

June 7, 2005

The Honorable Bill Frist, MD  
Majority Leader  
United States Senate  
Washington, DC 20510

Dear Mr. Leader:

Since the landmark 1999 Institute of Medicine (IOM) report “To Err is Human, Building a Safer Health System,” there have been ongoing efforts by healthcare systems, healthcare professionals, public health organizations, and other stakeholders to encourage the reporting and evaluation of patient safety information and the sharing of such information with others. The full potential for these efforts will remain unrealized, however, until federal patient safety legislation is passed by Congress, as recommended by the IOM, that establishes an environment in which health care professionals and organizations can report and analyze health care errors and share their experiences with others in order to prevent similar occurrences.

Broad agreement has been reached on the need for patient safety legislation that incorporates the attached General Principles for Patient Safety Reporting Systems. Even with such widespread support, legislation has not been enacted because efforts to negotiate a bicameral, bipartisan comprehensive patient safety bill have not yielded an agreement.

The undersigned organizations have no shared position on the issues that divide negotiators but in unison we strongly urge that Congress find common ground and pass a bill without further delay. Such legislation will allow the full implementation of reporting programs and improve patient safety and the quality of care for patients nationwide.

We respectfully urge you and your colleagues to pass a patient safety bill that the President will sign and that will improve and protect the safety of America’s patients.

Respectfully,

Academy of Managed Care Pharmacy  
Alaska State Medical Association  
American Academy of Child and Adolescent Psychiatry  
American Academy of Dermatology Association  
American Academy of Facial, Plastic and Reconstructive Surgery  
American Academy of Family Physicians  
American Academy of Neurology  
American Academy of Ophthalmology  
American Academy of Otolaryngology – Head and Neck Surgery

American Academy of Physical Medicine and Rehabilitation  
American Academy of Cosmetic Surgery  
American Academy of Physician Assistants  
American Academy of Sleep Medicine  
American Association of Clinical Endocrinologists  
American Association of Clinical Urologists  
American Association of Hip and Knee Surgeons  
American Association of Neurological Surgeons  
American Association of Neuromuscular and Electrodiagnostic Medicine  
American Association of Orthopaedic Surgeons  
American College of Cardiology  
American College of Chest Physicians  
American College of Emergency Physicians  
American College of Gastroenterology  
American College of Medical Quality  
American College of Obstetricians and Gynecologists  
American College of Osteopathic Family Physicians  
American College of Osteopathic Surgeons  
American College of Physicians  
American College of Preventive Medicine  
American College of Radiology Association  
American College of Rheumatology  
American College of Surgeons  
American Gastroenterological Association  
America Geriatrics Society  
American Health Care Association  
American Hospital Association  
American Medical Association  
American Medical Directors Association  
American Medical Group Association  
American Nurses Association  
American Osteopathic Academy of Orthopedics  
American Osteopathic Association  
American Pharmacists Association  
American Psychiatric Association  
American Society for Clinical Pathology  
American Society for Gastrointestinal Endoscopy  
American Society for Healthcare Risk Management  
American Society for Quality  
American Society for Reproductive Medicine  
American Society for Therapeutic Radiology and Oncology  
American Society of Addiction Medicine  
American Society of Anesthesiologists  
American Society of Cataract and Refractive Surgery  
American Society of Cytopathology  
American Society of General Surgeons

American Society of Health-System Pharmacists  
American Society of Nephrology  
American Society of Plastic Surgeons  
American Thoracic Society  
American Urological Association  
America's Health Insurance Plans  
Arizona Medical Association  
Arkansas Medical Society  
Association of American Medical Colleges  
California Medical Association  
College of American Pathologists  
Colorado Medical Society  
Connecticut State Medical Society  
Congress of Neurological Surgeons  
Federation of American Hospitals  
Florida Medical Association  
Hawaii Pharmacists Association  
Heart Rhythm Society  
Illinois State Medical Society  
Indiana State Medical Association  
Institute for Safe Medication Practices  
Joint Commission on Accreditation of Healthcare Organizations  
Kansas Medical Society  
Kentucky Medical Association  
Maine Medical Association  
Maryland Pharmacists Association  
Massachusetts Medical Society  
MedChi, the Maryland State Medical Society  
Medical Association of Georgia  
Medical Group Management Association  
Medical Society of Delaware  
Medical Society of the District of Columbia  
Medical Society of the State of New York  
Medical Society of Virginia  
Midwestern University, Chicago College of Pharmacy  
Minnesota Medical Association  
Mississippi State Medical Association  
Missouri State Medical Association  
Montana Medical Association  
National Medical Association  
National Patient Safety Foundation  
Nebraska Medical Association  
Nevada State Medical Association  
New Hampshire Medical Society  
New Mexico Medical Society  
North Dakota Medical Association

Ohio State Medical Association  
Oklahoma State Medical Association  
Oregon Medical Association  
Pennsylvania Medical Society  
Pharmacy Society of Wisconsin  
Premier, Inc.  
Renal Physicians Association  
Rhode Island Medical Society  
Society for Cardiovascular Angiography and Interventions  
Society for Maternal-Fetal Medicine  
Society for Vascular Surgery  
Society of Critical Care Medicine  
Society of Hospital Medicine  
Society of Interventional Radiology  
Society of Thoracic Surgeons  
South Carolina Medical Association  
South Dakota State Medical Association  
SUNY-Upstate Medical University  
Tennessee Medical Association  
Texas Medical Association  
The United States Pharmacopeia Convention, Inc.  
Vermont Medical Society  
VHA Inc.  
Washington State Medical Association  
Washington State Pharmacy Association  
West Virginia Pharmacists Association  
Wisconsin Medical Society  
Wyoming Medical Society

cc: United States Senate

## Patient Safety Working Group

### General Principles for Patient Safety Reporting Systems

1. **Creating an Environment for Safety.** *There should be a nonpunitive culture for reporting healthcare errors that focuses on preventing and correcting systems failures and not on individual or organization culpability.*
  - Healthcare professionals and organizations should foster a positive atmosphere that encourages the submission of healthcare error reports to public or private oversight organizations, accrediting bodies, an official compendial body, or other generally recognized patient safety reporting systems. The existence of a reporting system does not relieve healthcare professionals and organizations of their responsibility to maintain professionally recognized standards of care.
2. **Data Analysis.** *Information submitted to reporting systems must be comprehensively analyzed to identify actions that would minimize the risk that reported events recur.*
  - Systems within organizations should be scrutinized to identify weaknesses and processes that make healthcare errors possible or likely to occur, and to identify actions to prevent future errors. Effective procedures and/or protocols developed through reporting systems should be compiled and widely disseminated to all healthcare professionals and organizations.
3. **Confidentiality.** *Confidentiality protections for patients, healthcare professionals, and healthcare organizations are essential to the ability of any reporting system to learn about errors and effect their reduction.*
  - Reporting systems should protect the identity of individual patients and abide by all relevant confidentiality laws and regulations. The identities of healthcare professionals and organizations involved in errors should not be disclosed outside a reporting system without consent.
4. **Information Sharing.** *Reporting systems should facilitate the sharing of patient safety information among healthcare organizations and foster confidential collaboration with other healthcare reporting systems.*
  - Sharing information is fundamental to a reporting system's ability to achieve widespread improvements in patient safety and to instill a confidence in the public that safety issues are being addressed. Sharing of error-related information is subject to the confidentiality principle.
  - The causes of errors and their solutions must be widely shared so that all healthcare organizations can learn from the experiences of others.

- In some circumstances, it will be desirable to share reports of errors among reporting systems, and with other appropriate quality improvement entities, in order to accomplish root cause analyses, to construct action plans, and to engage in other efforts to enhance patient safety.

5. **Legal Status of Reporting System Information.** *The absence of federal protection for information submitted to patient safety reporting systems discourages the use of such systems, which reduces the opportunity to identify trends and implement corrective measures. Information developed in connection with reporting systems should be privileged for purposes of federal and state judicial proceedings and for purposes of federal and state administrative proceedings, including with respect to discovery, subpoenas, testimony, or any other form of disclosure.*

**(a) Scope.** The privilege for the information prepared for a reporting system should extend to any data, report, memorandum, analysis, statement, or other communication developed for the purposes of the system. This privilege should not interfere with the disclosure of information that is otherwise available, including the right of individuals to access their own medical records.

**(b) No Waiver.** The submission of healthcare error information to a reporting system, or the sharing of information by healthcare organizations or reporting systems with third parties in accordance with these principles, should not be construed as waiving this privilege or any other privilege under federal or state law that exists with respect to the information.

**(c) Freedom of Information Act.** Healthcare error information received by and from reporting systems should be exempt from the Freedom of Information Act and other similar state laws. Such an exemption is necessary to preserve the privilege discussed in this principle.

**(d) Impact on State Law.** A federal law is necessary to assure protection of information submitted to national reporting systems, but the federal protection should not preempt state evidentiary laws that provide greater protection than federal law. Providing such information to reporting systems should not constitute a waiver of any state law privilege.