APPENDIX D

Characteristics of State Adverse Event Reporting Systems

CALIFORNIA

Reportable event	Occurrences such as epidemic outbreaks, poisonings, fires, major accidents, death from unnatural causes, or other catastrophes and unusual occurrences that threaten the welfare, safety, or health of patients, personnel, or visitors. Other occurrences include, but are not limited to, prevalence of communicable disease; infestation by parasites or vectors; disappearance or loss of a patient or inmate-patient; sexual acts involving patients who are minors; nonconsenting adults, or persons incapable of consent; physical assaults on inmate–patients, employees, or visitors; and all suspected criminal activity involving inmate–patients, employees, or visitors.
Who submits reports	General acute care hospitals, acute psychiatric hospitals, skilled nursing facilities, immediate care facilities, home health agencies, primary care clinics, psychology clinics, psychiatric health facilities, adult day health centers, chemical dependency recovery hospitals, and correctional treatment centers.
Number of reports	4,337 (1998)
Year initiated	1972 (approximately)
Mandatory or voluntary	Mandatory; must be submitted within 24 hours of the incident.
Access to information	Reports that do not contain confidential information are accessible to the public. Reports that do contain confidential information can be obtained only by subpoena. The local licensing and certification office handles all requests for copies of reports.

Use of Information	The state reviews the reported event and determines if an onsite visit is warranted. If violations of the regulations are suspected an onsite visit is conducted. If deficiencies are noted the facility must submit an acceptable plan of correction. Violation of regulations can also result in state or federal citations. Civil penalties of up to $50 per day or enforcement actions can be imposed.

COLORADO

Reportable event	All deaths arising from unexplained causes or under suspicious circumstances. Brain and spinal cord injuries. Life-threatening complications of anesthesia. Life-threatening transfusion errors or reactions. Burns; missing persons; physical, sexual, and verbal abuse; neglect, misappropriation of property; diverted drugs; malfunction or misuse of equipment.
Who submits reports	All state-licensed health care facilities.
Number of reports	1,233 (1998)
Year initiated	1989
Mandatory or voluntary	Mandatory under Colorado State Statute 25-1-124(2).
Access to information	The name of the facility is disclosed. Patient and personnel information is kept confidential. Report summaries are posted on the Internet once the facility investigation is complete.
Use of information	An advisory committee meets monthly to identify patterns and issues. Summaries of the reviewed reports are sent out to the facilities and they have seven days to comment. The state will issue deficiencies if deemed necessary. All information is entered into a computer program for tracking. Surveyors and investigators review the information in the institution-specific database prior to conducting the regular survey and complaint investigations.

CONNECTICUT

Reportable event	All accidents or incidents that resulted in serious injury, death, or disruption of facility services.
Who submits reports	Nursing homes and hospitals.
Number of reports	14,783 (1996)—approximately 14,000 from nursing homes.
Year initiated	1987
Mandatory or voluntary	Mandatory for nursing homes; voluntary for hospitals.

Access to information	Reports disclose the name of the facility, but no information on patients or personnel. To obtain a report, one must fill out a Freedom of Information Act form and submit the request to the health department.
Use of information	Information is reviewed by a nurse consultant who determines if there needs to be an investigation by the health department.

FLORIDA

Reportable event	Urgent issue: life-threatening situation, epidemic outbreak. Code 15: serious adverse event (i.e., wrongful death, brain injury, wrong limb removal, incorrect surgery).
Who submits reports	Hospitals and ambulatory surgical centers.
Number of reports	Approximately 5,000 a year; 4,000 are urgent issue and 1,000 are Code 15.
Year initiated	1985
Mandatory or voluntary	Mandatory
Access to information	A summary of the aggregate data collected from reports is issued once a year. All other information is confidential and cannot be released without a subpoena.
Use of information	Urgent-issue situations are considered to be outside the facility's control; and thus no facility follow-up is required. When reporting a Code 15, an analysis of the injury and a plan of correction must be submitted by the facility within 15 days. The state's risk management program tracks trends in the reporting.

MASSACHUSETTS

Reportable event	Injury that is life-threatening, results in death, or requires a patient to undergo significant additional diagnostic or treatment measures. Medication errors. Major biomedical device or other equipment failure resulting in serious injury or having potential for serious injury. Surgical errors involving the wrong patient, the wrong side of the body, the wrong organ, or the retention of a foreign object. Blood transfusion errors. Any maternal death within 90 days of delivery or termination of a pregnancy. Death of a patient by suicide.
Who submits reports	All licensed health care facilities.
Number of reports	10,500 (1997); 390 were from hospitals
Year initiated	1986
Mandatory or voluntary	Mandatory

Access to information	Copies of reports submitted by facilities are available to the public after official action has been taken by the health department. The identity of the patient is removed. Reports relating to abuse, neglect, or misappropriation are confidential and are not released.
Use of information	All reports are entered into a Massachusetts Health Department database and are reviewed. This database is used to retain information on the individual case and look for general patterns across cases. Depending on the incident, the department can decide to contact the facility for more information or conduct a site visit. Deficiencies are cited if the facility is found to have not reported all relevant information.

NEW JERSEY

Reportable event	Any incident that endangers the health and safety of a patient or employee and any death or injury associated with anesthetics.
Who submits reports	All state licensed health care facilities
Number of reports	Not provided
Year initiated	1986
Mandatory or voluntary	Mandatory
Access to information	Information is disclosed only in the event that the facility receives a citation from the state. Penalty letters revealing the name of the facility and describing the incident that led to the citation are posted on the Internet. Patient and personnel information is kept confidential.
Use of information	If deemed necessary, a state inspection team is sent to investigate the facility. The team's findings are shared with the facility, which must comply with the report's recommendations or be cited with deficiencies. Then the facility must submit a plan of correction for each deficiency. The health department can impose fines, curtail admissions, appoint a temporary manager, issue a provisional license, suspend a facility's license, or close the facility.

NEW YORK

Reportable event	An unintended adverse and undesirable development in an individual patient's condition occurring in a hospital. A list of 47 occurrences is included on a specification of reportable events.
Who submits reports	Hospitals
Number of reports	15,000–20,000 reports each year
Year initiated	1986

Mandatory or voluntary	Mandatory
Access to information	Narrative reports on incidents and the investigations conducted are protected by law, but the state can release aggregate data by hospital, including the number of reports submitted. State actions against a facility are posted on the Internet (whether the source was the reporting system, patient complaint, or other).
Use of Information	The state may investigate specific incidents. If the hospital has taken action acceptable to the department, the case is closed. If the violation persists, the state may issue deficiencies or fines. The state also intends to develop regional error rates for benchmarking and dissemination to regional councils that are being formed.

OHIO

Reportable event	Death or injury resulting from equipment malfunction or treatment of the wrong subject or wrong modality.
Who submits reports	Free-standing therapy, imaging, and chemotherapy centers
Number of reports	Not provided
Year initiated	1997
Mandatory or voluntary	Mandatory
Access to information	Governed under Ohio's public record law. This law prohibits the collection of patient-specific information. The state will only be releasing aggregate data on the incidents reported. Facilities will have access only to their own information. The state plans to compile an annual report on incidents that will be available to the public.
Use of information	A database is being developed to track the number of reports received and provide an indicator of which facilities should be investigated. The goal is to identify noticeable trends in types of errors. The director of health monitors compliance and can inspect any health care provider. Health care providers may be required to regularly issue reports and undergo independent audits.

PENNSYLVANIA

Reportable event	An event that seriously compromises quality assurance or patient safety, including: deaths due to injuries, suicide, or unusual circumstances; deaths due to medication error; deaths due to malnutrition, dehydration, or sepsis; elopements; patient abuse; rape; surgery on the wrong patient or modality; hemolytic transfusion reaction; infant abduction or discharge to wrong family; fire or structural damage; unlicensed practice of a regulated profession.

Who submits reports	Hospitals, nursing homes, home health agencies, ambulatory surgical facilities, intermediate care facilities for persons with developmental disabilities.
Number of reports	Not provided
Year initiated	1990
Mandatory or voluntary	Mandatory
Access to information	All collected information is confidential. Reports are often shared only with another state agency. They are not considered public material and were not intended to provide information to the public. The department usually requests that courts overrule subpoenas, and in the majority of cases its request is granted.
Use of information	On some occasions, the department will request more information from a facility and conduct investigations. This is usually done when there is a recurrence of incidents or drug misappropriation. Very few cases have resulted in a fine to a facility following an adverse event.

KANSAS

Reportable event	An act by a health care provider that (1) is or may be below the applicable standard of care and has a reasonable probability of causing injury to a patient or (2) may be grounds for disciplinary action by the appropriate licensing agency.
Who submits reports	All licensed medical care facilities.
Number of Reports	488 (1997)
Year Initiated	1986
Mandatory or voluntary	Mandatory
Access to information	All reports are confidential. All peer review information and standard of care determinations are protected under the risk management statutes. Only the facts of the case have been subpoenaed. The name of the reporter is protected.
Use of information	Each facility must establish a written plan for risk management and patient care quality assessment on a facility-wide basis. This initial plan must be submitted to the health department at least 60 days prior to the licensure date. The plan will be reviewed and the facility will be notified in writing concerning plan approval. The facility's governing board must review and approve the risk management plan on an annual basis. All changes must be approved by the department. Following an incident, the department will review the facility's plan to ensure that it is adequate. Depending on the severity of the incident, the department will then possibly conduct an investigation.

MISSISSIPPI

Reportable event	Suicide or attempted suicide, wrongful death, unexplained injuries, abuse, and interruptions of service at the facility.
Who submits reports	All licensed health care facilities.
Number of reports	Not provided
Year initiated	1993
Mandatory or voluntary	Mandatory
Access to information	Actual reports are not accessible to the public; however statements of deficiencies and plans of correction are available by request. The health department does spend a great deal of time in litigation with malpractice attorneys who are attempting to subpoena its records.
Use of information	Attempts are made to identify trends in the data received, and the department's findings are discussed with the facility.

RHODE ISLAND

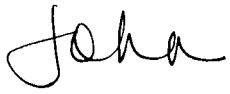
Reportable event	Any incident causing or involving the following: brain injury; mental impairment; paraplegia; quadriplegia; paralysis; loss of use of limb or organ; birth injury; impairment of sight or hearing; surgery on the wrong patient; subjecting a patient to any procedure that was not ordered or intended by the physician.
Who submits reports	Hospitals
Number of reports	134 (1998) from 15 facilities
Year initiated	1994
Mandatory or voluntary	Mandatory
Access to information	The names of personnel and patients are not disclosed in submitted reports. All reports are confidential and are protected by law. The hospital involved is contacted whenever the health department receives a subpoena from an attorney. The hospital may initiate proceedings to quash the subpoena. However, if the state takes action against the facility—for example, following a site investigation—then this information may be disclosed to the public.
Use of information	Reports are reviewed by department staff and filed. If deemed warranted, an investigation of the incident will be conducted. After submitting a report the hospital must conduct a peer review process to determine whether the incident falls within the normal range of outcomes, given the patient's condition. If the hospital's findings conclude that the incident was outside the normal range, the hospital must provide the health department with the following information: an explanation of the circumstances surround-

	ing the incident; an updated assessment of the effect of the incident on the patient; a summary of current patient status including follow-up care provided and post-incident diagnosis; and a summary of all actions taken to correct the problems identified to prevent recurrence and/or improve overall patient care. Incidents that are determined to have fallen within a normal range of outcomes by the hospital are reviewed by the health department. In the event that the health department disagrees with the hospital's findings, a separate investigation is conducted and peer review documents are examined.

SOUTH DAKOTA

Reportable event	Unnatural deaths; missing patients or residents; incidents of abuse, neglect, or misappropriation.
Who submits reports	All licensed health care facilities.
Number of reports	The health department has not kept track of the exact number of reports received. The majority are submitted by nursing homes.
Year initiated	1994
Mandatory or voluntary	Mandatory
Access to information	Reports are completely confidential, unless a deficient practice is identified at the facility. A summary of the cited deficiency is releasable information. As required by state law, a judicial court order must be issued before the health department will release any other information.
Use of information	Each incident report is analyzed to assess whether the facility did everything possible to avert the incident. If it did not, the facility will be cited and then they must develop a plan of correction.

SOURCE: Information for this table was collected from each state health department by telephone between February 24 and May 5, 1999. Each respondent was given the opportunity to review the draft and correct any errors.



Executive Summary

The knowledgeable health reporter for the Boston Globe, Betsy Lehman, died from an overdose during chemotherapy. Willie King had the wrong leg amputated. Ben Kolb was eight years old when he died during "minor" surgery due to a drug mix-up.[1]

These horrific cases that make the headlines are just the tip of the iceberg. Two large studies, one conducted in Colorado and Utah and the other in New York, found that adverse events occurred in 2.9 and 3.7 percent of hospitalizations, respectively.[2] In Colorado and Utah hospitals, 8.8 percent of adverse events led to death, as compared with 13.6 percent in New York hospitals. In both of these studies, over half of these adverse events resulted from medical errors and could have been prevented.

When extrapolated to the over 33.6 million admissions to U.S. hospitals in 1997, the results of the study in Colorado and Utah imply that at least 44,000 Americans die each year as a result of medical errors.[3] The results of the New York Study suggest the number may be as high as 98,000.[4] Even when using the lower estimate, deaths due to medical errors exceed the number attributable to the 8th leading cause of death.[5] More people die in a given year as a result of medical errors than from motor vehicle accidents (43,458), breast cancer (42,297), or AIDS (16,516).[6]

Total national costs (lost income, lost household production, disability and health care costs) of preventable adverse events (medical errors resulting in injury) are estimated to be between $17 billion and $29 billion, of which health care costs represent over one-half.[7]

In terms of lives lost, patient safety is as important an issue as worker safety. Every year, over 6,000 Americans die from workplace injuries.[8] Medication errors alone, occurring either in or out of the hospital, are estimated to account for over 7,000 deaths annually.[9]

Medication-related errors occur frequently in hospitals and although not all result in actual harm, those that do, are costly. One recent study conducted at two prestigious teaching hospitals, found that about two out of every 100 admissions experienced a preventable adverse drug event, resulting in average increased hospital costs of $4,700 per admission or about $2.8 million annually for a 700-bed teaching hospital.[10] If these findings are generalizable, the increased hospital costs alone of preventable adverse drug events affecting inpatients are about $2 billion for the nation as a whole.

These figures offer only a very modest estimate of the magnitude of the problem since hospital patients represent only a small proportion of the total population at risk, and direct hospital costs are only a fraction of total costs. More care and increasingly complex care is provided in ambulatory settings. Outpatient surgical centers, physician offices and clinics serve thousands of patients daily. Home care requires patients and their families to use complicated equipment and perform follow-up care. Retail pharmacies play a major role in filling prescriptions for patients and educating them about their use. Other institutional settings, such as nursing homes, provide a broad array of services to vulnerable populations. Although many of the available studies have focused on the hospital setting, medical errors present a problem in any setting, not just hospitals.

Errors are also costly in terms of opportunity costs. Dollars spent on having to repeat diagnostic tests or counteract adverse drug events are dollars unavailable for other purposes. Purchasers and patients pay for errors when insurance costs and copayments are inflated by services that would not have been necessary had proper care been provided. It is impossible for the nation to achieve the greatest value possible from the hundreds of millions of dollars spent on medical care if the care contains errors.

But not all the costs can be directly measured. Errors are also costly in terms of loss of trust in the system by patients and diminished satisfaction by both patients and health professionals. Patients who experience a longer hospital stay or disability as a result of errors pay with physical and psychological discomfort. Health care professionals pay with loss of morale and frustration at not being able to provide the best care possible. Employers and society, in general, pay in terms of lost worker productivity, reduced school attendance by children, and lower levels of population health status.

Yet silence surrounds this issue. For the most part, consumers believe they are protected. Media coverage has been limited to reporting of anecdotal cases. Licensure and accreditation confer, in the eyes of the public, a "Good Housekeeping Seal of Approval." Yet, licensing and accreditation processes have focused only limited attention on the issue, and even these minimal efforts have confronted some resistance from health care organizations and providers. Providers also perceive the medical liability system as a serious impediment to systematic efforts to uncover and learn from errors.[11]

The decentralized and fragmented nature of the health care delivery system (some would say "nonsystem") also contributes to unsafe conditions for pa-

tients, and serves as an impediment to efforts to improve safety. Even within hospitals and large medical groups, there are rigidly-defined areas of specialization and influence. For example, when patients see multiple providers in different settings, none of whom have access to complete information, it is easier for something to go wrong than when care is better coordinated. At the same time, the provision of care to patients by a collection of loosely affiliated organizations and providers makes it difficult to implement improved clinical information systems capable of providing timely access to complete patient information. Unsafe care is one of the prices we pay for not having organized systems of care with clear lines of accountability.

Lastly, the context in which health care is purchased further exacerbates these problems. Group purchasers have made few demands for improvements in safety.[12] Most third party payment systems provide little incentive for a health care organization to improve safety, nor do they recognize and reward safety or quality.

The goal of this report is to break this cycle of inaction. The status quo is not acceptable and cannot be tolerated any longer. Despite the cost pressures, liability constraints, resistance to change and other seemingly insurmountable barriers, it is simply not acceptable for patients to be harmed by the same health care system that is supposed to offer healing and comfort. "First do no harm" is an often quoted term from Hippocrates.[13] Everyone working in health care is familiar with the term. At a very minimum, the health system needs to offer that assurance and security to the public.

A comprehensive approach to improving patient safety is needed. This approach cannot focus on a single solution since there is no "magic bullet" that will solve this problem, and indeed, no single recommendation in this report should be considered as *the* answer. Rather, large, complex problems require thoughtful, multifaceted responses. The combined goal of the recommendations is for the external environment to create sufficient pressure to make errors costly to health care organizations and providers, so they are compelled to take action to improve safety. At the same time, there is a need to enhance knowledge and tools to improve safety and break down legal and cultural barriers that impede safety improvement. Given current knowledge about the magnitude of the problem, the committee believes it would be irresponsible to expect anything less than a 50 percent reduction in errors over five years.

In this report, safety is defined as freedom from accidental injury. This definition recognizes that this is the primary safety goal from the patient's perspective. Error is defined as the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim. According to noted expert James Reason, errors depend on two kinds of failures: either the correct action does not proceed as intended (an error of execution) or the original intended action is not correct, (an error of planning).[14] Errors can happen in all stages in the process of care, from diagnosis, to treatment, to preventive care.

Not all errors result in harm. Errors that do result in injury are sometimes called preventable adverse events. An adverse event is an injury resulting from a medical intervention, or in other words, it is not due to the underlying condition

of the patient. While all adverse events result from medical management, not all are preventable (i.e., not all are attributable to errors). For example, if a patient has surgery and dies from pneumonia he or she got postoperatively, it is an adverse event. If analysis of the case reveals that the patient got pneumonia because of poor hand washing or instrument cleaning techniques by staff, the adverse event was preventable (attributable to an error of execution). But the analysis may conclude that no error occurred and the patient would be presumed to have had a difficult surgery and recovery (not a preventable adverse event).

Much can be learned from the analysis of errors. All adverse events resulting in serious injury or death should be evaluated to assess whether improvements in the delivery system can be made to reduce the likelihood of similar events occurring in the future. Errors that do not result in harm also represent an important opportunity to identify system improvements having the potential to prevent adverse events.

Preventing errors means designing the health care system at all levels to make it safer. Building safety into processes of care is a more effective way to reduce errors than blaming individuals (some experts, such as Deming, believe improving processes is the *only* way to improve quality[15]). The focus must shift from blaming individuals for past errors to a focus on preventing future errors by designing safety into the system. This does not mean that individuals can be careless. People must still be vigilant and held responsible for their actions. But when an error occurs, blaming an individual does little to make the system safer and prevent someone else from committing the same error.

Health care is a decade or more behind other high-risk industries in its attention to ensuring basic safety. Aviation has focused extensively on building safe systems and has been doing so since World War II. Between 1990 and 1994, the U.S. airline fatality rate was less than one-third the rate experienced in mid century.[16] In 1998, there were no deaths in the United States in commercial aviation. In health care, preventable injuries from care have been estimated to affect between three to four percent of hospital patients.[17] Although health care may never achieve aviation's impressive record, there is clearly room for improvement.

To err is human, but errors can be prevented. Safety is a critical first step in improving quality of care. The Harvard Medical Practice Study, a seminal research study on this issue, was published almost ten years ago; other studies have corroborated its findings. Yet few tangible actions to improve patient safety can be found. Must we wait another decade to be safe in our health system?

RECOMMENDATIONS

The IOM Quality of Health Care in America Committee was formed in June 1998 to develop a strategy that will result in a threshold improvement in quality over the next ten years. This report addresses issues related to patient safety, a subset of overall quality-related concerns, and lays out a national

agenda for reducing errors in health care and improving patient safety. Although it is a national agenda, many activities are aimed at prompting responses at the state and local levels and within health care organizations and professional groups.

The committee believes that although there is still much to learn about the types of errors committed in health care and why they occur, enough is known today to recognize that a serious concern exists for patients. Whether a person is sick or just trying to stay healthy, they should not have to worry about being harmed by the health system itself. This report is a call to action to make health care safer for patients.

The committee believes that a major force for improving patient safety is the intrinsic motivation of health care providers, shaped by professional ethics, norms and expectations. But the interaction between factors in the external environment and factors inside health care organizations can also prompt the changes needed to improve patient safety. Factors in the external environment include availability of knowledge and tools to improve safety, strong and visible professional leadership, legislative and regulatory initiatives, and actions of purchasers and consumers to demand safety improvements. Factors inside health care organizations include strong leadership for safety, an organizational culture that encourages recognition and learning from errors, and an effective patient safety program.

In developing its recommendations, the committee seeks to strike a balance between regulatory and market-based initiatives, and between the roles of professionals and organizations. No single action represents a complete answer, nor can any single group or sector offer a complete fix to the problem. However, different groups can, and should, make significant contributions to the solution. The committee recognizes that a number of groups are already working on improving patient safety, such as the National Patient Safety Foundation and the Anesthesia Patient Safety Foundation.

The recommendations contained in this report lay out a four-tiered approach:

- establishing a national focus to create leadership, research, tools and protocols to enhance the knowledge base about safety;
- identifying and learning from errors through the immediate and strong mandatory reporting efforts, as well as the encouragement of voluntary efforts, both with the aim of making sure the system continues to be made safer for patients;
- raising standards and expectations for improvements in safety through the actions of oversight organizations, group purchasers, and professional groups; and
- creating safety systems inside health care organizations through the implementation of safe practices at the delivery level. This level is the ultimate target of all the recommendations.

Leadership and Knowledge

Other industries that have been successful in improving safety, such as aviation and occupational health, have had the support of a designated agency that sets and communicates priorities, monitors progress in achieving goals, directs resources toward areas of need, and brings visibility to important issues. Although various agencies and organizations in health care may contribute to certain of these activities, there is no focal point for raising and sustaining attention to patient safety. Without it, health care is unlikely to match the safety improvements achieved in other industries.

The growing awareness of the frequency and significance of errors in health care creates an imperative to improve our understanding of the problem and devise workable solutions. For some types of errors, the knowledge of how to prevent them exists today. In these areas, the need is for widespread dissemination of this information. For other areas, however, additional work is needed to develop and apply the knowledge that will make care safer for patients. Resources invested in building the knowledge base and diffusing the expertise throughout the industry can pay large dividends to both patients and the health professionals caring for them and produce savings for the health system.

RECOMMENDATION 4.1 Congress should create a Center for Patient Safety within the Agency for Health Care Policy and Research. This center should

- **set the national goals for patient safety, track progress in meeting these goals, and issue an annual report to the President and Congress on patient safety; and**
- **develop knowledge and understanding of errors in health care by developing a research agenda, funding Centers of Excellence, evaluating methods for identifying and preventing errors, and funding dissemination and communication activities to improve patient safety.**

To make significant improvements in patient safety, a highly visible center is needed, with secure and adequate funding. The Center should establish goals for safety; develop a research agenda; define prototype safety systems; develop and disseminate tools for identifying and analyzing errors and evaluate approaches taken; develop tools and methods for educating consumers about patient safety; issue an annual report on the state of patient safety, and recommend additional improvements as needed.

The committee recommends initial annual funding for the Center of $30 to $35 million. This initial funding would permit a center to conduct activities in goal setting, tracking, research and dissemination. Funding should grow over time to at least $100 million, or approximately 1% of the $8.8 billion in health care costs attributable to preventable adverse events.[18] This initial level of

funding is modest relative to the resources devoted to other public health issues. The Center for Patient Safety should be created within the Agency for Health Care Policy and Research because the agency is already involved in a broad range of quality and safety issues, and has established the infrastructure and experience to fund research, educational and coordinating activities.

Identifying and Learning from Errors

Another critical component of a comprehensive strategy to improve patient safety is to create an environment that encourages organizations to identify errors, evaluate causes and take appropriate actions to improve performance in the future. External reporting systems represent one mechanism to enhance our understanding of errors and the underlying factors that contribute to them.

Reporting systems can be designed to meet two purposes. They can be designed as part of a public system for holding health care organizations accountable for performance. In this instance, reporting is often mandatory, usually focuses on specific cases that involve serious harm or death, may result in fines or penalties relative to the specific case, and information about the event may become known to the public. Such systems ensure a response to specific reports of serious injury, hold organizations and providers accountable for maintaining safety, respond to the public's right to know, and provide incentives to health care organizations to implement internal safety systems that reduce the likelihood of such events occurring. Currently, at least twenty states have mandatory adverse event reporting systems.

Voluntary, confidential reporting systems can also be part of an overall program for improving patient safety and can be designed to complement the mandatory reporting systems previously described. Voluntary reporting systems, which generally focus on a much broader set of errors and strive to detect system weaknesses before the occurrence of serious harm, can provide rich information to health care organizations in support of their quality improvement efforts

For either purpose, the goal of reporting systems is to analyze the information they gather and identify ways to prevent future errors from occurring. The goal is *not* data collection. Collecting reports and not doing anything with the information serves no useful purpose. Adequate resources and other support must be provided for analysis and response to critical issues.

RECOMMENDATION 5.1 A nationwide mandatory reporting system should be established that provides for the collection of standardized information by state governments about adverse events that result in death or serious harm. Reporting should initially be required of hospitals and eventually be required of other institutional and ambulatory care delivery settings. Congress should

• designate the Forum for Health Care Quality Measurement and Reporting as the entity responsible for promulgating and maintaining a core set of reporting standards to be used by states, including a nomenclature and taxonomy for reporting;

• require all health care organizations to report standardized information on a defined list of adverse events;

• provide funds and technical expertise for state governments to establish or adapt their current error reporting systems to collect the standardized information, analyze it and conduct follow-up action as needed with health care organizations. Should a state choose not to implement the mandatory reporting system, the Department of Health and Human Services should be designated as the responsible entity; and

• designate the Center for Patient Safety to:

(1) convene states to share information and expertise, and to evaluate alternative approaches taken for implementing reporting programs, identify best practices for implementation, and assess the impact of state programs; and

(2) receive and analyze aggregate reports from States to identify persistent safety issues that require more intensive analysis and/or a broader-based response (e.g., designing prototype systems or requesting a response by agencies, manufacturers or others).

RECOMMENDATION 5.2 The development of voluntary reporting efforts should be encouraged. The Center for Patient Safety should

• describe and disseminate information on external voluntary reporting programs to encourage greater participation in them and track the development of new reporting systems as they form;

• convene sponsors and users of external reporting systems to evaluate what works and what does not work well in the programs, and ways to make them more effective;

• periodically assess whether additional efforts are needed to address gaps in information to improve patient safety and to encourage health care organizations to participate in voluntary reporting programs; and

• fund and evaluate pilot projects for reporting systems, both within individual health care organizations and collaborative efforts among health care organizations.

The committee believes there is a role both for mandatory, public reporting systems and voluntary, confidential reporting systems. However, because of

their distinct purposes, such systems should be operated and maintained separately. A nationwide mandatory reporting system should be established by building upon the current patchwork of state systems and by standardizing the types of adverse events and information to be reported. The newly established Forum for Health Care Quality Measurement and Reporting, a public/private partnership, should be charged with the establishment of such standards. Voluntary reporting systems should also be promoted and the participation of health care organizations in them should be encouraged by accrediting bodies.

RECOMMENDATION 6.1 Congress should pass legislation to extend peer review protections to data related to patient safety and quality improvement that are collected and analyzed by health care organizations for internal use or shared with others solely for purposes of improving safety and quality.

The committee believes that information about the most serious adverse events which result in harm to patients and which are subsequently found to result from errors should not be protected from public disclosure. However, the committee also recognizes that for events not falling under this category, fears about the legal discoverability of information may undercut motivations to detect and analyze errors to improve safety. Unless such data are assured protection, information about errors will continue to be hidden and errors will be repeated. A more conducive environment is needed to encourage health care professionals and organizations to identify, analyze, and report errors without threat of litigation and without compromising patients' legal rights.

Setting Performance Standards and Expectations for Safety

Setting and enforcing explicit standards for safety through regulatory and related mechanisms, such as licensing, certification, and accreditation, can define minimum performance levels for health care organizations and professionals. Additionally, the process of developing and adopting standards helps to form expectations for safety among providers and consumers. However, standards and expectations are not only set through regulations. The actions of purchasers and consumers affect the behaviors of health care organizations, and the values and norms set by health professions influence standards of practice, training and education for providers. Standards for patient safety can be applied to health care professionals, the organizations in which they work, and the tools (drugs and devices) they use to care for patients.

RECOMMENDATION 7.1 Performance standards and expectations for health care organizations should focus greater attention on patient safety.

• Regulators and accreditors should require health care organizations to implement meaningful patient safety programs with defined executive responsibility.

• Public and private purchasers should provide incentives to health care organizations to demonstrate continuous improvement in patient safety.

Health care organizations are currently subject to compliance with licensing and accreditation standards. Although both devote some attention to issues related to patient safety, there is opportunity to strengthen such efforts. Regulators and accreditors have a role in encouraging and supporting actions in health care organizations by holding them accountable for ensuring a safe environment for patients. After a reasonable period of time for health care organizations to develop patient safety programs, regulators and accreditors should require them as a minimum standard.

Purchaser and consumer demands also exert influence on health care organizations. Public and private purchasers should consider safety issues in their contracting decisions and reinforce the importance of patient safety by providing relevant information to their employees or beneficiaries. Purchasers should also communicate concerns about patient safety to accrediting bodies to support stronger oversight for patient safety.

RECOMMENDATION 7.2 Performance standards and expectations for health professionals should focus greater attention on patient safety.

• Health professional licensing bodies should

(1) implement periodic re-examinations and re-licensing of doctors, nurses, and other key providers, based on both competence and knowledge of safety practices; and

(2) work with certifying and credentialing organizations to develop more effective methods to identify unsafe providers and take action.

• Professional societies should make a visible commitment to patient safety by establishing a permanent committee dedicated to safety improvement. This committee should

(1) develop a curriculum on patient safety and encourage its adoption into training and certification requirements;

(2) disseminate information on patient safety to members through special sessions at annual conferences, journal articles and editorials, newsletters, publications and websites on a regular basis;

(3) recognize patient safety considerations in practice guidelines and in standards related to the introduction and diffusion of new technologies, therapies and drugs;

(4) work with the Center for Patient Safety to develop community-based, collaborative initiatives for error reporting and analysis and implementation of patient safety improvements; and

(5) collaborate with other professional societies and disciplines in a national summit on the professional's role in patient safety.

Although unsafe practitioners are believed to be few in number, the rapid identification of such practitioners and corrective action are important to a comprehensive safety program. Responsibilities for documenting continuing skills are dispersed among licensing boards, specialty boards and professional groups, and health care organizations with little communication or coordination. In their ongoing assessments, existing licensing, certification and accreditation processes for health professionals should place greater attention on safety and performance skills.

Additionally, professional societies and groups should become active leaders in encouraging and demanding improvements in patient safety. Setting standards, convening and communicating with members about safety, incorporating attention to patient safety into training programs and collaborating across disciplines are all mechanisms that will contribute to creating a culture of safety.

RECOMMENDATION 7.3 The Food and Drug Administration (FDA) should increase attention to the safe use of drugs in both pre- and post-marketing processes through the following actions:

- **develop and enforce standards for the design of drug packaging and labeling that will maximize safety in use;**
- **require pharmaceutical companies to test (using FDA-approved methods) proposed drug names to identify and remedy potential sound-alike and look-alike confusion with existing drug names; and**
- **work with physicians, pharmacists, consumers, and others to establish appropriate responses to problems identified through post-marketing surveillance, especially for concerns that are perceived to require immediate response to protect the safety of patients.**

The FDA's role is to regulate manufacturers for the safety and effectiveness of their drugs and devices. However, even approved products can present safety problems in practice. For example, different drugs with similar sounding names can create confusion for both patients and providers. Attention to the safety of products in actual use should be increased during approval processes and in

post-marketing monitoring systems. The FDA should also work with drug manufacturers, distributors, pharmacy benefit managers, health plans and other organizations to assist clinicians in identifying and preventing problems in the use of drugs.

Implementing Safety Systems in Health Care Organizations

Experience in other high-risk industries has provided well-understood illustrations that can be used to improve health care safety. However, health care management and professionals have rarely provided specific, clear, high-level, organization-wide incentives to apply what has been learned in other industries about ways to prevent error and reduce harm within their own organizations. Chief Executive Officers and Boards of Trustees should be held accountable for making a serious, visible and on-going commitment to creating safe systems of care.

RECOMMENDATION 8.1 Health care organizations and the professionals affiliated with them should make continually improved patient safety a declared and serious aim by establishing patient safety programs with defined executive responsibility. Patient safety programs should

- **provide strong, clear and visible attention to safety;**
- **implement non-punitive systems for reporting and analyzing errors within their organizations;**
- **incorporate well-understood safety principles, such as, standardizing and simplifying equipment, supplies and processes; and**
- **establish interdisciplinary team training programs for providers that incorporate proven methods of team training, such as simulation.**

Health care organizations must develop a culture of safety such that an organization's care processes and workforce are focused on improving the reliability and safety of care for patients. Safety should be an explicit organizational goal that is demonstrated by the strong direction and involvement of governance, management and clinical leadership. In addition, a meaningful patient safety program should include defined program objectives, personnel, and budget and should be monitored by regular progress reports to governance.

RECOMMENDATION 8.2 Health care organizations should implement proven medication safety practices.

A number of practices have been shown to reduce errors in the medication process. Several professional and collaborative organizations interested in pa-

tient safety have developed and published recommendations for safe medication practices, especially for hospitals. Although some of these recommendations have been implemented, none have been universally adopted and some are not yet implemented in a majority of hospitals. Safe medication practices should be implemented in all hospitals and health care organizations in which they are appropriate.

SUMMARY

This report lays out a comprehensive strategy for addressing a serious problem in health care to which we are all vulnerable. By laying out a concise list of recommendations, the committee does not underestimate the many barriers that must be overcome to accomplish this agenda. Significant changes are required to improve awareness of the problem by the public and health professionals, to align payment systems and the liability system so they encourage safety improvements, to develop training and education programs that emphasize the importance of safety and for chief executive officers and trustees of health care organizations to create a culture of safety and demonstrate it in their daily decisions.

Although no single activity can offer the solution, the combination of activities proposed offers a roadmap toward a safer health system. The proposed program should be evaluated after five years to assess progress in making the health system safer. With adequate leadership, attention and resources, improvements can be made. It may be part of human nature to err, but it is also part of human nature to create solutions, find better alternatives and meet the challenges ahead.

REFERENCES

1. Cook, Richard; Woods, David; Miller, Charlotte, *A Tale of Two Stories: Contrasting Views of Patient Safety*, Chicago, Illinois: National Patient Safety Foundation, 1998.

2. Brennan, Troyen A.; Leape, Lucian L.; Laird, Nan M., et al. Incidence of adverse events and negligence in hospitalized patients: Results of the Harvard Medical Practice Study I. N Engl J Med. 324:370–376, 1991. See also; Leape, Lucian L.; Brennan, Troyen A.; Laird, Nan M., et al. The Nature of Adverse Events in Hospitalized Patients: Results of the Harvard Medical Practice Study II. N Engl J Med. 324(6):377–384, 1991. See also;. Thomas, Eric J.; Studdert, David M.; Burstin, Helen R., et al. Incidence and Types of Adverse Events and Negligent Care in Utah and Colorado. Med Care forthcoming Spring 2000.

3. American Hospital Association. Hospital Statistics. Chicago, Il. 1999. See also: Thomas, Eric J.; Studdert, David M.; Burstin, Helen R., et al. Incidence and Types of Adverse Events and Negligent Care in Utah and Colorado. Med Care forthcoming Spring 2000. see also; Thomas, Eric J.; Studdert, David M.; Newhouse, Joseph P.; et al. Costs of Medical Injuries in Utah and Colorado. Inquiry 36:255-264, 1999

4. American Hospital Association. Hospital Statistics. Chicago, Il. 1999. See also; Brennan, Troyen A.; Leape, Lucian L.; Laird, Nan M., et al. Incidence of adverse events and negligence in hospitalized patients: Results of the Harvard Medical Practice Study I. N Engl J Med. 324:370-376, 1991. See also: Leape, Lucian L.; Brennan, Troyen A.; Laird, Nan M., et al. The Nature of Adverse Events in Hospitalized Patients: Results of the Harvard Medical Practice Study II. N Engl J Med. 324(6):377-384, 1991.

5. Centers for Disease Control and Prevention (National Center for Health Statistics). Deaths: Final Data for 1997. *National Vital Statistics Reports*. 47(19):27, 1999.

6. Centers for Disease Control and Prevention (National Center for Health Statistics). Births and Deaths: Preliminary Data for 1998. *National Vital Statistics Reports*. 47(25):6, 1999.

7. Thomas, Eric J.; Studdert, David M.; Newhouse, Joseph P.; et al. Costs of Medical Injuries in Utah and Colorado. *Inquiry* 36:255–264, 1999. See also; Johnson, W.G.; Brennan, Troyen A.; Newhouse, Joseph P.; et al. The Economic Consequences of Medical Injuries. *JAMA*. 267:2487-2492, 1992.

8. Occupational Safety and Health Administration. The New OSHA: Reinventing Worker Safety and Health [Web Page]. Dec 16 1998. Available at: www.osha.gov/oshinfo/reinvent.html.

9. Phillips, David P.; Christenfeld, Nicholas; and Glynn, Laura M. Increase in US Medication-Error Deaths between 1983 and 1993. *The Lancet*, 351:643–44, 1998.

10. Bates, David W.; Spell, Nathan; Cullen, David J.; et al. The Costs of Adverse Drug Events in Hospitalized Patients. *JAMA*. 277:307–311, 1997

11. Leape, Lucian; Brennan, Troyen; Laird, Nan; et al., The Nature of Adverse Events in Hospitalized Patients, Results of the Harvard Medical Practice Study II. *N Engl J Med*. 324(6):377–384, 1991.

12. Milstein, Arnold, presentation at "Building a National Agenda for Patient Safety," meeting sponsored by National Patient Safety Foundation, Joint Commission on Accreditation of Health Care Organizations an American Hospital Association, July 15, 1999, Washington, D.C.

13. Veatch, Robert M., Cross-Cultural Perspectives in Medical Ethics: Readings. Boston, MA: Jones and Bartlett Publishers, 1989.

14. Reason, James T., *Human Error*, Cambridge: Cambridge University Press, 1990.

15. Deming, W. Edwards, *Out of the Crisis*, Cambridge, MA: Massachusetts Institute of Technology, Center for Advanced Engineering Study, 1993.

16. Berwick, Donald M. and Leape, Lucian L. Reducing Errors In Medicine. *BMJ*. 319:136–137, 1999.

17. Brennan, Troyen A.; Leape, Lucian L.; Laird, Nan M.; et al. Incidence of Adverse Events and Negligence in Hospitalized Patients. *NEJM*. 324(6):370–76, 1991. see also: Thomas, Eric J.; Studdert, David M.; Newhouse, Joseph P.; et al. Costs of Medical Injuries in Utah and Colorado. *Inquiry* 36:255–264, 1999.

18. Thomas, Eric J.; Studdert, David M.; Newhouse, Joseph P.; et al. Costs of Medical Injuries in Utah and Colorado. *Inquiry* 36:255–264, 1999.

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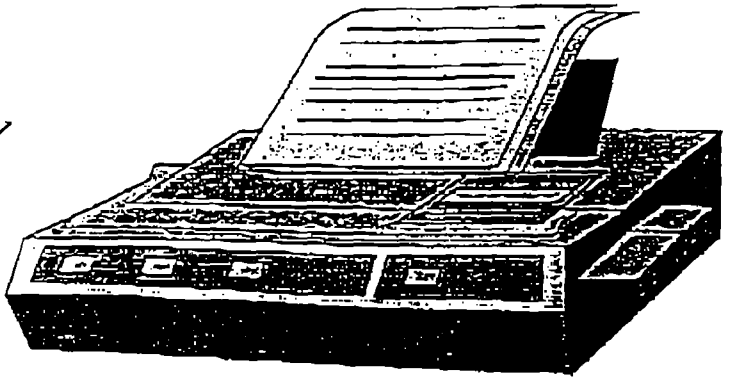


Fax

To: Deborah Ayler **From:** COR Wyatt Smith

Fax: 202-456-5557 **Pages:** (including cover) 2

Phone: **Date:** 2/11/00

Re:

☐ Urgent ☐ FYI ☐ For Your Review ☐ Comment ☐ Please Reply

703 575 6620

SKYLINE SIX, SUITE 817
5109 LEESBURG PIKE
FALLS CHURCH, VA 22041

PHONE: (703) 681-5611
DSN: 761-5611
FAX: (703) 681-8845

Message:

Military CPR

Patient Safety Initiatives in the Department of Defense for FY 2001

Many current and proposed programs in the Military Health Systems affect patient safety. The initiatives highlighted here have the potential for significant improvements in patient safety.

Program	FY01 Budget	Increase in FY01 Budget Needed to Initiate or Accelerate Program	Discussion
Deployment of the Military Computer-based Patient Record (CPR)	78.1M	+70M	CPR will provide the ambulatory clinical information needed for a computer-based patient record. Most adverse medical incidents result from errors of omission or commission. These errors can be significantly reduced only through widespread use of tools that ensure availability, completeness, and accuracy of patient records. This is the single most important objective of the military computerized patient record. It assures availability, completeness, and accuracy of medical information about each patient, provides relevant scientific medical knowledge to the clinician, includes alerts and reminders and supports clinical practice guidelines. Key to reduction of pharmaceutical errors, a large portion of medical errors, alerts and reminders will be available during patient care encounters. The CPR will provide the ability to assess clinical outcomes information and enable providers to take appropriate remedial action. Significant reduction in medical errors cannot be achieved consistently and globally without broad-based investment in the CPR. Acceleration of CPR deployment will bring the

			advantages of a computer-based patient record to the MHS worldwide by end FY 01 instead of end FY 02 as currently planned.
Pharmacy Data Transaction Service (PDTS)	3.5M	0	PDTS provides a single medication profile that enables clinical screening for drug interactions among dispensing systems, i.e.: retail pharmacy, National Mail Order Pharmacy, and Military Treatment Facilities, thus reducing the risk of medication errors.
Integrated Pharmacy System (IPS)	0	+10M	The IPS will enhance functionality of PDTS and the current Composite Health Care System (CHCS) Pharmacy module, including drug-diagnosis interaction and inpatient drug screening. The IPS is a necessary component for prospective drug utilization review, and provides complete medication information to providers through the CPR therefor reducing possible death from medication errors. IPS will enable interfaces to other proven Pharmacy technology, such as robotics, to eliminate drug dispensing errors across the MHS. IPS will further reduce medication errors by standardizing drug nomenclature across the MHS.
Full Pharmacy Barcoding Capability	0	+2M	Removes the risk of providing a patient with a prescription intended for someone else by scanning a patient's military ID card and the medication bar code at the time of delivery, thus enabling timely recording and tracking of pharmaceuticals dispensed. Fully funds all hardware needed to complete worldwide deployment of this Pharmacy functionality
Commercial Standardized Medication Error Tracking System	0	+2M	Will anonymously record and standardize pharmaceutical error reporting and facilitate provider education and process changes to decrease patient risk. Will significantly enhance medication error reporting.
Establish a Patient Safety Center at the Armed Forces Institute of Pathology	0	+2M	The Patient Safety Center will support the DoD Medical Error Reporting System and related quality improvement programs with data management and analysis, technical assistance, and dissemination of information.
Enhance Patient Safety	0	+30M	MTFs will enhance their patient safety programs through participation

Department of Veterans Affairs

VHA FAX TRANSMITTAL

DEPARTMENT OF VETERANS AFFAIRS
Veterans Health Administration
National Center for Patient Safety (10X)
2215 Fuller Rd.
Ann Arbor, Michigan 48105

(734) 930-5890
FAX (734) 930-5899

TO	FAX NUMBER ☐ FTS ☐ COMMERCIAL	DATE	NO. PAGES ATTACHED
DEVORAH ADLER	202-456-5557	2/14/00	1

SUBJECT

Attached is the information that you requested. Sorry that it took longer than we expected to get it to you. If you need further information or have questions, don't hesitate to call us.

FROM	TELEPHONE NUMBER ☐ FTS ☐ COMMERCIAL
Martha Morgan, Secretary, National Center for Patient Safety (10X)	734-930-5890

DEPARTMENT OF VETERANS AFFAIRS

In addition, the Veterans Health Administration at VA has installed a computerized medical record in 100 percent of its hospitals nationwide, making it possible to significantly reduce errors and correctly measure risks by providing complete information about patients at the point of care as it achieves full implementation. Over the past 3 years, VA redesigned an error reporting system, established four Patient Safety Centers of Inquiry, and began to use barcode technology to reduce errors in the use of medications and blood transfusions.

Implement a voluntary reporting system nationwide for VA health care facilities. VA currently operates a mandatory reporting system. By the end of the year, VA will implement a voluntary reporting system for both adverse events and close calls nationwide. Information will be collected by an independent external entity, analyzed, and disseminated to all VA health care networks to help prevent medical errors before they occur. Implementing this system is likely to lead to a richer database of information, as incidents are reported on an de-identified basis, and will allow researchers to compare the effectiveness of identified systems to de-identified ones.

Training, support and reward. VA is considered one of the national leaders in patient safety, having instituted patient safety programs in all of its health care facilities, serving 3.8 million patients nationwide. This year, VA will invest a total of over $47.6 million to increase the requirement for patient safety training for staff from 15 to 20 hours a year, provide "VA Quality Scholars" fellowships for ten physicians, recognize innovations developed within health care facilities through a patient safety awards program, and place "patient safety checklists" on anesthesia machines in operating rooms in VA health care facilities nationwide.

This year, VA will invest a total of $75.1 million to complete the implementation of an automated order entry system in all of its health care facilities along with bar coding for blood transfusions and medication administration. A 1999 evaluation of this system indicates that it has reduced medication errors by 67% since its implementation.

To: Devorah Adler
From: Nancy Foster
Date: February 14, 2000
Subject: Additional Comments

John, Gregg and I have reviewed the revised Executive Summary and want to express our appreciation for dealing with so many of our comments over the weekend. You did a remarkable job!

We do still have some things about which we feel strongly, and we offer these comments along with our pledge to be of help to you in making needed changes:

Page 1 – In the second paragraph, it would be important to note that the WH asked us to go beyond the IOM recommendations in thinking about how to improve patient safety, and that there are proposed actions in this report that address that request, particularly with regard to the use of information technology and collaboratin with other organizations.

Page 3, last paragraph:
- After the first sentence, please add a sentence that notes that we are integrating the patient safety activities into our work on the broader quality agenda. Since we are not creating a new center, but modifying the activities of an existing one, it is important that we not seem to be saying we are starting afresh.

- After the words "research agenda," please add "providing grants for research into patient safety."

Page 4,
- top paragraph: Please change the "data" in the last sentence to "information." We are not going to provide data. We are going to provide information. If you make this change, you can drop the "to the researchers" and let it say that we are providing information to the public and private sectors.

- After the second paragraph, please insert the paragraph John sent you on Accountability and learning systems.
- 5th paragraph - Please change the "Administration" to "QuIC"
- 6th paragraph - We think that you meant to imply that the patients affected by the errors --- or their surviving family members --- would be given information, but that is not how it reads right now. This could be read to imply that all patients would be given information about all errors occuring, and that is not what the IOM recommended or what we think people will agree to do. It also would be difficult to do it without violating confidentiality.

Page 5
- Middle of the top paragraph: The sentence that starts " The QuIC believes..." says information should be aggregated by health system and made public. Did you mean hospital? Or health system? They are not the same. People won't find health system level data useful and hospitals will find it difficult if we display data by hospital.
- Last paragraph - you and John talked about the issue of measures versus practices. We are really talking about patient safety practices here, and people will be confused by "measures." Also, this bullet is not describing a mandoatory reporting process. We have no vehicle for making this mandatory. If the Forum urges folks to report on this --- or purchasers to request the reports from provider organizations ---- which we believe they will, it is voluntary reporting, and should go in that section of the report, if you insist on the distinction between mandatory and voluntary.

Page 6
- First bullet. HCFa is not instituting a mandaotry reporting system. They are proposing to run this pilot in conjunction with a state that has an existing mandatory reporting system that they are willing to modify to collect the specific information on "never" events. Also, the second sentence describes this as implementing a "mandatory reporting systems on a voluntary basis..." Sounds like an act for a

contortionist, but does not actually describe what this pilot will do. The state will volunteer to participate, the hospitals will be mandated by the state.

- Second bullet, the second sentence should read: "HCFA, OPM and AHRQ will lead a QuIC effort to..." The last phrase of this bullet needs some clarification. For example, "this pilot will provide substantive insights on how critical information might best be provided."
- 3rd bullet, AHRQ should have the lead on this with the QuIC agencies helping.
- 4th paragraph (first one after the bullets) should not be here. It is not related to madaotry reporting, but is one of those items that the President asked us to report on in addition to the IOM recommendations. It might best be placed before the conclusions with a lead in sentence about the President's request that we look more broadly at how to improve safety.
- 6th paragraph . The end of the first sentence refers to a QuIC annual report. What annual report? Did you mean the one delivered at the end of three years? Did you mean the national quality report with the info on errors?
- The first paragraph under the Voluntary reporting section refers to Federal data systems, but many of them aren't voluntary.

Page 7

- Second bullet should read that the AHRQ will do this assessment with its QuIC partners. Also, it is not accurate. We are evaluating more than the voluntary systems. We are evaluating all of the systems we can lay our hands on and assessing their usefulness to a national learning system.
- The HCFA PRO pilot should be mentioned in here in the voluntary reporting system. It will be a pilot of one.
- 5th paragraph – (first bullet under "Setting Performance...") HCFA was previously uncomforatble with saying that hospitals are likely to institute drug order entry systems. This is actually a pretty expensive thing to do, especially for smaller hospitals. We should not assert that they are likely to do it. We could give it as an example as one of the things that they might try.

Page 8

- Second paragraph suggests the QuIC will provide technical assistance. It should say "QuIC agenices" because the QuIC itself has no capacity to do this.

Page 9

- In the DoD paragraph, the collaborative on errors in high hazard environments is not a DoD thing. VA actually has the lead on this, but it is being done by the QuIC with teams from all over the QuIC. It needs to be put as a third bullet and not characterized as a DoD thing.
- 4th paragraph again states that hospitals are likely to institute drug order entry systems. This needs to be softened to reflect what is realistic to expect --- that they may do it, but not that they are likely to do it.

FAX

Department of Veterans Affairs
810 Vermont Avenue, NW
Washington, DC 20420

Date 2/14/2000
Number of pages including cover sheet 8

To: Dan Mendelson, Office of Management Budget

Phone 395.5178
Fax Phone 395.5631
CC:

From: Thomas L. Garthwaite, M.D., Deputy Under Secretary for Health (10)

Phone 202.273.5781
Fax Phone 202.273.5787

REMARKS:

☐ Urgent ☐ For your review ☐ Reply ASAP ☐ Please comment

→ ADUSH ✓
VAETH
HUSMD

FG.

Garthwaite, Thomas L

From: Mail Delivery Subsystem [MAILER-DAEMON@rems5a.cio.med.va.gov]
Sent: Monday, February 14, 2000 8:08 AM
To: Garthwaite, Thomas L
Subject: Returned mail: User unknown


ATT563738.TXT


Test

The original message was received at Mon, 14 Feb 2000 08:08:11 -0500 (EST)
from vhacoexc1.cio.med.va.gov [152.125.6.50]

---- The following addresses had permanent fatal errors ----
<Mendelson_D@A1.eop.gov>

--- Transcript of session follows ---
... while talking to eop253.eop.gov.:
>>> RCPT To:<Mendelson_D@A1.eop.gov> NOTIFY=FAILURE,DELAY
<<< 550 5.7.1 Service unavailable code 0 (RTv2.2c/jms/990501)
550 <Mendelson_D@A1.eop.gov>... User unknown

Please FAX to Mr Mendelson

Garthwaite, Thomas L

From: Garthwaite, Thomas L
Sent: Friday, February 11, 2000 12:43 PM
To: Dan Mendelsen
Subject: Med errors

FYI per phone conversation. Feedback always helpful.

Oral testimony HVAC+ 020900.do...

Thoughts on Patient Safety 1.0...

Mr. Chairman and Members of the Committees:

Thank you for inviting us to testify today on the critical issue of patient safety.

Almost 3 years ago, under the visionary leadership of Dr. Kenneth Kizer, who you have just heard from on the first panel, VA began a major initiative to establish a system and a culture to improve the safety of our healthcare system, and by sharing our results, to improve the safety of healthcare for everyone.

Our written testimony details our extensive efforts and I will not reiterate it. I would like to comment on VA's approach to three areas that continue to be debated:

- Accountability vs. learning systems
- Mandatory vs. voluntary reporting
- Public disclosure vs. need for candor

First, we all make errors. Healthcare providers certainly do. Dr. Bagian, who will speak to you next and who is an astronaut *and* a physician, can tell

you - even rocket scientists make errors. Since the release of the IOM report, considerable debate has centered on finding an appropriate balance between assuring accountability for errors versus designing better systems to prevent errors and to minimize the consequences of errors. We believe that the institution delivering care has a responsibility to assume that individuals will make errors. Those institutions must find the systems that allowed the errors to occur and improve the design of those systems. Those institutions also have a responsibility to detect incompetent providers and to take appropriate action.

In VA, we have sought to approach the error portion by 1) openly informing patients or families about errors, 2) mandatory reporting and analysis of adverse events within a process protected from public disclosure of individual patients and practitioners, 3) early identification of intentional unsafe acts (anything that appears to be intentional, anything under influence of drugs or alcohol, any criminal acts, alleged patient abuse) for administrative review and action, 4) ongoing analysis of adverse events for possible systemic fixes and new standards, 5) implementation of new standards across our system, and 6) performance contracts with our

executives holding them accountable to implement new processes and procedures to improve patient safety.

On the accountability side of the systems versus individuals issue, we continue to hold individuals accountable for their competence through a set of other processes including credentialing, privileging, re-privileging, administrative investigations, performance management systems, personnel management systems, reporting to state licensing bodies and reporting of tort claim information to the National Practitioner Data Bank.

A second issue that has triggered considerable debate is whether reporting should be mandatory or voluntary. The expert panel which helped design our system and the experience of the aviation industry led us to conclude that both systems are important and together yield more useful information that either can alone.

A third issue which has been central to many of the discussions of what should be done to improve patient safety is the need to find the balance between the public's right to have information to choose a safe healthcare system for their care versus the need to create a culture of open disclosure

without blame of individuals for system weaknesses. Take mandatory reporting of error rates as an example. Since the occurrence of error is not always obvious and is more likely in more highly complex and technical procedures, error rates would be predicted to be highest in systems that take care of the most medically complex patients, that perform the most advanced procedures and that have the most aggressive reporting systems. These are often the systems that we would want to use for our own treatment yet simple reporting of error rates would mislead us. We believe that additional study will be necessary before meaningful data that guide rather than mislead the public will be available.

VA has chosen to use its unique position as a publicly accountable healthcare system to lead in the effort to ensure the safety of patients. We also will use our strengths as a major research and education organization to conduct research on safety and to add human factors and organizational design to the curriculum of clinical and administrative students in VA.

Thoughts on Patient Safety
February 2, 2000

The public has a need for:

- a safer system
- disclosure and compensation for injury
- ability to chose a safe system for care

The development of a safer system requires:

- ability of organizations to disclose error without threat of adverse publicity
- ability of individuals in organizations to disclose errors without threat of punishment
- analysis and discussion of mistakes (broad disclosure increases the likelihood of creative and effective solutions)
- implementation of new standards

Six part proposal:

1. Full disclosure of error to patient or family [full disclosure is simply the right thing to do; provides an incentive for just compensation and honest admission as the risk of publicity is dependent on the patient]

2. Mandatory reporting of error to a state and national safety database - either protected by statute from disclosure or reported in de-identified manner [cannot do rates of error as identification is ultimately voluntary and denominator is not measurable – thus, the most honest are likely to appear most error prone; cannot fix problems if they are not identified and shared; would need clear standards for what is to be reported]

3. Separate voluntary reporting system similar to Aviation Safety Reporting System [mandatory and voluntary systems are complementary and in aviation have yielded significantly different information]

4. Rigorous process of analysis of the safety database and formal adoption of new safety standards [requires an open process to identify new standards which every system must implement; might be best to start with a new standard setting body with representation from healthcare organizations *and* patients; recent examples of such standards might include the universal use of pulse oximetry in anesthesia, the removal of concentrated KCl from medical wards, etc.]

5. Required implementation of safety standards [at a minimum, public disclosure of safety standards so patients could ask and select providers based on adherence to those standards; stronger statement might be making adherence to new safety standards a condition of participation in Medicare]

6. Recurring audits [either by existing organizations such as Peer Review Organizations or Joint Commission on Accreditation of Health Care Organizations; or new organizations] with public disclosure of:
   - adherence to policy to disclose errors to the patient or family
   - adherence to mandatory database reporting
   - implementation of safety standards
   - implementation of an effective safety program

Thomas L. Garthwaite, MD

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Assistant Secretary for Legislation

Washington, D.C. 20201

April 3, 2000

TO: Rebecca Jones, Office of Sen. Charles Grassley
Kyle Kinner, Legislative Assistant to Sen. Robert Kerrey
Ned McCullough, Legislative Assistant to Sen. Joseph Lieberman

FROM: Leopold J. Luberecki, Jr., Legislative Analyst, Office of the Assistant Secretary for Legislation, DHHS

SUBJECT: Agency comments on draft bill concerning amendment of Social Security Act for reporting of medical errors

As you requested, this office is submitting on behalf of the Health Care Financing Administration (HCFA) and the Agency for Healthcare Research and Quality (AHRQ) comments to the proposed legislation drafted by the staffs of Sens. Grassley, Kerrey, and Lieberman that concerns the establishment of patient safety programs and a patient safety reporting system for Medicare providers. Note that these comments have been prepared by the agencies themselves, with additional input from the Food and Drug Administration and the Centers for Disease Control, which have been working with HCFA and AHRQ to create a coordinated, intra-Departmental response to the issue of medical errors reporting. These comments have not been submitted to the Department administration for clearance.

In addition to the more specific comments that the agencies have provided on the attached pages, this office notes that there are other laws, such as the Public Health Service Act, that may require amendment to more fully effect a comprehensive system of reporting of medical errors, which this proposed bill, dealing only with the Social Security Act and reporting by Medicaid providers, cannot address. Therefore, the staffs of other committees that generally have jurisdiction over other pertinent statutes may have to be consulted to create a more universal system of medical errors reporting.

If you have any further questions concerning these comments, do not hesitate to contact me at (202) 690-7450.

DATE: **April 3, 2000**

FROM: HCFA, AHRQ (in consultation with CDC and FDA)

RE: Technical comments on Grassley, Lieberman, and Kerrey bill

As requested, we have reviewed the bill and have the following technical comments. An overall comment is that references should be to the Secretary not to specific agencies or offices within the Department. HCFA conferred with AHRQ, CDC, and FDA in preparing these comments.

Section 3

Section 1860A(6), page 4, line 18.

- Definition of Sentinel Event. Both the IOM and QuIC recommended that such definitions should be developed by the National Forum for Health Care Quality Measurement and Reporting (the Forum) and adopted by the Secretary. The partial definitions in this draft, such as "death not related to the natural course of illness...", may prove a straightjacket rather than a help when the detailed definitions are to be written. FDA, for example, has had serious problems with the legislated definitions in the Medical Device Act.

- We believe that you intend the "sentinel events" to be as clearly defined as possible, and that the Secretary should emphasize clarity even when precise definition reduces the fraction of events that would be reported. Administratively, ambiguous definitions, which penalize providers that try to report conscientiously, would be a serious implementation problem. The draft does not, however, address this issue clearly.

- Although the term sentinel event is used by some authors in the same sense used in this bill, there is an implication that sentinel events are a guide to general provider performance (which is unproven) and you may wish to use another term such as "critical adverse event".

Section 1860B(a)(2), page 6, line 25

- The draft is titled and apparently has a goal of reducing "frequent errors", but the bill seems to focus on events such as in 1860A(6) that are quite rare. Specifically, the focus on sentinel events in 1860B(a)(1) would make it difficult for a provider's plan to focus on the frequent errors that cause most harm to patients. Patient safety programs in hospitals should encompass more than sentinel events and 1 additional source of health care errors. (Although some events in the "sentinel" list could be defined more broadly to capture more events, broad definitions raise the implementation issues discussed above.

Section 1860C, page 7, line 19

- Is the intent to have the reporting requirements apply to all pr viders? Segmenting the medical errors reporting effort by payer (which is the effect of using Medicare conditions of participation) will be problematic. CLIA may pr vide a model for a system applying to all providers.

Section 1860C(b)(1), page 7, line 25

- Add (D) or other Public Health Service agencies or entities, as required by the Secretary so that the Secretary can make the reports available to FDA, CDC, etc.

- Making reports to multiple entities would be burdensome to the hospital or other provider unless a single-point reporting system is created.

Section 1860C(b)(2) page 8 and 9

- The QuIC recommended a role for the Quality Forum in determining a core reporting set and standards.

Section 1860C(b)(3)(A) page 10

- It is unrealistic to suppose that the data submissions can be achieved within 1 year of passage. As written, this proposal would require rulemaking. 2-3 years would be more realistic.

Section 1860C(c)(1), page 10, line 12

- Designating PROs as a possible oversight authority duplicates the availability to the provider of a State Health Department. It would also put the PRO in the position of making public judgements that certain providers have a "pattern of poor performance." It is HCFA's current direction that, to the extent possible, responsibility for enforcement and public judgements should be in the State Health Departments and the Survey and Certification program and that PRO activities should be educational and nonpunitive. PROs would better able to support improvement efforts if they were not in the position of publicly judging whether a provider has a pattern of poor performance. This section could, for example, read, "Each provider of services shall designate either an accreditor or a State survey agency or a contractor approved by the Secretary to have oversight authority with regard to sentinel events for which a report is required...."

Section 1860(C)(c) page 10

- The logic of granting authority to the Administrator of HCFA (written in the draft as the Director of the Office of Clinical Standards and Quality) to disapprove a provider's choice of a reporting authority is unclear; criteria for disapproval are not specified. Given that the Department has authority to remove a State Health Department or an accreditor as a reporting authority, the purpose of this section is unclear.

Section 1860(C)(d)(1)(B), page 11

- Requiring a root cause analysis for every event may not be useful. Root cause analyses are not always meaningful – some events are singular and result from a failure that is not likely to recur, not the result of a system failure appropriate for root cause analysis. Adding "when appropriate" might be clearer.

Section 1860(C)(e)(2), page 12, line 4

- Change language to read- "(1) shall be submitted to the Administrator of HCFA, who shall also make the information available to other appropriate organizations."

- The definition of "provider" is unclear. Is it the nominal list under 1860A(5), or is it those providers that have conditions of participation as designated in 1860B(4)(b)? (The draft provisions are in conflict with existing statutory definitions at 1866 of the Act and with the regulations at 42CFR 489.2.)

- You may wish to suggest that reports from different reporting authorities be synthesized at, for example, the State level. As proposed, there would be 2-3 reports from reporting authorities in each step. In order to understand possible common problems causing the reportable events, some entity (the State PRO?) should synthesize the reports.

Section 1860C(e)(3)(C)(i), page 14, lines 6-16

- The Forum may also be the best organization to develop the definition of "pattern of poor performance." The partial definition in the draft is likely to interfere with the Forum reaching the best and most defensible definition. At line 15, it might be clearer to say "included in the definition of" rather than "deemed to be"

Section 1860C(f)(2), page 15, lines 11-17

- In line 12 and again on line 4 on the next page, "fails or refuses" would be much easier to administer than "refuses".

- Is the intended meaning, "revoke the authority of the accreditation under Sections 1864 and 1865 of the Social Security Act (the Act)"? The relation of this section to sections 1864 (Use of State Agencies to Determine Compliance by Providers of Services with Conditions of Participation), and 1865 (Effect of Accreditation) needs to be clearer.

- If the intent is revoke accrediting authority, it appears to be an extreme response and therefore unlikely to be employed in any but extremely rare circumstances. Do you want also to offer intermediate actions against the accreditor or State such as withdrawing eligibility for being a reporting authority? Do you want to give the Secretary authority to contract with other entities to serve as oversight authority if a State refuses or fails? What is the expected action if the facilities fail to report? What (if anything) is the expected action if the facilities report egregious errors?

Section 1860(C)(g), page 16, line 10

- If the intent is for PROs to provide feedback and technical assistance to providers on conducting analyses and reducing errors, it would be helpful to say so.

Section 1860D, page 17 and 18

- This section references civil action; you may wish to consider whether this section should also reference disciplinary and licensure actions as well as whether it should apply to some or all criminal actions.

- The draft references entities described in 1860(C)(b)(1); should this be broader to include reporting entities and relevant Federal agencies? Should there be blanket prohibition on "discovery/disclosure" on any agency/entity receiving such data?

Section 4

Page 20 General Comments

- The term "congregate care provider" as included in the draft legislation is an entirely new definition and/or entity. Although we understand the intent is to cover services in group homes under home and community based waivers, etc., the definition as presented requires extensive development. In addition, waiver services can be furnished to individuals living alone, and they should be afforded the same protections from error under the law.

Section 5 AHRQ -- (a)(1)/(2), page 21-24

- The language in this section seemed to place the entire role of research and demonstrations on medical errors at AHRQ. HCFA, CDC, and FDA are all active in this area.

- name: Center for Quality Improvement and Patient Safety

- director: Center should be established to assist Director of AHRQ in carrying out responsibilities of this section; head of Center should be appointed by Director, AHRQ and appointment should not be referenced in statute

- intro clause should reference duties of the Center; authority should not be vested in Center Director

- reference (3) to annual report should be linked to agency's existing requirement for an annual report on quality

- reference (4D) to "funding" computerized decision support systems should be changed to "evaluating"

- reference (5) to dissemination of information on existing repo ing programs should be changed to "effective components of" existing programs.

- reference (7) to convening panels needs to ensure that their w rk is based upon review of evidence regarding effective practices, not expert o inion

- reference (11) to high-risk organizations needs to be defined

- reference (13) needs to be Director of AHRQ

- overall needs restructuring to ensure better balance of researc role, development/analysis of national database, and evaluation of eporting systems; also, no funding is provided to carry out these functions

Section 6 Page 24

- authority needs to be vested in Director of AHRQ

- given the thousands of potential grantees for funds, is it wise o establish such a grant program? Traditionally, AHRQ evaluates programs establish d and operated without AHRQ funds.

Section 7

Section 7 of the proposed bill includes appropriated funds to carr out its provisions. In reading the proposed bill, it is unclear if these appropriated fund would be intended for the federal costs, state costs, provider costs, or a combination (all of all costs for implementation. Consideration needs to be given for funding reg rding the PRO program and survey and certification activities.

Section-By-Section
"Stop All Frequent Errors (SAFE) Act of 2000"

Section I. Title and Table of Contents

Section II. Purposes - This section describes the intent of the legislation which is to create a non-punitive medical error reduction program under the Medicare and Medicaid programs through identification of medical errors, extension of confidentiality with limited disclosure, and implementation of systems and processes to reduce the number of adverse events that occur.

Section III. Improvement of Patient Safety under the Medicare Program - This section establishes the guidelines for the medical error reduction program in the Medicare and Medicaid program as a condition of participation in the Medicare and Medicaid program.

Facilities that choose to participate in the Medicare and Medicaid program including, hospitals, critical access hospitals, skilled nursing facilities, comprehensive outpatient rehabilitation facilities, home health agencies, hospice, renal dialysis facilities, and ambulatory surgery centers would have to meet the requirements of this Act.

Hospitals would be required to participate one year after the date of enactment of this Act. The other institutions would be phased-in on a timetable to be determined by HCFA.

Providers would have to implement a patient safety program to reduce medical error. The program will target both sentinel events and additional events associated with injury as targeted by the Secretary, or local providers. The program shall utilize active investigation to discover health care errors and achieve measurable improvement in the rates of health care errors.

Providers would be required to report sentinel events to the following: (1) their state health department; (2) a national accrediting organization when applicable, i.e. the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO); and (3) the Medicare peer review organizations. These reports would then be submitted to HCFA. The facility would be responsible for performing a root-cause analysis and implementing a corrective action plan that achieves measurable results. Providers can designate which agency or entity described above to perform oversight on their sentinel event safety program.

Confidentiality and privacy protections in current federal law for Medicare Peer Review Organizations would be extended to ensure that institutions would be encouraged to report and to implement effective patient safety programs. Information would also be protected for the purposes of conducting peer review activities and root cause analysis.

If a provider has a pattern of poor performance, as determined by HCFA, JCAHO, the Agency for Healthcare Research and Quality (AHRQ), and peer review organizations, then this information can be released to the public. This would occur if the pattern of poor performance for more continues for more than two years, and a provider fails to report sentinel events and

implement corrective actions to address safety problems.

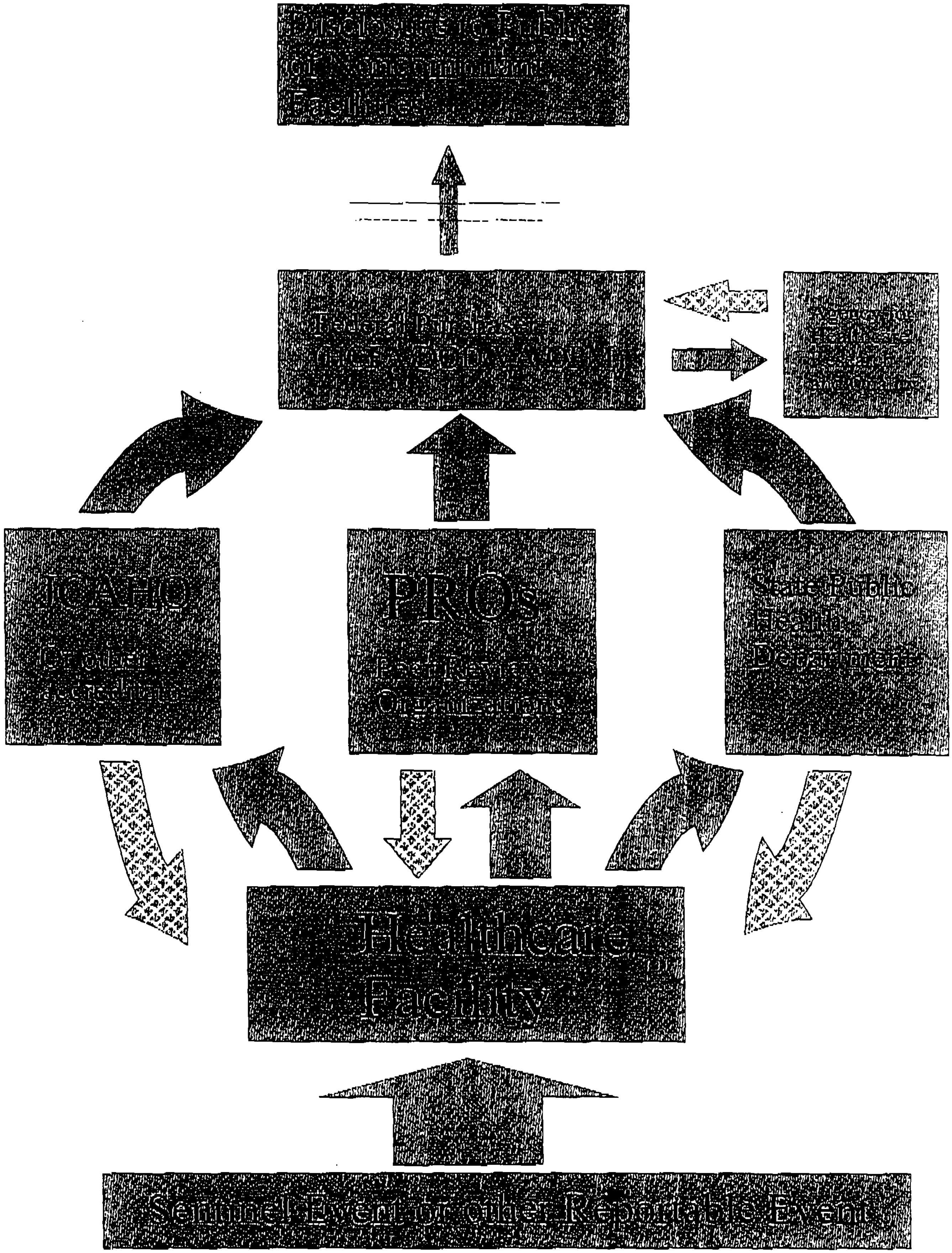
Section IV. Improvement of Patient Safety Under the Medicaid Program - This section extends the Medicare provisions above to congregate care providers in the Medicaid program. Congregate care providers is defined as facilities in the Medicaid program that provide hospital services, nursing facility services, services of intermediate care facilities for the mentally retarded, hospice care, residential treatment centers for children, services in an institution for mental diseases, and inpatient psychiatric hospital services for individuals under age of 21.

Section V. Establishment of the Center for Patient Safety - This section establishes a Center for Patient Safety (Center) within AHRQ. The mission of the Center is to improve patient safety and reduce the incidence of medical errors. The Center would establish national goals for patient safety and mechanisms to track such goals. In addition, the Center would prepare and submit an annual report to the President and Congress with recommendations concerning patient safety. Among some of its duties, the Center would develop a national health care patient safety research agenda, disseminate information and evaluate mechanisms to improve patient safety, and conduct pilot projects to conduct new or innovative patient safety reporting systems.

Section VI. Grants to Establish Patient Safety Programs - This section authorizes the Center to award grants to providers and health professionals affiliated with such providers for the establishment and operation of patient safety programs.

Section VII. Authorization of Appropriations - This section authorizes the following amounts:

(1) For fiscal year 2001, $30,000,000.
(2) For fiscal year 2002, $35,000,000.
(3) For fiscal year 2003, $40,000,000.
(4) For each fiscal year thereafter, such sums as may be necessary.


Disclosure to Public of Noncompliant Facilities
JCAHO
PROs
Peer Review Organizations
State Public Health Departments
Healthcare Facility
Sentinel Event or other Reportable Event

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106TH CONGRESS
2D SESSION

S. _____

IN THE SENATE OF THE UNITED STATES

Mr. GRASSLEY (for himself, Mr. LIEBERMAN, and Mr. KERREY) introduced the following bill; which was read twice and referred to the Committee on _____

A BILL

To amend titles XVIII and XIX of the Social Security Act to improve the safety of the medicare and medicaid programs, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the "Stop All Frequent Errors (SAFE) in Medicare and Medicaid Act of 2000".

(b) TABLE OF CONTENTS.—The table of contents of this Act is as follows:

Sec. 1. Short title; table of contents.
Sec. 2. Purposes.
Sec. 3. Improvement of patient safety under the medicare program.

"PART D—ADDITIONAL RESPONSIBILITIES FOR THE SECRETARY IN ORDER TO IMPROVE HEALTH CARE QUALITY

"Sec. 1860A. Definitions.
"Sec. 1860B. Establishment of patient safety programs.
"Sec. 1860C. Patient safety reporting system.
"Sec. 1860D. Confidentiality and privacy protections.
Sec. 4. Improvement of patient safety under the medicaid program.
Sec. 5. Establishment of the Center for Patient Safety.
Sec. 6. Grants to establish patient safety programs.

SEC. 2. PURPOSES.

The purposes of this Act are as follows:

(1) To develop a nonpunitive error reduction system under the medicare and medicaid programs under titles XVIII and XIX of the Social Security Act (42 U.S.C. 1395 et seq.; 1396 et seq.) with pragmatic reporting requirements and adequate legal protections to support the collection of information under such systems.

(2) To extend existing confidentiality and peer review protections to the additional required reports of error under such systems that are developed for safety and quality improvement purposes under the medicare and medicaid programs.

(3) To create leadership, research, tools, and protocols to enhance the knowledge base concerning patient safety under the medicare and medicaid programs.

(4) To raise standards and expectations for improvements in patient safety under the medicare and medicaid programs.

(5) To reduce deaths, serious injuries, and other health care errors under the medicare and medicaid programs through the implementation of safe practices at the delivery level.

SEC. 3. IMPROVEMENT OF PATIENT SAFETY UNDER THE MEDICARE PROGRAM.

(a) IN GENERAL.—Title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) is amended by redesignating part D as part E and by inserting after part C the following new part:

"PART D—ADDITIONAL RESPONSIBILITIES FOR THE SECRETARY IN ORDER TO IMPROVE HEALTH CARE QUALITY

"DEFINITIONS

"SEC. 1860A. In this part:

"(1) ADDITIONAL ERROR EVENT.—The term 'additional error event' means an event other than a sentinel event that the Secretary, in consultation with the Agency for Healthcare Research and Quality, national accrediting organizations, provider and consumer organizations, and peer review organizations, determines is a health care error, such as a medication error, that has been demonstrated to contribute substantially to morbidity and mortality.

"(2) APPLICABLE EVENT.—The term 'applicable event' means—

"(A) a sentinel event; and

"(B) an additional error event.

"(3) MEDICAID PROGRAM.—The term 'medicaid program' means the health care program under title XIX.

"(4) MEDICARE PROGRAM.—The term 'medicare program' means the health care program under this title.

"(5) PROVIDER OF SERVICES.—The term 'provider of services' means a hospital, critical access hospital, skilled nursing facility, comprehensive outpatient rehabilitation facility, home health agency, renal dialysis facility, ambulatory surgical center, or hospice program.

"(6) SENTINEL EVENT.—

"(A) IN GENERAL.—The term 'sentinel event' means any of the following:

"(i) An event that—

"(I) has resulted in an unanticipated death or major permanent loss of function; and

"(II) is not related to the natural course of the illness or underlying condition of the patient.

"(ii) Any of the following events (even if the outcome of the event did not result in death or major permanent loss of function):

"(I) Surgery on the wrong patient or wrong body part.

"(II) Hemolytic transfusion reaction involving administration of blood or blood products that have blood group incompatibilities.

"(III) Suicide of a patient in a setting where the patient receives around-the-clock care.

"(B) MAJOR PERMANENT LOSS OF FUNCTION.—For purposes of subparagraph (A), the term 'major permanent loss of function' means sensory, motor, physiologic, or intellectual impairment that—

"(i) requires continued treatment or imposes persistent major restrictions in activities of daily living; and

"(ii) was not present—

"(I) on admission of the patient; or

"(II) in the case of a patient who was not admitted, at the initiation of the provision of items or services to the patient.

"ESTABLISHMENT OF PATIENT SAFETY PROGRAMS

"SEC. 1860B. (a) ESTABLISHMENT OF REQUIREMENTS.—The Secretary shall establish requirements for the establishment and implementation of patient safety programs for providers of services participating in the medicare program. Such requirements shall ensure that a patient safety program—

"(1) targets applicable events;

"(2) targets at least 1 additional source of health care errors, to be determined by the provider of services, that contributes significantly to morbidity and mortality in the service area of the provider or in patients receiving care from the provider;

"(3) analyzes the organizational processes, functions, and services that are relevant to applicable events;

"(4) utilizes active investigation of medical records, medication utilization, laboratory results, and other information to discover health care errors; and

"(5) achieves significant measurable improvement in rates of health care errors.

"(b) ESTABLISHMENT AND IMPLEMENTATION OF A PATIENT SAFETY PROGRAM AS A CONDITION OF PARTICIPATION FOR PROVIDERS OF SERVICES.—The Secretary shall ensure that each provider of services participating in the medicare program (as a condition of such participation) has established and implemented a patient safety program that is in compliance with the requirements established under subsection (a).

"PATIENT SAFETY REPORTING SYSTEM

"SEC. 1860C. (a) ESTABLISHMENT.—The Secretary shall establish a patient safety reporting system that provides for the collection and analysis of standardized information concerning applicable events (including any root cause analysis of, or corrective actions taken with respect to, such events) under the medicare program.

"(b) REPORTS BY PROVIDERS OF SERVICES TO AGENCIES AND ENTITIES.—

"(1) IN GENERAL.—Under the system established under subsection (a), a provider of services shall report each applicable event that occurs to an individual while the individual is in the care or custody of the provider to—

"(A) the State health agency or other appropriate State agency of the State in which the

provider of services is furnishing the services involved;

"(B) in the case of a provider of services participating in the medicare program as a result of accreditation by a national accrediting body, the national accrediting body for the provider; and

"(C) the appropriate peer review organization under part B of title XI.

"(2) STANDARDIZED DATA FOR REPORTS SUBMITTED TO AGENCIES AND ENTITIES.—

"(A) REPORTING STANDARDS.—The Secretary, in consultation with the Agency for Healthcare Research and Quality, national accrediting organizations, provider and consumer organizations, and peer review organizations, shall, after consideration of existing reporting systems and standards, establish and maintain a core set of reporting standards to be used by providers of services in submitting the reports required under paragraph (1) to the agencies and entities described in such paragraph.

"(B) REQUIREMENTS FOR STANDARDS.—The reporting standards developed under subparagraph (A) shall—

"(i) require the inclusion of a description of the applicable events occurring during the period covered by the report;

"(ii) except as provided in subparagraph (D), require the inclusion of the root cause analysis of each applicable event included in the report and a description of any corrective action taken by the provider of services with respect to such event or any other measures necessary to prevent similar applicable events from occurring in the future;

"(iii) require that all provider of services provide the data required under this section;

"(iv) require that the privacy of individuals whose treatment is the subject of a report is protected;

"(v) include a nomenclature and taxonomy for the collection and reporting of such data; and

"(vi) meet such other requirements as the Secretary determines appropriate.

"(C) MEDICATION ERRORS.—In developing the reporting standards under this paragraph,

the Secretary shall give immediate priority to the establishment of taxonomies and reporting protocols relating to medication errors.

"(D) WAIVER OF CERTAIN REPORTING REQUIREMENTS.—If determined appropriate by the Secretary, the standards developed under this paragraph may permit a provider of services to waive the reporting requirement described in subparagraph (B)(ii) with respect to an additional error event.

"(3) PHASE-IN OF REPORTING.—

"(A) IN GENERAL.—The Secretary shall establish a phase-in period with respect to the submission of data by various providers of services pursuant to paragraph (1).

"(B) REQUIREMENTS.—The phase-in period described in subparagraph (A) shall require that—

"(i) all hospitals submit the data required under this section beginning not later than 1 year after the date of enactment of the Stop All Frequent Errors (SAFE) in Medicare and Medicaid Act of 2000; and

"(ii) all other providers of services submit such data beginning at a time determined appropriate by the Secretary.

"(c) DESIGNATION OF AGENCY OR ENTITY.—

"(1) IN GENERAL.—Each provider of services shall designate 1 of the agencies or entities described in subsection (b)(1) to determine compliance with the patient safety reporting system established under this section with respect to applicable events for which reports are required under such subsection.

"(2) DISAPPROVAL BY SECRETARY.—

"(A) IN GENERAL.—The Secretary may disapprove the designation made under paragraph (1) if the Secretary determines such disapproval to be appropriate.

"(B) DESIGNATION OF ANOTHER AGENCY OR ENTITY.—In the case of a disapproval under subparagraph (A), the provider of services shall designate another of the agencies or entities described in subsection (b)(1) to have designated authority.

"(d) INVESTIGATION OF APPLICABLE EVENTS BY AGENCY OR ENTITY WITH DESIGNATED AUTHORITY.—The agency or entity designated by a provider of services under subsection (c) shall—

"(1) ensure that the provider of services, with respect to any reported applicable event—

"(A) conducts an investigation of the applicable event;

"(B) determines the root cause or causes of the applicable event; and

"(C) establishes and implements a time-limited plan or strategy—

"(i) to correct the problem or problems that resulted in the applicable event;

"(ii) that leads to the reduction of the risk of such event happening in the future; and

"(iii) that allows the agency or entity to determine the appropriateness of the root cause analyses and any corrective actions proposed or taken by the provider of services; and

"(2) prepare and submit the reports required under subsection (c).

"(e) REPORTS TO THE SECRETARY BY AGENCY OR ENTITY WITH DESIGNATED AUTHORITY.—

"(1) IN GENERAL.—The agency or entity with designated authority shall submit a report containing the information described in paragraph (3)

to the Secretary in such form and manner, and by such date, as the Secretary prescribes.

"(2) FREQUENCY.—The report described in paragraph (1) shall be submitted to the Secretary at regular intervals, but not less frequently than annually.

"(3) INFORMATION TO BE REPORTED.—

"(A) IN GENERAL.—The report described in paragraph (1) shall include—

"(i) a description of the applicable events occurring during the period covered by the report;

"(ii) a description of any corrective action taken by the providers of services with respect to the applicable events or any other measures necessary to prevent similar applicable events from occurring in the future;

"(iii) a description of proposed systems changes identified as a result of analysis of events from multiple providers; and

"(iv) such additional information as the Secretary determines to be essential to ensure compliance with the requirements of this section.

"(B) INFORMATION EXCLUDED.—The report submitted under paragraph (1) shall not identify any provider of services, practitioner or other health care worker, or patient.

"(3) ADDITIONAL REPORTING REQUIREMENTS WHEN A PROVIDER HAS BEEN IDENTIFIED AS HAVING A PATTERN OF POOR PERFORMANCE.—

"(A) REPORT TO SECRETARY.—

"(i) IN GENERAL.—Notwithstanding any other provision of law, in addition to the report required under paragraph (1), the agency or entity with designated authority shall report to the Secretary the name and address of any provider of services with a pattern of poor performance.

"(ii) INFORMATION TO THE PUBLIC.—The Secretary shall make the information described in clause (i) available to the public if the pattern of poor performance continues for more than 2 years.

"(B) DETERMINATION OF PATTERN.—The agency or entity with designated authority shall determine if a pattern of poor performance exists with respect to a provider of services in accordance with the definition of pattern of poor

performance developed by the Secretary under subparagraph (C).

"(C) DEVELOPMENT OF DEFINITION.—

"(i) IN GENERAL.—The Secretary, in consultation with the Agency for Healthcare Research and Quality, national accrediting organizations, provider and consumer organizations, and peer review organizations, shall develop a definition to identify a provider of services with a pattern of poor performance. In developing such definition, the Secretary shall ensure that a provider of services described in clause (ii) is deemed to be a provider of services with a pattern of poor performance.

"(ii) PROVIDER DESCRIBED.—A provider of services described in this clause is a provider of services that has a pattern of—

"(I) failing to report applicable events pursuant to this part; or

"(II) except for events described in subsection (b)(2)(D), failing to implement corrective actions with re-

spect to applicable events or significantly delaying such implementation.

"(D) EFFECTIVE DATE.—An agency or entity with designated authority shall not submit a report to the Secretary pursuant to this paragraph until the Secretary has established the definition under paragraph (C).

"(f) ENFORCEMENT OF REQUIREMENTS FOR ENTITIES.—

"(1) PART OF CONTRACT FOR PEER REVIEW ORGANIZATIONS.—Pursuant to section 1154(a)(17)(A), the requirements under this part with respect to a peer review organization shall be considered to be requirements under a contract between the Secretary and the organization under part B of title XI.

"(2) FAILURE OF ACCREDITING BODY TO COMPLY WITH REQUIREMENTS.—If an accrediting body refuses to comply with the requirements under this part, the Secretary, after notice to the accrediting body and opportunity to comply, may revoke the authority of the accrediting body to serve as an agent of the medicare or medicaid program for certification purposes.

"(3) FAILURE OF HEALTH DEPARTMENT OF A STATE TO COMPLY WITH REQUIREMENTS.—If a State health agency or other appropriate State agency refuses to comply with the requirements under this part, the Secretary, after notice to the agency and opportunity to comply, shall revoke the ability of a provider of services to designate such agency as the agency with designated authority with respect to such provider pursuant to subsection (c).

"(g) LIMITATION ON USE OF INFORMATION.—

"(1) STATE.—Any State health agency or other appropriate State agency that receives information regarding applicable events with respect to a provider of services pursuant to this part (or a congregate care provider pursuant to the application of this part to such a provider under title XIX) shall not permit such information to be utilized in conjunction with the survey, certification, or enforcement process conducted by, or on behalf of, the agency with respect to such provider.

"(2) SECRETARY.—The Secretary shall not permit any information received by the Secretary regarding applicable events with respect to a provider of services pursuant to this part (or a congregate care provider pursuant to the application of this part

to such a provider under title XIX) to be utilized in conjunction with the survey, certification, or enforcement process conducted by, or on behalf of, the Secretary with respect to such provider.

"(h) ANALYSIS OF REPORTED INFORMATION BY THE SECRETARY.—The Secretary shall analyze the data received under this part with respect to the medicare program in a manner that permits the Secretary to identify pertinent patient safety issues that require more intensive analysis.

"(i) PROVISION OF INFORMATION TO CENTER FOR PATIENT SAFETY.—The Secretary shall provide the director of the Center for Patient Safety, established under section 5 of the Stop All Frequent Errors (SAFE) in Medicare and Medicaid Act of 2000, with any information obtained under this part (or under title XIX pursuant to the application of this part to congregate care providers under such title) that the director of the Center determines is necessary in order to carry out the mission of the Center.

"CONFIDENTIALITY AND PRIVACY PROTECTIONS

"SEC. 1860D. (a) CONFIDENTIALITY.—

"(1) IN GENERAL.—Notwithstanding any other provision of law, any information (including any data, reports, records, memoranda, analyses, statements, and other communications) developed by or

on behalf of a provider of services with respect to an applicable event pursuant to this part—

"(A) shall be privileged, strictly confidential, and may not be disclosed by any other person to which such information is transferred pursuant to this part without the authorization of the provider of services; and

"(B) shall—

"(i) be protected from disclosure by civil or administrative subpoena;

"(ii) not be subject to discovery or otherwise in connection with a civil, criminal, or administrative proceeding;

"(iii) not be subject to disclosure pursuant to the Freedom of Information Act (5 U.S.C. 552) or any other similar Federal or State statute or regulation; and

"(iv) not be admissible as evidence in any civil or administrative proceeding;

without regard to whether such information is held by the provider of services or by another person to which such information was transferred pursuant to this part.

"(2) RULES OF CONSTRUCTION.—Nothing in this subsection shall be construed as prohibiting—

"(A) subject to confidentiality laws, disclosure of a patient's medical record;

"(B) an entity or agency from requiring a provider of services to transfer information to the entity or agency to the extent required by law;

"(C) an agency or entity described in section 1860C(b)(1), the Secretary, or the Center for Patient Safety from transferring information received pursuant to this part to another such agency or entity, the Secretary, or such Center; or

"(D) the Center for Patient Safety from releasing data received pursuant to this part in a form that does not identify or permit the identification of providers of services, practitioners or other health care workers, or patients.

"(b) PROTECTION OF PATIENT INFORMATION.—The Secretary shall establish procedures to ensure that the privacy of individuals whose treatment is the subject of a report submitted under subsections (b) or (e) of section 1860C is protected.

"(c) LIABILITY.—Nothing in this section shall be construed as limiting the liability of an individual, provider

of services, agency, or entity for damages relating to the occurrence of an applicable event, including an applicable event that results in death.".

(b) CONTRACT FOR PEER REVIEW ORGANIZATION.—

(1) IN GENERAL.—Section 1154(a) of the Social Security Act (42 U.S.C. 1320c–3(a)) is amended by adding at the end the following:

"(17) The organization shall—

"(A) comply with the requirements for peer review organizations under part D of title XVIII; and

"(B) assist providers of services (as defined in section 1860A(5)) and congregate care providers (as defined in section 1905(x)) in identifying health care errors by utilizing the clinical indicators that the Secretary, in consultation with the Agency for Healthcare Research and Quality, national accrediting organizations, provider and consumer organizations, and peer review organizations, determines are most frequently associated with preventable morbidity and mortality.".

(2) EFFECTIVE DATE.—The amendment made by this subsection shall apply to contracts entered

into or renewed on or after the date of enactment of this Act.

SEC. 4. IMPROVEMENT OF PATIENT SAFETY UNDER THE MEDICAID PROGRAM.

(a) STATE PLANS FOR MEDICAL ASSISTANCE.—Section 1902(a) of the Social Security Act (42 U.S.C. 1396a(a)) is amended—

(1) in paragraph (64), by striking "and" at the end;

(2) in paragraph (65), by striking the period and inserting "; and"; and

(3) by inserting immediately after paragraph (65) the following new paragraph:

"(66) provide that the State will ensure that any congregate care provider (as defined in section 1905(x)) that provides services to an individual for which medical assistance is available shall—

"(A) establish and implement a patient safety program described in subsection (b) of section 1860B in the same manner as a provider of services under that section is required to establish and implement such a system; and

"(B) submit the reports required under subsection (b) of section 1860C (relating to applicable events) in the same manner as a pro-

vider of services under that section is required to submit such reports.".

(b) DEFINITION OF CONGREGATE CARE PROVIDER.—Section 1905 of the Social Security Act (42 U.S.C. 1396d) is amended by adding at the end the following new subsection:

"(x) The term 'congregate care provider' means an entity that provides hospital services, nursing facility services, services of intermediate care facilities for the mentally retarded, hospice care, residential treatment centers for children, services in an institution for mental diseases, inpatient psychiatric hospital services for individuals under age 21, or congregate care services under a waiver authorized under section 1915(c).".

(c) APPLICATION OF MEDICARE PART D RULES AND REQUIREMENTS TO CONGREGATE CARE PROVIDERS.—Title XIX of the Social Security Act (42 U.S.C. 1396 et seq.) is amended—

(1) by redesignating section 1935 as section 1936; and

(2) by inserting after section 1934 the following new section:

"APPLICATION OF MEDICARE PART D RULES AND REQUIREMENTS TO CONGREGATE CARE PROVIDERS

"SEC. 1935. The Secretary shall promulgate such regulations as are necessary in order to apply the rules

and requirements that are applicable to providers of services under part D of title XVIII to congregate care providers (as defined in section 1905(x)) pursuant to section 1902(a)(66) and shall provide an analysis described in section 1860C(g) with respect to the program under this title.".

SEC. 5. ESTABLISHMENT OF THE CENTER FOR PATIENT SAFETY.

(a) ESTABLISHMENT.—

(1) CENTER.—There is established within the Agency for Healthcare Research and Quality, a center to be known as the Center for Patient Safety (in this section referred to as the "Center").

(2) DIRECTOR.—The Secretary of Health and Human Services shall appoint a director of the Center. The director shall administer the Center and carry out the duties of the director under this section subject to the authority, direction, and control of the Secretary.

(b) MISSION.—The mission of the Center is to improve patient safety and reduce the incidence of errors in the provision of health care.

(c) DUTIES.—In carrying out the mission of the Center, the director of the Center shall provide for the following:

(1) The establishment of national goals for patient safety and mechanisms to track the progress of the Nation in meeting such goals.

(2) The provision of recommendations to the Secretary of Health and Human Services regarding—

(A) the establishment of additional error events under section 1860A(1) of the Social Security Act (as added by section 3); and

(B) the development of a definition of a—

(i) provider of services with a pattern of poor performance under section 1860C(e)(3)(C) of the Social Security (as so added); and

(ii) congregate care provider with a pattern of poor performance (by reason of the application of such section to such a provider pursuant to section 1902(a)(66) of the Social Security Act (42 U.S.C. 1396a(a)(66)) (as added by section 4)).

(3) The preparation and submission to the President and Congress of an annual report and recommendations concerning patient safety.

(4) The development of knowledge and understanding concerning errors in health care through—

(A) the development of a national health care patient safety research agenda;

(B) the provision of funding for dissemination and communication activities to improve patient safety;

(C) the evaluation of methods for identifying and preventing health care errors; and

(D) the provision of funding for computerized decision support systems to reduce health care errors and to improve care.

(5) The dissemination of information concerning existing patient safety reporting programs.

(6) The conduct of activities to track the development of new, or modification of existing, patient safety reporting programs.

(7) The convening of panels of patient safety reporting program coordinators and users to evaluate reporting practices that are effective in improving patient safety.

(8) The periodic assessment of whether additional efforts are needed to—

(A) address gaps in patient safety information; and

(B) encourage organizations to voluntarily participate in patient safety reporting programs.

(9) The provision of funding for pilot projects for the establishment or operation of new or innovative patient safety reporting systems.

(10) The provision of funding for pilot projects that reduce health care errors.

(11) The provision of funding for the review of existing databases of medical errors in order to identify best practices.

(12) The provision of funding for research to identify the attributes of high-risk organizations and processes.

(13) The conduct of activities to encourage all entities and health care providers to demonstrate continuous improvements in patient safety to the public and private purchasers of the health care services provided by such entities or providers.

(14) The conduct of other activities determined appropriate by the director of the Center.

(d) PROTECTION OF PATIENT INFORMATION.—The director of the Center shall establish procedures to ensure that the privacy of individuals whose treatment is de-

scribed in any information received by the director pursuant to this part is protected.

SEC. 6. GRANTS TO ESTABLISH PATIENT SAFETY PROGRAMS.

(a) IN GENERAL.—The director of the Center for Patient Safety (established under section 5) may award grants to providers of services (as defined in section 1860A(5) of the Social Security Act (as added by section 3)), congregate care providers (as defined in section 1905(x) of such Act (42 U.S.C. 1396d(x)) (as added by section 4)), and health professionals affiliated with such providers of services or congregate care providers for the establishment and operation of patient safety programs.

(b) APPLICATION.—To be eligible to receive a grant under subsection (a), a provider of services, a congregate care provider, or a health professional affiliated with such a provider of services or congregate care provider shall prepare and submit to the director of the Center an application at such time, in such manner, and containing such information as the director may require.

(c) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated the following amounts to carry out this section:

(1) For fiscal year 2001, $30,000,000.

(2) For fiscal year 2002, $35,000,000.

(3) For fiscal year 2003, $40,000,000.

(4) For each fiscal year thereafter, such sums as may be necessary.

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