsed a set of *Serious Reportable Events in Healthcare*, which now serves as the basis of state-based mandatory adverse event reporting initiatives in several states, and *Safe Practices for Better Healthcare*, a set of 30 practices that, if universally utilized in all applicable settings, would substantially reduce the risk of medical error. These 30 practices provide a clear roadmap for what needs to be done now to improve the safety of healthcare. It is to these two latter projects that I would like to direct the Subcommittee's attention.

Serious Reportable Events in Healthcare

Lapses in patient safety are a major healthcare quality problem. Currently, few data exist to provide reliable and consistent information on the number and type of the most serious, preventable adverse events. Moreover, even where data are reported, the completeness and reliability of such reporting varies widely by locale.

The objective of NQF's project on Serious Reportable Events in Healthcare, which was completed in 2002, was to establish consensus on a set of serious, preventable adverse events that might form the basis for a national state-based event reporting system and that could lead to substantial improvements in patient safety. The primary reason for identifying an unambiguous, standardized set of serious reportable events that would be reported was to facilitate public accountability toward improvement of safety.

While NQF's work in this area did not explicitly call for mandatory reporting of these events, the IOM did recommend such. Clearly, using the list of events recommended in this report would enable standardized data collection and reporting of such events within and across states.

NQF's report on Serious Reportable Events in Healthcare identifies 27 adverse events that should be reported by all licensed healthcare facilities. The events are grouped into six categories: surgical, product or device, patient protection, care management, environmental, and criminal acts. (List is attached at the end of this statement.)

The states of Minnesota, New Jersey and Connecticut have enacted statutes making this list the basis for their medical error reporting requirements. Other states have adopted the list by regulation. The Department of Defense now requires that TRICARE providers report on these events. Multiple other states are considering adoption of the list of reportable events as well.

We believe that there would be distinct advantages for a national approach to the utilization of a well-defined, standardized list of reportable events about which healthcare consumers, providers, purchasers and other stakeholders have come to consensus.

Safe Practices for Better Healthcare

In 2003, the NQF published *Safe Practices for Better Healthcare*, a set of 30 practices that, if universally utilized in all applicable settings, would substantially reduce the risk of medical error. Examples from the set of practices include: create a culture of safety; implement a standardized protocol to prevent the occurrence of wrong-site procedures or wrong-patient procedures; repeat back of verbal orders; and vaccinate healthcare workers against influenza to protect both them and patients from influenza. (Please see attached list of the 30 Safe Practices.) Although this set of safe practices does not capture all activities that might reduce adverse healthcare events, it, like all NQF consensus projects, was carefully reviewed and endorsed by a diverse group of stakeholders.

Specifically, the set focuses on high-priority practices that:

- have strong evidence that they are effective in reducing the likelihood of harming a patient;
- are generalizable (i.e., they may be applied in multiple clinical care settings and/or multiple types of patients);
- are likely to have a significant benefit to patient safety if fully implemented; and
- have knowledge about them that is usable by consumers purchasers, providers, and researchers.

Since the NQF endorsed Safe Practices in 2003, we have seen multiple examples of its implementation. For example, the Leapfrog Group, a coalition of approximately 170 Fortune 500 companies and other large private and public organizations that provide health benefits for their employees, retirees and dependents, incorporates all 30 Safe Practices into its survey of hospitals that collects data on patient safety and encourages hospitals to implement safety practices. The net effect is that the Leapfrog Group is collecting data on

implementation of Safe Practices by nearly 1,100 hospitals in selected regions across the United States.

The NQF has also selectively pursued its own implementation activities with Safe Practices. These include, but are not limited to, work on “informed consent” (Safe Practice 10). The “informed consent” discussion is designed, using words or means understandable to the patient, to ensure that the patient understands the healthcare procedure or service he or she is about to receive. In December 2003, under a grant from the Commonwealth Fund, the NQF embarked on a project to identify strategies for accelerating widespread adoption of the NQF-endorsed voluntary consensus standard for informed consent. This safe practice stood out among the 30 practices because of its cross-cutting relevance across clinical areas, its focus on patient-centered care, and its importance to patients who are particularly vulnerable to receiving poor-quality care and being exposed to medical errors because of communication barriers. These patients often are those with limited health literacy, which includes both those with limited English proficiency (LEP) and native English speakers who have difficulty understanding healthcare terms and concepts. We would be happy to provide more detailed information about the project if the Subcommittee would like to know more about it.

The NQF is publishing an informed consent “user’s guide” designed to assist providers and hospital administrators to implement this safe practice. The user’s guide and findings from the project, including workshop proceedings, are currently in press and will be made available to the public this summer.

Safe Medication Use is a key issue that is addressed in a number of the Safe Practices. One longstanding concern between healthcare providers and the patients they serve is how to ensure that patients follow treatment recommendations once they leave the medical setting—often referred to as “adherence” or “compliance” in healthcare. Poor patient adherence in use of

prescription medications is especially problematic, given medication use by the majority of those who receive healthcare services, and its impact on healthcare spending.

In 2002, approximately 1.5 billion prescription drugs were provided or prescribed in outpatient care alone. Outpatient prescription medicine spending totaled \$102 billion in 2000, comprising about one-tenth of the total U.S. healthcare spending and representing the fastest growing medical expenditure. More than 40% of Americans take at least one prescription drug and 16% take at least three. Given the magnitude of use and the cost of prescription medications, improving adherence could potentially have a far greater impact on population health than any individual advancement in medical treatment. While appropriate use of prescription medications improves health outcomes, inappropriate use—which commonly occurs—can result in permanent harm, life-threatening situations, and death, not to mention the waste of valuable healthcare resources.

NQF initiated a project in March 2004 to address the need for a coordinated, national action plan to improve consumer adherence in the use of prescription medications. The project was an initial exploratory effort to evaluate the major issues and promising practices or measures for their potential future use as voluntary consensus standards, with a special emphasis on populations that have greater difficulty understanding how to take these medications appropriately—i.e., those with limited health literacy, including those with limited English proficiency. The project culminated in a multi-stakeholder workshop to recommend a national action plan for improving use of prescription medications. A project report is under development and will be available in mid-summer 2005.

Conclusion

The quality of American healthcare is not as good as it could or should be. Overuse, underuse, and misuse of medical care are found in all types of healthcare delivery systems and with all types of healthcare financing. These

quality problems affect all patients, regardless of age, gender, financial resources, race, or ethnicity. Although tens of millions of Americans reap the benefits of modern healthcare each year, millions of others are exposed to unnecessary risks, denied opportunities for improved health, or are injured or killed as a result of medical errors. We need to do a better job of reporting these errors, and of providing a safe and confidential environment for doing so, within the context of a reporting system that encourages a culture of safety.

I do not believe that anyone expects the federal government to solve these problems singlehandedly. However, in its dual role as maker and enforcer of laws and the nation's largest single purchaser of healthcare, the federal government can have a very important catalytic effect on healthcare quality and safety improvement, to the benefit of the American healthcare consumer, by rewarding quality and by encouraging healthcare providers to implement proven strategies that would substantially reduce medical errors and improve patient safety. The National Quality Forum has already provided a roadmap for how such work can be done and is continuing to move this agenda forward. The NQF stands ready to work with both the government and the private sector in any way that we can to help make these efforts more effective.

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Consumers Advancing Patient Safety
Consumers' Checkbook
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Council of Medical Specialty Societies
CRG Medical
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Exempla Healthcare
Federation of American Hospitals
First Consulting Group
First Health
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Florida Initiative for Children's Healthcare Quality
Ford Motor Company
Forum of End Stage Renal Disease Networks
General Motors
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Robert Wood Johnson University Hospital - New Brunswick
Roswell Park Cancer Institute
Sanofi-Synthelabo
Schaller Anderson
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Sisters of Charity of Leavenworth Health System
Sisters of Mercy Health System
Society for Healthcare Epidemiology of America
Society of Thoracic Surgeons
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St. Mary's Hospital Medical Center
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Sutter Health
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Tenet Healthcare
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Triad Hospitals
Trinity Health
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United Hospital Fund
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US Office of Personnel Management
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Washington State Health Care Authority
WellPoint
West Virginia Medical Institute
Wisconsin Collaborative for Healthcare Quality
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NQF-Endorsed Set of Safe Practices

1. Create a healthcare culture of safety.
2. For designated high-risk, elective surgical procedures or other specified care, patients should be clearly informed of the likely reduced risk of an adverse outcome at treatment facilities that have demonstrated superior outcomes and should be referred to such facilities in accordance with the patient's stated preference.
3. Specify an explicit protocol to be used to ensure an adequate level of nursing based on the institution's usual patient mix and the experience and training of its nursing staff.
4. All patients in general intensive care units (both adult and pediatric) should be managed by physicians having specific training and certification in critical care medicine ("critical care certified").
5. Pharmacists should actively participate in the medication-use process, including, at a minimum, being available for consultation with prescribers on medication ordering, interpretation and review of medication orders, preparation of medications, dispensing of medications, and administration and monitoring of medications.
6. Verbal orders should be recorded whenever possible and immediately read back to the prescriber – i.e., a healthcare provider receiving a verbal order should read or repeat back the information that the prescriber conveys in order to verify the accuracy of what was heard.
7. Use only standardized abbreviations and dose designations.
8. Patient care summaries or other similar records should not be prepared from memory.
9. Ensure that care information, especially changes in orders and new diagnostic information, is transmitted in a timely and clearly understandable form to all of the patient's current healthcare providers who need that information to provide care.
10. Ask each patient or legal surrogate to recount what he or she has been told during the informed consent discussion.
11. Ensure that written documentation of the patient's preference for life-sustaining treatments is prominently displayed in his or her chart.
12. Implement a computerized prescriber order entry system.
13. Implement a standardized protocol to prevent the mislabeling of radiographs.
14. Implement standardized protocols to prevent the occurrence of wrong-site procedures or wrong-patient procedures.
15. Evaluate each patient undergoing elective surgery for risk of an acute ischemic cardiac event during surgery, and provide prophylactic treatment of high-risk patients with beta blockers.
16. Evaluate each patient upon admission, and regularly thereafter, for the risk of developing pressure ulcers. This evaluation should be repeated at regular intervals during care. Clinically appropriate preventive methods should be implemented consequent to the evaluation.
17. Evaluate each patient upon admission, and regularly thereafter, for the risk of developing deep vein thrombosis (DVT)/venous thromboembolism (VTE). Utilize clinically appropriate methods to prevent DVT/VTE.
18. Utilize dedicated anti-thrombotic (anti-coagulation) services that facilitate coordinated care management.
19. Upon admission, and regularly thereafter, evaluate each patient for the risk of aspiration.
20. Adhere to effective methods of preventing central venous catheter-associated blood stream infections.

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21. Evaluate each pre-operative patient in light of his or her planned surgical procedure for the risk of surgical site infection, and implement appropriate antibiotic prophylaxis and other preventive measures based on that evaluation.
22. Utilize validated protocols to evaluate patients who are at risk for contrast media-induced renal failure, and utilize a clinically appropriate method for reducing risk of renal injury based on the patient's kidney function evaluation.
23. Evaluate each patient upon admission, and regularly thereafter, for risk of malnutrition. Employ clinically appropriate strategies to prevent malnutrition.
24. Whenever a pneumatic tourniquet is used, evaluate the patient for the risk of an ischemic and/or thrombotic complication, and utilize appropriate prophylactic measures.
25. Decontaminate hands with either a hygienic hand rub or by washing with a disinfectant soap prior to and after direct contact with the patient or objects immediately around the patient.
26. Vaccinate healthcare workers against influenza to protect both them and patients from influenza.
27. Keep workspaces where medications are prepared clean, orderly, well lit, and free of clutter, distraction, and noise.
28. Standardize the methods for labeling, packaging, and storing medications.
29. Identify all "high alert" drugs (e.g., intravenous adrenergic agonists and antagonists, chemotherapy agents, anticoagulants and anti-thrombotics, concentrated parenteral electrolytes, general anesthetics, neuromuscular blockers, insulin and oral hypoglycemics, narcotics and opiates).
30. Dispense medications in unit-dose or, when appropriate, unit-of-use form, whenever possible.

See full report for applicable care settings for each practice, detailed specifications, and additional background and reference material.

Source: National Quality Forum,
Safe Practices for Better Healthcare,
NQF: Washington, DC, 2003

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Serious Reportable Events in Healthcare

1. SURGICAL EVENTS

- A. Surgery performed on the wrong body part
- B. Surgery performed on the wrong patient
- C. Wrong surgical procedure performed on a patient
- D. Retention of a foreign object in a patient after surgery or other procedure
- E. Intraoperative or immediately post-operative death in an ASA Class I patient

2. PRODUCT OR DEVICE EVENTS

- A. Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the healthcare facility
- B. Patient death or serious disability associated with the use or function of a device in patient care in which the device is used or functions other than as intended
- C. Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in a healthcare facility

3. PATIENT PROTECTION EVENTS

- A. Infant discharged to the wrong person
- B. Patient death or serious disability associated with patient elopement (disappearance) for more than four hours
- C. Patient suicide, or attempted suicide resulting in serious disability, while being cared for in a healthcare facility

4. CARE MANAGEMENT EVENTS

- A. Patient death or serious disability associated with a medication error (e.g., errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation or wrong route of administration)
- B. Patient death or serious disability associated with a hemolytic reaction due to the administration of ABO-incompatible blood or blood products
- C. Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in a healthcare facility
- D. Patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for in a healthcare facility
- E. Death or serious disability (kernicterus) associated with failure to identify and treat hyperbilirubinemia in neonates
- F. Stage 3 or 4 pressure ulcers acquired after admission to a healthcare facility
- G. Patient death or serious disability due to spinal manipulative therapy

5. ENVIRONMENTAL EVENTS

- A. Patient death or serious disability associated with an electric shock while being cared for in a healthcare facility
- B. Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by toxic substances
- C. Patient death or serious disability associated with a burn incurred from any source while being cared for in a healthcare facility
- D. Patient death associated with a fall while being cared for in a healthcare facility
- E. Patient death or serious disability associated with the use of restraints or bedrails while being cared for in a healthcare facility

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6. CRIMINAL EVENTS

- A. Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider
- B. Abduction of a patient of any age
- C. Sexual assault on a patient within or on the grounds of a healthcare facility
- D. Death or significant injury of a patient or staff member resulting from a physical assault (i.e., battery) that occurs within or on the grounds of a healthcare facility

See full report for applicable care settings for each practice, detailed specifications, and additional background.

Source: National Quality Forum,
Serious Reportable Events in Healthcare,
NQF: Washington, DC, 2002