

REPORT ON MEDICAL ERRORS AND MEDICAL INJURY COMPENSATION

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**Prepared by the Medical Errors Subcommittee
of the Wyoming Health Care Commission**

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This report is compiled to meet the requirement of the Wyoming Health Care Commission under Enrolled Act No. 2 of the 2004 Special Session of the Wyoming Legislature to address the feasibility, costs and benefits of a new system to address and resolve healthcare errors and healthcare malpractice.

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I. IDENTIFICATION OF MEDICAL ERRORS

This section addresses the following elements of the Commission's charge:

- Definition and identification of health care errors
- Identification of general and systemic causes of health care errors
- Reporting of health care errors to a health care commission
- Prevention of health care errors through systemic improvements that enhance patient safety

A. BACKGROUND

The often quoted report by the Institute of Medicine (IOM), *To Err is Human*, determined more than one million medical adverse events occur annually in the United States, between 44,000 and 98,000 of which are fatal.¹ Hospital studies of medical error occurrence and associated malpractice claims conclude that iatrogenic injury is large, enduring and an innate feature of hospital care.²

To determine the frequency with which negligent and non-negligent care led to medical malpractice claims, the Harvard Medical Practice Study (HMPS) used physician reviewers to evaluate over 30,000 patient records from hospitalizations in New York.³ The study found that 98% of all negligent care which fell below the community standard for physicians did not result in malpractice claims. Adverse events, or those injuries caused by medical management which prolong hospitalization and result in disability, were found to occur in over 3% of hospitalizations.

The HMPS also made population estimates for adverse events and adverse events due to negligence. Of more than 2,500,000 hospital discharges in New York, the authors estimated over 98,000 adverse events took place, 56% of which resulted in minor disability, with recovery in one month.⁴ However, more than 27,000 injuries were estimated to have occurred from negligence, 6895 resulting in death and 877 in permanent and total disability.⁵

In a study involving hospitals in Utah and Colorado, review of over 14,000 medical records revealed nearly one half of all adverse medical events were related to surgery, one-third as a result of technical complications of the operation and nearly 17% from negligence. Drug related events comprised 19% of all adverse events. One-third of drug events were due to negligence,

¹ , Kohn LT, Corrigan JM, Donaldson MS. eds. *To Err is Human: Building a Safer Health System*. Washington DC.: National Academy Press, 2000.

² Brennan TA, et al., *Incidence of Adverse Events and Negligence in Hospitalized Patients*, 324 New Engl. J. of Med. 370 (1991); Studdert DM , et al., *Negligent Care and Malpractice Claiming Behavior in Utah and Colorado*, 38 Med. Care 25 (2000).

³ Brennan, *supra*, n. 2.

⁴ *Id.*

⁵ *Id.*

specifically, mistakes in prescribing the wrong drug or wrong dose, or prescribing a drug to a patient with a known allergy to that medication.⁶

The Utah/Colorado study found 97% of all negligently caused adverse events did not result in a malpractice claim, or over 1,700 and 3,100 injuries went uncompensated in Utah and Colorado, respectively. Those who did not bring claims tended to be of lower income and less seriously injured than those who filed claims and were four times more likely to be Medicare patients.⁷ Both the Harvard Medical Practice Study⁸ and the Utah/Colorado study support serious concerns regarding patient safety in U.S. hospitals and the relative inability of the current tort system to either assist in improving patient safety or compensate victims of medical malpractice.

The theory behind malpractice litigation is not only to provide a remedy whereby an injured claimant can be made whole through monetary means. It is also intended “to promote better quality care by fixing economic sanctions on those who provide substandard care that leads to injury.”⁹ Yet the rate of negligent care compared to the rate of malpractice claims found in these studies raises questions regarding whether relying on malpractice claims is sufficient to identify problems in the delivery of care, or can provide meaningful data on the quality of care.¹⁰ The probability a case of medical negligence would result in a malpractice claim has been estimated at less than 2%, reinforcing the ineffectiveness of the litigation process in fettering out and providing compensation for specific problems in the delivery of health care.¹¹ The “civil-justice system only infrequently compensates injured patients and rarely identifies and holds health care providers accountable for substandard medical care.”¹² A ten year follow-up study of medical malpractice claims revealed that the severity of a patient’s disability, not whether an adverse event or negligence had occurred, was predictive of payment, suggesting that there are also problems with the accuracy of the system in channeling payment to plaintiffs with meritorious claims.¹³

B. APPROACHING THE PROBLEM

Since the IOM report, Congress established the Agency for Healthcare Research and Quality (AHRQ) as the lead federal agency for patient safety.¹⁴ The AHRQ has created a Center for Quality Improvement and Safety, for the purpose of “education, training, convening agenda setting workshops, disseminating information, developing measures, and facilitating the setting of standards” in the area of patient safety, as well as supporting demonstration projects to enhance medical error reporting.¹⁵ Since 2001, AHRQ has invested \$165 million to support

⁶ Studdert, *supra*, n. 2.

⁷ *Id.*

⁸ Brennan, *supra*, n. 2.

⁹ *Id.*

¹⁰ Localio AR, Lawthers AG, Brennan TA. et al., *Relation Between Malpractice Claims and Adverse Events Due to Negligence: Results of the Harvard Medical Malpractice Study III*, 325 N. Engl. J. Med. 245 (1991).

¹¹ *Id.*

¹² *Id.*

¹³ Brennan TA, et al., *Relation Between Negligent Adverse Events and the Outcomes of Medical-Malpractice Litigation*, 225 N. Engl. J. of Med. 1963 (1996).

¹⁴ <http://www.ahrq.gov>

¹⁵ Leape LL, Berwick DM, *Five Years After To Err is Human. What Have We Learned?* 293 JAMA 2384 (2005).

patient safety research and in 2004 provided nearly \$4 million to support research in risk assessment, reduction and patient safety implementation.¹⁶ Clearly, the federal government has strong interest in patient safety.

At the state level, interest in medical error legislation has been steadily increasing. In 1999, states introduced 11 medical error bills, with 34 introduced in 2000 and 61 in 2001.¹⁷ The focus of these bills has been varied and includes consideration of a comprehensive approach to error reduction; establishing patient safety centers; reporting of medical errors; addressing disclosure and whistleblower protections; considering patient safety-related activities as conditions of licensure; medication error reduction; minimum nurse staffing requirements; financial incentives to invest in medical error reduction; funding for patient safety activities and public disclosure requirements.¹⁸ Wyoming has joined the ranks of states interested in improving patient safety with the passage of Enrolled Act No. 2 of the 2004 Special Session, which authorizes the current study and Wyoming Statute §35-2-912 (2005), creating a medical errors reporting system.¹⁹

C. DEFINING MEDICAL ERRORS

The last several years have brought broad consensus on defining adverse events and medical errors. An **adverse event** is generally defined as an injury that is attributable to medical management. Two important elements of the definition are the existence of an actual injury, which differentiates adverse events from near misses, and a causal link to medical management rather than underlying disease process. It is understood that medical management may create injuries either through acts of commission, such as a drug administered at the wrong time, or in the wrong dosage, surgery performed on the wrong side of the body or transfusion errors involving blood cross-matched for another patient, or through errors of omission, such as a nurse failing to give a medication dose, or when a physician fails to diagnose a condition such as cancer. Thus, the key factual determination in ascertaining whether an adverse event has occurred is whether the patient's morbidity can be linked to medical management.

“**Error**” is generally defined according to the IOM's definition: “the failure of a planned action to be completed as intended (i.e. error of execution) or the use of a wrong plan to achieve an aim (i.e. error of planning).”²⁰ This definition excludes “acts that do not achieve desired outcomes but are not the result of negligence, outcomes resulting from underlying or comorbid illnesses, and outcomes known to be unavoidable risks of a procedure.”²¹ The key determination is whether medical management constituted a lapse or deviation from appropriate care. There is some disagreement about the standard for making this judgment. Some conceptualize error in the same way as the liability system conceptualizes negligence: by comparing the provider's conduct to what other skilled providers would do in the same situation. However, others

¹⁶ AHRQ Fact Sheet: Patient Safety Challenge Grants, AHRQ Pub No. 04-P013, March 2004.

¹⁷ Flowers L, *State Responses to the Problem of Medical Errors: An analysis of recent state legislative proposals*, National Academy for State Health Policy, February, 2002.

¹⁸ *Id.*

¹⁹ Enrolled Act No.2 of the 2004 Special Session of the Wyoming Legislature; Wyo. Stat. Ann. § 35-2-912 (2005).

²⁰ Quality Interagency Coordination Task Force, *Doing What Counts for Patient Safety: Federal Actions to Reduce Medical Errors and Their Impact* (Washington: QuIC Task Force, 2000)

²¹ Romano PS, Geppert JJ, Davies S, Miller, MR, A Elixhauser, KM McDonald, *A National Profile of Patient Safety in U.S. Hospitals*, 22 Health Affairs 154 (2003).

conceive of error as closer to the concept of preventability or avoidability than to negligence. In this view, adverse events that could have been prevented, regardless of whether the provider's conduct fell below the customary standard of care, should be considered errors.

Patient safety, which refers to prevention of iatrogenic injury (adverse events), has just recently been recognized as a separate area of health care quality assurance. Quality assurance is more broadly oriented toward improving health outcomes through improved processes, conducting medical decision-making on best evidence and ensuring patients get the care they need.²² Yet the two are often confused, perhaps in part due to the difficulty in detecting and responding to safety problems, such as latent errors which lie dormant in healthcare systems.²³ Research on medical injury has concentrated on categorizing injuries and determining their prevalence. What is known about errors, how they occur and how to eliminate them is more limited.²⁴

National patient safety organizations and accrediting bodies have also developed definitions designed to capture and categorize these problems. A "sentinel event" is a type of adverse event reported to the Joint Commission on Accreditation of Healthcare Organizations, (JCAHO), a hospital accrediting organization. The JCAHO conducts reviews of sentinel events which it defines as an "unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof."²⁵ "Risk thereof" is defined as any process variation for which a recurrence would carry a significant chance of serious adverse outcome. Organizations subject to the JCAHO review are permitted latitude in developing parameters to define "unexpected," "serious" and "the risk thereof," so long as the definition includes at a minimum, the JCAHO defined reviewable events.²⁶

Several states with reporting systems have arrived at varying definitions of reportable adverse events. Pennsylvania recently enacted comprehensive adverse event reporting requirements for licensed health care facilities that became effective in June, 2004. Inherent in the system are broad definitions of "serious event," "incident" and "infrastructure failure" all of which are reportable.²⁷ In contrast, Minnesota, recognizing the importance of coordinating reporting

²² Mello MM, Kelly CN, Brennan, TA. *Fostering Rational Regulation of Patient Safety*, 30 J. of Health Politics, Pol'y and Law 376 (2005).

²³ *Id.*

²⁴ *Id.*

²⁵ Joint Commission on Accreditation of Healthcare Organizations. Sentinel Event Policies and Procedures. Updated March 2005. Available at: http://www.jcaho.org/accredited+organizations/sentinel+event/se_pp.htm. Accessed June 2005.

²⁶ *Id.*

²⁷ Medical Care Availability and Reduction of Error (MCARE) Act, 2002 Pa. Laws 154 § 302. Definitions: "Incident." An event, occurrence or situation involving the clinical care of a patient in a medical facility which could have injured the patient but did not either cause an unanticipated injury or require the delivery of additional health care services to the patient. The term does not include a serious event.

"Serious event." An event, occurrence or situation involving the clinical care of a patient in a medical facility that results in death or compromises patient safety and results in an unanticipated injury requiring the delivery of additional health care services to the patient. The term does not include an incident.

"Infrastructure failure." An undesirable or unintended event, occurrence or situation involving the infrastructure of a medical facility or the discontinuation or significant disruption of a service which could seriously compromise patient safety.

efforts with other states and the need for uniformity, chose to adopt the categories of error developed by the National Quality Forum (NQF).²⁸

The National Quality Forum, a nonprofit organization comprised of national, state, regional and local groups representing consumers, employers, health care professionals, health plans and accrediting bodies, has worked since 1999 to develop and implement a national strategy for health care quality measurement and reporting.²⁹ NQF stresses the standardization of terminology to ensure consistent implementation across states.³⁰ (See Appendix A and B for the National Quality Forum's List of Serious Reportable Events and definitions.) The NQF has also developed a list of safety enhancing interventions, though many of them address issues of clinical effectiveness as opposed to providing specific error-reducing interventions.³¹

Research has begun to move toward a common taxonomy of adverse events, enabling the counting and analysis of particular types of adverse events and errors. These systems tend to classify adverse events by clinical area and by clinical stage within each area. In the obstetrical area, for example, adverse events are classified as antenatal, intrapartum and postpartum events.

Patient safety systems also focus on classification systems for human factors, or circumstances of care, that contribute to the occurrence of errors or adverse events. Human factor typologies include both individual and systemic contributing factors. The patient safety movement has assumed that systemic breakdowns, rather than individual incompetence are responsible for a large proportion of errors, though evidence on this issue has yet to emerge. Whether systemic factors are defined broadly or narrowly determines how extensively systemic breakdowns may be seen as contributing to errors. Narrowly viewed, systemic factors would include problems aside from individual failures, such as insufficient equipment in a hospital. More broadly defined, they would include things that had they been present in the system, would have prevented an individual failure. One such example is an automated reminder system, which would have reminded a physician to check a test result.

Some argue that "near misses," the situations and mistakes that don't result in injury, should also be identified because those mistakes lay latent in the system, with increasing probability of future patient injury associated with the same mistake.³² At least one well known health care facility has instituted an anonymous system for close call reporting which provides feedback on interventions developed as a result of reporting the near miss or close call.³³

Any patient safety effort must have the commitment of those who provide care. Health care providers' understanding of patient safety may depend heavily on their preconceived notions of

²⁸ Minnesota Adverse Health Care Events Reporting Act of 2003, Sec. 5, S.F. No. 1019, 3rd Engrossment-83rd Legislative Session (2003-2004).

²⁹ <http://www.qualityforum.org/about/home.htm>

³⁰ The National Quality Forum, Serious Reportable Events in Healthcare, a Consensus Report, 2002.

³¹ Mello, *supra*, n. 22. See, *Safe Practices for Better Healthcare: A Consensus Report*, 2003, Washington, DC: National Quality Forum.

³² Liang, BA, *Dr. Arthur Grayson Distinguished Lecture in Law & Medicine; Promoting Patient Safety Through Reducing Medical Error: A Paradigm of Cooperation Between Patient, Physician, and Attorney*, 24 S. Ill U. L. J. 541 (2000).

³³ The University of Texas M.D. Anderson Cancer Center, www.utccrs.org accessed June 15, 2005.

what constitutes error as well as their professional role within the hospital.³⁴ A three year study of 29 small rural hospitals underscored the uncertainty among physicians, nurses, pharmacists and administrators about what comprises a medical error. Physicians tended to categorize problems associated with delays in treatment, use of outmoded treatments, failure to employ necessary diagnostics, failure to act on results of testing, errors in administration of treatment and failure to communicate with staff and patients, not as errors, but as “practice variances, suboptimal outcomes, or differences in clinical judgment.”³⁵ Even when a patient suffered harm, many physicians did not agree an error had occurred and usually deemed it unnecessary to provide disclosure to the patient, make chart notations, refer the case to the hospital’s morbidity and mortality committee, or file an incident report. Nurses were hesitant to designate treatment and diagnostic problems as errors, noting their lack of authority to question a physician’s clinical decision. Administrators recognized their responsibility for ensuring patient safety, but also realized they lacked the clinical knowledge needed to determine whether an event constituted an error.³⁶

Establishing that an error has occurred is often difficult and represents one reason why reporting systems collect incidents of adverse events, whether due to error or not. Deciding what to classify as error and the standard to use for defining whether an error has been committed may pose problems as well. Establishing the elements of negligence, specifically the provider’s duty to the patient, breach of duty, whether an injury occurred and whether it was caused by the actions or inactions of the provider, is the most difficult threshold to meet. If the standard for defining error includes preventable or avoidable adverse events, regardless of whether the provider’s conduct meets the negligence threshold, many more events become classified as errors.

D. HOW ARE ERRORS DETECTED?

Once definitions and classification of errors can be agreed upon, the issue shifts to how errors can be identified. Error identification is made retrospectively, after the injury or near miss has occurred. Academic studies, hospital review panels, mortality and morbidity committees, as well as insurance companies take this approach.

Reporting systems are one method of identifying adverse events that are due to error. Another method is medical record review, sometimes called chart audit. In primary care, a combination of medical record review and interviews with staff and patients has been helpful in determining whether errors have been committed and the underlying cause of such errors.³⁷ In a study of two hospitals, a review of medical records identified almost all adverse events that resulted in medical malpractice claims. Though less rigorous than the scrutiny of legal proceedings, the record review was able to identify some negligent adverse events that did not come to the attention of the hospital’s risk management review or result in litigation.³⁸ Although

³⁴ Cook AF, et al., *An Error by Any Other Name*, 104 American Journal of Nursing 32 (2004).

³⁵ *Id.*

³⁶ *Id.*

³⁷ A.J. Avery, *Classifying and Identifying Errors*, 12 Quality and Safety in Health Care 404 (2003).

³⁸ Brennan, TA, Localis, RA, Leape, LL, Laird, NN, Peterson, L, Hiatt, HH and Barnes, BB. *Identification of Adverse Events Occurring during Hospitalization*, 112 Annals of Internal Medicine 221 (1990).

retrospective in nature, this type of review indicates not all substandard care results in litigation, nor does it come to the attention of quality assurance personnel. Even though case record review may currently perform better than any other modality in detecting frequency of adverse events,³⁹ it is expensive to use routinely and occurs after the fact.⁴⁰ To facilitate effective use of this method for identification and allow comparisons across health care systems, essential elements in all medical records need be uniform.⁴¹

As health care facilities and providers move more towards the integration of information technology into health care delivery, utilization of these systems to identify medical error can be more timely and cost-effective than medical record review, and in some instances early enough to prevent patient harm.⁴² Computerized physician order entry (CPOE) systems have been successfully used to eliminate some medication errors by providing means for rapid dose-checking and determining drug-to-drug interactions. However in some instances, CPOE systems intended to alleviate medication errors have had the opposite effect.⁴³ These issues might be primarily seen as requiring refinement of technology applications to account for workflow, and human factors inherent in their use.⁴⁴ Other concerns surround the expense of CPOE implementation, which depending on the type of institution, may range between \$1.5 million and \$25 million.⁴⁵

Computer-based event monitoring and natural language processing have worked well in identifying adverse drug events and nosocomial infections, two of the most frequent adverse events identified by the 1991 Harvard Medical Malpractice Study.⁴⁶ International Classification of Diseases (ICD9-CM) and Current Procedural Terminology (CPT) codes provide evidence of the clinical state of the patient, comorbid conditions, and progress during hospitalization or a physician visit. When queried electronically, this information may signal the presence of an

³⁹ Wilson RM. *Reviewing Case Record Review*, 12 *Quality and Safety in Health Care* 402 (2003).

⁴⁰ Bates DW, Evans SR, Murff H, Stetson PD, Pizziferri L, Hripcsak G. *Detecting Adverse Events Using Information Technology*, 10 *J. Am. Med. Informatics Assoc.* 115 (2003).

⁴¹ Wilson, *supra*, n. 39. The following are considered essential elements in the medical record and should be in standardized format: Medical admission; medical discharge; discharge summary; medical continuation notes; management or treatment plans; consultations; results of investigations; short stay documentation; referral/follow up letters from GPs or specialists; all volumes of the medical record simultaneously accessible. In addition, the author advocates: a standardized layout of the medical record; use of admission dividers as standard requirements for medical record filing; policy for loose sheet filing in medical records; use of an integrated medical record for all health care professionals; keeping all records relating to a patient in a single medical record rather than divided between clinics or sites of care; devising standardized systems of linking mother and baby records after discharge. See also discussion of latent error in: Reason J. *Human Error*. Cambridge: Cambridge University Press (1990).

⁴² Bates, *supra*, n. 40.

⁴³ Koppel R, Metlay JP, Cohen A, et al. *Role of Computerized Physician Order Entry Systems in Facilitating Medication Errors*, 293 *JAMA* 1197 (2005).

⁴⁴ *Id.* Review of computerized physician order entry systems revealed physicians: 1) were uncertain about prescription drugs or dosages because they were unable to review all medication on one screen; 2) CPOE did not have a reminder system, so antibiotics were not received on time; 3) names and drugs were listed close together in small type, and the patient's name did not appear on each computer screen so some orders were made under the incorrect patient name; 4) misread pharmacy inventory information as dosage recommendations; 5) ordered new prescriptions but did not cancel previous orders 6) made medication orders for incorrect patients as when physicians previously using the system failed to log out.

⁴⁵ Mello MM, Studdert, DM, Brennan TA. *The Leapfrog standards: Ready to jump from the marketplace to courtroom?* 22 *Health Affairs* 46 (2003).

⁴⁶ Bates, *supra*, n. 40.

adverse event which can then be investigated through human intervention. However, this method of detection is not without problems: coding is prone to errors and lacks temporal information, since it is usually entered following a patient visit. Coding also lacks clinical content and may suffer from “code creep,” a bias toward higher paying diagnosis related groups. Queries of pharmacy and clinical laboratory data may provide direct evidence for medication and laboratory adverse events by searching for medication orders used to rescue or treat patients for adverse drug reactions like epinephrine, steroids, and antihistamines. This assumes hospital drug and laboratory databases are integrated.⁴⁷

A recent study estimated the national incidence of potential safety-related events utilizing information from a large computerized database. Researchers applied twenty Patient Safety Indicators developed by AHRQ to the Healthcare Cost and Utilization Project (HCUP) Nationwide Inpatient Sample.⁴⁸ The Nationwide Inpatient Sample is the largest publicly available U.S. all-payer computerized database, with all discharge data from nearly 1,000 hospitals in 35 states.⁴⁹ Using an event-based approach, the study looked for corresponding ICD-9-CM codes, finding 1.12 million potential safety-related events that occurred in 1.07 million hospitalizations in the year 2000. Thirty-four percent of events occurred in surgical hospitalizations, 31 percent in obstetric hospitalizations and 35 percent in medical hospitalizations.⁵⁰ The study found risk of experiencing a patient safety event increased with age, with the lowest risk among older children and young adults.⁵¹ Using this extensive database is low cost, unobtrusive, requires no additional effort by healthcare staff and provides a method to identify potential safety problems for further investigation, allowing monitoring of local, state, regional and national patient safety indicator (PSI) rates. Local PSI rates could be used as benchmarks for evaluating local performance or tracking impact of safety-enhancing interventions.⁵² Despite its advantages over a medical record review, there are some limitations to this approach: corresponding ICD-9-CM codes must exist, and accuracy depends on the quality and completeness of coding. Also unavailable is information regarding the severity, timing or etiology of the event, which would put the medical event in context.

Technology applications, as well as any other means designed to detect medical errors, would have a much greater chance of identifying adverse events and classifying them by cause if clinical information such as patient history, clinical plan and rationale for diagnosis was entered into a standard format.⁵³ International, or at least national, standardization of written medical records would enable case record review to detect frequency of adverse events, and avoid automating what some see as an already “faulty” paper system into an electronic medical record to only expensively perpetuate the problem.⁵⁴ Radiology, in which text tends to be more focused in format, has seen success with natural language processing, using methods like pattern matching of words and phrases, to detect adverse events.⁵⁵

⁴⁷ *Id.*

⁴⁸ Romano, *supra*, n. 21.

⁴⁹ <http://www.hcup-us.ahrq.gov/nisoverview.jsp>

⁵⁰ Romano, *supra*, n. 21.

⁵¹ *Id.*

⁵² *Id.*

⁵³ Koppel, *supra*, n. 43.

⁵⁴ Wilson, *supra*, n. 39.

⁵⁵ *Supra* at 9.

A consistent method of classifying adverse events and medical errors is needed to facilitate counting and analysis of these events across systems. With no standardized nomenclature of events, different focus, definitions and data specifications, the ability to compare data is compromised.

E. ISSUES IN REPORTING ADVERSE EVENTS

Reporting systems are an attempt to provide regulation in the area of patient safety. Ideally, a reporting system will “achieve cost-effective safety gains in a manner that minimizes costs, waste, and negative externalities and permits regulatory flexibility in response to variations in health care settings, markets and cultures.”⁵⁶

Determining the primary purpose for reporting adverse events is the initial step in designing a reporting system. Is the system intended to provide a mechanism to evaluate data and disseminate information for improvement or to punish providers and facilities for deviations in care? What events should be reported? Should the focus be on systems issues inherent in the facility or human factors involved in the delivery of care? Should the system of reporting be mandatory or voluntary? Will the information collected be made available to consumers, providers, and regulators or protected from discovery?

The NQF has noted that existing reporting systems have major problems of severe underreporting, lack of knowledge of what and how to report, few incentives and many disincentives to report.⁵⁷ At a recent IOM/Commonwealth Fund meeting evaluating progress on patient safety since the *To Err Is Human* report, reporting systems were criticized for being duplicative and lacking a common set of data fields to permit cross-system data merging.⁵⁸ The NQF has determined a reportable event should be: 1) a concern to both the public and health care professionals; 2) clearly identifiable and measurable and; 3) an event the risk of which can be significantly influenced by policies and procedures of the health care facility.⁵⁹ The event must be unambiguous (clearly definable, quantifiable and able to be audited) usually preventable, serious and adverse, indicative of a problem in a healthcare facility’s safety and/or important for public credibility or public accountability. Frequency of the event should not be a criterion, as many serious events are infrequent.

Adverse event reporting systems should be designed to gain knowledge about how medical care is delivered and use this information to promote safe practice. Specifically, information can be employed to alert providers to drug complications or new medication hazards as well as analyze trends and determine best practices in medicine and error prevention.⁶⁰ Reporting systems designed to be punitive which ineffectively use the data collected will be less able to generate

⁵⁶ Mello, *supra*, n. 22.

⁵⁷ The National Quality Forum, *supra*, n. 30.

⁵⁸ See material collected at http://www.cmwf.org/General/General_show.htm?doc_id=249059, particularly the transcript of the Wachter presentation and subsequent discussion.

⁵⁹ The National Quality Forum, *supra*, n. 30.

⁶⁰ Leape LL, *Reporting of Adverse Events*, 347 N Eng J Med 1633 (2002).

knowledge about medical errors or hold providers accountable.⁶¹ Voluntary systems, which place greater value on resolving systematic problems rather than punishment and work proactively to disclose safe practice recommendations and prevention measures, are seen as garnering the trust and respect of error reporters.⁶² If reporting is to become routine, it must have cultural acceptance in the health care community and reporters must feel safe doing so.⁶³ Focusing blame and shame on individuals instead of system issues for improvement will discourage reporting and may encourage cover-ups.⁶⁴ It may also have the effect of elevating patient risk, if providers increase defensive medicine practices, thereby exposing patients to more procedures because it is legally, rather than medically, prudent to do so.⁶⁵

Whether reporting is mandatory or voluntary, the act of reporting should be streamlined and easy for busy professionals to accomplish. Creating one report to one entity, which is then accessible and in a form acceptable to any other licensing board or oversight agency requiring the information, would help to reduce the burden of reporting.⁶⁶

Who makes the report and who analyzes the data may be critical to the usefulness of the information collected. Practitioners on the front line, as opposed to someone designated as the reporting liaison, will be more familiar with the specifics of the event and provide better information to the reporting body.⁶⁷ Managers or administrators, who may be designated as reporters, may be less able to effectively communicate the medical incident and may overlook, exclude or minimize the information reported in order to limit perceived distrust of the public or organizational liability.⁶⁸

The IOM has criticized reporting systems for not doing enough analysis of data and feedback to reporting facilities.⁶⁹ The NQF echoes this concern, noting existing reporting systems suffer from lack of information sharing and feedback to providers and consumers.⁷⁰ Once collected, reported data should be analyzed by those who will best understand it and its implications. Independent, multidisciplinary groups and content experts familiar with the type of data collected should be charged with making objective determinations of causes of error and recommendations for change.⁷¹ More importantly, what is eventually done with the data will either instill confidence in the process or discourage reporting. Although the effect of providing newsletters and safety alerts has not been studied among state systems, greater value is attributed to a process which pairs reporting with timely dissemination of data to those who need the information to improve practice, support prevention and redesign systems.⁷² Regulatory and accrediting bodies must support system changes to enhance patient safety and monitor

⁶¹ Discussion Paper on Adverse Event and Error Reporting in Healthcare. Institute for Safe Medication Practices. January 24, 2000.

⁶² *Id.*

⁶³ Cohen, *Why Error Reporting Systems Should Be Voluntary (Editorial)*, 320 *BMJ* 7237 (2000)

⁶⁴ Institute for Safe Medication Practices, *supra*, n. 61; Liang, *supra*, n. 32.

⁶⁵ Liang, *supra*, n. 32.

⁶⁶ The National Quality Forum, *supra*, n. 30

⁶⁷ Institute for Safe Medication Practices, *supra*, n. 61.

⁶⁸ *Id.*; Cohen, *supra*, n. 63.

⁶⁹ *See supra*, n. 58.

⁷⁰ The National Quality Forum, *supra*, n. 30.

⁷¹ Institute for Safe Medication Practices, *supra*, n. 61.

⁷² The National Quality Forum, *supra*, n. 30

compliance,⁷³ and research should investigate whether state oversight makes hospitals more careful and promotes corrective action which would not otherwise be taken.⁷⁴

1. MANDATORY OR VOLUNTARY?

Currently, there are four national voluntary external medical error reporting systems: 1) the JCAHO; 2) the Medication Error Reporting Program operated by the United States Pharmacopoeia, a nonprofit, standard-setting organization promoting safe and proper use of medications and the Institute for Safe Medication Practices; 3) the National Nosocomial Infection Survey, through the Centers for Disease Control,⁷⁵ and 4) Med MARx created by the United States Pharmacopoeia (USP).^{76,77}

The Medication Error Reporting Program, a confidential, voluntary system, receives about 1,000 error reports annually from health care professionals. This information is used to make practical recommendations through a widely distributed newsletter and educational efforts to avoid reoccurrence of errors.⁷⁸ Data from this program has been used to prompt drug manufacturers to change labeling, packaging and nomenclature, and issue safety warnings.⁷⁹ Still, the receipt of 1,000 reports annually suggests even a voluntary system which directly uses information for improvement of care may experience substantial underreporting.

The Safe Medical Devices Act of 1990, a federal act mandating that healthcare facilities and manufacturers report serious injury and illness related to the failure or misuse of medical devices, has experienced little reporting compliance. This system takes little action unless a significant number of harmful errors have been reported and uses reported information as a basis for taking punitive measures against practitioners and healthcare organizations.⁸⁰ As a result, these reports often do not contain in-depth information. Reporters under the Safe Medical

⁷³ Institute for Safe Medication Practices, *supra*, n. 61; Cohen, *supra*, n. 63.

⁷⁴ Leape, *supra*, n. 60.

⁷⁵ Hospitals that implemented the full program, realized 32 % lower infection rates.

⁷⁶ MEDMARX is a national, Internet-accessible anonymous reporting database that hospitals and health care systems use to track and trend medication errors. Hospitals and health care systems participate in MEDMARX voluntarily. USP created MEDMARX to help health care facilities understand the causes of medication errors and the factors that contribute to them in order to improve patient care and safety. <https://www.medmarx.com/index.jsp> The Medication Errors Reporting Program operated by USP in cooperation with the Institute for Safe Medication Practices allows healthcare professionals to report potential and actual medication errors directly to USP on a confidential and anonymous basis. <http://www.usp.org/patientSafety/mer/> accessed Aug. 10, 2005. The Federal Drug Administration's (FDA) Adverse Event Reporting System (AERS) is a computerized database supporting the FDA's post-marketing safety surveillance program for all approved drug and therapeutic biologic products. The FDA receives adverse drug reaction reports from manufacturers as required by regulation. The FDA's MedWatch program allows healthcare professionals and consumers to voluntarily report serious problems thought to be associated with drugs and medical devices they prescribe, dispense, or use. Medical product safety alerts, recalls, withdrawals, and labeling changes are disseminated through the MedWatch website. <http://www.fda.gov/medwatch/index.html> accessed Aug. 10, 2005.

⁷⁷ Leape, *supra*, n. 60.

⁷⁸ Cohen, *supra*, n. 63.

⁷⁹ *Id.*

⁸⁰ *Id.*

Devices Act may fear repercussions and potential legal discovery of these reports, and may believe adverse events will be viewed as a measure of their competence.⁸¹

The JCAHO no longer requires hospitals to report sentinel events. However, if a sentinel event is discovered during the accreditation process, a root cause analysis is required.⁸² Voluntary reports under the JCAHO's sentinel event policy have been low: only 60% of all reports since 1995 were voluntarily made and only 800 total reports came to the JCAHO's attention in the period from 1998 to 2002, compared to hundreds of thousands of error related deaths during that period.⁸³ The JCAHO reporting relies mainly on the state's protections for peer review/quality assessment (PR/QA) activities under peer review and quality assurance laws. Some argue that protection under state PR/QA statutes may be tenuous as often only the deliberations which take place are considered privileged, not the information itself.⁸⁴ Also, the Sentinel Event Policy involves incident and occurrence reports which are compiled in the health care entity's ordinary course of business and would be discoverable at trial. Evidence on the cost-effectiveness of the JCAHO's regulations, as well as the effect on patient outcomes is scant and needs to be developed.⁸⁵ No evaluation has been undertaken to determine the value of this adverse event reporting in improving patient safety.⁸⁶

Twenty states have implemented mandatory reporting systems with death being the only common event reportable among all of them.⁸⁷ Most require serious mishaps to be reported and provide for citations, penalties, or sanctions. Most hospitals receive no feedback after investigations, and some states do not track error trends. Some states issue regular reports⁸⁸ and some issue periodic alerts or newsletters.⁸⁹ Reporting among these states is infrequent, with only six states receiving more than 100 reports annually.⁹⁰

Non-health care industries with national reporting systems provide examples of error reporting design. The Aviation Safety Reporting System (ASRS), which receives reports of errors in the aviation industry, has the following attributes: 1) reporting provides immunity from sanctions for pilots who report promptly; 2) reporting is a simple task using a one page form; and 3) the process is seen as worthwhile by those who participate, with confidential information analyzed by experts who make recommendations to the Federal Aviation Association.⁹¹ Building on the aviation error reporting model, medical centers in Texas have instituted a pilot project allowing nurses to anonymously self-report errors for analysis.⁹² National health related organizations, the Medication Error Reporting Program, MedMARx and National Nosocomial Infection Survey

⁸¹ *Id.*

⁸² Liang BA. *Risks of Reporting Sentinel Events*, 19 Health Affairs 112 (2002).

⁸³ *Id.*

⁸⁴ *Id.*

⁸⁵ Mello, *supra*, n. 22 (citing Corrigan JM, Eden J and Smith BM, eds. *Leadership by Example: Coordinating Government Roles in Improving Health Care Quality*, Washington, DC: National Academies Press (2002)).

⁸⁶ *Id.*, (citing Shojania K, Duncan B, et al., eds. *Making Health Care Safer: A Critical Analysis of Patient Safety Practices*. Rockville, MD: Agency for Healthcare Research and Quality (2001)).

⁸⁷ Leape, *supra*, n. 60.

⁸⁸ *Id.* (Colorado, Kansas, Massachusetts and Florida)

⁸⁹ *Id.* (Colorado, Kansas, Massachusetts and New York)

⁹⁰ *Id.*

⁹¹ *Id.*

⁹² Texas medical centers, *supra*, n. 33.

all share these same characteristics. Some argue the ASRS is successful because it is voluntary, nondiscoverable, anonymous, and nonpunitive. Additionally, the life of the pilot, as well as the passengers, may be at stake. By comparison, in the health care system, it is the patient, not the provider who is at risk from medical errors. The primary incentive to report, the preservation of one's own life, is present in aviation error reporting but is missing in medicine and replaced with the preservation of one's livelihood.⁹³

Regardless of whether a medical error reporting system is mandatory or voluntary, it seems likely the volume of error reporting will be low until providers are certain about three things: (1) what should be reported? (2) will the information be used in a timely fashion to improve patient safety? (3) will the information reported be used punitively?

2. PUBLIC OR CONFIDENTIAL?

Whether to provide public disclosure of reported adverse event data must be addressed. The public wants to know that oversight of health care institutions is taking place.⁹⁴ Over 70% of Americans feel error information should be publicly available.⁹⁵ Currently in every state, the public is able to access information regarding deficiencies issued to health care institutions as a result of state licensing surveys or investigations.⁹⁶ This type of information, in addition to hospital safety participation efforts, could be used by consumers for comparison purposes.⁹⁷ As consumer-directed healthcare programs grow, consumers will demand cost and quality data for potential sources of care in order to choose services that provide the most value for the resources expended, which will likely increase demand for information on patient safety as well.⁹⁸ Consumer access to information should be paired with patient education, to help patients interpret what the data do and do not mean, and define the patient's role in reducing medical errors.⁹⁹ Consumers should be cautioned about using information to determine whether one institution is better than another, as most of the events reported may be rare in frequency, limiting fair comparison by error rate alone.¹⁰⁰ More importantly, reporting rates vary and the public may wrongly infer that certain institutions are less safe when in fact they are simply more conscientious about reporting adverse events. Information aggregated by regions across states might be more useful to consumers and relevant to error trends.¹⁰¹

The possibility that reported information could be discoverable and may prompt or support litigation causes many health care entities to be wary of systems which mandate error reporting.

⁹³ Andrus C, Villasenor EG, Kettel JB, Roth R, Sweeney AM, Matolo NM. *"To Err is Human": Uniformly Reporting Medical Errors and Near Misses, A Naïve, costly and Misdirected Goal*, 196 J. Am. College of Surgeons 911 (2003).

⁹⁴ Leape, *supra*, n. 60.

⁹⁵ *Id.*

⁹⁶ Marchev M. *Medical Malpractice and Medical Error Disclosure: Balancing Facts and Fears*, December 2003, report for the National Academy for State Health Policy, prepared with support from the Robert Wood Johnson Foundation.

⁹⁷ Liang, *supra*, n. 32.

⁹⁸ Chaiken BP. *Consumer-Directed Healthcare: Increasing Demand for Quality Data, Patient Safety & Quality Healthcare*, July-Aug, 2005, 6-7.

⁹⁹ The National Quality Forum, *supra*, n. 30; Liang, *supra*, n. 32.

¹⁰⁰ The National Quality Forum, *supra*, n. 30.

¹⁰¹ *Id.*

Is there a connection between mandatory reporting and malpractice litigation? Does the perceived possibility of litigation curb medical error reporting and thus hinder the effectiveness of reporting systems? Nineteen of twenty-one states with mandatory reporting systems were surveyed on these issues.¹⁰² The majority of states reported no indication their mandatory reporting system had resulted in an increased number of malpractice suits, regardless of whether or not the reported information was protected from disclosure.¹⁰³ Indeed, any link between reporting and litigation has yet to be demonstrated.¹⁰⁴ Most states which did disclose data did so in aggregate form. The noticeable lack of increase in malpractice litigation from mandatory error reporting may be due to error information being available from other sources and egregious events already being known to patients and families.¹⁰⁵

As long as information in error reporting systems is perceived as subject to discovery, providers may be reluctant to participate. Strong system design features, with comprehensive data protection strategies outlining allowable data uses should be considered.¹⁰⁶ State statutes preceded by a clear declaration of legislative intent asserting that all reported data are confidential, privileged, and exempt from public disclosure laws would afford more robust protection against legal challenges.¹⁰⁷ However, there has been very little testing of these provisions in the court system. As well, little information is available about how peer-review laws apply to error reporting databases that reside beyond the hospital's walls.¹⁰⁸

Because reports will be made in a malpractice litigation environment it appears "no mix of mandatory/voluntary and public/confidential features can avoid trading off important interests of patients against those of providers."¹⁰⁹ Anonymous reporting and de-identified data offer protection against discovery but limit the ability of regulators to identify and analyze clusters of injuries at particular hospitals or healthcare facilities.¹¹⁰ To ensure accountability, regulators may need the flexibility to use the data to impose sanctions or require corrective action plans. But as long as provisions for accountability exist, some speculate reporting systems will never be completely "safe" for providers.¹¹¹

Specific confidentiality and discoverability protections should also extend to types of data also required to be reported to entities beyond the state system.¹¹² For instance, sentinel event reporting to the JCAHO requiring an extensive root cause analysis of the error depends on the state's PR/QA protections from discovery. Although the JCAHO has developed alternative methods for reporting if the reporting entity fears the information's protection under state law

¹⁰² Marchev, *supra*, n. 96.

¹⁰³ *Id.*

¹⁰⁴ Leape, *supra*, n. 60.

¹⁰⁵ Marchev, *supra*, n. 96.

¹⁰⁶ *Id.*

¹⁰⁷ *Id.*

¹⁰⁸ Mello, *supra*, n. 22.

¹⁰⁹ Studdert DM and Brennan TA. *No-Fault Compensation for Medical Injuries the Prospect for Error Prevention*, 286 JAMA 217 (2001).

¹¹⁰ Marchev, *supra*, n. 96.

¹¹¹ Leape, *supra*, n. 60.

¹¹² Marchev, *supra*, n. 96.

would be waived by reporting to the JCAHO, some argue that absent a specific legal privilege, information regarding the sentinel event would be discoverable.¹¹³

Numerous issues regarding the discoverability of medical error information should be considered in designing a reporting system, including whether creation of incident and occurrence reports would be considered as compiled in the ordinary course of business and hence discoverable; whether state PR/QA privilege would protect the committee's deliberations but not the information used for deliberation; whether subsequent remedial measures initiated to improve the safety of systems could be used as proof of negligence at trial; whether discussions with the JCAHO waive any state law privilege; or whether a federal court would recognize state law privilege of state claims if pled with a federal cause of action. All these issues may expose providers to risk, and some might be more adequately addressed with federal legislation.¹¹⁴

There is conflict between the belief that transparency regarding adverse events is good and the opposing view which supports confidentiality of adverse events so that reporting is encouraged.¹¹⁵ Those who favor disclosure to patients suggest open, honest communication will result in patients who are less likely to sue, but little evidence is available to support this assertion. Physicians are reluctant to participate in state reporting systems without significant legal protections against discovery. These conflicting beliefs create the potential for diverse regulations regarding reporting and disclosure.¹¹⁶

The JCAHO now requires facilities to have a policy of full disclosure to their patients of "unanticipated outcomes of care" that are associated with the JCAHO's sentinel events.¹¹⁷ Some advocate that this information be limited to what is known to be accurate about the event, without speculation, focusing on what the patient needs to know about how or why her treatment plan has changed and what may be reactions or consequences. While patients are becoming more sophisticated about aspects of care, increasing demands for information from providers, the medical profession has not kept pace in teaching communication and conflict management skills to physicians.¹¹⁸

Wyoming recently passed "I'm Sorry" legislation that prohibits the admission of an expression of sympathy by a health care provider to a patient or patient's relative relating to an unanticipated outcome of medical care as evidence of liability or an admission against interest in any civil action or arbitration.¹¹⁹ The legislation is too new to know whether it will encourage disclosure or how it will be interpreted by the courts though some insight may be gained from research exploring attitudes of physicians and patients regarding medical error disclosure. Patients queried about medical errors were unanimous in desiring information on the cause, consequences and future prevention of errors, while physicians were wary about providing this information due to fear of litigation and uncertainty about what had actually happened. Patients involved in the study were interested in an explanation of why the error had occurred, not to

¹¹³ Liang, *supra*, n. 82.

¹¹⁴ *Id.*

¹¹⁵ Mello, *supra*, n. 22.

¹¹⁶ *Id.*

¹¹⁷ Popp PL. *How will disclosure affect future litigation?*, 23 J. of Healthcare Risk Management 239 (2003).

¹¹⁸ *Id.*

¹¹⁹ Wyo. Stat. Ann. §1-1-130 (2005).

assign blame, but in order to know what had happened to them and to know that those involved, including the institution, had learned from the event.¹²⁰ Opinions of patients and physicians were mixed concerning disclosure of near misses. Though knowing about near misses could assist patients in making better informed choices about care, many patients did not want to know and physicians felt disclosure was impractical.¹²¹ The study also found patients wanted apologies and physicians wanted to apologize but feared litigation if they did so. The researchers posited that apology might be a useful tool to resolve the distress of both parties following a medical error.¹²² If this is indeed the case, Wyoming's "I'm Sorry" statute may make this outcome more achievable.

F. WYOMING'S REPORTING STATUTE: W.S. §35-2-912 (2005). MANDATORY REPORTING OF SAFETY EVENTS.

With the passage of Senate File 113 during the 2005 Wyoming Legislative session, Wyoming is about to embark on mandatory reporting of safety events.¹²³ Every licensed health care facility within the state will be required to report any safety event occurring after June 30, 2005 to the Wyoming Department of Health (department).¹²⁴ Events causing serious injury or death or the risk thereof will be reported through the facility's designated safety officer.¹²⁵ The broad categories of reportable events include surgical, product or device, patient protection, care management, environmental and criminal events.¹²⁶ The department is prohibited from sharing any reported information with the office of health care licensing which also resides in the department.¹²⁷ Safety event reports will identify the facility, but not the health care professional, employees of the facility or patients involved in the event.¹²⁸ The department is instructed to encourage electronic filing and when practical, to use information already being generated by the health facility for other reporting requirements.¹²⁹ The law deems confidential and protects from discovery or admissibility in any legal or administrative proceeding and exempts from public record "any notice, report, document and other information compiled or disseminated" under the act.¹³⁰ Similarly, it protects any "contractor, employee or other member of the department" who receives information from being required or permitted to testify in civil proceedings regarding "any evidence or any other matters presented to the department or as to any findings, recommendations, evaluations, opinions or other actions of the department."¹³¹ However, information that would be available from other sources is not protected from discovery, nor is anyone who provides information to the department under the act prevented from testifying "as to matters within his knowledge" although testimony regarding communications with the

¹²⁰ Gallagher TH, Waterman AD, Ebers AG, Fraser VJ, Levinson W. *Patients' and Physicians' Attitudes Regarding the Disclosure of Medical Errors*, 289 JAMA 252 (2003).

¹²¹ *Id.*

¹²² *Id.*

¹²³ 2005 Wyo. Laws ch. 243.

¹²⁴ Wyo. Stat. Ann. § 35-2-912(b) (2005).

¹²⁵ *Id.* at (a) and (b).

¹²⁶ *Id.* at (a)(i) through (vi).

¹²⁷ *Id.* at (b).

¹²⁸ *Id.* at (c).

¹²⁹ *Id.* at (c), (d).

¹³⁰ *Id.* at (e).

¹³¹ *Id.*

department is prohibited.¹³² Beginning in 2006, the department will be required to publish a report of aggregate data, analyzing all reported safety events, including a trend analysis and make recommendations for systemic improvements.¹³³

In August, 2005, acting under the authority provided by W.S. §35-2-912, the department promulgated Rules and Regulations for Health Care Facility Safety Event Reporting, which essentially mirror the requirements outlined in the statute, with no attempt at clarification.¹³⁴

1. ANALYSIS OF WYOMING STATUTE §35-2-912

The Wyoming reporting statute is the state's first attempt to define, identify and collect information on medical errors in health care facilities and the legislature should be commended for this effort. Analyzing the Wyoming statutory provisions in light of current research findings and literature on this subject enables the following comparisons to be made.

Mandatory reporting: The purpose of the statute appears to be to gain knowledge of health care errors in facilities throughout the state in order to recommend "systemic improvements that are likely to enhance patient safety and health care."¹³⁵ The statute requires reporting but provides no incentive to report, nor sanction for those who fail to report. Although voluntary reporting systems like the Aviation Safety Reporting System and Medication Error Reporting Program, seem to have the best reporting rates, non-punitive systems that emphasize resolution of systemic problems may earn the trust of those who are required to report.¹³⁶

Reportable events should be unambiguous, usually preventable, and serious events.¹³⁷ The safety events required to be reported by Wyoming's statute cover six areas and are nearly identical to the List of Serious Reportable Events specified by the National Quality Forum, increasing the chance for meaningful comparisons of data with other reporting systems designating these same events.¹³⁸ The department might consider adopting by rule, the definitions provided by the National Quality Forum to standardize terminology associated with reportable events.¹³⁹ The type of event reported under the statute must involve death or serious physical or psychological injury or the risk thereof, though the statute does not define "risk thereof," leaving that interpretation to the reporter. Neither does it consider "near miss" events, which might later be the cause of future injurious error.¹⁴⁰

Provision for corrective action plan: The Wyoming statute does not require the reporting facility to take measures to correct and prevent the identified error from reoccurrence.¹⁴¹ In contrast, other entities, like the JCAHO, Pennsylvania and Minnesota state reporting systems, have

¹³² *Id.*

¹³³ *Id.* at (f).

¹³⁴ See Appendix E: Wyoming Department of Health Rules and Regulations for Health Care Facility Safety Event Reporting *infra*, p. FF.

¹³⁵ W.S. § 35-2-912(f).

¹³⁶ Cohen, *supra*, n. 63; Leape, *supra*, n. 60.; Institute for Safe Medication Practices, *supra*, n. 61.

¹³⁷ Leape, *supra*, n. 60.; The National Quality Forum, *supra*, n. 30.

¹³⁸ See Appendix A: List of Serious Reportable Events, *infra*, p. B.

¹³⁹ See Appendix B: The National Quality Forum, *infra*, p. F.

¹⁴⁰ Liang, *supra*, n. 32.

¹⁴¹ Liang, *supra*, n. 82.

incorporated corrective action as part of the reporting scheme.¹⁴² The Pennsylvania Medical Care Availability and Reduction of Error (Mcare) Act mandates the establishment of patient safety plans, patient safety officers and patient safety committees in all licensed health care facilities.

The Minnesota Adverse Health Care Events Reporting Act of 2003 requires hospitals to report the categories of events designated by the NQF and undertake a root cause analysis.¹⁴³ Upon completion of the analysis, the reporting facility must specifically implement a corrective action plan, and report findings of the analysis and plan.¹⁴⁴ The Commissioner of Health receives the reports and is charged with determining patterns of systemic failure and methods for correction through analysis of adverse event reports, root cause analyses and corrective action plans.¹⁴⁵ More importantly, the Commissioner of Health must communicate recommendations for corrective action to individual facilities, based on the events reported.¹⁴⁶

Provision for state analysis of report data: The Pennsylvania Medical Care Availability and Reduction of Error (Mcare) Act of 2002 aimed to reduce medical errors by identifying problems and implementing solutions that promote patient safety. The Pennsylvania Patient Safety Reporting System (PSRS) is focused on patient safety through learning and quality improvement, by identifying patterns and trends in serious events and incidents across facilities. The system recognizes its role as a “knowledge broker” determining one measure of success as the extent to which the PSRS can collect lessons learned the “hard way” at a few facilities and impart those lessons to others in a “pain free” fashion.¹⁴⁷ The act establishes an independent, eleven member Patient Safety Authority (PSA), appointed by the Governor and General Assembly, which includes the state Physician General, a physician, nurse, pharmacist, hospital employee, health care worker, non-health care worker and four other Pennsylvania residents.

The Pennsylvania Patient Safety Reporting System has two reporting systems that operate simultaneously. The Pennsylvania Department of Health is the designated entity to receive reports regarding facility infrastructure failures.¹⁴⁸ The PSA has general authority to collect, analyze and evaluate data regarding reports of serious events and incidents, as well as identify

¹⁴² The JCAHO has designated the following events as reportable sentinel events:

1. Results in unanticipated death or major permanent loss of function, not related to the natural course of the patient’s illness or underlying condition
2. Suicide in setting where patient receives around the clock care
3. Infant abduction, or discharge to wrong family
4. Rape
5. Hemolytic transfusion reaction having major blood group incompatibilities
6. Surgery on wrong patient/body part

¹⁴³ Minnesota Adverse Health Care Events Reporting Act of 2003, *supra*, n. 28, § 3, Subdiv. 8.

¹⁴⁴ *Id.*

¹⁴⁵ *Id.* at § 4, Subdiv. 2(1).

¹⁴⁶ *Id.* at § 4, Subdiv. 2(2) and (3).

¹⁴⁷ Solomon RP. *Can Reporting Help to Prevent Injury and Assure Competency?* Presentation given Nov. 8, 2004, A Prescription for Patient Safety and Medical Liability, Alexandria, VA.

¹⁴⁸ “Infrastructure failure” is defined as: an undesirable or unintended event, occurrence or situation involving the infrastructure of a medical facility or the discontinuation or significant disruption of a service which could seriously compromise patient safety.

“performance indicators and patterns of frequency or severity at certain medical facilities or in certain regions” of the Commonwealth.¹⁴⁹ The reporting of incidents may be the state’s attempt to collect “near miss” data.¹⁵⁰ The data collected are given a “harm score” and analyzed for likelihood of recurrence and potential contributing factors. In this way, the system is able to triage the reports for severity.

In addition, the PSA is tasked with recommending changes in health care practices and procedures and directly advising facilities of immediate changes to reduce medical errors.¹⁵¹ In offering recommendations for change, the PSA must consider the expectations for improved quality care, feasibility of implementation, costs to stakeholders, including patients, and other relevant practices which could be implemented.¹⁵² The PSA issues quarterly advisories to providers and facilities, with supplements issued as needed for problems requiring a timely response. The act also requires mandatory written disclosure of serious events to patients and continuing medical education on patient safety and risk management for physicians.

The JCAHO’s requirement that an event must result in “unanticipated death or major permanent loss of function,” excludes by definition most adverse events that may occur. The JCAHO has also established National Patient Safety Goals, and requires organizations to implement the recommendations accompanying these goals, or acceptable alternatives, or face problems with JCAHO accreditation.¹⁵³ Some of these mandates appear to have come from the effectiveness rather than the safety domain.¹⁵⁴

The Wyoming statute encourages reporting to be streamlined and mesh with other reporting requirements the facility may have, and provides for electronic reporting. Department rules should emphasize a secure system for collection of this data. The department may employ experts to review the reported data which may be more objective as well as more insightful in determining causes of error and changes required.¹⁵⁵ The department will report its results annually of aggregate information and make it publicly available. Whether or not issuing an annual report of aggregate data will be considered timely by those who need to make improvements, as well as usable by the public, remains to be seen.

¹⁴⁹ MCARE Act, *supra*, n. 27 at § 304(a)(5)(i). “Serious event” is defined as: an event, occurrence, or current situation involving the clinical care of a patient at a medical facility that results in death, or compromises patient safety and results in an unanticipated injury requiring the delivery of additional health care services to the patient.

¹⁵⁰ “Incident” is defined as: an event, occurrence, or current situation involving the clinical care of a patient in a medical facility, which could have injured the patient, but did not either cause an unanticipated injury or require the delivery of additional health care services to the patient.

¹⁵¹ MCARE Act, *supra*, n. 27 at § 304(a)(5)(ii) and (iii).

¹⁵² MCARE Act, *supra*, n. 27 at § 304(6).

¹⁵³ Starting with six goals in 2002, the JCAHO has developed a set of 14 goals for compliance in 2006, with specific goals designated for each of nine different healthcare entities: ambulatory care and office-based surgery; assisted living; behavioral health care; critical access hospital and hospital; disease-specific care; home care; laboratory; long-term care; and networks.

<http://www.jcaho.org/accredited+organizations/patient+safety/facts+about+patient+safety.htm> accessed Aug. 11, 2005.

¹⁵⁴ Mello, *supra*, n. 22

¹⁵⁵ Institute for Safe Medication Practices, *supra*, n. 61

Protection for reporters: In Pennsylvania, reports to both entities may be anonymous and must be made within 24 hours of occurrence or discovery. The act protects the confidentiality of identifying information about patients and health care workers. Safety reports are protected from discovery and individuals as well as employees of the department of health and the PSA are not permitted to testify regarding the reported information.

The Wyoming statute requires error information to pass through a designated safety officer, which may dilute the details of the event or minimize the information reported.¹⁵⁶ However, the statute also provides anonymity for health care professionals and employees involved in the safety event, extending the whistleblower and immunity protections of W.S. §35-2-910(a) and (b) which should instill confidence that information reported will be used to monitor health care systems, and a sense that it is safe to report.¹⁵⁷ The trade-off for confidentiality and anonymity may be limitations in holding providers accountable for patient safety.¹⁵⁸ It should be noted W.S. §35-2-910(a) does not extend immunity to negligent, intentional acts or omissions in the provision of care. This provision, read in conjunction with W.S. § 35-2-912(e), suggests those who participate in reporting, collection or evaluation of errors of omission, which would likely be reported under the act, would not be immune from suit and perhaps discovery.

Protection of reported information: Wyoming's medical error reporting statute specifically elects to adopt the immunity coverage provided by the Health Care Quality Improvement Act as it applies to the Wyoming Department of Health's duties in the new medical errors reporting system.¹⁵⁹ Congress enacted Chapter 117 of the Health Care Quality Improvement Act, United States Code Title 42 §§ 11101-11152, for the express purpose of "provid[ing] incentive and protection for physicians engaging in effective professional peer review."¹⁶⁰ It specifically provides immunity from monetary damages for professional review bodies and to any person "providing information to a professional review body."¹⁶¹

It is unlikely the Federal law will provide any additional immunity protections for reports generated in conformance with Wyoming's law or rules generated by the Department of Health. A "professional review action" is defined as "an action or recommendation of a professional review body which is taken or made in the conduct of *professional review activity* . . . and which affects (or may affect) adversely the clinical privileges, or membership in a professional society, of the physician."¹⁶² (Emphasis added). Professional review activity is defined as "an activity of a health care entity . . . (A) to determine whether the physician may have clinical privileges[,] . . . [(B)] the scope or conditions of such privileges or membership, or (C) to change or modify such privileges or membership."¹⁶³ Wyoming's error reporting statute takes no action towards a physician or physicians involved in a medical error, nor does it provide for peer review action as defined by the Health Care Quality Improvement Act. Quite to the contrary, in Wyoming, the reporting entity is identified but all identifying information related to health care professionals,

¹⁵⁶ Institute for Safe Medication Practices, *supra*, n. 61; Cohen, *supra*, n. 63

¹⁵⁷ Institute for Safe Medication Practices, *supra*, n. 61; Liang, *supra*, n. 32.; Cohen, *supra*, n. 63

¹⁵⁸ Marche, *supra*, n. 96.

¹⁵⁹ W.S. § 35-2-912(j).

¹⁶⁰ 42 U.S.C. § 11101(5).

¹⁶¹ *Id.* at § 11111(a)(1).

¹⁶² *Id.* at § 11151(9).

¹⁶³ *Id.* at § 11151(10).

employees and patients is excluded from the report.¹⁶⁴ This requirement precludes the reports under Wyoming's act from involvement in any actions affecting or potentially affecting a physician's privileges.

Evaluation of the law: Although the statute will sunset in 2010 and might possibly be assessed at that time, no provision is made for an on-going evaluation of the reporting system while in effect.¹⁶⁵ Matching reported errors to a review of patient records or looking at the frequency and types of errors reported may indicate whether the system is fulfilling its legislative intent. A larger question, however, is whether the reporting of errors has led to a change in practices and enhancement of patient safety. The ability to measure progress in identifying errors, demonstrate change in practice and that change resulted in improved patient safety is a necessary component of any system and should not be overlooked. As with other national reporting schemes, like the JCAHO's system, the need to know whether Wyoming's reporting system is both cost-effective and effects patient outcomes is important.¹⁶⁶ The Agency for Healthcare Research and Quality's set of patient safety indicators may be helpful in this regard, if information on changes and improvement is available from the reporting facilities.¹⁶⁷

2. INTERFACE OF W.S. §35-2-912 AND THE FEDERAL PATIENT SAFETY AND QUALITY IMPROVEMENT ACT OF 2005

In July, 2005, President Bush signed into law the Patient Safety and Quality Improvement Act of 2005 (Act), which amends Title IX of the Public Health Service Act.¹⁶⁸ Generally, the Act provides legal privilege and confidentiality protections for "patient safety work products" assembled or developed "by a provider for reporting to a patient safety organization" or "by a patient safety organization for the conduct of patient safety activities."¹⁶⁹ To be covered under the Act, a patient safety organization must be certified by the Secretary of Health and Human Services and have policies and procedures in place to perform the patient safety activities described in the Act.¹⁷⁰ Among those activities listed is a requirement for the "utilization of patient safety work product for the purposes of encouraging a culture of safety and of providing feedback and assistance to effectively minimize patient risk."¹⁷¹ Whether Wyoming's reporting statute, which provides only for the publication of annual aggregate data, would meet this certification requirement is questionable.

The Act also prohibits an employer from taking an "adverse employment action" which includes an "adverse evaluation or decision made in relation to accreditation, certification, credentialing, or licensing of an individual" against a provider for having reported information in good faith to a patient safety organization.¹⁷² As in the Wyoming statute, the federal law does not intend for

¹⁶⁴ W.S. § 35-2-912(c).

¹⁶⁵ W.S. § 35-2-912(k).

¹⁶⁶ Mello, *supra*, n. 22 (citing Corrigan, *supra*, n. 85).

¹⁶⁷ <http://www.qualityindicators.ahrq.gov>

¹⁶⁸ Public Health Service Act, 42 U.S.C. § 299 et seq., *See*, Appendix D: Federal Patient Safety and Quality Improvement Act of 2005, *infra*, p. R.

¹⁶⁹ 42 U.S.C §§ 921(7)(A)(i)(I) and (II).

¹⁷⁰ *Id.* at § 924(a)(1)(A) (referencing §§ 921(5)(A) through (H)).

¹⁷¹ *Id.* at § 921(5)(D).

¹⁷² *Id.* at § 922(e).

these provisions to be used as a means to support physician accountability. Finally, the Act promotes the creation of a network of patient safety databases that “provide an interactive evidence-based management resource for providers, patient safety organizations, and other entities.”¹⁷³ To facilitate this effort the Secretary may determine common reporting formats, work product elements, definitions and a standardized computer interface.

Should Wyoming pursue certification and choose to participate in the nation-wide database, once developed, it will need to conform its reporting practices to the national standard. If Wyoming chooses not to participate, the existing protections provided in Wyoming’s reporting statute will not be diminished. At most, the Act provides only for another layer of protection for patient safety work product and those who report to patient safety organizations.

G. PREVENTION

1. NATIONAL APPROACHES TO PREVENTION

Once medical errors have been defined, identified, and a reporting system put in place, how should this information be used to prevent recurrence of errors and injuries? Prevention proceeds by investigating safety problems, identifying solutions, and disseminating them. Specifically, the National Quality Forum (NQF) recommends “identifying points in the system of care where protocols should be changed, new or different technology implemented, training revised, and/or other processes changed,”¹⁷⁴ and sharing lessons learned from investigations of underlying system problems with other health care facilities, allowing prevention of similar errors elsewhere.¹⁷⁵

The duty to identify sentinel events, the JCAHO stresses, requires the health care facility to respond appropriately in a three step sequence: 1) initiating a timely, thorough and credible root cause analysis, 2) implementing improvements to reduce risk, and 3) monitoring the effectiveness of those improvements.¹⁷⁶ A barrier analysis offers a structured way to visualize events related to creation of problems or system failure by studying safeguards which could prevent or mitigate error.¹⁷⁷ Another type of analysis is “FMECA” or Failure, Mode, Effect and Criticality Analysis, a prospective design examination to identify possibilities for system failure.¹⁷⁸ Under this method, latent failures, precipitated by management and organizational processes, are recognized as presenting the greatest danger to complex systems, because they are not foreseeable and are difficult to detect.

On its Morbidity and Mortality website, the Agency for Healthcare Research and Quality has created a patient safety network to allow anonymous posting of cases involving medical error. Three cases are presented monthly for review and commentary.¹⁷⁹ Both the Institute for Health

¹⁷³ *Id.* at § 923.

¹⁷⁴ The National Quality Forum, *supra*, n. 30

¹⁷⁵ *Id.*

¹⁷⁶ <http://www.jcaho.org>

¹⁷⁷ <http://www.jcaho.org/accredited+organizations/ambulatory+care/sentinel+events/glossary.html>

¹⁷⁸ *Id.*

¹⁷⁹ <http://www.webmm.ahrq.gov/index.aspx>

Care Improvement (IHI), a nonprofit organization pursuing improvement in health care, and the JCAHO has initiated patient safety campaigns and adopted explicit patient safety goals.¹⁸⁰

The Institute for Healthcare Improvement has initiated a 100,000 Lives Campaign, aimed at promoting safety change in hospitals.¹⁸¹ The campaign seeks to reduce error and prolonged hospitalization associated with error by making improvements in six areas: (1) rapid response teams to intervene at the first sign of patient decline; (2) improved care for acute myocardial infarction; (3) prevention of adverse drug events; (4) prevention of central line associated bloodstream infection; (5) prevention of surgical site infection; and (6) prevention of ventilator-associated pneumonia. Citing serious medical errors that have resulted from lack of attention to these problems, the IHI hopes to enlist thousands of hospitals to focus efforts in these areas.¹⁸² Nearly one-fifth of the nation's 5,500 hospitals have already committed to the program with promising results. Participating hospitals in Michigan believe 73 deaths from pneumonia and four from blood transfusions were averted over the past year due to safety practices designed to eliminate catheter-related blood infections and ventilator-associated pneumonia.¹⁸³

Researching closed medical malpractice claims gives some indication of where serious medical errors occur. A recent study reviewing closed claims from five malpractice insurers, covering 33,000 physicians, showed 80% of claims resulted from four clinical categories: obstetrics, medication, diagnostic and surgical related claims. The most frequent malpractice claim in an outpatient setting was diagnostic related claims, about half of which were failure to diagnose cancer, with breast cancer comprising 50% of the missed cancer diagnoses.¹⁸⁴ Generally, this type of statistical information is available through the National Practitioner Data Bank, which records all malpractice judgments and settlements against physicians.¹⁸⁵

¹⁸⁰ JCAHO's 2005 National Patient Safety Goals include: 1) improve accuracy of patient identification; 2) improve the effectiveness of communication among caregivers; 3) improve the safety of using medications; 4) improve the safety of using infusion pumps; 5) improve the effectiveness of clinical alarm systems; 6) reduce the risk of health care-associated infections; 7) accurately and completely reconcile medications across the continuum of care; 8) reduce the risk of patient harm resulting from falls; 9) reduce the risk of influenza and pneumococcal disease in institutionalized older adults; 10) reduce the risk of surgical fires, and; 11) eliminate wrong site, wrong procedure and wrong person surgery. <http://www.jcaho.org>.

¹⁸¹ <http://www.ih.org/ih>.

¹⁸² Rapid response teams would intervene to prevent death at the first sign of patient decline, noting most patients who experience cardiac arrest first exhibit identifiable signs of deterioration, and only 17% of those who experience cardiac arrest in the hospital survive; 1.1million people annually experience myocardial infarction, 1/3 of which die; patients who experience adverse drug events are twice as likely to die as those who don't; 1993 death certificate data showed 1,200 deaths from medication errors; 14, 000 deaths annually are attributed to catheter-related blood stream infections; surgical site infections account for 40% of hospital acquired infections, and those who are infected are twice as likely to die as other surgical patients; ventilator-associated pneumonia occurs in 15% of ventilated patients, causing prolonged ICU stay and 46% death rate. *Id.*

¹⁸³ Johnson LA. *Hospitals Cut Patient Complications*, Las Vegas Sun, June 3, 2005, available at: <http://www.lasvegassun.com/sunbin/stories/thrive/2005/jun/03/060300236.html>.

¹⁸⁴ Studdert, DM. Presentation to the 2005 Annual Patient Safety and Health Information Technology Conference sponsored by AHRQ, June 6, 2005.

¹⁸⁵ The NPDB was established by the Health Care Quality Improvement Act of 1986 in order to prevent physicians who have been judged dishonest or incompetent from moving to another state and misrepresenting their credentials. <http://www.npdb-hipdb.com/npdb.html>; accessed Aug. 9, 2005.

One physician specialty group has undertaken the task of improving patient safety with impressive results. Through the Anesthesia Patient Safety Foundation, over the last twenty years, anesthesiologists have instituted the use of devices that alert physicians of potentially dangerous problems, simulation training and procedural changes that collectively have dropped patient death from anesthesia from one in every 5,000 cases to one in every 2,000,000 to 3,000,000 cases. In this effort, the foundation members included not only doctors, but nurses, insurers and vendors who make anesthesiology products. Doing their own research where none had existed, the foundation reviewed over 6,000 closed malpractice claims to determine how anesthesia accidents occur. As a result of the study findings, pulse oximetry, which measures the amount of oxygen in the blood and capnography, which measures carbon dioxide from exhaled breath, have been instituted as basic standard of care in American hospitals, nearly eliminating intubation errors. Anesthesia machines are equipped with audible alarms that signal potentially serious problems, although many alarms have been found to have been disabled during surgery by surgeons who found them irritating. Anesthesiologists are pursuing adoption of standards that would prohibit turning off the alarms. With the decrease in deaths from anesthesia have come decreases in the number of malpractice claims against anesthesiologists, the size of payments from successful suits, and a 37% decrease in malpractice premiums over the last twenty years.¹⁸⁶

2. LEADERSHIP AND TEAMWORK

Though specific prevention goals are important to identify, equally important is determining appropriate strategies for implementation. Making patient safety a priority, committing to replace systems that are not functional and interdisciplinary training are all seen as measures required to strengthen the health care team.¹⁸⁷ Compromised awareness of medical error contributes to error occurrence. Resources to support critical thinking, including standards of practice and timely notification of changes in procedures can help eliminate gaps in knowledge that lead to error.¹⁸⁸ Focusing on the interaction of technology and human resources as well as the value systems and culture of the health care facility will be steps toward improved patient safety.¹⁸⁹ The greater the gap in the organization between the view of management and that of health care workers in regard to safety risks, the larger the actual number of medical errors experienced.¹⁹⁰ Leadership must buy into patient safety prevention and promote culture change.¹⁹¹

Borrowing from successes in the aviation industry, crew resource management (CRM), may have promise in the patient safety arena. This model is used in aviation to improve teamwork through sharing intentions, enhancing planning and increasing overall situational awareness, as well as the anticipation and recognition of current events or events likely to occur in the near future.¹⁹² Better crew coordination has improved team decision-making, as the pilot receives

¹⁸⁶ Hallinan JT. *Heal Thy Self: Once Seen as Risky, One Group of Doctors Changes its Ways*, Wall Street Journal, 2005.

¹⁸⁷ Cook AF. et al., *An Error by Any Other Name*, 104 American Journal of Nursing 32 (2004).

¹⁸⁸ *Id.*

¹⁸⁹ Firth-Cozens J. *Evaluating the Culture of Safety*, 12 Quality and Safety in Health Care 401 (2003).

¹⁹⁰ *Id.*

¹⁹¹ Leape LL. *Error in Medicine*, 272 JAMA 1851 (1994).

¹⁹² Powell SM. et al. *Delivering the Promise to Healthcare: Improving Patient Safety and Quality of Care Using Aviation CRM*, Patient Safety & Quality Healthcare, July-Aug, 2005, 28-33.

shared information from the team, to assist in making better decisions. The steep hierarchal structure in which the captain is considered “king” begins to flatten with the introduction of CRW.¹⁹³ Similar behaviors and attitudes are found in hospital operating rooms, emergency rooms and intensive care units. A risk management study has shown 43% of emergency room errors were caused by problems with team coordination.¹⁹⁴ Steep hierarchies in healthcare place most of the decision making responsibilities with the doctor and leave staff feeling reluctant to share valuable information. At one hospital implementing the CRW model in obstetrics, a 53% decline in adverse outcomes was realized over a four year period.¹⁹⁵ The JCAHO also recommends team training as part of a hospital’s patient safety program.

Five years after the Institute of Medicine’s report, *To Err is Human*, the primary obstacles to achieving patient safety are not technical but “beliefs, intentions, cultures, and choices.”¹⁹⁶ The Agency for Healthcare Research and Quality (AHRQ) has developed a survey to assess hospital safety culture as a first step in determining how a healthcare facility’s staff views patient safety issues. This toolkit, available online, includes information on how to provide feedback on the survey and utilize results.¹⁹⁷

3. ASSESSING RISK AND IMPLEMENTING CHANGE

Drawn from an analysis of systems and processes, the health care facility’s risk management team of clinicians and administrators should craft an action plan to reduce risk. Risk containment measures may include removing drugs or checking medical devices to ensure that a repetition of error does not occur. For example, medication errors may be caused by performance lapses at the point of order entry and dispensing that have nothing to do with knowledge of the pharmacist, but could be attributed to lack of focus on the task at hand; socializing while engaged in the task; interruptions; poor working environment or too much or too little work.¹⁹⁸ Among the strategies that may reduce the risk of medication errors are having one professional check the work of another, using independent services to check the quality of products produced in the pharmacy, running computer checks for medication allergies and contraindications, verifying barcodes at the point of dispensing and administering medications, and use of forcing mechanisms that won’t allow some actions to be taken (such as oral alimentation tubing that is incompatible with IV lines or computer systems that prohibit lethal drug doses from being prescribed).¹⁹⁹ Additional prevention tools include utilizing computers for tasks requiring short term memory or prolonged attention and making computerized patient records available where they are needed are prevention tools.²⁰⁰ Making dangerous items like potassium chloride unavailable on hospital floors eliminates any potential for its erroronous

¹⁹³ *Id.*

¹⁹⁴ Shapiro M, et al. *Simulation Based Teamwork Training for Emergency Department Staff: Does it Improve Clinical Team Performance When Added to an Existing Didactic Teamwork Curriculum?*, 13 *Quality & Safety in Health Care* 417 (2004) (<http://qhc.bmjournals.com/cgi/reprint/13/6/417>).

¹⁹⁵ American College of Obstetricians and Gynecologists (ACOG) May 3, 2004. *Beyond blame: Ob-Gyns Investigating Model Reforms on Patient Safety*. Press Release. http://www.acog.org/from_home/publications/press_releases/nr05-03-04.cfm

¹⁹⁶ Leape, *supra*, n. 15.

¹⁹⁷ <http://www.ahrq.gov/qual/hospculture/>

¹⁹⁸ Davis NM. *Performance Lapses as a Cause of Medication Errors*, 31 *Hospital Pharmacy* 1524 (1996).

¹⁹⁹ Davis NM. *Lack or Failure of the Safety Net as a Cause of Medication Errors*, 32 *Hospital Pharmacy* 143 (1997).

²⁰⁰ Leape, *supra*, n. 191.

administration.²⁰¹ Not adding a new medication to the formulary, unless it has clear advantages over one already in place makes any error with a new drug impossible if it is not on the shelf to be dispensed.²⁰² Standardizing drug concentration selections and creating calculations for administration eliminate the need to do it every time and avoid math errors.²⁰³ Common practices and procedures, like locations of supplies and equipment or how surgical dressings are applied could all be standardized.²⁰⁴

4. EDUCATION AND TRAINING

For health care professionals to effectively prevent medical errors, they must first have the knowledge to prevent error (including an understanding of the importance of safe practice) be positioned so they can use this knowledge, and have the time and interest to use it.²⁰⁵ Rigorous academic programs and board examinations for students in the health care field are the beginning. Identifying the relationship between fatigue and errors has recently prompted the Accreditation Council on Graduate Medical Education to impose work hour limitations in residency training programs.²⁰⁶ Once on the job, all health care professionals must have the support of health care facility administration, access to current information relevant to safe practice, such as best practices and drug references, and a culture that recognizes the importance of patient safety.²⁰⁷ States can do their part by recognizing the importance of continuing medical education for providers and emphasizing a need to train professionals in patient safety practices. Pennsylvania's comprehensive medical errors legislation requires individuals licensed to practice medicine and surgery to complete 100 hours of continuing medical education every two years, with hours designated to patient safety training and risk management.²⁰⁸ Such a requirement should be considered for Wyoming physicians.

Patient education should not be left out of the equation to improve patient safety. The National Patient Safety Foundation provides information for patients to facilitate understanding of medical procedures, like anesthesia, and identify ways the patient can contribute to making the procedure safer.²⁰⁹ The AHRQ offers a patient guide to safer care, by identifying five steps patients can take when interacting with health care providers and institutions.²¹⁰ Helping patients organize and store their own personal health record and vital information, either electronically or on paper, permits important health information to be shared with providers and family members and may lead to safer medical practices.²¹¹ Noting patients have no communication privilege to lose, patient safety advocates encourage including health care

²⁰¹ Davis, *supra*, n. 199.

²⁰² *Id.*

²⁰³ Davis, *supra*, n. 199.

²⁰⁴ Leape, *supra*, n. 191.

²⁰⁵ Davis NM. *Lack of Knowledge as a Cause of Medication Errors*, 32 Hospital Pharmacy 16 (1997).

²⁰⁶ Leape, *supra*, n. 15.

²⁰⁷ Davis, *supra*, n. 205; Leape, *supra*, n. 15.

²⁰⁸ MCARE Act, *supra*, n. 27 at § 910(b).

²⁰⁹ http://www.npsf.org/html/patients_web.html

²¹⁰ <http://www.ahrq.gov/consumer/5steps.pdf>

²¹¹ As noted by the Institute for Healthcare Improvement, <http://ihi.org/IHI/Topics/PatientCenteredCare/PatientCenteredCareGeneral/ImprovementStories/PursuingPerfectionReportfromWhatcomCountyWashingtononPatientCenteredCare.htm> personal health records, or a Shared Care Plan, www.sharedcareplan.org accessed June 15, 2005.

consumers as adverse event and near miss reporters as a means of improving outcomes and communication with healthcare providers.²¹²

5. PATIENT SAFETY REGULATORY ISSUES

State and federal legislatures, state and federal administrative agencies, industry accrediting, professional and peer review organizations, courts and litigants, and purchaser organizations are all active regulators of patient safety today.²¹³ The pluralistic character of the current regulatory scheme begs the question: Who should regulate patient safety and how should efforts be coordinated to maximize value and minimize costs?

Recently, the IOM reviewed quality improvement regulation in federal health care programs, including patient safety regulation. That review found many of the existing efforts at quality regulation to be “duplicative or ineffective” specifically: “1) that performance measures were hindered by a lack of consistency in reporting standards; 2) absence of an underlying conceptual framework, and conflicting methodologies for performance measurement; 3) regulation had resulted in little useful information being made available to consumers, health plans, or health professionals; 4) lack of standardized performance measures had resulted in an unnecessary burden on providers and diminished usefulness of quality information and; 5) that there was no systematic approach for assessing the cost-effectiveness of quality improvement initiatives.”²¹⁴ Though this report focused on quality improvement measures, the possibility that patient safety regulation may fall victim to the same problems is seen by some as quite real, particularly due to relatively thin evidence supporting appropriate patient safety standards and the variety of organizations at both the state and national levels issuing such standards.²¹⁵

Patient safety regulation can be seen as a four step process: 1) identifying patient safety issues; 2) identifying patient safety interventions through research; 3) developing standards for health care providers and facilities, which may take the form of certification or accreditation standards and recommended or legislated approaches; and 4) creating enforcement mechanisms through systems of rewards or penalties.²¹⁶ Wyoming has begun the process of identifying patient safety issues through passage of the error reporting statute and may eventually be able to profile healthcare errors specific to this state. As it did in adopting the NQF List of Serious Reportable Events, in W.S. § 35-2-912 (2005), Wyoming should look to national efforts to guide development of evidence-based patient safety interventions and standards by closely following emerging research. As research institutions move forward in these areas, the state of Wyoming’s efforts might be better spent investigating issues and answering questions that need to be resolved at the local level. Specifically:

- 1) What would motivate providers to change their current practices to promote patient safety?

²¹² Hatlie, M. Presentation to the 2005 Annual Patient Safety and Health Information Technology Conference sponsored by AHRQ, June 6, 2005, *Partnership for Patient Safety*, www.p4ps.org

²¹³ Mello, *supra*, n. 22.

²¹⁴ *Id.* (citing Corrigan, *supra*, n. 85).

²¹⁵ *Id.*

²¹⁶ *Id.*

- 2) What constrains implementation by providers and where do opportunities lie for implementation?
- 3) What assistance can legislation provide to address these issues?
- 4) What can be done to inform the health care industry about safety issues?
- 5) How can efforts among various entities work together in consultation and collaboration on these issues?
- 6) Are measures like W.S. § 35-2-912 (2005) effective in promoting patient safety?²¹⁷

6. COSTS OF ERRORS AND COSTS OF PREVENTION

Annually, the cost of preventable medical injuries is estimated to be between \$17 to \$29 billion, most of which falls on patients and their families, insurers, employers and state support programs, including costs of acute and long-term care, lost income and lost household production. Though the actual cost of medical injuries is the burden of others, healthcare facilities bear the expense of implementing safety improvements, with little financial incentive to do so.²¹⁸ Pay for performance reimbursement schemes or incentive bonuses for facilities that meet safety goals may contribute to change in healthcare systems and enhancement of safety.²¹⁹ However, at least one health plan has decided to use negative incentives, by seeking adverse event reports from hospitals and refusing to pay hospital claims involving any of the serious reportable events defined by the NQF.²²⁰

The costs of prevention will include government costs to monitor the regulated entities, impose sanctions, inspect facilities, monitor corrective action plans, and defend litigation by sanctioned facilities. Consumer costs for health care may include increase in price or decrease in quality of the service received, as a result of the provider/facility compliance with the regulation. Healthcare facilities may incur costs for new equipment, administrative overhead, hiring new employees, fines or sanctions. Hidden costs to health care facilities may include the cost of inefficiency, if regulators issue duplicative or conflicting requirements or there is uncertainty in the regulations themselves.²²¹ The possibility of overcompliance with regulations must also be considered. This situation will exist if the organization perceives the penalty for noncompliance as high and being risk averse, does more than needed to comply with regulations, as did some providers and hospitals when implementing the Health Insurance Portability and Accountability Act (HIPAA).²²²

7. MORE RESEARCH NEEDED

At this time, much is unknown about appropriate interventions to prevent medical errors. Avenues for intervention and prevention of medical errors need to be defined through on-going research that examines the epidemiology of error. This approach helped determine the value of

²¹⁷ *Id.*

²¹⁸ *Id.*

²¹⁹ Leape, *supra*, n. 15.

²²⁰ *Minnesota Insurer Won't Pay Hospitals For "Near Events."* AMNews, Nov. 8, 2004. <http://www.ama-assn.org/amednews/2004/11/08/bisd1108.htm>

²²¹ Mello, *supra*, n. 22.

²²² *Id.*

CPOE systems in preventing medication errors.²²³ Following these determinations, discussion should focus on what interventions are cost-effective, little of which has been analyzed at this time.²²⁴ Research to determine appropriate evidence-based patient safety interventions, the cost-effectiveness of regulations to promote patient safety and the effects of pluralistic regulations must be undertaken. Together, regulators should strive to provide healthcare institutions with a variety of cost-effective interventions for implementation.²²⁵

H. SUMMARY AND ACTION STATEMENTS

1. The National Quality Forum (NQF) has created a national strategy for health care quality measurement and reporting through the development of the List of Serious Reportable Events. (Page 5) Adopting this list of designated events will make it possible for Wyoming to compare data and identify trends across systems, states, regions and the nation. Wyoming has taken this important step by passing W.S. §35-2-912(2005), utilizing the National Quality Forum’s List of Serious Reportable Events. (Page 17)
 - **ACTION STATEMENT:** Monitor on-going research in the area of patient safety to ensure Wyoming’s reporting system tracks adverse events that are shown by research to significantly impact patient safety. Monitor revisions to the List of Serious Reportable Events to ensure Wyoming’s reporting system reflects the most recent changes and information relevant to this system.
2. Defining what constitutes a reportable event requires detailed definitions to ensure uniformity. W.S. §35-2-912(2005), as it now stands, provides the reporter with too much discretion in interpreting terms. (Page 17) To eliminate the potential for varied construction, Wyoming should adopt, either by statute or rule, the NQF definitions associated with List of Serious Reportable Events. (See Appendix B)
 - **ACTION STATEMENT:** Adopt the NQF definitions associated with the List of Serious Reportable Events.
3. W.S. §35-2-912 is designed as a method to gather data on frequency and type of errors in Wyoming healthcare facilities. The statute only requires the data to be reported in aggregate fashion and makes no provision to use the reported information to improve healthcare systems or share lessons learned with other healthcare facilities in order to prevent a similar occurrence at other locations. No root cause analysis of events is required, nor evidence that the facility took any action to improve the error prone system to prevent recurrence. A stronger system would include requirements for facilities to analyze events and take corrective action, as well as providing this information to other facilities to avoid similar errors. (Page 17-21)
 - **ACTION STATEMENT:** Continually promote error analysis and corrective action within reporting institutions. Establish distribution of “lessons learned”

²²³ *Id.*

²²⁴ *Id.*

²²⁵ *Id.*

from error reporting and corrective measures.

4. Certification as a patient safety organization under the Federal Patient Safety and Quality Improvement Act of 2005 may enable Wyoming to participate in a national databank of error reporting information and may provide additional discovery protection for patient safety work product, including analysis of medical errors. If certified, Wyoming would be required to conform its reporting practices to any national standards that may be set. Wyoming should investigate certification under the Federal Patient Safety and Quality Improvement Act of 2005, including whether Wyoming's current safety reporting statute would permit Wyoming to be certified or would require further state legislation. (Page 21-22)
 - **ACTION STATEMENT:** Determine the benefits and burdens encompassed by pursuing certification under the Federal Patient Safety and Quality Improvement Act of 2005.
5. W.S. §35-2-912 authorizes the Wyoming Department of Health to collect adverse event data from healthcare facilities. A better approach would be to empower an independent commission to perform this function, as well as act on the information received to improve patient safety in Wyoming's health care facilities. This independent commission should include front line practitioners, employers and health care consumers in the creation of the reporting system and identify content experts, within and outside the commission, to make correction and prevention recommendations to reporting facilities. An appointed independent commission which is authorized to require system changes and monitor results will allow prevention efforts to emerge from error tracking and address issues of accountability. The Pennsylvania Patient Safety Authority provides one example of an independent commission charged with being a knowledge broker of patient safety and prevention information, as well as determining the feasibility and cost to stakeholders of recommendations for change. Allowing practitioners, employers and health care consumers to participate in the important work of event reporting and patient safety will promote buy in from those most directly affected by these efforts. Specific duties should be identified for an independent commission engaged in the work of patient safety by reviewing states and countries with existing models to determine the potential make up of a Wyoming independent commission. (Page 17-21)
 - **ACTION STATEMENT:** Determine preferred size, method of appointment and make up of an independent commission by reviewing commissions established in other states and countries. Engage stakeholder participation on an independent commission to collect data on adverse events and recommend practice improvements based on review and analysis of data.
6. W.S. §35-2-912 does not identify any individual involved in the error, which should encourage providers to report. Anonymous reporting and de-identified data offer protection against discovery but limit the ability of regulators to identify and analyze clusters of injuries at particular hospitals or healthcare facilities. (Page 13-16) With no provision for feedback to licensing boards or agencies for either individuals or facilities

involved, there is no accountability for prevention or error reduction. It appears no mix of mandatory/voluntary and public/confidential features can avoid trading off important interests of patients against those of providers. By enacting W.S. §5-2-912, the state has opted to forego disclosure in order to promote reporting. (Page 17) However, the state must realize that healthcare consumers believe error information should be available. Realizing this conflict exists, the Wyoming legislature or independent commission should at least strive to promote error prevention at every opportunity. Encouraging adoption of nationally recognized prevention campaigns, such as the Institute of Healthcare Improvement's 100,000 Lives Campaign, would begin to move prevention initiatives forward. (Page 23)

- **ACTION STATEMENT:** Encourage healthcare facilities to adopt prevention initiatives, such as the Institute of Healthcare Improvement's 100,000 Lives Campaign. Begin dialogue with licensing boards on error accountability.

7. Error reporting is not the same as peer review and provisions to protect peer review information from legal discovery may not protect those involved in error reporting. Error reporting will not occur, even if it is mandated, unless reporters know information will be safe from discovery. Statutes to specifically protect error reporting activities from discovery should be considered by the legislature. (Page 14-15) Encouraging reporting through legal protections should be balanced by sanctions for facilities that fail to report errors.

- **ACTION STATEMENT:** Review Wyoming statutes to determine discovery protections for error reporting and activities associated with reporting, such as error analysis or remediation measures. To assist in drafting legislation for discovery protection of Wyoming's reporting activities, review statutes and case law of established state adverse event reporting systems to determine court interpretation of discovery protections. Explore sanctions for facilities which fail to report errors under Wyoming's reporting statute, W.S. §35-2-912. Determine the applicability of protections under the Federal Patient Safety and Quality Improvement Act.

8. Technology applications, such as electronic medical record systems, may assist in reducing medical error. However, automating data will be of limited use if the information available from paper records is not first standardized. Only then will meaningful comparisons of electronic data be made within and across systems in the state as well as even regionally and nationally. Standardized record keeping should be mandated to facilitate accurate tracking of errors, keeping in mind state standards must eventually correspond with any national standards developed. (Page 8)

- **ACTION STATEMENT:** Support an independent commission of stakeholders, such as the newly formed Wyoming Health Information Organization (WYHIO), to develop a standard medical record keeping system and require adoption by healthcare providers and facilities, being cognizant of national standards that may be developed in this area.

9. If medical error reporting is to become routine, it must have cultural acceptance in the health care community and reporters must feel safe to do so. Placing blame and shame on individuals instead of focusing on system issues for improvement will discourage reporting and may encourage cover-ups. It may also have the effect of elevating patient risk, if providers increase defensive medicine practices, thereby exposing patients to more procedures because it is legally, rather than medically, prudent to do so. Efforts should be supported for healthcare providers and healthcare facilities to make patient safety a priority, commit to replace systems that are not functional and institute interdisciplinary training to strengthen the healthcare team. Investigating techniques that have been successful in other industries, such as crew resource management, may determine potential application for Wyoming's healthcare community. (Page 24-25)
 - **ACTION STATEMENT:** Make patient safety a priority of Wyoming's healthcare community through state support of education and training of administrators, providers and healthcare workers on patient safety issues.
10. The Wyoming Board of Medicine and hospital facilities should be encouraged to adopt regulations requiring physicians to participate in annual continuing medical education (CME) devoted to patient safety initiatives, design and application. (Page 26)
 - **ACTION STATEMENT:** Require the Wyoming Board of Medicine and hospital facilities to mandate that providers acquire annual CME in patient safety initiatives, design, application and interdisciplinary training.
11. Patients injured by medical error or negligence want to know what happened, not because they want to blame the physician, but in order to understand their future treatment needs and to know the same mistake does not happen to others. Patients want to receive an apology from their physician and physicians would like to be able to offer an apology without fear of litigation. Wyoming's "I'm Sorry" legislation, W.S. §1-1-130 (2005), provides legal protection for providers who extend an expression of apology to a patient. Training for physicians and health care providers in use of tools provided in the "I'm Sorry" legislation, as well as training on the importance of open disclosure to patients should be authorized and supported. (Page 15-16)
 - **ACTION STATEMENT:** Develop and support awareness campaigns on the elements and protections extended to Wyoming healthcare providers under W.S. §1-1-130(2005). Support the development of provider communication skills in the patient setting.
12. As consumer-directed healthcare programs grow, consumers will demand cost and quality data for potential sources of care in order to choose services that provide the most value for the resources expended, which is likely to increase demand for information on patient safety as well. Consumer access to information should be paired with patient education to help patients interpret what the data do and do not mean, and define the patient's role in reducing medical errors, ensuring safe care. (Page 26)

- **ACTION STATEMENT:** Empower an independent commission to support educational efforts to promote the patient’s role in the safe delivery of medical care and understanding adverse event data.
13. At this time, not much is known about appropriate interventions to prevent medical errors. Avenues for intervention and prevention of medical errors need to be defined through on-going research that examines the epidemiology of error. Wyoming must stay abreast of these issues as they are identified in national research literature. Evidence-based patient safety interventions should be reviewed along with the cost-effectiveness of regulations promoting patient safety with the effects of pluralistic regulations on healthcare providers and facilities. Wyoming must work towards providing healthcare institutions with a variety of cost-effective interventions for implementation. (Page 28-29)
- **ACTION STATEMENT:** Empower an independent commission to continuously review evidence-based patient safety interventions to determine clinical effectiveness as well as cost-effectiveness in avoiding adverse events and following review, promote specific interventions for implementation.
14. Methods to motivate providers should be studied to encourage changes in their current practices to promote patient safety; determine constraints in implementing safety practices; identify where opportunities lie to implement patient safety practices; determine how best to inform the healthcare industry about safety issues; and how healthcare stakeholders can work together in consultation and collaboration on patient safety issues. (Page 27-28)
- **ACTION STATEMENT:** Conduct a survey of healthcare providers and facilities to determine current barriers to implementing patient safety practices. Convene a meeting of healthcare providers and stakeholders to identify methods to overcome barriers and create collaborations to promote patient safety.
15. Healthcare providers and facilities should be offered incentives and assistance to establish a business case for patient safety efforts by identifying and promoting evidence-based, cost-effective patient safety interventions. Employers, insurers and consumers valuing safety driven care will then be better able to support the efforts of healthcare facilities and providers who can demonstrate a commitment to these shared values. (Page 27-28; 58-59)
- **ACTION STATEMENT:** Investigate healthcare facilities with established business case models promoting patient safety. Empower an independent commission to develop a model business case to assist healthcare facilities to establish this approach to supporting patient safety. Determine and provide the level and extent of assistance needed by Wyoming healthcare facilities to create a business case to support patient safety efforts. Empower an independent commission to work with employers, insurers and consumer groups to support

healthcare facilities and providers who demonstrate a commitment to patient safety.

II. COMPENSATION SYSTEMS FOR MEDICAL INJURIES

A. COMPENSATION PROCESS

This section addresses the following elements of the Commission’s charge:

- **A system for compensating individuals, as their exclusive remedy, for damages resulting from health care errors.**

Efforts to reform the current system of compensation for medical injury have included administrative fault-based systems, scheduling of awards, alternative dispute resolution measures, enterprise liability and the implementation of medical practice guidelines.²²⁶ The focus of most reforms is improvement in compensation by broadening eligibility for coverage and increasing the ease of presenting claims. Deterrence of injury is also sought through more systematic filing of claims, expert resolution, better monitoring of practices and improved economic incentives.²²⁷

A system meeting the above definition of an exclusive remedy for damages resulting from errors could take at least three forms:

1. Preserve the tort liability standard and trial process but replace juries with expert judges.
2. Preserve the tort liability standard but replace trials with mandatory, binding arbitration.
3. Replace the tort liability standard and trial process with an administrative compensation system in which the liability standard is avoidability rather than negligence.

In system (1), all of the existing rules and processes of medical malpractice law would apply, except that the trial would be presided over by an expert adjudicator rather than a general judge, and juries would be eliminated altogether. Proposals for “medical courts” have been floated for at least 20 years, primarily by medical professional groups,²²⁸ who doubt the competence of lay juries to evaluate complex questions of scientific causation and medical appropriateness. The expert adjudicators could be general judges who receive special training in adjudicating medical malpractice claims, or persons who have direct experience in the practice of medicine. Each case could be heard by a single judge or a panel of judges, perhaps with different backgrounds. Judges could be assisted by court-appointed experts in addition to hearing expert testimony provided by the parties.

Although technically appealing, medical courts proposals have tended to encounter strong suspicion from consumer groups and trial lawyers that a panel of physicians would be inherently biased towards defendants. Such objections may be difficult to overcome, particularly since

²²⁶ Bovbjerg RR, Sloan FA. *No-Fault for Medical Injury: Theory and Evidence*, 67 U. Cin. L. Rev. 53 (1998).

²²⁷ *Id.*

²²⁸ See, e.g., AMA-Specialty Society Medical Liability Project. *A Proposed Alternative to the Civil Justice System for Resolving Medical Liability Disputes: A Fault-Based, Administrative System*. Chicago: AMA, 1988.

proposals for medical courts have emanated almost exclusively from provider groups, who are perceived as acting out of self-interest. An additional concern is that because the negligence standard is retained in medical courts schemes, liability determinations may remain difficult and unpredictable. Even experts frequently disagree about the presence or absence of negligence in a particular case.

Since 1993, Wyoming has employed a version of the expert judge model to decide medically contested workers' compensation cases.²²⁹ The Medical Commission of Wyoming's Worker's Safety and Compensation Division is comprised of 22 physicians, appointed by the governor, with input from the Wyoming Medical Society and health care provider groups. Three physicians are selected from this group to sit as administrative law judges on cases determined by the Division of Worker's Safety and Compensation to be contested on medical issues as opposed to legal questions. Those cases determined to have primarily legal issues at their core are referred to the Office of Administrative Hearings for resolution. Selection of physicians to compose the administrative panel is based on the medical condition at issue and availability of physicians to hear cases. An attorney, working for the commission, presides over the administrative hearing. Applying statutory, rule and case law guidelines, the commission determines the compensability of individual claims. Calculation of benefit amounts is conducted by the Division according to its rules. Decisions of the commission may be appealed to the district court and Wyoming Supreme Court for review.

Since inception of the Medical Commission, 1,430 cases have been referred to the commission, with 55% to 60% settled before hearing.²³⁰ Approximately 21-24 cases are scheduled for hearing monthly with hearings scheduled as long as one year from the date of referral. An option to have the case decided by an expedited process, foregoing a formal hearing, is available by motion from the parties and can facilitate a more timely resolution. Approximately half of the commission's final determinations find in favor of the claimant and half find favor of the Division or employer. The percentage of appeals from final determinations has increased over the last two years, from 10% to 20%, with 95% of the commission's final determinations upheld on appeal. Commission members receive \$125 per hour for time spent reviewing or hearing cases, with the average case requiring 5 to 7 hours.²³¹

In system (2), all of the existing rules of medical malpractice law would apply, except that the case would be heard by an arbitrator appointed by the state, rather than a court and jury. The best available model for this is the mandatory arbitration system in the Kaiser Permanente Health System in California. This scheme, which has been upheld by the California supreme court,²³² makes arbitration obligatory for all plan subscribers and providers, who submit to it by contract.

The Kaiser system is considered by most to be a success story in the sense of functioning more efficiently than the judicial process. However, it does not address any of the more fundamental problems with the medical malpractice system, such as the difficulties associated with the

²²⁹ W.S. § 27-14-616.

²³⁰ Discussion with Scott Smith, J.D., Executive Director of the Wyoming Workers' Safety and Compensation Medical Commission, June 30, 2005.

²³¹ *Id.*

²³² *Engalla v. Permanente Med. Group*, 64 Cal. Rptr. 2d 843 (1997).

negligence determination. No state has adopted mandatory binding arbitration, though some, such as Florida, have laws encouraging parties to voluntarily submit to arbitration.

The alternative that has received the most attention is system (3), which involves the reorientation of compensation away from the concept of negligence. In this system, the tort liability system is abandoned altogether in favor of an administrative process based on an alternative liability standard. The rise of the patient safety movement has fueled interest in this approach. However, its promise has gone untested. Lack of clarity about operational details has led some policymakers to overlook such a far-reaching departure from tort law in crafting reforms.

Administrative compensations systems (“ACS”) have been called “no-fault” systems, but that is a misnomer in that it suggests strict liability. Universally, the compensability standard advocated by proponents of administrative compensation systems is “avoidability” or “preventability.” Although concise operational definitions of avoidability are lacking, the concept is thought to refer to a broader range of adverse events than are compensable under the negligence standard. A simple definition of avoidability is that the adverse event would not have happened in a well-designed system of care. Such a definition raises many questions, as discussed below.

1. STRUCTURE OF AN ACS

Generally, an administrative compensation system should work to prevent errors and efficiently compensate those who experience them by accomplishing the following objectives: 1) encourage error reporting and provide for data analysis; 2) support quality improvement with financial incentives to reduce errors; 3) refer the infrequent, incompetent, or malevolent physician to disciplinary entities; 4) support physician openness to patients about medical errors; and 5) provide patients with quick, equitable, affordable and predictable compensation.²³³

An administrative compensation system could take a variety of forms, but would have four core features:²³⁴

- (a) Compensation decisions are made outside the regular tort system by trained adjudicators. An explicit record of decision making is kept in order to provide greater clarity in key areas (for example, expected levels of compensation, what constitutes acceptable/optimal care) to improve reliability of decision making.
- (b) Compensation decisions are based on a standard of care that is broader than the negligence standard, but does not approach strict liability.
- (c) Compensation criteria are “evidence-based,” in the sense that they are grounded in experts’ interpretations of the leading scientific literature. To the maximum extent feasible, compensation decisions are guided by *ex ante* determinations about the

²³³ Studdert, *supra*, n. 109.

²³⁴ Brennan TA, Howard PK, Mello MM, Studdert DM, Stone F, Udell N. *Design of a Reliable System of Medical Justice*. Grant application to the Robert Wood Johnson Foundation, 2004.

preventability of common medical adverse events made through a process of deliberation and review of scientific evidence involving clinical experts and other key stakeholders.

- (d) Guidelines for compensating both economic and noneconomic losses are created for the system and applied to each claim that is judged eligible for compensation. Valuations of noneconomic damages are made using methods that are explicit, rational, and consistent.

Consortia of key stakeholders in Utah and Colorado seriously considered movement toward an administrative scheme in the mid-1990s, but the proposals foundered as the liability insurance markets environment settled down in the late-1990s.²³⁵ The proposals also encountered political opposition, although they did not proceed to a legislative vote in either state. In January 2003, an Institute of Medicine committee endorsed experiments with administrative compensation in the form of either statewide systems or voluntary demonstration projects based at the level of individual liability insurers.

In July 2003, Senator Mike Enzi introduced a bill in the U.S. Senate to provide federal funds for such experiments. In June, 2005, Senator Enzi, Chairman of the Senate Health, Education, Labor and Pensions (HELP) Committee, introduced the “Fair and Reliable Medical Justice Act,” S.1337, which would provide funding to states choosing among three alternative models to tort litigation. The proposed models include: 1) Early Disclosure and Compensation: A state would provide health care providers and organizations with immunity from lawsuits if they disclose an error that caused an injury and make a timely offer to compensate an injured patient for his or her actual net economic loss, plus a defined and scheduled payment for pain and suffering if appropriate; 2) Administrative Determination of Compensation: A state would set up classes of avoidable injuries and establish an administrative board to resolve claims related to those injuries. The state would have the option to administer the program as a fault-based or no-fault model. The administrative board would develop a schedule of compensation that would include payment for the patient’s actual net economic loss, plus a defined and scheduled payment for pain and suffering if appropriate; 3) Special Health Care Court: A state would establish a special court for adjudication of disputes over injuries allegedly caused by health care providers and organizations. The state would ensure the presiding judges have expertise in and understanding of health care.²³⁶ See Attachment C for the full text of the bill.

Last year in Massachusetts, the Governor’s Office expressed interest in designing a voluntary, insurer-based demonstration project of administrative compensation for obstetrical injuries, and worked with legal teams at the Harvard School of Public Health to draft model authorizing legislation. That proposal encountered resistance from attorneys who raised questions about the constitutionality of the scheme under the Massachusetts Constitution. The proposal was tabled and the key proponent of the proposal left the Governor’s Office.

Existing proposals have left several of the important design choices for an administrative compensation system undetermined, or described a menu of options. Policymakers will need to make political decisions about, and develop specific plans for, the following components:²³⁷

²³⁵ *Id.*

²³⁶ News release from Senator Mike Enzi’s office, July 11, 2005.

²³⁷ Brennan, et al., *supra*, at n. 234.

- (a) **Jurisdiction.** Define the range of covered disputes, including the scope of the demonstration project (government versus institutionally based; all clinical areas or select clinical areas) and the mandatory or voluntary nature of the system.
- (b) **Decision makers.** Explore qualifications for judges and possible appointment processes. Explore methods for using rulings on standards of care and compensation to provide guidance to stakeholders going forward.

Wyoming's Workers' Safety and Compensation Medical Commission is one example of physician judges which hear and decide medically contested workers' compensation cases.

- (c) **Neutral expert witnesses.** Consider pros and cons of having designated panels of experts from which judges can draw in each case. Define qualifications for experts, possible compensation structure, and appointment process.
- (d) **Procedure.** Critically review the experiences of other compensation systems, including procedural and structural methods for increasing efficiency and reducing transaction costs. Outline possible streamlined procedures and timetable to final decision. Design appropriate notice and consent procedures for patients covered by the system.

Currently Wyoming's Medical Commission is required to render a written final determination within 45 days after the close of the record in the case.²³⁸

- (e) **Access for claimants.** Review possible methods for accessing the compensation system, including nonlegal mechanisms for resolution of simple claims and provision of lawyers to claimants for more complex cases. Review possible methods for compensating lawyers.

For example, the Medical Commission may conduct a "small claims hearing" for those cases in which the amount of compensation at issue is less than \$2,000 and the compensability of the injury is not contested.²³⁹ Such a proceeding is conducted without representation by the state Attorney General's office or payment by the state for any party's legal fees and is meant to be a quick way to find resolution of simple claims.²⁴⁰

- (f) **Standards for liability.** Define and operationalize the compensability standard. To the extent possible, pre-designate common adverse events as compensable or noncompensable based on expert consensus.
- (g) **Standards for setting compensation amounts.** Select structures for determining economic and noneconomic damages.

²³⁸ W.S. § 27-14-602(b)(ii).

²³⁹ *Id.* at (b)(i).

²⁴⁰ *Id.*

- (h) **Appellate review.** Determine the scope of appeal rights and possible structures for hearing appeals of the ACS.
- (i) **Relationship to other patient safety regulation.** Explore the integration of the system with other structures designed to promote patient safety (e.g., state reporting systems and licensure boards, the National Practitioner Data Bank).
- (j) **Integration with Wyoming’s Medical Review Panel.** Determine how an ACS would work alongside the medical review panel. Define the roles of each system. Determine whether a review panel would be necessary with the implementation of an ACS.
- (k) **Additional considerations include:**
 - a. **Administration.** Public or private administration, dispute resolution measures.
 - b. **Procedures.** Formal or informal.
 - c. **Coverage.** Mandatory or voluntary; should the no-fault system be a secondary or first payer of claims?
 - d. **Eligibility.** Broad criteria or limited
 - e. **Benefits.** Basic compensation or comprehensive; periodic payment of benefits with the potential of creating on-going moral hazard.
 - f. **Coordination of benefits.** Primary payer or secondary to other sources of payment.
 - g. **Funding.** Secured from premium payers or public funds.
 - h. **Premium setting.** Community or experience based with many or few classifications.
 - i. **Solvency.** Assured through public funds, regulatory oversight, or private reinsurance.
 - j. **Loss-prevention mechanisms.** Built in or reserved for administrative determination.²⁴¹

Many variations in design are possible, however some argue the most important element is ensuring no-fault is the exclusive remedy in the sphere in which it applies, to avoid the system becoming “simply another form of insurance for injuries, readily purchased but with no beneficial effect upon the problems of tort meant to be addressed by no fault.”²⁴²

2. COMPENSATION CRITERIA

Among the most critical aspects of ACS design is the set of criteria that will be used to distinguish compensable adverse events from noncompensable incidents.²⁴³ The choice of compensation criteria will have enormous implications for the cost of the scheme, the administrative efficiencies that are attainable, the volume and types of injuries compensated, and the potential gains in the area of patient safety. There is reasonable agreement, at least in the academic community, about what types of events an administrative scheme should seek to compensate—namely, avoidable or preventable events, as opposed to injuries due to negligence. Redoubled attention to error in medicine over the last five years solidifies the focus on this type of event.

²⁴¹ Bovbjerg, *supra*, n. 226.

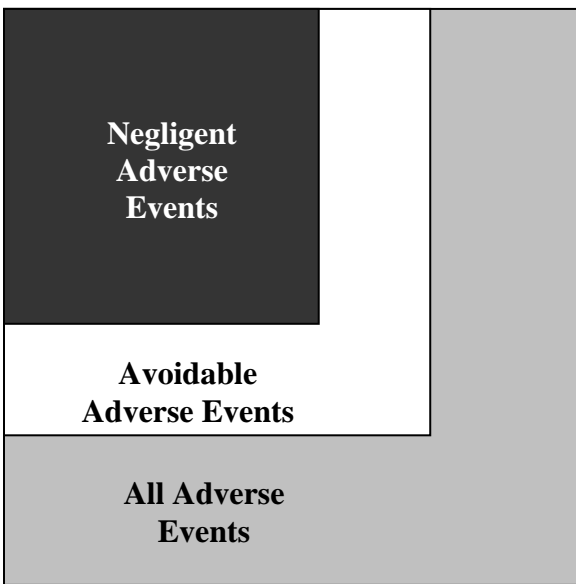
²⁴² *Id.*

²⁴³ The following discussion is adapted from Brennan et al., *supra* n. 234.

Beneath this consensus, however, lies a great deal of uncertainty. The distinction between negligence and avoidability is not easily grasped. Policymakers have expressed concerns about whether experts would be able to distinguish avoidable from unavoidable events in a reliable manner, and whether this adjudication process would avoid the problems associated with traditional negligence determinations.

In theory, avoidability encompasses a set of adverse events that is broader and more easily identifiable than negligence in the tort system, but narrower than the group of all adverse outcomes that are causally linked to medical treatment. The relationship between adverse outcomes, negligence, and avoidability can be conceptualized as described in Figure 1. Epidemiological studies suggest that about 30% of hospital adverse events are attributable to negligence; that is, the black square is roughly one-third the size of the grey square.²⁴⁴ The same studies indicate that about 55% of hospital adverse events are preventable; that is, the white square is a little over half the size of the grey square and about twice the size of the black square.²⁴⁵ Comparable figures are not available for adverse events in ambulatory care although a recent study found one-quarter of all outpatients experienced an adverse drug event during a three month period.²⁴⁶

Figure 1. Negligence and Avoidability in Hospital Adverse Events



Note: Scale is approximate

²⁴⁴ Thomas EJ, Studdert DM, et al. *Incidence and Types of Adverse Events and Negligent Care in Utah and Colorado*, 38 *Med Care* 261 (2000).

²⁴⁵ Thomas EJ, Studdert DM, et al. *Costs of Medical Injuries in Utah and Colorado*, 36 *Inquiry* 155 (1999).

²⁴⁶ Gandhi TK, Weingart SN, Borus J, et al. *Adverse Drug Events in Ambulatory Care*, 348 *N. Engl. J. Med.* 1556 (2003). The authors looked at preventable medication events which could have been entirely avoided and ameliorable events whose severity or duration could have been reduced by actions of the physician. 28% were found to be ameliorable and 11 % preventable, due to prescribing errors, some of which could have been prevented with the use of computerized prescribing.

A limited body of scholarly work has attempted to operationalize the avoidability standard for compensation decision-making. It is clear that a general definition of avoidability alone will not be sufficient to demonstrate the workability of ACS to policymakers. Repeated case-by-case determinations of compensability would be costly and inefficient. The preferred approach is to develop lists of adverse events within specific clinical areas that carry a rebuttable presumption of compensability. Events on these lists would then be fast-tracked for compensation.

Lawrence Tancredi, Clark Havighurst, and Randall Bovbjerg have published a series of papers, the earliest of which dates back to the 1970s, describing how lists of “accelerated-compensation events” (“ACEs”) could be developed and used in select clinical areas. Although updates to this work are needed to support a demonstration project of ACS, these papers provide a very useful starting point for thinking about the use of ACEs.

Accelerated-compensation events, also called “avoidable classes of events,” are medical injuries that should not normally happen.²⁴⁷ ACEs identify a subset of all adverse events that experts have agreed in advance are avoidable, meaning that they “should not often occur when patients receive good care.”²⁴⁸ The key word “often” has been defined as referring to injuries that are 70% to 90% preventable as a group. The crux of ACE proposals is that an expert body develops a list of such adverse events, and an alternative compensation system is set up for handling claims involving these events. The alternative system provides expedited compensation for injuries on the list, and could take the form of an ACS.²⁴⁹ The information generated by the system can also be used for quality improvement purposes, since ACEs are thought to be good indicators of where care systems have failed, resulting in serious harm to patients.²⁵⁰

The proposals call for medical experts to generate lists of ACEs in each clinical specialty based on “generalized expert judgments about statistical outcomes of medical care.”²⁵¹ The working groups would apply three criteria in selecting injuries as ACEs.²⁵² First, the injuries are 70-90% preventable as a class. Second, the injuries are readily detectable, meaning readily specified, with clear boundaries distinguishing them from other adverse outcomes. Third, selection of the injuries will not give rise to perverse incentive effects in medical decision-making, such as avoiding certain medically necessary services. Specifying compensable no-fault events in advance may eliminate to some extent, the need for expert testimony and elaborate fact-finding at the time of the claim and re-creation of the adversarial process common in tort, which would undermine the potential no-fault savings in time and administrative costs.²⁵³

²⁴⁷ Tancredi LR, Bovbjerg RR. *Rethinking Responsibility for Patient Injury: Accelerated-Compensation Events, Are Malpractice and Quality Reform Ripe For a Test*, 54 L. & Contemp. Probs. 147 (1991).

²⁴⁸ Tancredi LR, Bovbjerg RR. *Advancing the Epidemiology of Injury and Methods of Quality Control: ACEs as an Outcomes-Based System for Quality Improvement*, QRB 1992:201-209.

²⁴⁹ Bovbjerg RR, Tancredi LR. *Focusing on Avoidable Classes of Events Can Improve Patient Safety and Compensation for Medical Injury*. J Law Med Ethics 2005 (forthcoming).

²⁵⁰ Tancredi, *supra*, n. 248.

²⁵¹ *Id.*

²⁵² Tancredi LR. *Identifying Avoidable Adverse Events in Medicine*, 12 Med. Care 935 (1974); Tancredi LR. *No-Fault and Medical Malpractice: The Causation Issues of Defining Compensable Events*, 14 Inquiry 341 (1977).

²⁵³ Bovbjerg, *supra*, n. 226.

Tancredi and Bovbjerg led an effort to develop a list of ACEs for select clinical areas (obstetrics, orthopedic surgery, and general surgery) in 1991 by reviewing 2,300 Florida malpractice closed claims from 1985 to 1988.²⁵⁴ One expert reviewed all claims and eliminated those that were clearly unavoidable or had insufficient information with which to judge avoidability. Then other specialists (OBGYNs, orthopedists, and general surgeons) reviewed case summaries of the remaining claims and rated their avoidability (as high, moderate, none, or insufficient information). For the claims judged moderately or highly avoidable, the experts developed a class of adverse outcomes by generalizing across similar cases.

ACE lists were developed for the following kinds of events within the three clinical areas: infections, nerve injuries, complications of procedures, puncture or laceration wounds, joint and device misplacement, drug and blood disorders, failure to diagnose, foreign bodies, falls, vascular events, and death. An example of a failure to diagnose ACE is “Consequences to women after nondiagnosis of early breast malignancy.” An example of a procedure-related ACE is “Neurologic complications to mother or infant(s) from spinal anesthesia given during delivery.”

Two feasibility studies have been conducted to determine the ease with which ACEs can be applied to actual claims and the compensation costs that would result from their use. The first study analyzed a limited amount of claims information on closed surgical claims from the mid-1970s.²⁵⁵ The second, which is more useful to examine in depth because it is based on more recent data, was a study of 280 obstetrical claims incurred by a self-insured, multi-hospital system in 1983-1989.²⁵⁶

In the obstetrical study, expert abstracters reviewed each claim and made a judgment about whether it was covered by a previously developed list of obstetrical ACEs. The reviewers also recorded the degree of disability associated with the injury and the payment amount. The key findings were as follows:

- Overall, a quarter of claims had been paid by the insurer, but 52% were classified as ACEs. Thus, about twice as many injuries would have been eligible for compensation under the ACE standard as under the tort standard.
- ACEs were more likely than non-ACEs to have been paid (35% vs. 18%), and received more, on average, than non-ACEs (\$716,000 vs. \$181,000 in 1989 dollars).
- In all, ACEs comprised three quarters of indemnity payments, and ACEs were disproportionately high-severity injuries. Thus, ACEs tend to capture serious and high-cost events.

²⁵⁴ The process is described in detail in Tancredi, *supra*, n. 247.

²⁵⁵ American Bar Association Commission on Medical Professional Liability, ed. *Designated Compensable Event System: A Feasibility Study*. Chicago: American Bar Association, 1979.

²⁵⁶ Bovbjerg RR, Tancredi LR, Gaylin DS. *Obstetrics and Malpractice: Evidence on the Performance of a Selective No-Fault System*, 265 JAMA 2836 (1991).

- The insurer’s administrative costs were 2.8 times higher for ACEs than for paid non-ACEs. This suggests that ACEs could result in significant savings in administrative costs.
- Study reviewers “found it easy” to recognize ACE cases.
- The authors concluded that “for obstetrics, ACEs would remove the bulk of claims from the current system.”

Based on the empirical work conducted to date, the authors of ACE proposals have asserted several advantages of using them as the basis for compensation systems.²⁵⁷ First, the compensation process is greatly expedited, and no attorneys are needed to press claims. Second, the compensation system would have lower administrative costs, as well as reduce adversarial tension involved in pursuing compensation. Third, a substantially greater proportion of patients who are hurt by avoidable adverse events would receive compensation than under the present system and should do so at a faster rate than if litigation were pursued. Fourth, the accuracy and reliability of compensation decisions (both liability and amount of damages) would increase. This translates into greater predictability for insurers, providers, and patients. Periodic payments to claimants can be made as needs arise that should protect against unanticipated changes in needs.

Fifth, the greater predictability would lead to reduced defensive medicine. Defensive medicine is essentially a response to uncertainty about what kinds of care will result in liability for the provider. Providers may engage in assurance behaviors, which include “supplying additional services of marginal or no medical value with the aim of reducing adverse outcome, deterring patients from filing malpractice claims, or persuading the legal system that the standard of care was met.”²⁵⁸ Negative defensive medicine, or avoidance behavior, includes refusal to treat particular patients, or systematically altering the provider’s practice.²⁵⁹ Avoidance behavior by rural specialists is likely to affect access to care.²⁶⁰ A recent study of physicians in Pennsylvania, a state experiencing a decline in liability insurers and a dramatic increase in premium rates, with 9 out of 10 high-risk specialists engaging in defensive practice, showed many acts of defensive medicine involved imaging studies.²⁶¹ As more physicians engage in defensive medicine, the more likely these practices are to become the legal standard of care.²⁶²

²⁵⁷ Tancredi, *supra*, n. 248; Bovbjerg, *supra*, n. 256.

²⁵⁸ Studdert DM, et al., *Defensive Medicine Among High-Risk Specialist Physicians in a Volatile Malpractice Environment*, 293 JAMA 2609 (2005).

²⁵⁹ *Id.* The study found physician specialist perceptions of the burden of their malpractice premiums and lack of adequacy of malpractice coverage were the strongest predictors of defensive medicine practice. Physicians who perceived malpractice premiums as burdensome were twice as likely to order unnecessary diagnostic tests, refer patients unnecessarily to other patients, or suggest clinically unnecessary invasive procedures, as well as avoid high-risk patients and procedures. Physicians who perceived their coverage as inadequate were 1 ½ times more likely to overprescribe medication, refer patients unnecessarily to other physicians, and order unnecessary tests.

²⁶⁰ *Id.*

²⁶¹ *Id.*

²⁶² *Id.*

Sixth, an ACE system can function as a quality improvement tool for hospitals, and ultimately lead to improved deterrence of medical error. Hospitals can track the prevalence of ACEs and identify areas for improvement, and can feed outcomes data back to individual providers to help them understand and improve their own safety record. Experience rating should provide incentive for providers to improve practices as well. Finally, improved physician/patient relationships will result from a system in which providers can be candid about what the likely risks of treatment are and assure patients that they will be compensated in the event that they suffer an avoidable injury.

Several scholarly criticisms have been made of ACE proposals, most of which have been rebutted fairly effectively.²⁶³ The argument that ACEs will not cover most events that show up in malpractice claims, leaving a large number of claims for case-by-case review, does not appear to hold for obstetrical claims, though ACEs have not been thoroughly tested in other areas. It has been argued that it is not technically feasible to design ACE lists because of complicated issues of medical causation, but the evidence from the obstetrical study suggests otherwise. The obstetrical findings also suggest that, contrary to criticisms, ACEs have the potential to save a great deal on administrative costs. They do not merely skim off the “easy cases,” but rather capture a large proportion of the most serious cases.

Finally, it is argued that a move to ACEs would result in a significant cost increase. This is the strongest of the critiques, and is buttressed by empirical evidence that a much greater proportion of claims would be compensated under the ACE system than under the tort standard. Additionally, it is unknown how many additional claims would be filed under an ACE system. To address cost concerns, ACE systems would have to impose reasonable and equitable limitations on damages.

In summary, ACEs are a promising reform idea backed by good empirical evidence. However, some additional work would be needed in order to use them as the basis for liability reform today. The previously developed lists of ACEs need to be reviewed and updated in light of advances in medical knowledge. Lists need to be developed for other clinical specialties. Finally, another “virtual demonstration” of their application should be conducted to evaluate their operation in practice. For example, a hospital could apply the updated lists of ACEs to a sample of closed claims.²⁶⁴

3. CLAIMS PROCESS

The nature of the claims process in an ACS depends to some extent on the jurisdictional choices made for the scheme. The two choices that have been endorsed by the Institute of Medicine²⁶⁵ are a mandatory, statewide scheme or a voluntary, insurer-based demonstration project. A mandatory, statewide ACS would include all medical providers, or all providers in a given clinical area, whereas a demonstration project would cover all providers who are insured by the

²⁶³ Bovbjerg, *supra*, n. 256; Tancredi, *supra*, n. 247.

²⁶⁴ Bovbjerg, *supra*, n. 249.

²⁶⁵ Institute of Medicine. *Fostering Rapid Advances in Health Care: Learning from System Demonstrations*, chapter 6. Washington, DC: National Academies Press, 2002.

participating liability insurer. Taking the case of a mandatory system, one possible claims process would be as follows:

- (a) When an adverse event occurred, the hospital would determine whether the event fell within the class of adverse events covered by the ACS. If so, the hospital would be required by state law to notify the patient and/or the family of their right to seek compensation under the ACS.
- (b) The patient or family would file a claim for compensation with the hospital by completing a simple form describing from their own perspective what happened. They would have the option of involving legal counsel if they wished.
- (c) The hospital would be required to notify the state Administrative Compensation Agency (ACA) that it had received a claim within the ACS's jurisdiction.
- (d) The hospital would have delegated authority to make an initial determination on the disposition of the claim. Specifically, it would use an expert panel of clinicians to render a judgment on the clinical avoidability of the event, as described above. A hearing would be held if appropriate, although it would not be necessary in straightforward cases. Basic laws of evidence would be observed, similar to an administrative law hearing. The panel would be able to call the involved physician and/or the patient before it to present additional information, although this would not occur as a matter of course. The panel would also call upon additional experts' opinions as appropriate. The decision-making process would be guided by pre-established decision aids, including a definition of avoidability and a compendium of common adverse events ("accelerated compensation events") in the relevant specialty that carry a presumption of avoidability. There are three possible outcomes of the expert panel's decision: (1) clearly compensable; (2) clearly not compensable; (3) uncertain compensability.
- (e) If the hospital panel judged the claim to be clearly compensable, the hospital would make the patient/family an offer of compensation. The panel's determination of the amount of compensation would be guided by a previously published and publicly available schedule of damages. If the patient/family felt that the hospital did not correctly apply the damages guidelines or failed to take into consideration some factor in their case that affected damages, they could request a redetermination of damages from the ACA. If the ACA found that the hospital had made a clear error in applying the damages guidelines, it could assess a financial penalty on the hospital, in addition to awarding the patient/family the correct amount of damages.
- (f) If the claim is judged to be clearly not compensable, the patient/family would receive a notice of the decision and the reasons for the decision. The patient/family would have the option of appealing the hospital panel's decision to an ACA tribunal. The tribunal would review the claim de novo using all available materials and a process similar to that of the hospital panel. If it judged the event to be compensable, it would assess damages using the same guidelines as the hospital panel. If the ACA overturned the hospital's decision of non-compensability and made a finding that the case was clearly compensable, this finding would trigger a financial penalty for the hospital. (A penalty would also be

imposed if it came to light that that the hospital or its health care providers failed to disclose information known about the injury to the patient/family.)

- (g) If the claim is judged to be of uncertain compensability, the claim would be referred to the ACA tribunal for adjudication. The tribunal would adjudicate the claim through a process similar to that of the hospital panel, except that it would have to arrive at a finding of either compensability or noncompensability. It would assess damages using the same guidelines as the hospital panel. The patient/family would receive a notice of the ACA's decision and reasons for decision.
- (h) The system might give the patient/family the right to appeal determinations of the ACA to a state administrative law judge or court (or the system might make ACA decisions final or reviewable only through a rehearing).
- (i) If the final determination in the case was that the patient/family was entitled to compensation, the payments would be made out of the state ACA compensation fund on a periodic basis. The final disposition of the case would be recorded at ACA and all written decisions in the case stored in ACA's database. An ACA administrator would have responsibility for periodically contacting the patient/family to query whether any adjustment to compensation for future medical expenses, rehabilitation, custodial care, home care, or other expenses was required due to unforeseen circumstances. The patient/family could also apply for such an adjustment directly.
- (j) The hospital at which the incident took place, and/or the individual physicians involved in the case, would see their mandatory contributions to the ACS increase if the ACA made a payment on the claim. In other words, an experience based system of indemnity would be created.

4. EXISTING SYSTEMS

Several existing administrative compensation systems provide useful case studies in the consequences of particular design choices. The Nordic countries (Sweden, Denmark, Finland, Norway, and Iceland) and New Zealand have comprehensive government-run medical injury compensation programs. Additionally, the states of Virginia and Florida have state-run administrative compensation schemes for serious neurological birth injuries.

Virginia's program was established in 1987 through the state's Birth-Related Neurological Injury Compensation Act. The Florida Birth-Related Neurological Injury Compensation Plan (called NICA) was established in 1988 and modeled after Virginia's program. Participation in both programs is voluntary for physicians and hospitals, though more than 80% of obstetricians in Florida have elected coverage under the plan.²⁶⁶ Obstetricians who want to participate in the plan pay \$5,000 into the Fund each year. All other physicians (including those who do not practice obstetrics) are required to contribute \$250. Participating hospitals pay an amount equal to 50 times their previous year's number of deliveries, with a cap at \$150,000. Virginia also

²⁶⁶ Studdert DM, Fritz LA, Brennan TA. *The Jury is Still In: Florida's Birth-Related Neurological Injury Compensation Plan After a Decade*. J. Health Pol. Pol'y L. 499 (2000).

levies a surcharge on liability insurers. The compensation programs are intended to be entirely self-funded, but Florida initially capitalized its program with a \$20 million appropriation from the state.²⁶⁷ The Florida law also authorizes the Department of Insurance to increase assessments in order to maintain the Plan on an “actuarially sound” basis.

The compensation schemes cover only infants with severe neurological birth-related injury. Specifically, the compensation criteria in Virginia are that the infant must (1) meet the statutory definition of birth-related neurological injury and (2) have been delivered by a participating provider or in a participating hospital. The injury definition describes permanent serious disability associated with oxygen deprivation or mechanical injury to the brain or spinal cord during labor, delivery, or resuscitation.

In Florida, eligible families receive periodic payments for necessary and reasonable expenses for medical and rehabilitative care, custodial care, medical equipment and special facilities, drugs, and attorney fees. “Parental awards” may be received for noneconomic damages up to \$100,000 at the discretion of the hearing officer.²⁶⁸ From the plan’s beginning in 1989 through 1997, parental award payments averaged \$88,000 and accounted for \$7.6 million expended, with another \$3.6 million spent for administrative costs, which includes attorneys’ fees, and independent medical examinations.²⁶⁹ Payments are made after collateral sources such as health insurance are exhausted. Some compensation for lost earnings is also provided. Compensation decisions are made by the Workers’ Compensation Commission in Virginia and by administrative law judges in Florida.

Academic evaluations have concluded in its first decade of existence, the programs compensated families of infants with severe neurological injury efficiently, equitably, and generously.²⁷⁰ The frequency and average size of tort claims decreased in Florida after NICA implementation; however, the number of claims to NICA was lower than expected.²⁷¹ The system’s impact on frequency and severity of tort claims was relatively small because the scope of NICA coverage is limited and the system contains (ill-advised) design features that permit claimants to pursue tort claims in addition to NICA claims.

Compensation for claims brought under NICA, though lower than the average tort award, is considered to be adequate. The NICA program distributed \$14.7 million to 86 families from January, 1989 through December, 1997. An additional 139 families were denied compensation.²⁷² Of those families denied compensation under NICA, one in six brought a malpractice claim for the same injury.²⁷³ For those filing in both forums, the usual practice appears to be to file an initial tort claim, then pursue recovery through NICA, and then resume

²⁶⁷ Spiegel S. *Virginia and Florida Child Brain Injury Compensation Funds*. <http://biotech.law.lsu.edu/policy/2003-R-0620.htm>.

²⁶⁸ Studdert, *supra*, n. 266.

²⁶⁹ *Id.*

²⁷⁰ *Id.*; Bovbjerg RR, Sloan FA, Rankin PJ. *Administrative Performance of “No-Fault” Compensation for Medical Injury*, 60 L. & Contemp. Probs. 71 (1997).

²⁷¹ Horwitz J, Brennan TA. *No-Fault Compensation for Medical Injury: A Case Study*, 14 Health Aff 164 (1995).

²⁷² Studdert, *supra*, n. 266.

²⁷³ *Id.*

the tort claim following dismissal of the claim before NICA.²⁷⁴ Eighty-three percent of claims filed in tort were successful, even though denied compensation by NICA.²⁷⁵ This result is due in part to the criteria NICA sets for compensation, which is “considerably higher than the baseline of all injury caused by medical treatment (i.e., adverse events), and perhaps higher even than the negligence standard.”²⁷⁶ This design runs counter to the characteristics of a no-fault system, which envisions compensation of more claims than under a tort system. As the possibility of tort action continues, the need for NICA participating physicians to also carry malpractice insurance is not abated.²⁷⁷ In designing such a system, careful consideration must be given to balancing a restrictive scope of compensation and possible jurisdictional ambiguity with a more clearly defined and encompassing scope of compensation, more definite jurisdictional lines and the possibility of greater resistance from the trial bar and judiciary from any such broadening of exclusivity. To define a clearer demarcation of injuries that are compensable or not compensable under the plan, with more opportunity to realize the benefits of a no-fault system, compensation might encompass an entire subgroup of medical injury or limit jurisdiction to injury suffered by participating physicians or facilities.²⁷⁸

Claimants in both the Florida and Virginia systems are the only parties to hearings. Hearings do not include physicians, hospitals, medical personnel or insurers, though both systems provide for independent medical review of claims²⁷⁹ and judicial review of administrative determinations on questions of law.²⁸⁰ Virginia and Florida both operate their systems as secondary payers, behind private health and disability insurance and Medicaid. An opinion from the Virginia attorney general has authorized Medicaid to pay prior to the no-fault system, although usually Medicaid is seen as the payer of last resort.²⁸¹

Both plans are governed by independent boards representing affected interests, selected by the governor or insurance commissioner.²⁸² The Florida system is financially stable and its administrative costs are substantially lower than those of the tort system. The Virginia system is less stable and is believed to have a substantial unfunded liability.²⁸³

The Virginia Legislature’s Joint Legislative Audit and Review Commission completed a comprehensive evaluation of its NICA in November 2002 and found that both health care providers and patients had fared well under the scheme.²⁸⁴

The compensation systems in the Nordic countries are far more comprehensive than the two American schemes. The systems in the five Nordic nations are based on a joint code emanating

²⁷⁴ *Id.*

²⁷⁵ *Id.*

²⁷⁶ *Id.*

²⁷⁷ *Id.*

²⁷⁸ *Id.*

²⁷⁹ See Fla. Stat. Ann. § 766.307 (West 2005); Va. Code Ann. § 38.2-5006 (2005).

²⁸⁰ See Fla. Stat. Ann. § 766.311; Va. Code Ann. § 38.2-5011.

²⁸¹ See Fla. Stat. Ann. § 766.31(1)(a)1-4; V. Code Ann. § 38.2-5009(1)a-d.

²⁸² See Fla. Stat. Ann. § 766.315(1); Va. Code Ann. § 38.2-5016.

²⁸³ Spiegel, *supra*, n. 267.

²⁸⁴ Joint Legislative Audit and Review Commission of the Virginia General Assembly. Review of the Virginia Birth-Injury Neurological Injury Compensation Program. <http://jlarc.state.va.us/Reports/Rpt284.pdf>.

from the system pioneered in Sweden in 1975.²⁸⁵ Initially voluntary, and now mandatory, these social insurance schemes provide limited administrative compensation for avoidable adverse events. To be eligible for compensation, injuries must be causally related to the provision of medical care (as opposed to underlying disease process) and must have been avoidable (however, even some unavoidable injuries may be covered if the injury is rare and extremely serious). The precise definitions of avoidability vary somewhat from country to country, but basically revolve around the notion that the injury would not have occurred if the physician had acted differently, if equipment failures had not occurred, or if another treatment had been selected. The avoidability standard thus captures all injuries due to substandard care (negligence), and some additional injuries as well, but not so low as to capture all iatrogenic injuries. The key determination is avoidability.

The Nordic schemes are funded through tax dollars and administered by the national government. Sweden's system is funded by premiums charged to physicians and regional councils.²⁸⁶ Health care providers are involved in about 60% to 80% of patient claims, assisting with claim filing and informing patients of a possible medical injury.²⁸⁷ The claim is initially reviewed for compensability by an adjuster, then referred to a specialist for a final determination. The time from claim filing to final determination is approximately six months.²⁸⁸ A board hears appeals from initial compensation decisions, and arbitration may follow. Patients are not precluded from pursuing a solution in court, during or after the claims process, though historically malpractice claims have been infrequent.

A number of evaluations of the Nordic systems have been performed, but there is relatively little updated information available. It is thought that only about 10% of patients with injuries eligible for compensation actually file claims with the patient insurance schemes.²⁸⁹ Claims rates vary across the schemes, from a low of 3 claims per 10,000 population in Iceland (where the scheme has only been running for a few years) to a high of 14.5 per 10,000 in Finland. Overall, claims rates after implementation of the schemes grew to about 20 times the rate at which claims were filed before the schemes were established. Between 31% (Finland) and 50% (Iceland) of claims have been judged eligible for compensation. Notwithstanding the growth in claims since implementation, the schemes enjoy wide public and governmental support, and the total expenses are only a very small fraction of the countries' overall health budgets (in Denmark, 0.3%).

The New Zealand system, like the Nordic schemes, is a government-run, publicly funded accident insurance system. The Accident Compensation Corporation (ACC) was established by statute in 1974, and covers not only medical injuries but also work and non-work injuries as well as motor vehicle injuries. Initial claims determinations and appeals are handled by the ACC.

The compensation criteria for medical injuries in the New Zealand system have evolved over time, and are different from those used in the Nordic schemes. Initially, the statute provided for

²⁸⁵ The following discussion draws on Erichsen M, *The Nordic Patient Insurance Schemes*, working paper, 2005.

²⁸⁶ Studdert, *supra*, n. 109.

²⁸⁷ *Id.*

²⁸⁸ *Id.*

²⁸⁹ *Id.*

compensation for “personal injury by accident,” including “physical and mental damage caused by medical, surgical, dental, and first aid misadventure.” In practice, this resulted in compensation for not only injuries due to negligence but also other low-probability, high-severity adverse outcomes.²⁹⁰ High compensation costs led to retrenchment in 1992. The standard was replaced with a narrower “medical misadventure” standard which limited eligibility to injuries “resulting from medical error or medical mishap.” “Medical error” was defined similarly to negligence, while “medical mishap” referred to serious injuries that have less than a 1% probability of occurring.²⁹¹ In late 2004, the government announced that it would replace the current medical error and medical mishap definitions with coverage for “treatment injuries” (injuries due to medical treatment rather than underlying disease) that are “not more than likely to occur and not the condition for which the patient sought treatment.” This will eliminate the requirement that claimants must prove fault (for some kinds of misadventure claims) or prove that the injury is rare and severe.²⁹²

The ACC pays for economic losses (medical and rehabilitation costs, lost earnings) and provides modest additional compensation (which it refrains from calling “noneconomic damages”) in cases of permanent impairment. In 2003, the maximum such payment was NZ\$100,000 (about USD\$71,000). The ACC is the exclusive remedy for covered injuries, although there are provisions for punitive damages to be awarded in exceptional cases through the courts.

Evaluations of the ACC have estimated that about 5% of eligible medical injuries result in claims to the ACC, and about two-thirds of claims are paid.²⁹³ The system has very low overhead costs, around 7-10% of total expenditures, and pays claims very promptly. Some have argued that the high payment rate, rather than administrative efficiency, is the reason for the low administrative costs.²⁹⁴ The scheme has been criticized for its high payment rate and the relatively low compensation that is available to unemployed persons.²⁹⁵

B. DAMAGES

This section addresses the following elements of the Commission’s charge:

- **The schedules or formulas necessary to determine the compensation of people injured by health care errors.**
- **A system to compensate individuals, as their exclusive remedy, for damages resulting from health care errors, including payment for:**

²⁹⁰ Danzon P. *Liability Reform: Traditional and Radical Alternatives*. In: Pauly MV, American Health Care: Government, Market Processes, and the Public Interest. London: Transaction, 2000.

²⁹¹ Some such injuries were specifically excluded: abnormal reactions and complications of procedures, and injuries relating to informed consent, misdiagnosis, and treatment omission, unless due to negligence. *See id.*

²⁹² New Zealand Department of Labour. Changes to ACC medical misadventure. <http://www.acc.co.nz/providers/news-for-providers/review-of-acc-medical-misadventure---consultation/>.

²⁹³ Davis P, Lay-Yee R, Fitzjohn J, Hider P, Briant R, Schug S. *Compensation for Medical Injury in New Zealand: Does “No-Fault” Increase the Level of Claims Making and Reduce Social and Clinical Selectivity?* 27 J Health Polit. Pol’y L. 833 (2002).

²⁹⁴ Danzon, *supra*, n. 290.

²⁹⁵ Miller RS. *An Analysis and Critique of the 1992 Changes to New Zealand’s Accident Compensation Scheme*, 52 Md. L. Rev. 1070 (1993). An updated evaluation of the New Zealand experience is currently underway at the Harvard School of Public Health.

- (A) All health care expenses arising from the error; and**
- (B) Other expenses and lost opportunities, including loss of actual and potential earnings, increased living expenses, decreased quality of life and other appropriate compensation as provided through a schedule or formula.**

Because the avoidability standard on which compensation in an ACS is based is broader than the negligence standard, an intended result of a move to an ACS is that a broader range of injuries will receive compensation. Notwithstanding the greater volume of claims, proponents of ACS have suggested that expenditures could be kept within manageable levels through savings in two key areas: (1) administrative costs; and (2) greater predictability in awards, due in part to elimination of some very high-cost awards.²⁹⁶ Careful design of compensation criteria positions a scheme to reap savings in the first area. Stabilization of awards requires political decisions about the appropriate content of the compensation package.

Compensation methodologies for economic losses are relatively straightforward. An ACS could employ existing valuation methods from the tort system concerning calculation of lost wages, household production, and medical expenses; and estimation of future expenses. Political decisions would have to be made about (1) the percentage of salary covered by awards; (2) whether a “deductible” period of lost work time would apply before compensation is triggered; (3) whether medical expenses would be offset by collateral sources, such as health and disability insurance; and (4) whether losses would be compensated in a lump sum or through periodic payments.

Most state legislatures have worked through such decisions in the context of establishing workers’ compensation and auto accident schemes. The epidemiology of medical injury suggests that including a deductible period, or disability threshold (which would exclude many low-severity, temporary injuries from compensation for economic losses) would result in significant cost savings for the ACS.²⁹⁷ Sweden employs such a system, requiring at least 10 days in the hospital or the patient to have been sick for more than 30 days.²⁹⁸ Evaluations of existing tort reforms suggest that a collateral-source offset rule would also be cost-saving.²⁹⁹ Structuring compensation as periodic payments, with periodic review by the ACS to determine whether adjustments are needed to the amount, would be desirable both economically and in order to ensure that economic damages neither overestimate nor underestimate claimants’ needs.

Decisions about compensation of noneconomic losses involve harder political choices.³⁰⁰ The lack of standardization and controversial nature of valuations in this area drive the current policy interest in caps on damages. To bring the needed stability to system costs, an ACS would need to include a rational method for compensating noneconomic losses. Some limitations would have to be imposed on recoveries in this area in order to contain system costs.

²⁹⁶ Brennan, *supra*, n. 234.

²⁹⁷ Studdert, *supra*, n. 109.

²⁹⁸ *Id.*

²⁹⁹ Kinney ED. *Malpractice Reform in the 1990s: Past Disappointments, Future Success?*, 20 J. Health Polit. Pol’y L. 99 (1995).

³⁰⁰ The following discussion is adapted from Brennan, *supra*, n. 234.

A variety of scholarly analyses of noneconomic losses over the past 30 years, including the American Law Institute's 1991 study of personal injury, have pointed to a schedule or sliding scale for damages as the best method for valuing noneconomic damages in an ACS. This approach would generate a matrix of levels of injury severity and assign a range of dollar values to each cell in the matrix. The ACS adjudicator would then select an amount for noneconomic damages that falls somewhere within the range, depending on the specific facts of the case.

The tiers of the matrix could be constructed using an existing injury severity scale, such as the one developed by the National Association of Insurance Commissioners (NAIC). The NAIC scale is used widely by insurers to evaluate the severity of malpractice claims. The scale is as follows:

1. Emotional disability only: fright; no physical damage
2. Temporary insignificant: lacerations, contusions, minor scars, rash; no delay in recovery
3. Temporary minor: infections, missed fracture, fall in hospital; recovery delayed
4. Temporary major: burns, surgical material left, drug side effect, brain damage; recovery delayed
5. Permanent minor: loss of fingers, loss or damage to organs includes non-disabling injuries
6. Permanent significant: deafness, loss of limb, loss of eye, loss of one kidney or lung
7. Permanent major: paraplegia, blindness, loss of two limbs, brain damage
8. Permanent grave: quadriplegia, severe brain damage, lifelong care, or fatal prognosis
9. Death

One shortcoming of the scale is that it is geared toward ranking physical injuries and is not sensitive to the concept of "pain and suffering" specifically. An additional resource for evaluating injuries on the high end of the scale is the American Medical Association's *Guides to the Evaluation of Permanent Impairment*,³⁰¹ although they have been criticized.³⁰²

An alternative approach would be to base the injury tiers on some quality of life measure. A significant body of scholarship in the decision sciences has developed methods for quantifying the utility losses associated with different health states. The utility scales are typically based on surveys of physicians and/or the general public. Two examples of these scales are the Injury Priority Ratings, which was developed and refined through a series of studies supported by the United States Department of Transportation; and the Quality of Life Valuations developed by the Ontario Institute for Work and Health for the workers' compensation program in that province.

Formulation of the severity matrix would define relative values of a range of injury types commonly seen in claims. The next step would be to determine the dollar value ranges assigned to each tier. This could be accomplished through expert, political, or public deliberation about (1) what constitutes reasonable compensation for the various levels of noneconomic loss; and (2) what the total costs of the compensation system should be limited to. Bovbjerg and colleagues

³⁰¹ Andersson GBJ, Cocchiarella L. *Guides to the Evaluation of Permanent Impairment*, 5th ed. Chicago: American Medical Association, 2002.

³⁰² Speiler E, Barth PS, Burton JF, Himmelstein J, Rudolf L. *Recommendations to Guide Revision of the Guides to the Evaluation of Permanent Impairment*, 283 JAMA 519 (2000).

have proposed using median jury awards from past verdicts in the state,³⁰³ but the costs associated with this approach would likely be excessive. Moreover, the variability in jury awards is so great that it is questionable whether they form a rational basis for a compensation scale.

Dollar values in a damages matrix could be designed to respect an existing cap on noneconomic damages in the state, or could be designed to replace a flat cap. Given the equity concerns associated with a low-dollar, flat cap, it may be desirable to replace it.³⁰⁴ It should be noted that the total cost of noneconomic damages theoretically could be lower under a schedule than under a flat cap even if the maximum allowable damages under the schedule is higher. This is because the matrix would result in limits on a great number of claims that fall below the trigger value for the flat cap.

C. APPEAL RIGHTS

This section addresses the following elements of the Commission’s charge:

- **The appropriate means for a person aggrieved by an action of the commission to seek judicial review.**

Previous initiatives to design an alternative compensation system for medical injury have always included a process through which the decisions of the administrative adjudicator may be appealed. Building an appeals process into an administrative compensation system is important for both political and legal reasons. In the past, proposals to replace juries with expert adjudicators have been perceived as having the potential to favor defendants. Thus, appeal processes are crucial to persuading key constituencies that the alternative system is fair to claimants. Additionally, the law of many states requires that when tort remedies are modified and eliminated, they must be replaced with an adequate substitute remedy. A system with no opportunity for appeal is unlikely to meet this requirement, or comport with more general requirements of due process.

Relatively little has been written in the academic literature about potential appeal processes in an administrative compensation system for medical injury. However, processes used in other systems are readily exportable to medical injury compensation schemes. Relevant systems include worker’s compensation, Social Security Disability Insurance, the 9/11 victim’s compensation fund, and the Black Lung Benefits Program. The appeal process could be single-stage or multiple-stage, and could incorporate administrative and/or judicial review.

The compensation process described in the **Claims Process** section described previously, incorporates the following appeal mechanisms:

³⁰³ Bovbjerg RR, Sloan RA, Blumstein JF. *Valuing Life and Limb in Tort: Scheduling “Pain and Suffering,”* 83 Nw. U. L. Rev. 908 (1989).

³⁰⁴ Studdert DM, Yang YT, Mello MM. *Are Damage Caps Regressive? A Study of Malpractice Jury Verdicts in California,* 23 Health Aff. 54 (2004).

- Decisions of the hospital panel as to the amount of damages in cases in which a compensation award is made are subject to appeal via a request for redetermination of damages from the state ACA.
- Decisions of the hospital panel as to the compensability of the injury are appealable to an ACA tribunal, which would conduct a de novo review.
- Decisions of the ACA tribunal could be appealable to a state administrative law judge or reviewable by a rehearing of a different panel of the ACA tribunal or subject to judicial review.

Clearly, there are tradeoffs between providing extensive appeal processes and ensuring expeditious disposition of claims. Referring appeals back to the courts for adjudication is probably not advisable, (unless it appears to be constitutionally required) as it would result in substantial delay and remove cases from review by specialized experts. However, providing a robust appeals process at the ACA level or through alternative administrative processes is important because the initial compensability decisions are made by health care providers and their insurers, who have a financial interest in denying claims. The system will not be credible to patients unless there is recourse to an impartial body and penalties for clearly unsupportable compensability decisions by providers.

D. ADMINISTRATION

This section addresses the following elements of the Commission's charge:

- **The size of the health care errors commission and the appropriate mix of health care professionals, attorneys and public representatives on the commission.**
- **The administration and management of the commission including staffing and procedures for handling claims.**

This section of the Commission's charge raises two key questions: (1) how should an ACS for medical injury be administered; and (2) what body should have responsibility for implementation of new patient safety mandates?

As described in the Institute of Medicine's report on systems demonstrations,³⁰⁵ trials of ACS could be based either in state governments or in private systems, such as liability insurers. The private system would be voluntary, the state system mandatory. A private system could be administered by, for example, the insurer of a group of hospitals or the captive insurer of a single hospital. The insurer would receive and process claims, and some external process would be created for appeals. In both systems, most initial compensation decisions are made at the level of the hospital or insurer and are appealable to a tribunal at the state ACA.

A statewide system could be administered by the Department of Health, the Department of Insurance, or a new dedicated agency similar to a worker's compensation board or independent commission. New Zealand's ACC and Florida's NICA provide useful examples of how an independent agency could be structured.

³⁰⁵ Institute of Medicine, *supra*, n. 265.

The composition of the ACA tribunal is to some degree a political question. The political circumstances in the state, particularly with respect to the power and position of the trial bar, may argue for the representation of certain stakeholder groups (such as malpractice attorneys) on the tribunal. However, the core of the tribunal should be a panel of specialized medical experts. The state ACA would maintain a roster of national experts in all major specialty fields, and would compose panels to adjudicate particular kinds of cases. The adjudicators would be appointed by the state and would have an advanced medical or nursing degree; some might also have a law degree. This is the model currently in use by Wyoming's Medical Commission.

The ACA as a whole would be governed by a commission whose function would be to periodically evaluate the system on the key criteria of fairness to claimants, time to disposition of claims, administrative costs, compensation costs, and demonstrated evidence of patient safety impacts. The composition of the commission, too, should be sensitive to political exigencies in the state, but should probably include representation from the trial bar, insurance, hospital, and patient communities.

With respect to administration and management, states have generally either assigned responsibility for patient safety activities to the Department of Health or created a new, independent patient safety office. A third approach would be to create a nongovernmental or quasi-governmental patient safety organization, but this would seem to have disadvantages in terms of its ability to enforce mandates.

A fourth option, if a statewide ACS is implemented, would be to repose responsibility for both claims processing and patient safety improvement with the ACA. Common administrative structures would facilitate information sharing and learning from claims data. For example, the claims arm of the ACA would have responsibility for entry of detailed claims information into a database that is subsequently analyzed by the safety arm of the ACA in order to learn about prevalent causes of medical injuries and feed information back to providers.

E. SYSTEM COSTS

This section addresses the following elements of the Commission's charge:

- **The probable costs of the system including but not limited to the costs of administration, the costs of improvements to the health care system needed to prevent future errors, the cost of compensating those persons injured by errors and the costs to health care professionals in providing the financial resources necessary to support the system.**

1. COSTS OF AN ACS

There are no hard data on what a comprehensive ACS for medical injury in the United States would cost. However, one academic study performed a simulation using actual data on medical injuries in Utah and Colorado and the compensation rules of the Swedish injury compensation

system.³⁰⁶ It determined that a much broader range of injuries could be compensated than are eligible for compensation under the tort liability system at about the same cost.

More data of this kind are needed in order to persuade policymakers and insurers that the cost of an ACS system will be manageable.³⁰⁷ The Utah-Colorado study relied on ad hoc judgments of preventability by two physician investigators using a general compensation criterion of avoidability, but did not measure costs using specific predetermined lists of accelerated compensation events. Additionally, the Utah-Colorado analysis included all medical injuries detected in a review of a random sample of hospitalizations, but what insurers are interested in with respect to administrative health court demonstration proposals is comparing the expected costs under an ACS with the expected costs for their existing portfolio of claims under the tort system. Finally, the Utah-Colorado data are from 1992. Although there is no particular reason to think that either incidence or costs of adverse events (in real terms) has changed much over the last 12 years, the validity of estimates based on data this old will be questioned by policymakers and insurers. Updated cost estimates are needed. A two-year study is currently being conducted by the Harvard School of Public Health to add to the base of available data; results should be available in late 2006.

As a theoretical matter, ACS system costs will depend on three main factors: (1) the number of claims brought, (2) the average payout on claims, and (3) administrative costs. There is reason to be confident about the prospects for (2) and (3). Payout levels are controllable; they are a product of specific design choices made, such as ex ante determinations of how generously noneconomic losses will be covered. There is good evidence from other kinds of administrative compensation systems that administrative costs are much lower than overhead costs in the tort liability system. Administrative costs in systems such as Social Security Disability Insurance and Workers Compensation are on the order of 5% to 30%, as compared to 55% to 60% for the tort liability system.³⁰⁸

Administrative costs will depend to some extent upon system design choices, including the procedures that govern liability determinations and appeals. For instance, a system that is designed to be simple enough that patients can file and press claims without aid of legal counsel will have lower costs (but would be considerably less palatable to the trial bar). A system that provides two or more layers of appeal would be more costly than a system that limited appeals to a single review by the ACA tribunal.

The major area of uncertainty is around the volume of claims in an administrative system. Theoretically, one would expect the frequency of claiming to be considerably higher than in the tort liability system (indeed, increasing the proportion of patients with preventable injuries who access the compensation system is one of the goals of reform). The best available estimates of medical injury rates suggest that the pool of “avoidable” injuries is about twice the size of the

³⁰⁶ Studdert DM, Thomas EJ, Zbar IW, Newhouse JP, Weiler PC, Bayuk J, Brennan TA. *Can the United States Afford a “No-Fault” System of Compensation for Medical Injury?* 60 L. & Contemp. Probs. 1 (1997); Studdert, *supra*, n. 297.

³⁰⁷ Brennan, *supra*, n. 234.

³⁰⁸ Mello MM, Brennan TA. *Deterrence of Medical Errors: Theory and Evidence for Malpractice Reform*, 80 Tex. L. Rev. 1595 (2002).

group that meets the negligence standard. Of course, not all of these injuries will result in claims. In the present system, about 2% of injuries due to negligence result in malpractice claims.³⁰⁹ An ACS would be deliberately designed to reduce barriers to claiming, such as the adversarial nature of the litigation process and the long time to claim disposition. This would be expected to result in considerably higher rates of claiming, but there is no way to predict an exact rate. Claiming rates can likely be manipulated to some extent through particular system design choices, including eligibility criteria, compensation levels, and complexity of claims procedures.

Insurers are understandably concerned about their potential exposure, and it is difficult to offer assurances. (It is important to keep in mind that proposals for ACS typically recommend that liability insurance remain privatized and that compensation costs continue to be funded by liability insurance premiums.) Clearly limitations on damages will be critical. A second measure that may be helpful would be to provide insurers with a stoploss guarantee. This could come in the form of publicly subsidized reinsurance, as suggested by the Institute of Medicine,³¹⁰ or a full commitment from the state or federal government to absorb claims costs beyond a certain annual maximum.

Florida's Birth Related Neurological Injury Compensation Plan assesses a fee on physicians participating in the program, as well as non-participating physicians, with some exceptions. Hospitals are assessed a fee on live births, with provisions to except births to Medicaid patients in some instances.³¹¹ The assessment scheme has been challenged by non-participating physicians. An intermediate appellate court determined that the physicians benefited from the plan and the legislature had a rational basis for leveling the assessment.³¹² The Florida Supreme Court held the assessment was a tax, though not an impermissible one, as the Department of Insurance was required to approve all assessment changes.³¹³

2. DEMONSTRATION PROJECTS

To support the development of demonstration projects of an administrative compensation system, the legislature should consider passing enabling legislation that would permit limited experimentation with an ACS (which may also include an enterprise liability model) and supporting data collection on compensation, errors and patient safety improvements.³¹⁴ Considerations include permitting patients to opt into an ACS system for medical injury compensation where offered by a physician or hospital, mindful of issues of informed consent and coercion.³¹⁵

Enterprise liability is the notion that the organizational unit ultimately responsible for efficient health care delivery, such as a hospital, should also share the financial risk for medical errors, in order to provide incentives to take appropriate precautions in designing and implementing cost-

³⁰⁹ Localio, *supra*, n. 10; Studdert, *supra*, n. 2.

³¹⁰ Institute of Medicine, *supra*, n. 265.

³¹¹ Fla. Stat. Ann. § 766.314(4)(a) and (b).

³¹² *McGibony v. Florida Birth-Related Neurological Injury Compen. Assn.*, 564 So. 2d 177 (Fla. App. 1 Dist. 1990).

³¹³ *Coy v. Florida Birth-Related Neurological Injury Compen. Assn.*, 595 So. 2d 943 (Fla. 1992).

³¹⁴ Studdert, *supra*, n. 109.

³¹⁵ *Id.*

containment policies.³¹⁶ Enterprise liability focuses on shifting malpractice liability from individual providers to healthcare enterprises. Provider organizations, such as hospitals, group practices and health maintenance organizations, rather than individual physicians carry the responsibility for medical malpractice.³¹⁷ Generally, four theories comprise discussion of enterprise liability: 1) under the doctrine of *respondeat superior*, hospitals, like any other employer, would be liable for the medical negligence of the physicians whom they employ; 2) hospitals are legally responsible for reviewing the credentials of physicians seeking staff privileges and review performance through the peer review process; 3) on an “apparent agency” theory, hospitals may be liable where it has advertised the competence of its physicians, or assured quality of care.³¹⁸

Under this particular theory of enterprise liability the organizations charged with facilitating the delivery of cost-effective care, should also experience direct financial liability for malpractice in order to internalize the cost of patient harm in designing cost-containment policies.³¹⁹ Enterprise liability is more than theoretical and already exists in some healthcare delivery systems. Liability for negligent acts of physicians is expressly assumed by Kaiser-Permanente, the Veterans Administration, Indian Health Services, and the Public Health Service.³²⁰ Hospitals that enter into enterprise liability arrangements should inform consumers of the transfer of liability and should require consumers to waive their rights against the individual provider to bring claims solely against the liable enterprise. Courts can be expected to scrutinize any such contractual arrangements with consumers for elements of adhesion.³²¹ For health care entities that selectively employ or contract with physicians, apply strict credentialing and privileging standards, and conduct meaningful peer review and quality assessment activities, the enterprise liability model may represent “sound business practice that simplifies the dispute resolution process and reduces burdens on physicians while also encouraging them to participate in the quality improvement efforts of the entire enterprise.”³²² Issues in enterprise liability should be researched along with administrative compensation system demonstration projects.

3. COSTS OF INTERVENTIONS TO PREVENT MEDICAL ERRORS

The costs associated with implementing clinical interventions to improve patient safety, of course, depend on the specific interventions selected. They therefore cannot be estimated in this report. However, once the Legislature has decided on a group of interventions to pursue, it should be possible to obtain cost estimates associated with those interventions from the published literature.

³¹⁶ Sage WM, Hastings KE, and Berenson RA. *Enterprise Liability for Medical Malpractice and Health Care Quality Improvement*, 20 Am. J.L. and Med. 1 (1994).

³¹⁷ Sage WM and Jorling JM. *A World That Won't Stand Still: Enterprise Liability by Private Contract*, 43 DePaul L. Rev. 1007 (1993).

³¹⁸ *Id.*

³¹⁹ Sage, *supra*, n. 316.

³²⁰ Sage, *supra*, n. 317316.

³²¹ *Id.*

³²² *Id.*

The high implementation costs of some of the most promising safety-enhancing interventions, such as computerized physician order entry (CPOE), have been much discussed as a barrier to widespread adoption.³²³ The lack of a “business case” for hospitals and other private entities to invest in these safety-enhancing technologies is also recognized. These considerations suggest that financial incentives may need to be offered to some or all healthcare organizations if the State wishes to encourage uptake of particular interventions.

F. COSTS AND BENEFITS COMPARED TO TORT

This section addresses the following elements of the Commission’s charge:

- **An analysis of this system’s costs and benefits for health care professionals, victims of health care errors and the public compared to the present system of tort.**

To date, this country has pursued tort reform in a piecemeal fashion, with mixed results. States that have adopted liability-limiting reforms such as caps on damage awards, abolition of punitive damages or collateral source rule reforms have experienced modest increases in the supply of physicians relative to states that adopted no reforms.³²⁴ However, “the tort system still seems to engender perverse behaviors such as widespread, sometimes serious, and often costly deviations from accepted medical practice” specifically defensive medicine practices.³²⁵ Reforms have not been tied to evidence-based changes in practice, reconciling medical and legal standards. Tort reform measures and patient safety efforts have not been well connected. In addition, malpractice carriers compound the issues by urging secrecy, disputing fault, deflecting responsibility and making the litigation process slow and expensive for plaintiffs. Resolving claims for serious injury often take five or more years, while the patient is denied information about the cause of injury for lengthy periods of time, as well as compensation when it is needed most.³²⁶ Quality feedback to providers is delayed to the point of being useless. Some advocate the time has come to link legal accountability with mandatory measures to ensure high quality of care.³²⁷

Advocates of administrative compensation have argued that it would have a number of advantages over the tort liability system. These fall into four main categories: reliability, costs, patient safety, and the general care environment. Detractors cite disadvantages in the areas of costs, fairness, constitutionality, and deterrence. There is voluminous literature discussing these arguments. Because a comprehensive scheme has never been implemented in the U.S., these proposed advantages and disadvantages have not been empirically tested.

1. ASSERTED ADVANTAGES

(a) Greater reliability

³²³ Mello, *supra*, n. 45.

³²⁴ Kessler DP, et al. *Impact of Malpractice Reforms on the Supply of Physician Services*, 293 JAMA 2618 (2005).

³²⁵ Budetti PP. *Tort Reform and the Patient Safety Movement: Seeking Common Ground*, 293 JAMA 2660 (2005) (citing Kessler, *supra*, n. 324 and Studdert, *supra*, n. 258).

³²⁶ Sage WM. *The Forgotten Third: Liability Insurance and the Medical Malpractice Crisis*, 23 Health Affs. 96 (2004).

³²⁷ Budetti, *supra*, n. 325.

An ACS would ground compensation decisions in the best available scientific evidence about the causes of adverse outcomes in health care, codified in predetermined ACE-based compensation guidelines that are available for all to see. This is very likely to result in improved consistency or reliability in decision-making across claims involving similar injuries. In the present system, there is no formal mechanism for incorporating information about the outcomes of past claims into future cases. As a result, there is substantial variation in liability determinations and damages determinations across similar cases. In an ACS, both precedent and external scientific judgments are incorporated into compensation guidelines, and decisions are recorded in a centralized database which future decision makers can consult.

(b) Cost savings

With improved reliability comes improved predictability, which has important cost implications. Uncertainty about what kinds of behavior will result in adverse liability determinations in the current system is a major reason for defensive medicine behaviors. With greater understanding of the sorts of events that will and will not be presumptively compensable under an ACS, doctors will have less incentive to behave defensively. The national costs of defensive medicine have never been reliably calculated, but most estimates converge at around 1% of all health care costs.

Improved predictability of both liability decisions and damages awards will also benefit insurers and may result in lower insurance premiums. Part of every premium dollar is an amount representing the insurer's uncertainty about what its actual liability will be. The greater this uncertainty, the more the insurer will charge for assuming the risk. Providing a concrete structure for noneconomic damages awards would be a great help to insurers in estimating their exposure, and this should translate into lower premiums.

Finally, an ACS is expected to reap substantial savings in the area of administrative costs. Although hard data are not available, ACS proponents anticipate that the overhead costs would be a third to a half those of the tort system. The savings would come from the elimination of battles over whether care was negligent; ACE lists would replace such determinations for most cases, and less adversarial avoidability determinations would be made in the remainder of cases.

(c) Greater potential to effect patient safety improvements

There are two mechanisms through which an ACS would likely prompt greater efforts to improve patient safety. First, an ACS can serve as a valuable data source for learning about preventable medical injuries. In the current system, there are few mechanisms for gathering information about adverse events across institutions for purposes of data analysis. In an ACS, every adverse event for which a patient filed a claim for compensation would be recorded in the system database, and could be analyzed either by system personnel or external researchers. Their findings could then be fed back to providers in the form of patient safety alerts identifying common problems and suggesting fixes.

Second, an ACS would improve the degree of accountability in the system. At present, only a small proportion of negligent injuries result in malpractice claims. Although these claims

generate a tremendous amount of anxiety among providers, the system does not send the kind of consistent signal that is needed to spur changes in providers' behavior that result in improved safety.³²⁸ In an ACS, a greater proportion of injured patients would bring claims, and the outcomes of those claims will be more predictable to providers. This should improve "deterrence" of medical error, by increasing the certainty that substandard care will result in a sanction (and, conversely, that unavoidable bad outcomes will not result in a sanction). Of course, the fact that a greater proportion of avoidably injured patients will receive compensation in an ACS is an advantage in and of itself.

(d) Improved environment of care

The tort liability system, particularly in these times of malpractice "crisis," creates an environment of care that is marred by mutual distrust in the physician/patient relationship, lack of candor about adverse events, an atmosphere of fear among physicians, and stigmatization associated with making errors. Moving to an ACS would involve the replacement of the concept of negligence, which is individualistic and punitive in orientation, with the more systems-oriented concept of avoidability. Hopefully, with a lessened degree of stigma would come a greater willingness among health care providers to discuss preventable adverse events among themselves and with affected patients and a willingness to assist patients in filing claims for compensation rather than fighting such efforts. Patients would have less reason to believe that providers will "cover up" errors where they occur, and physicians would have less reason to view every patient as presenting the potential for a devastating malpractice lawsuit. Describing classes of ACEs and making that information available to the public should improve public awareness that medical care often involves bad outcomes; that some are preventable and some are not; and that there is a kind of social contract in place, in which providers pledge that preventable injuries will be disclosed and compensated. All of these dynamics should result in an improved physician/patient relationship and environment of care.

2. ASSERTED DISADVANTAGES

(a) Uncertain and potentially enormous compensation costs

The greatest weakness of ACS proposals is the inability to project with any confidence how the propensity to file claims may increase under such a scheme. The pool of patients eligible for compensation would increase substantially—by 100%, if estimates of the prevalence of preventable and negligent injuries are accurate. But it is not known how many of these eligible persons would file claims. Even if damages are carefully limited, there is the potential for compensation costs to increase very significantly under such a system. It is not known whether the savings on administrative costs would be sufficient to offset this increase, or whether the improvements in patient safety that an ACS might spur would result in a substantial reduction in claims over the long term.

³²⁸ Mello, *supra*, n. 308.

(b) Unfairness to claimants

The trial bar opposes ACS on the basis that they deny injured patients both corrective justice and fair compensation for their injuries. Whatever its flaws, attorneys argue, the tort system does succeed in providing claimants with a “day in court” in which they can confront persons who have wronged them, explain how the wrongdoing has affected them, and seek restitution. An ACS provides a mechanism for obtaining restitution from those responsible for injuries—indeed, patients are much more likely to receive compensation from an ACS than from the tort system. However, the process would be less public, less adversarial, and involve less shaming of the defendant. Thus, some would claim that the opportunities to receive corrective justice are diminished.

The trial bar and many consumer groups also vehemently oppose any form of limitations on damages. Arguments that are commonly advanced in opposition to flat caps have less application to a sliding schedule of noneconomic damages, but it is certainly the case that many claimants would receive less under an ACS than they would in tort.

(c) Constitutional infirmities

Trial attorneys have also argued that an ACS would violate state constitutional guarantees for malpractice plaintiffs. Constitutional challenges could be brought under the following provisions:³²⁹

- **Access to courts:** Thirty-nine state constitutions contain a provision guaranteeing citizens access to the court system for civil lawsuits. An ACS would clearly infringe this right, which courts would consider justified only if limiting access to the courts serves some important countervailing public purpose and if an adequate substitute remedy is provided.
- **Right to trial by jury:** All but two state constitutions provide that civil claims with more than a nominal amount of money in dispute will be heard by a jury unless the litigants waive that right. (The 7th Amendment to the U.S. Constitution enshrines a similar right but has not been incorporated against the states.) Mandatory ACS schemes clearly impact upon this right.
- **Equal protection:** The 14th Amendment to the U.S. Constitution, and similar provisions in state constitutions, guarantee that similarly situated classes of persons will be treated similarly before the law. It can be argued that ACS schemes treat malpractice plaintiffs less favorably than other plaintiffs without sufficient justification.
- **Due process:** The 14th Amendment to the U.S. Constitution, and similar provisions in state constitutions, guarantee that individuals will be deprived of liberty or property only through fair procedures. It is argued that an ACE would involve reduced procedural protections for plaintiffs, such as reduced assistance of legal counsel and restricted appeal rights. Any such

³²⁹ Brennan, *supra*, n. 234.

curtailments of procedural protections must be adequately justified through a balancing of individual and societal interests.

- **Separation of powers:** Many state constitutions contain provisions that vest judicial powers exclusively in the court system, similar to Article III of the U.S. Constitution. Arguably, the legislative branch infringes on judicial power when it enacts laws that alter or impact the court's rules of civil procedure.

Legal researchers at the Harvard School of Public Health are currently investigating these issues in general terms. It is believed that each of these challenges is answerable, and ultimately would not threaten the viability of an ACS demonstration. (Indeed, both the Virginia and the Florida birth injury compensation schemes have been upheld.) State constitutions, as interpreted in relevant case law, generally provide that these constitutional rights may be abrogated if a strong public policy purpose exists and the deprivation is no more burdensome than necessary to achieve the public purpose. Specifically how Wyoming's Constitution addresses any of these issues would need to be researched as well.

Creating an ACS demonstration project will require careful drafting. A demonstration project similar to the Florida and Virginia plans, might be limited to a group of OBGYN providers and patients, providing the ACS as an exclusive remedy for injuries of a certain type, involving a defined set of providers. Provisions must be made to provide reasonable notice of the administrative compensation scheme to patients to permit them to make an informed choice of providers.³³⁰ Consequences of failure to notify the patient of the provider's participation in the ACS should be clearly stated in any authorizing statute, eliminating any ambiguity that would require litigation to resolve. How notice should be provided in group practices must also be determined.³³¹ Though the Florida Supreme Court determined that failure to notify nullifies the exclusivity of the ACS remedy, addressing this issue initially would be preferable.³³² To avoid litigation prior to an administrative determination on issues of compensability, explicit jurisdiction to decide threshold issues, such as whether the notice requirement has been met, should be clearly given to the administrative tribunal.³³³ Which party bears the burden of proof and the standard of proof to be applied should be clearly addressed by statute.

Jurisdiction issues and compensation criteria of the plan have compromised NICA's attempt to provide exclusive remedies for birth-related neurological injuries, creating more an alternate system as opposed to a substitute for tort claims.³³⁴ Realizing the threshold jurisdiction issue as problematic, in 1998, the Florida legislature attempted to correct this difficulty by passing legislation prohibiting a suit in tort against a NICA participating physician, prior to an administrative determination of compensability under NICA.³³⁵

³³⁰ *Galen v. Braniff*, 696 So. 2d 308 (Fla. 1997).

³³¹ *Schur v. Fla. Birth-Related Neurological Injury Compen. Assn.*, 832 So. 2d 188 (Fla. App. 1 Dist. 2002)

³³² *Galen*, *supra*, n. 330.

³³³ Florida currently has a split in the appellate court districts as to whether an administrative law judge (ALJ) has jurisdiction to resolve issues of adequate notice. Compare *O'Leary v. Fla. Birth-Related Neurological Injury Compen. Assn.*, 757 So. 2d 624 (Fla. App. 5 Dist. 2000) with *All Children's Hosp. v. Dept. of Admin. Hrgs.*, 863 So. 2d 450 (Fla. App. 2 Dist. 2004).

³³⁴ Studdert, *supra*, n. 266.

³³⁵ Studdert, *supra*, n. 266.

Given reasonable notice, patients may decide not to receive services from an ACS participating physician. In that instance, concerns regarding whether patients in Wyoming, who may already experience limited access to providers, particularly specialists, will have a meaningful choice of providers not part of the ACS if they chose to opt out of an ACS system, may be at issue.³³⁶ If choice of a non-ACS participating provider is not an option, would patient participation in the ACS scheme be considered coercive? Unfortunately, the legal literature at present provides extremely scant analysis of the issue.

(d) Enervated deterrence of medical errors

An ACS would make the malpractice claiming process less adversarial and punitive than under the tort system. Many commentators believe that these qualities of tort suits are valuable in influencing health care providers to practice safely. Even if they do not feel the economic consequences of lawsuits because they have insurance to pay judgments, it is argued, providers seek to avoid the psychological and reputational costs of being sued. Opponents fear that if stigma is removed from the system, the deterrent effect of claims will be reduced.

G. AVOIDANCE OF UNFOUNDED CLAIMS

This section addresses the following elements of the Commission’s charge:

- **Prevention and elimination of unfounded allegations and unnecessary actions against health care providers in cases which do not amount to medical malpractice.**

In this malpractice crisis as in previous ones, much of policymakers’ rhetoric has focused on the need to reduce the number of “frivolous” malpractice claims. Despite extensive experimentation, states have yet to hit upon a policy solution that is effective in screening out nonmeritorious claims. The primary mechanisms employed to date have been pretrial screening panels and expert witness precertification requirements. Unfortunately, neither has demonstrated much efficacy in achieving its intended purpose, and both add to the administrative costs of the malpractice system.³³⁷ Precertification requirements tend not to have a significant impact because plaintiff attorneys do not find it difficult to locate a paid expert who is willing to vouch that their claim has a reasonable basis. Screening panels are generally considered ineffectual because the standard for allowing a claim to proceed is quite low, and is met by most claims.³³⁸ Moreover, the panels add an extra layer of bureaucracy to the claiming process, which increases the costs and time to disposition of claims. Notwithstanding previous experiences, many states continue to express interest in these reforms. Wyoming is once again instituting a medical review panel to prescreen malpractice claims.

³³⁶ *Board of Regents v. Athey*, 694 So.2d 46 (Fla.1st DCA 1997), aff’d, 699 So. 2d 1350 (Fla. 1997).

³³⁷ Kinney, *supra*, n. 299.

³³⁸ Mardfin JK. *Medical Malpractice in the State of Hawaii* (Honolulu: Department of Consumer Affairs, 1986); Howard DA. *An Evaluation of Medical Liability Review Panels in Arizona*. State Courts J. 519 (1981); Shmanske S, Stevens T, *The Performance of Medical Malpractice Review Panels*. 11 J Health Polit Pol’y Law 525 (1986); Goldschmid J. *Where Have All the Panels Gone? A History of the Arizona Medical Liability Review Panel*, Ariz. State L. J. 23 (1991).

Academic commentators have suggested that a potentially more successful means of reducing nonmeritorious claims is to focus on improving communication between patients and providers. Studies have shown that patients who sue are often motivated by feelings of anger and perceptions that providers have not dealt with them fairly and honestly.³³⁹ Although it has not been empirically demonstrated, it is theoretically plausible that such feelings are especially likely to be the reason for claims that do not involve actual negligence or a cognizable injury. If so, then interventions aimed at improving providers' communication skills and relationships with patients, as well as interventions designed to defuse conflicts and mediate disputes at an early stage, could be a promising means of reducing claims. Wyoming's "I'm sorry" legislation may prove to be helpful here.

Two concrete policy recommendations along these lines would be to encourage or require liability insurers to offer premium discounts to physicians who undergo a workshop in communication skills, and to implement ombudsman programs in hospitals. A number of health care systems, including Kaiser Permanente and the National Naval Medical Center, have begun to experiment with Health Care Ombuds programs as a means of reducing malpractice claims and increasing patient satisfaction with the resolution of health care disputes.³⁴⁰ Ombudspersons provide "shuttle diplomacy," working quickly and informally to investigate and resolve patient complaints ranging from perceived medical errors and adverse events to dissatisfaction with quality of care or outcomes. These programs, which are typically developed by private mediation firms, claim striking results: at the National Naval Medical Center, for example, it is claimed that over 250 cases have been resolved without a single claim or payment (as compared to a normal claims rate of 10-12% among potentially compensable events). Ombuds programs have not been subjected to a rigorous independent evaluation, but are worthy of a closer look.

One final proposal that health care provider groups have often made for reducing nonmeritorious claims is to exact some penalty on the attorneys who bring them. Providers reason that it costs attorneys very little, in time or money, to file a malpractice claim; that the current rules of professional ethics are not efficacious in sanctioning attorneys who bring frivolous lawsuits; and that there is a need to change attorneys' cost-benefit calculations around the decision to bring a claim. Indeed, although sanctions are available under Federal Rule of Civil Procedure 11 for attorneys who repeatedly bring frivolous claims, these sanctions are levied very infrequently. There is sufficient inherent uncertainty around the facts of malpractice claims that they rarely violate the Rule 11 standard. Rule 11 requires only that "the allegations and other factual contentions ... are likely to have evidentiary support after a reasonable opportunity for further investigation or discovery." This essentially rules out only those claims that the attorney knows or suspects to be false at the outset.

Unfortunately, the inherent uncertainty about the clinical circumstances leading up to many adverse events also makes it difficult to design an intelligent public policy to penalize attorneys

³³⁹ Hickson GB, Clayton EW, Githens PB, Sloan FA. *Factors That Prompted Families to File Medical Malpractice Claims Following Perinatal Injuries*, 267 JAMA 1359 (1992).

³⁴⁰ Resolve Advisors LLC. HealthCare Ombudsman/Mediator: The Next Big Thing in Medical Dispute Resolution? <http://www.prhi.org/pdfs/HCOM%20Description.pdf>; Houk C. ADR: At the Tipping Point from Dispute Resolution to Conflict Management. [www.nadrac.gov.au/.../\\$file/0+CAROLE+HOUKThoughts+on+NADRAC+Keynote+Speech.doc](http://www.nadrac.gov.au/.../$file/0+CAROLE+HOUKThoughts+on+NADRAC+Keynote+Speech.doc).

who bring nonmeritorious claims. To be procedurally fair, the rule would have to apply only to those claims that attorneys could not reasonably have believed were legitimate at the time of filing, but such claims are probably the exception rather than the rule. An alternative approach might be to penalize any attorney who lost a certain number of malpractice suits in a year, or in a row. In the status quo, about 7 in 10 lawsuits are closed with no payment, suggesting that a very substantial number of attorneys would be sanctioned under such a regime in the absence of a change in the kinds of cases they brought. Would they alter their decision making around cases in the way reformers would like?

Such a rule would encourage attorneys to bring cases they believed they could win. But it is worth noting that (1) the contingent fee system already provides a strong incentive for attorneys to do this, and (2) some studies suggest that case outcomes may depend on the severity of injury as much as whether or not the defendant was negligent. Thus, attorneys may adopt a strategy of avoiding low-severity cases rather than trying to identify cases that did not involve negligence. Overall, the use of attorney sanctions probably would not have a substantial impact on claims rates, and might result in the avoidance of the wrong kinds of claims.

H. SUMMARY AND ACTION STATEMENTS

There is now general agreement in the patient safety community that setting broad goals for reducing medical errors, such as the Institute of Medicine's demand that errors be reduced by 50% within 5 years of publication of its 2000 report,³⁴¹ is not helpful, and indeed may be self-defeating. We simply do not know enough about how to measure and reduce errors that such goals can be met at this time. A better strategy is to focus on the few safety-enhancing interventions that have been documented to be effective and consider how to best support hospitals, physician practices, and liability insurers in implementing them.

Similarly, when it comes to medical injury compensation, innumerable studies have documented the shortcomings of the current system and called for far-reaching change. Liability insurers and lawmakers will always be risk averse, however, and it must be recognized that the case for a move to an administrative compensation system is a difficult one to make in the absence of hard evidence that costs will not skyrocket. In this area, too, it is prudent to start small. States can use the flexibility of our federal system of government to experiment with pilot projects of administrative compensation, capitalizing on insurers' and hospitals' high level of interest in alternatives during this malpractice crisis. Such experiments are most likely to be implemented where the government is willing to provide some kind of stoploss guarantee to nervous insurers.

1. A system that compensates patients for avoidable injuries that can be readily defined and identified, known as accelerated compensation events, may provide a remedy for more individuals than those currently compensated through the tort litigation system. An administrative compensation system demonstration or pilot project should be supported with enabling legislation to permit organizations to experiment with these models on a limited basis. These efforts could follow Senator Enzi's proposed federal legislation. (Page 36-44)

³⁴¹ Kohn, *supra*, n. 1.

- **ACTION STATEMENT:** Legislation enabling entities to develop demonstration or pilot projects to compensate patients for well defined and readily identifiable errors or adverse events should be passed by the Wyoming Legislature.
2. Certain medical specialties may experience greater frequency of malpractice claims, or involve procedures that permit errors to be more readily identified and categorized. These medical treatment areas offer potential for experimentation with administrative compensation systems (ACS). Data from the Wyoming Insurance Commissioner will assist in determining which specialty might benefit by using an administrative compensation system for claim determination and payment. Experts in the medical specialty area selected would be helpful in determining a discrete set of medical injuries for which an ACS could be designed. (Page 36-44)
- **ACTION STATEMENT:** Review and analyze claims data from the Wyoming Insurance Commissioner to identify medical practice areas experiencing high rates of malpractice claims. Identify and define a discrete set of medical injuries eligible for compensation through an administrative compensation system.
3. Enterprise liability makes the organizational unit ultimately responsible for efficient health care delivery, such as a hospital or physician group practice, should also share the financial risk for medical errors, in order to take appropriate steps when designing patient safety systems that eliminate error and establish prevention measures. With a financial stake in patient safety, healthcare institutions will also become more cautious in designing and implementing cost-containment policies. The application of enterprise liability in Wyoming to facilitate medical error prevention and buy-in from healthcare institutions should be supported. (Page 57-58)
- **ACTION STATEMENT:** The Wyoming Legislature should support research to identify the potential costs and benefits of implementing enterprise liability in Wyoming, including direct effects on patient safety.

Appendices

APPENDIX A: LIST OF SERIOUS REPORTABLE EVENTS

EVENT	ADDITIONAL SPECIFICATIONS
<p>1. SURGICAL EVENTS</p> <p>A. Surgery performed on the wrong body part</p>	<p>Defined as any surgery performed on a body part that is not consistent with the documented informed consent for that patient.</p> <p>Excludes emergent situations that occur in the course of surgery and/or whose exigency precludes obtaining informed consent.</p> <p>Surgery includes endoscopies and other invasive procedures.</p>
<p>B. Surgery performed on the wrong patient</p>	<p>Defined as any surgery on a patient that is not consistent with the documented, informed consent for that patient.</p> <p>Surgery includes endoscopies and other invasive procedures.</p>
<p>C. Wrong surgical procedure performed on a patient</p>	<p>Defined as any procedure performed on a patient that is not consistent with the documented informed consent for that patient.</p> <p>Excludes emergent situations that occur in the course of surgery and/or whose exigency precludes obtaining informed consent.</p> <p>Surgery includes endoscopies and other invasive procedures.</p>
<p>D. Retention of a foreign object in a patient after surgery or other procedure</p>	<p>Excludes objects intentionally implanted as part of a planned intervention and objects present prior to surgery that were intentionally retained.</p>

<p>E. Intraoperative or immediately post-operative death in an ASA Class I patient</p>	<p>Includes all ASA Class I patient deaths in situations where anesthesia was administered; the planned surgical procedure may or may not have been carried out.</p> <p>Immediately post-operative means within 24 hours after induction of anesthesia (if surgery not completed), surgery, or other invasive procedure was completed.</p>
<p>2. PRODUCT OR DEVICE EVENTS A. Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the healthcare facility</p>	<p>Includes generally detectable contaminants in drugs, devices, or biologics regardless of the source of contamination and/or product.</p>
<p>B. Patient death or serious disability associated with the use or function of a device in patient care in which the device is used or functions other than as intended</p>	<p>Includes, but is not limited to, catheters, drains, and other specialized tubes, infusion pumps, and ventilators.</p>
<p>C. Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in a healthcare facility</p>	<p>Excludes deaths associated with neurosurgical procedures known to present a high risk of intravascular air embolism.</p>
<p>3. PATIENT PROTECTION EVENTS A. Infant discharged to the wrong person</p>	
<p>B. Patient death or serious disability associated with patient elopement (disappearance) for more than four hours</p>	<p>Excludes events involving competent adults.</p>
<p>C. Patient suicide or attempted suicide resulting in serious disability while being cared for in a healthcare facility</p>	<p>Defined as events that result from patient actions after admission to a healthcare facility.</p> <p>Excludes deaths resulting from self-inflicted injuries that were the reason for admission to the healthcare facility.</p>

<p>4. CARE MANAGEMENT EVENTS</p> <p>A. Patient death or serious disability associated with a medication error (e.g., errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation or wrong route of administration)</p>	<p>Excludes reasonable differences in clinical judgment on drug selection and dose.</p>
<p>B. Patient death or serious disability associated with a hemolytic reaction due to the administration of ABO-incompatible blood or blood products</p>	
<p>C. Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in a healthcare facility</p>	<p>Includes events that occur within 42 days post-delivery. Excludes deaths from pulmonary or amniotic fluid embolism, acute fatty liver of pregnancy or cardiomyopathy.</p>
<p>D. Patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for in a healthcare facility</p>	
<p>E. Death or serious disability (kernicterus) associated with failure to identify and treat hyperbilirubinemia in neonates</p>	<p>Hyperbilirubinemia is defined as bilirubin levels >30 mg/dl. Neonates refers to the first 28 days of life.</p>
<p>F. Stage 3 or 4 pressure ulcers acquired after admission to a healthcare facility</p>	<p>Excludes progression from Stage 2 to Stage 3 if Stage 2 was recognized upon admission.</p>
<p>G. Patient death or serious disability due to spinal manipulative therapy</p>	
<p>5. ENVIRONMENTAL EVENTS</p> <p>A. Patient death or serious disability associated with an electric shock while being cared for in a healthcare facility</p>	<p>Excludes events involving planned treatments such as electric countershock.</p>
<p>B. Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by toxic substances</p>	
<p>C. Patient death or serious disability associated with a burn incurred from any source while being cared facility for in a healthcare</p>	

D. Patient death associated with a fall while being cared for in a healthcare facility	
E. Patient death or serious disability associated with the use of restraints or bedrails while being cared for in a healthcare facility	
6. CRIMINAL EVENTS	
A. Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider	
B. Abduction of a patient of any age	
C. Sexual assault on a patient within or on the grounds of a healthcare facility	
D. Death or significant injury of a patient or staff member resulting from a physical assault (i.e., battery) that occurs within or on the grounds of a healthcare facility	

APPENDIX B: THE NATIONAL QUALITY FORUM GLOSSARY

The following terms are defined as they apply to the NQF's list of serious reportable events.

Adverse describes a negative consequence of care that results in unintended injury or illness, which may or may not have been preventable.

ASA (American Society of Anesthesiologists) Class I patient refers to a normal, healthy patient, i.e., one who has no organic, physiological, biochemical, or psychiatric disturbance. The pathologic processes for which the operation is to be performed are localized and do not entail a systemic disturbance.

Associated with means that it is reasonable to assume initially that the adverse event was due to the referenced course of care; the unplanned event may be subject to further investigation and/or root cause analysis in order to confirm or refute the presumed relationship.

Biologics refers to therapeutics and products, including blood and vaccines, derived from living sources (such as humans, animals, and microorganisms).

Device refers to an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part or accessory, which is recognized in the official National Formulary, the U.S. Pharmacopeia, or any supplement to them; intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease; or intended to affect the structure or any function; and that does not achieve any of its primary intended purposes through chemical action and that is not dependent upon being metabolized for the achievement of any of its primary intended purposes. This includes items such as sutures, prepackaged procedure kits, Laerdal defibrillators, pacemakers, contact lenses, etc.

Disability means a physical or mental impairment that substantially limits one or more of the major life activities of an individual.

Electrocution is death by electric shock.

Error is the failure of a planned action to be completed as intended (i.e., error of execution) or the use of a wrong plan to achieve an aim (i.e., error of planning).

Event means a discrete, auditable, and clearly defined occurrence.

Healthcare facility means any licensed facility that is organized, maintained, and operated for the diagnosis, prevention, treatment, rehabilitation, convalescence, or other human illness or injury, physical or mental, including care during and after pregnancy. Healthcare facilities include hospitals, nursing homes, rehabilitation centers, reproductive

health centers, independent clinical laboratories, hospices, and ambulatory surgical centers.

Hypoglycemia is a physiologic state in which the blood sugar falls below 60 mg/dl and physiological and/or neurological dysfunction begins.

Intended use is the use of a device as described on the label and associated materials provided by the device's manufacturers.

Kernicterus refers to the medical condition in which elevated levels of bilirubin cause brain damage.

Low-risk pregnancy refers to a woman aged 18-39, with no previous diagnosis of essential hypertension, renal disease, collagen-vascular disease, liver disease, cardiovascular disease, placenta previa, multiple gestation, intrauterine growth retardation, smoking, pregnancy-induced hypertension, premature rupture of membranes, or other previously documented condition that poses a high risk of poor pregnancy outcome.

Patient elopement refers to any situation in which an admitted patient (i.e., inpatient) leaves the healthcare facility without staff being aware that the patient has done so.

Preventable describes an event that could have been anticipated and prepared for, but that occurs because of an error or other system failure.

Public accountability is the obligation or duty of specific individuals and/or institutions to make information about their actions or performance available to the public or a public organization or agency (or its designee) that has responsibility for oversight and is answerable to the general public.

Serious describes an event that results in death or loss of a body part or disability or loss of bodily function lasting more than seven days or still present at the time of discharge from an inpatient healthcare facility or, when referring to other than an adverse event, an event whose occurrence is grave.

Spinal manipulative therapy encompasses all types of manual techniques, including spinal mobilization (movement of a joint within its physiological range of motion) and manipulation (movement beyond its physiological range of motion), regardless of their precise anatomic and physiological focus or their discipline of origin.

Toxic substance refers to chemicals that are present in sufficient concentration to pose a hazard to human health.

Unambiguous refers to an event that is clearly defined and easily identified.

**APPENDIX C: TEXT OF THE FAIR AND RELIABLE MEDICAL JUSTICE
BILL**

Fair and Reliable Medical Justice Act (Introduced in Senate)
109th CONGRESS
1st Session

To restore fairness and reliability to the medical justice system and promote patient safety by fostering alternatives to current medical tort litigation, and for other purposes.

IN THE SENATE OF THE UNITED STATES
June 29, 2005

Mr. ENZI (for himself and Mr. BAUCUS) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions.

A BILL

To restore fairness and reliability to the medical justice system and promote patient safety by fostering alternatives to current medical tort litigation, 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.

This Act may be cited as the 'Fair and Reliable Medical Justice Act'.

SEC. 2. PURPOSES.

The purposes of this Act are--

- (1) to restore fairness and reliability to the medical justice system by fostering alternatives to current medical tort litigation that promote early disclosure of health care errors and provide prompt, fair, and reasonable compensation to patients who are injured by health care errors;
- (2) to promote patient safety through early disclosure of health care errors; and
- (3) to support and assist States in developing such alternatives.

**SEC. 3. STATE DEMONSTRATION PROGRAMS TO EVALUATE
ALTERNATIVES TO CURRENT MEDICAL TORT LITIGATION.**

Part P of Title 111 of the Public Health Service Act (42 U.S.C. 280g et seq.) is amended by adding at the end the following:

SEC. 3990. STATE DEMONSTRATION PROGRAMS TO EVALUATE ALTERNATIVES TO CURRENT MEDICAL TORT LITIGATION.

'(a) In General- The Secretary is authorized to award demonstration grants to States for the development, implementation, and evaluation of alternatives to current tort litigation for resolving disputes over injuries allegedly caused by health care providers or health care organizations.

'(b) Duration- The Secretary may award up to 10 grants under subsection (a) and each grant awarded under such subsection may not exceed a period of 5 years.

'(c) Conditions for Demonstration Grants-

'(1) REQUIREMENTS- Each State desiring a grant under subsection (a) shall--

'(A) develop an alternative to current tort litigation for resolving disputes over injuries allegedly caused by health care providers or health care organizations that may be 1 of the models described in subsection (d); and

'(B) promote a reduction of health care errors by allowing for patient safety data related to disputes resolved under subparagraph (A) to be collected and analyzed by organizations that engage in voluntary efforts to improve patient safety and the quality of health care delivery.

'(2) ALTERNATIVE TO CURRENT TORT LITIGATION- Each State desiring a grant under subsection (a) shall demonstrate how the proposed alternative described in paragraph (1)(A)--

'(A) makes the medical liability system more reliable through prompt and fair resolution of disputes;

'(B) encourages the early disclosure of health care errors;

'(C) enhances patient safety; and

'(D) maintains access to liability insurance.

'(3) SOURCES OF COMPENSATION- Each State desiring a grant under subsection (a) shall identify the sources from and methods by which compensation would be paid for claims resolved under the proposed alternative to current tort litigation, which may include public or private funding sources, or a combination of such sources. Funding methods shall to the extent practicable provide financial incentives for activities that improve patient safety.

'(4) SCOPE-

'(A) IN GENERAL- Each State desiring a grant under subsection (a) may establish a scope of jurisdiction (such as a designated geographic region, a

designated area of health care practice, or a designated group of health care providers or health care organizations) for the proposed alternative to current tort litigation that is sufficient to evaluate the effects of the alternative.

'(B) NOTIFICATION OF PATIENTS- A State proposing a scope of jurisdiction under subparagraph (A) shall demonstrate how patients would be notified that they are receiving health care services that fall within such scope.

'(5) PREFERENCE IN AWARDING DEMONSTRATION GRANTS- In awarding grants under subsection (a), the Secretary shall give preference to States—

'(A) that have developed the proposed alternative through substantive consultation with relevant stakeholders; and

'(B) in which State law at the time of the application would not prohibit the adoption of an alternative to current tort litigation.

'(d) Models-

'(1) IN GENERAL- Any State desiring a grant under subsection (a) that proposes an alternative described in paragraph (2), (3), or (4) shall be deemed to meet the criteria under subsection (c)(2).

'(2) EARLY DISCLOSURE AND COMPENSATION MODEL- In the early disclosure and compensation model, the State shall--

'(A) require that health care providers or health care organizations notify a patient (or an immediate family member or designee of the patient) of an adverse event that results in serious injury to the patient, and that such notification shall not constitute an acknowledgment or an admission of liability;

'(B) provide immunity from tort liability to any health care provider or health care organization that offers in good faith to pay compensation in accordance with this section to a patient for an injury incurred in the provision of health care services (limited to claims arising out of the same nucleus of operative facts as the injury, and except in cases of fraud related to the provision of health care services, or in cases of criminal or intentional harm);

'(C) set a limited time period during which a health care provider or health care organization may make an offer of compensation benefits under subparagraph (B), with consideration for instances where prompt recognition of an injury is unlikely or impossible;

'(D) require that the compensation provided under subparagraph (B) include--

'(i) payment for the net economic loss of the patient, on a periodic basis, reduced by any payments received by the patient under--

'(I) any health or accident insurance;

'(II) any wage or salary continuation plan; or

'(III) any disability income insurance;

'(ii) payment for the non-economic damages of the patient, if appropriate for the injury, based on a defined payment schedule developed by the State in consultation with relevant experts and with the Secretary in accordance with subsection (g); and

'(iii) reasonable attorney's fees;

'(E) not abridge the right of an injured patient to seek redress through the State tort system if a health care provider does not enter into a compensation agreement with the patient in accordance with subparagraph (B) or if the compensation offered does not meet the requirements of subparagraph (D) or is not offered in good faith;

'(F) permit a health care provider or health care organization that offers in good faith to pay compensation benefits to an individual under subparagraph (B) to join in the payment of the compensation benefits any health care provider or health care organization that is potentially liable, in whole or in part, for the injury; and

'(G) permit any health care provider or health care organization to contribute voluntarily in the payment of compensation benefits to an individual under subparagraph (B).

'(3) ADMINISTRATIVE DETERMINATION OF COMPENSATION MODEL-

'(A) IN GENERAL- In the administrative determination of compensation model--

'(i) the State shall--

'(I) designate an administrative entity (in this paragraph referred to as the 'Board') that shall include representatives of--

'(aa) relevant State licensing boards;

'(bb) patient advocacy groups;

'(cc) health care providers and health care organizations; and

'(dd) attorneys in relevant practice areas;

'(II) set up classes of avoidable injuries, in consultation with relevant experts and with the Secretary in accordance with subsection (g), that will be used by the Board to determine compensation under clause (ii) (II);

'(III) modify tort liability, through statute or contract, to bar negligence claims in court against health care providers and health care organizations for the classes of injuries established under subclause (II), except in cases of fraud related to an injury, or in cases of criminal or intentional harm;

'(IV) outline a procedure for informing patients about the modified liability system described in this paragraph and, in systems where participation by the health care provider, health care organization, or patient is voluntary, allow for the decision by the provider, organization, or patient of whether to participate to be made prior to the provision of, use of, or payment for the health care service;

'(V) provide for an appeals process to allow for review of decisions; and

'(VI) establish procedures to coordinate settlement payments with other sources of payment;

'(ii) the Board shall--

'(I) resolve health care liability claims for certain classes of avoidable injuries as determined by the State and determine compensation for such claims;

'(II) develop a schedule of compensation to be used in making such determinations that includes--

'(aa) payment for the net economic loss of the patient, on a periodic basis, reduced by any payments received by the patient under any health or accident insurance, any wage or salary continuation plan, or any disability income insurance;

'(bb) payment for the non-economic damages of the patient, if appropriate for the injury, based on a defined payment schedule developed by the State in consultation with relevant experts and with the Secretary in accordance with subsection (g); and

'(cc) reasonable attorney's fees; and

'(III) update the schedule under subclause (II) on a regular basis.

'(B) APPEALS- The State, in establishing the appeals process described in subparagraph (A)(i)(V), may choose whether to allow for de novo review, review with deference, or some opportunity for parties to reject determinations by the Board and elect to file a civil action after such rejection. Any State desiring to adopt the model described in this paragraph shall indicate how such review method meets the criteria under subsection (c)(2).

'(C) TIMELINESS- The State shall establish timeframes to ensure that claims handled under the system described in this paragraph provide for adjudication that is more timely and expedited than adjudication in a traditional tort system.

'(4) SPECIAL HEALTH CARE COURT MODEL- In the special health care court model, the State shall--

'(A) establish a special court for the timely adjudication of disputes over injuries allegedly caused by health care providers or health care organizations in the provision of health care services;

'(B) ensure that such court is presided over by judges with health care expertise who meet applicable State standards for judges and who agree to preside over such court voluntarily;

'(C) provide authority to such judges to make binding rulings on causation, compensation, standards of care, and related issues with reliance on independent expert witnesses commissioned by the court;

'(D) provide for an appeals process to allow for review of decisions; and

'(E) at its option, establish an administrative entity similar to the entity described in paragraph (3)(A)(i)(I) to provide advice and guidance to the special court.

'(e) Application-

'(1) IN GENERAL- Each State desiring a grant under subsection (a) shall submit to the Secretary an application, at such time, in such manner, and containing such information as the Secretary may require.

'(2) REVIEW PANEL-

'(A) IN GENERAL- In reviewing applications under paragraph (I), the Secretary shall consult with a review panel composed of relevant experts appointed by the Comptroller General.

'(B) COMPOSITION-

'(i) NOMINATIONS- The Comptroller General shall solicit nominations from the public for individuals to serve on the review panel.

'(ii) APPOINTMENT- The Comptroller General shall appoint, at least 11 but not more than 15, highly qualified and knowledgeable individuals to serve on the review panel and shall ensure that the following entities receive fair representation on such panel:

'(I) Patient advocates.

'(II) Health care providers and health care organizations.

'(III) Attorneys with expertise in representing patients and health care providers.

'(IV) Insurers.

'(V) State officials.

'(C) CHAIRPERSON- The Comptroller General, or an individual within the Government Accountability Office designated by the Comptroller General, shall be the chairperson of the review panel.

'(D) AVAILABILITY OF INFORMATION- The Comptroller General shall make available to the review panel such information, personnel, and administrative services and assistance as the review panel may reasonably require to carry out its duties.

'(E) INFORMATION FROM AGENCIES- The review panel may request directly from any department or agency of the United States any information that such panel considers necessary to carry out its duties. To the extent consistent with applicable laws and regulations, the head of such department or agency shall furnish the requested information to the review panel.

'(f) Report- Each State receiving a grant under subsection (a) shall submit to the Secretary a report evaluating the effectiveness of activities funded with grants awarded under such subsection at such time and in such manner as the Secretary may require.

'(g) Technical Assistance-

'(1) IN GENERAL- The Secretary shall provide technical assistance to the States awarded grants under subsection (a).

'(2) REQUIREMENTS- Technical assistance under paragraph (1) shall include--

'(A) the development of a defined payment schedule for non-economic damages (including guidance on -the consideration of individual facts and

circumstances in determining appropriate payment), the development of classes of avoidable injuries, and guidance on early disclosure to patients of adverse events; and

'(B) the development, in consultation with States, of common definitions, formats, and data collection infrastructure for States receiving grants under this section to use in reporting to facilitate aggregation and analysis of data both within and between States.

'(3) USE OF COMMON DEFINITIONS, FORMATS, AND DATA COLLECTION INFRASTRUCTURE- States not receiving grants under this section may also use the common definitions, formats, and data collection infrastructure developed under paragraph (2)(B)-

'(h) Evaluation-

'(1) IN GENERAL- The Secretary, in consultation with the review panel established under subsection (e)(2), shall enter into a contract with an appropriate research organization to conduct an overall evaluation of the effectiveness of grants awarded under subsection (a) and to annually prepare and submit a report to the appropriate committees of Congress. Such an evaluation shall begin not later than 18 months following the date of implementation of the first program funded by a grant under subsection (a).

'(2) CONTENTS- The evaluation under paragraph (1) shall include--

'(A) an analysis of the effect of the grants awarded under subsection (a) on the number, nature, and costs of health care liability claims;

'(B) a comparison of the claim and cost information of each State receiving a grant under subsection (a); and

'(C) a comparison between States receiving a grant under this section and States that did not receive such a grant, matched to ensure similar legal and health care environments, and to determine the effects of the grants and subsequent reforms on--

'(i) the liability environment;

'(ii) health care quality;

'(iii) patient safety; and

'(iv) patient and health care provider and organization satisfaction with the reforms.

'(i) Option to Provide for Initial Planning Grants- Of the funds appropriated pursuant to subsection (k), the Secretary may use a portion not to exceed \$500,000 per State to

provide planning grants to such States for the development of demonstration project applications meeting the criteria described in subsection (c). In selecting States to receive such planning grants, the Secretary shall give preference to those States in which State law at the time of the application would not prohibit the adoption of an alternative to current tort litigation.

'(j) Definitions-In this section:

'(1) HEALTH CARE SERVICES- The term 'health care services' means any services provided by a health care provider, or by any individual working under the supervision of a health care provider, that relate to--

'(A) the diagnosis, prevention, or treatment of any human disease or impairment; or

'(B) the assessment of the health of human beings.

'(2) HEALTH CARE ORGANIZATION- The term 'health care organization' means any individual or entity which is obligated to provide, pay for, or administer health benefits under any health plan.

'(3) HEALTH CARE PROVIDER- The term 'health care provider' means any individual or entity--

'(A) licensed, registered, or certified under Federal or State laws or regulations to provide health care services; or

'(B) required to be so licensed, registered, or certified but that is exempted by other statute or regulation.

'(4) NET ECONOMIC LOSS- The term 'net economic loss' means--

'(A) reasonable expenses incurred for products, services, and accommodations needed for health care, training, and other remedial treatment and care of an injured individual;

'(B) reasonable and appropriate expenses for rehabilitation treatment and occupational training;

'(C) 100 percent of the loss of income from work that an injured individual would have performed if not injured, reduced by any income from substitute work actually performed; and

'(D) reasonable expenses incurred in obtaining ordinary and necessary services to replace services an injured individual would have performed for the benefit of the individual or the family of such individual if the individual had not been injured.

'(5) NON-ECONOMIC DAMAGES- The term 'non-economic damages' means losses for physical and emotional pain, suffering, inconvenience, physical impairment, mental anguish, disfigurement, loss of enjoyment of life, loss of society and companionship, loss of consortium (other than loss of domestic service), injury to reputation, and all other non-pecuniary losses of any kind or nature, to the extent permitted under State law.

'(k) Authorization of Appropriations- There are authorized to be appropriated to carry out this section such sums as may be necessary. Amounts appropriated pursuant to this subsection shall remain available until expended.

**APPENDIX D: FEDERAL PATIENT SAFETY AND QUALITY IMPROVEMENT
ACT OF 2005**

Begun and held at the City of Washington on Tuesday, the fourth day of January, two thousand and five An Act To amend title IX of the Public Health Service Act to provide for the improvement of patient safety and to reduce the incidence of events that adversely effect patient safety.

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 'Patient Safety and Quality Improvement Act of 2005'.

(b) Table of Contents- The table of contents for this Act is as follows:

Sec. 1. Short title; table of contents.

Sec. 2. Amendments to Public Health Service Act.

 'Part C--Patient Safety Improvement

 'Sec. 921. Definitions.

 'Sec. 922. Privilege and confidentiality protections.

 'Sec. 923. Network of patient safety databases.

 'Sec. 924. Patient safety organization certification and listing.

 'Sec. 925. Technical assistance.

 'Sec. 926. Severability.

SEC. 2. AMENDMENTS TO PUBLIC HEALTH SERVICE ACT.

(a) In General- Title IX of the Public Health Service Act (42 U.S.C. 299 et seq.) is amended--

(1) in section 912(c), by inserting ', in accordance with part C,' after 'The Director shall';

(2) by redesignating part C as part D;

(3) by redesignating sections 921 through 928, as sections 931 through 938, respectively;

- (4) in section 938(1) (as so redesignated), by striking `921' and inserting `931'; and
- (5) by inserting after part B the following:

`PART C--PATIENT SAFETY IMPROVEMENT

`SEC. 921. DEFINITIONS.

`In this part:

`(1) HIPAA CONFIDENTIALITY REGULATIONS- The term `HIPAA confidentiality regulations' means regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (Public Law 104-191; 110 Stat. 2033).

`(2) IDENTIFIABLE PATIENT SAFETY WORK PRODUCT- The term `identifiable patient safety work product' means patient safety work product that--

`(A) is presented in a form and manner that allows the identification of any provider that is a subject of the work product, or any providers that participate in activities that are a subject of the work product;

`(B) constitutes individually identifiable health information as that term is defined in the HIPAA confidentiality regulations; or

`(C) is presented in a form and manner that allows the identification of an individual who reported information in the manner specified in section 922(e).

`(3) NONIDENTIFIABLE PATIENT SAFETY WORK PRODUCT- The term `nonidentifiable patient safety work product' means patient safety work product that is not identifiable patient safety work product (as defined in paragraph (2)).

`(4) PATIENT SAFETY ORGANIZATION- The term `patient safety organization' means a private or public entity or component thereof that is listed by the Secretary pursuant to section 924(d).

`(5) PATIENT SAFETY ACTIVITIES- The term `patient safety activities' means the following activities:

`(A) Efforts to improve patient safety and the quality of health care delivery.

`(B) The collection and analysis of patient safety work product.

`(C) The development and dissemination of information with respect to improving patient safety, such as recommendations, protocols, or information regarding best practices.

`(D) The utilization of patient safety work product for the purposes of encouraging a culture of safety and of providing feedback and assistance to effectively minimize patient risk.

`(E) The maintenance of procedures to preserve confidentiality with respect to patient safety work product.

`(F) The provision of appropriate security measures with respect to patient safety work product.

`(G) The utilization of qualified staff.

`(H) Activities related to the operation of a patient safety evaluation system and to the provision of feedback to participants in a patient safety evaluation system.

`(6) PATIENT SAFETY EVALUATION SYSTEM- The term `patient safety evaluation system' means the collection, management, or analysis of information for reporting to or by a patient safety organization.

`(7) PATIENT SAFETY WORK PRODUCT-

`(A) IN GENERAL- Except as provided in subparagraph (B), the term `patient safety work product' means any data, reports, records, memoranda, analyses (such as root cause analyses), or written or oral statements--

`(i) which--

`(I) are assembled or developed by a provider for reporting to a patient safety organization and are reported to a patient safety organization; or

`(II) are developed by a patient safety organization for the conduct of patient safety activities;

and which could result in improved patient safety, health care quality, or health care outcomes; or

`(ii) which identify or constitute the deliberations or analysis of, or identify the fact of reporting pursuant to, a patient safety evaluation system.

`(B) CLARIFICATION-

`(i) Information described in subparagraph (A) does not include a patient's medical record, billing and discharge information, or any other original patient or provider record.

`(ii) Information described in subparagraph (A) does not include information that is collected, maintained, or developed separately, or exists separately, from a patient safety evaluation system. Such separate information or a copy

thereof reported to a patient safety organization shall not by reason of its reporting be considered patient safety work product.

`(iii) Nothing in this part shall be construed to limit--

`(I) the discovery of or admissibility of information described in this subparagraph in a criminal, civil, or administrative proceeding;

`(II) the reporting of information described in this subparagraph to a Federal, State, or local governmental agency for public health surveillance, investigation, or other public health purposes or health oversight purposes; or

`(III) a provider's recordkeeping obligation with respect to information described in this subparagraph under Federal, State, or local law.

`(8) PROVIDER- The term `provider' means--

`(A) an individual or entity licensed or otherwise authorized under State law to provide health care services, including--

`(i) a hospital, nursing facility, comprehensive outpatient rehabilitation facility, home health agency, hospice program, renal dialysis facility, ambulatory surgical center, pharmacy, physician or health care practitioner's office, long term care facility, behavior health residential treatment facility, clinical laboratory, or health center; or

`(ii) a physician, physician assistant, nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse midwife, psychologist, certified social worker, registered dietitian or nutrition professional, physical or occupational therapist, pharmacist, or other individual health care practitioner; or

`(B) any other individual or entity specified in regulations promulgated by the Secretary.

`SEC. 922. PRIVILEGE AND CONFIDENTIALITY PROTECTIONS.

`(a) Privilege- Notwithstanding any other provision of Federal, State, or local law, and subject to subsection (c), patient safety work product shall be privileged and shall not be-

`(1) subject to a Federal, State, or local civil, criminal, or administrative subpoena or order, including in a Federal, State, or local civil or administrative disciplinary proceeding against a provider;

`(2) subject to discovery in connection with a Federal, State, or local civil, criminal, or administrative proceeding, including in a Federal, State, or local civil or administrative disciplinary proceeding against a provider;

`(3) subject to disclosure pursuant to section 552 of title 5, United States Code (commonly known as the Freedom of Information Act) or any other similar Federal, State, or local law;

`(4) admitted as evidence in any Federal, State, or local governmental civil proceeding, criminal proceeding, administrative rulemaking proceeding, or administrative adjudicatory proceeding, including any such proceeding against a provider; or

`(5) admitted in a professional disciplinary proceeding of a professional disciplinary body established or specifically authorized under State law.

`(b) CONFIDENTIALITY OF PATIENT SAFETY WORK PRODUCT-

Notwithstanding any other provision of Federal, State, or local law, and subject to subsection (c), patient safety work product shall be confidential and shall not be disclosed.

`(c) Exceptions- Except as provided in subsection (g)(3)--

`(1) EXCEPTIONS FROM PRIVILEGE AND CONFIDENTIALITY- Subsections (a) and (b) shall not apply to (and shall not be construed to prohibit) one or more of the following disclosures:

`(A) Disclosure of relevant patient safety work product for use in a criminal proceeding, but only after a court makes an in camera determination that such patient safety work product contains evidence of a criminal act and that such patient safety work product is material to the proceeding and not reasonably available from any other source.

`(B) Disclosure of patient safety work product to the extent required to carry out subsection (f)(4)(A).

`(C) Disclosure of identifiable patient safety work product if authorized by each provider identified in such work product.

`(2) EXCEPTIONS FROM CONFIDENTIALITY- Subsection (b) shall not apply to (and shall not be construed to prohibit) one or more of the following disclosures:

`(A) Disclosure of patient safety work product to carry out patient safety activities.

`(B) Disclosure of nonidentifiable patient safety work product.

`(C) Disclosure of patient safety work product to grantees, contractors, or other entities carrying out research, evaluation, or demonstration projects authorized, funded, certified, or otherwise sanctioned by rule or other means by the Secretary, for the purpose of conducting research to the extent that disclosure of protected

health information would be allowed for such purpose under the HIPAA confidentiality regulations.

`(D) Disclosure by a provider to the Food and Drug Administration with respect to a product or activity regulated by the Food and Drug Administration.

`(E) Voluntary disclosure of patient safety work product by a provider to an accrediting body that accredits that provider.

`(F) Disclosures that the Secretary may determine, by rule or other means, are necessary for business operations and are consistent with the goals of this part.

`(G) Disclosure of patient safety work product to law enforcement authorities relating to the commission of a crime (or to an event reasonably believed to be a crime) if the person making the disclosure believes, reasonably under the circumstances, that the patient safety work product that is disclosed is necessary for criminal law enforcement purposes.

`(H) With respect to a person other than a patient safety organization, the disclosure of patient safety work product that does not include materials that--

 `(i) assess the quality of care of an identifiable provider; or

 `(ii) describe or pertain to one or more actions or failures to act by an identifiable provider.

`(3) EXCEPTION FROM PRIVILEGE- Subsection (a) shall not apply to (and shall not be construed to prohibit) voluntary disclosure of nonidentifiable patient safety work product.

`(d) Continued Protection of Information After Disclosure-

`(1) IN GENERAL- Patient safety work product that is disclosed under subsection (c) shall continue to be privileged and confidential as provided for in subsections (a) and (b), and such disclosure shall not be treated as a waiver of privilege or confidentiality, and the privileged and confidential nature of such work product shall also apply to such work product in the possession or control of a person to whom such work product was disclosed.

`(2) EXCEPTION- Notwithstanding paragraph (1), and subject to paragraph (3)--

 `(A) if patient safety work product is disclosed in a criminal proceeding, the confidentiality protections provided for in subsection (b) shall no longer apply to the work product so disclosed; and

 `(B) if patient safety work product is disclosed as provided for in subsection (c)(2)(B) (relating to disclosure of nonidentifiable patient safety work product),

the privilege and confidentiality protections provided for in subsections (a) and (b) shall no longer apply to such work product.

`(3) CONSTRUCTION- Paragraph (2) shall not be construed as terminating or limiting the privilege or confidentiality protections provided for in subsection (a) or (b) with respect to patient safety work product other than the specific patient safety work product disclosed as provided for in subsection (c).

`(4) LIMITATIONS ON ACTIONS-

`(A) PATIENT SAFETY ORGANIZATIONS-

`(i) IN GENERAL- A patient safety organization shall not be compelled to disclose information collected or developed under this part whether or not such information is patient safety work product unless such information is identified, is not patient safety work product, and is not reasonably available from another source.

`(ii) NONAPPLICATION- The limitation contained in clause (i) shall not apply in an action against a patient safety organization or with respect to disclosures pursuant to subsection (c)(1).

`(B) PROVIDERS- An accrediting body shall not take an accrediting action against a provider based on the good faith participation of the provider in the collection, development, reporting, or maintenance of patient safety work product in accordance with this part. An accrediting body may not require a provider to reveal its communications with any patient safety organization established in accordance with this part.

`(e) Reporter Protection-

`(1) IN GENERAL- A provider may not take an adverse employment action, as described in paragraph (2), against an individual based upon the fact that the individual in good faith reported information--

`(A) to the provider with the intention of having the information reported to a patient safety organization; or

`(B) directly to a patient safety organization.

`(2) ADVERSE EMPLOYMENT ACTION- For purposes of this subsection, an 'adverse employment action' includes--

`(A) loss of employment, the failure to promote an individual, or the failure to provide any other employment-related benefit for which the individual would otherwise be eligible; or

`(B) an adverse evaluation or decision made in relation to accreditation, certification, credentialing, or licensing of the individual.

`(f) Enforcement-

`(1) CIVIL MONETARY PENALTY- Subject to paragraphs (2) and (3), a person who discloses identifiable patient safety work product in knowing or reckless violation of subsection (b) shall be subject to a civil monetary penalty of not more than \$10,000 for each act constituting such violation.

`(2) PROCEDURE- The provisions of section 1128A of the Social Security Act, other than subsections (a) and (b) and the first sentence of subsection (c)(1), shall apply to civil money penalties under this subsection in the same manner as such provisions apply to a penalty or proceeding under section 1128A of the Social Security Act.

`(3) RELATION TO HIPAA- Penalties shall not be imposed both under this subsection and under the regulations issued pursuant to section 264(c)(1) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d-2 note) for a single act or omission.

`(4) EQUITABLE RELIEF-

`(A) IN GENERAL- Without limiting remedies available to other parties, a civil action may be brought by any aggrieved individual to enjoin any act or practice that violates subsection (e) and to obtain other appropriate equitable relief (including reinstatement, back pay, and restoration of benefits) to redress such violation.

`(B) AGAINST STATE EMPLOYEES- An entity that is a State or an agency of a State government may not assert the privilege described in subsection (a) unless before the time of the assertion, the entity or, in the case of and with respect to an agency, the State has consented to be subject to an action described in subparagraph (A), and that consent has remained in effect.

`(g) Rule of Construction- Nothing in this section shall be construed--

`(1) to limit the application of other Federal, State, or local laws that provide greater privilege or confidentiality protections than the privilege and confidentiality protections provided for in this section;

`(2) to limit, alter, or affect the requirements of Federal, State, or local law pertaining to information that is not privileged or confidential under this section;

`(3) except as provided in subsection (i), to alter or affect the implementation of any provision of the HIPAA confidentiality regulations or section 1176 of the Social Security Act (or regulations promulgated under such section);

`(4) to limit the authority of any provider, patient safety organization, or other entity to enter into a contract requiring greater confidentiality or delegating authority to make a disclosure or use in accordance with this section;

`(5) as preempting or otherwise affecting any State law requiring a provider to report information that is not patient safety work product; or

`(6) to limit, alter, or affect any requirement for reporting to the Food and Drug Administration information regarding the safety of a product or activity regulated by the Food and Drug Administration.

`(h) CLARIFICATION- Nothing in this part prohibits any person from conducting additional analysis for any purpose regardless of whether such additional analysis involves issues identical to or similar to those for which information was reported to or assessed by a patient safety organization or a patient safety evaluation system.

`(i) CLARIFICATION OF APPLICATION OF HIPAA CONFIDENTIALITY REGULATIONS TO PATIENT SAFETY ORGANIZATIONS- For purposes of applying the HIPAA confidentiality regulations--

`(1) patient safety organizations shall be treated as business associates; and

`(2) patient safety activities of such organizations in relation to a provider are deemed to be health care operations (as defined in such regulations) of the provider.

`(j) Reports on Strategies to Improve Patient Safety-

`(1) DRAFT REPORT- Not later than the date that is 18 months after any network of patient safety databases is operational, the Secretary, in consultation with the Director, shall prepare a draft report on effective strategies for reducing medical errors and increasing patient safety. The draft report shall include any measure determined appropriate by the Secretary to encourage the appropriate use of such strategies, including use in any federally funded programs. The Secretary shall make the draft report available for public comment and submit the draft report to the Institute of Medicine for review.

`(2) FINAL REPORT- Not later than 1 year after the date described in paragraph (1), the Secretary shall submit a final report to the Congress.

`SEC. 923. NETWORK OF PATIENT SAFETY DATABASES.

`(a) In General- The Secretary shall facilitate the creation of, and maintain, a network of patient safety databases that provides an interactive evidence-based management resource for providers, patient safety organizations, and other entities. The network of databases shall have the capacity to accept, aggregate across the network, and analyze nonidentifiable patient safety work product voluntarily reported by patient safety organizations, providers, or other entities. The Secretary shall assess the feasibility of

providing for a single point of access to the network for qualified researchers for information aggregated across the network and, if feasible, provide for implementation.

`(b) Data Standards- The Secretary may determine common formats for the reporting to and among the network of patient safety databases maintained under subsection (a) of nonidentifiable patient safety work product, including necessary work product elements, common and consistent definitions, and a standardized computer interface for the processing of such work product. To the extent practicable, such standards shall be consistent with the administrative simplification provisions of part C of title XI of the Social Security Act.

`(c) Use of Information- Information reported to and among the network of patient safety databases under subsection (a) shall be used to analyze national and regional statistics, including trends and patterns of health care errors. The information resulting from such analyses shall be made available to the public and included in the annual quality reports prepared under section 913(b)(2).

`SEC. 924. PATIENT SAFETY ORGANIZATION CERTIFICATION AND LISTING.

`(a) CERTIFICATION-

`(1) INITIAL CERTIFICATION- An entity that seeks to be a patient safety organization shall submit an initial certification to the Secretary that the entity--

`(A) has policies and procedures in place to perform each of the patient safety activities described in section 921(5); and

`(B) upon being listed under subsection (d), will comply with the criteria described in subsection (b).

`(2) SUBSEQUENT CERTIFICATIONS- An entity that is a patient safety organization shall submit every 3 years after the date of its initial listing under subsection (d) a subsequent certification to the Secretary that the entity--

`(A) is performing each of the patient safety activities described in section 921(5); and

`(B) is complying with the criteria described in subsection (b).

`(b) CRITERIA-

`(1) IN GENERAL- The following are criteria for the initial and subsequent certification of an entity as a patient safety organization:

`(A) The mission and primary activity of the entity are to conduct activities that are to improve patient safety and the quality of health care delivery.

`(B) The entity has appropriately qualified staff (whether directly or through contract), including licensed or certified medical professionals.

`(C) The entity, within each 24-month period that begins after the date of the initial listing under subsection (d), has bona fide contracts, each of a reasonable period of time, with more than 1 provider for the purpose of receiving and reviewing patient safety work product.

`(D) The entity is not, and is not a component of, a health insurance issuer (as defined in section 2791(b)(2)).

`(E) The entity shall fully disclose--

`(i) any financial, reporting, or contractual relationship between the entity and any provider that contracts with the entity; and

`(ii) if applicable, the fact that the entity is not managed, controlled, and operated independently from any provider that contracts with the entity.

`(F) To the extent practical and appropriate, the entity collects patient safety work product from providers in a standardized manner that permits valid comparisons of similar cases among similar providers.

`(G) The utilization of patient safety work product for the purpose of providing direct feedback and assistance to providers to effectively minimize patient risk.

`(2) ADDITIONAL CRITERIA FOR COMPONENT ORGANIZATIONS- If an entity that seeks to be a patient safety organization is a component of another organization, the following are additional criteria for the initial and subsequent certification of the entity as a patient safety organization:

`(A) The entity maintains patient safety work product separately from the rest of the organization, and establishes appropriate security measures to maintain the confidentiality of the patient safety work product.

`(B) The entity does not make an unauthorized disclosure under this part of patient safety work product to the rest of the organization in breach of confidentiality.

`(C) The mission of the entity does not create a conflict of interest with the rest of the organization.

`(c) REVIEW OF CERTIFICATION-

`(1) IN GENERAL-

`(A) INITIAL CERTIFICATION- Upon the submission by an entity of an initial certification under subsection (a)(1), the Secretary shall determine if the

certification meets the requirements of subparagraphs (A) and (B) of such subsection.

`(B) SUBSEQUENT CERTIFICATION- Upon the submission by an entity of a subsequent certification under subsection (a)(2), the Secretary shall review the certification with respect to requirements of subparagraphs (A) and (B) of such subsection.

`(2) NOTICE OF ACCEPTANCE OR NON-ACCEPTANCE- If the Secretary determines that--

`(A) an entity's initial certification meets requirements referred to in paragraph (1)(A), the Secretary shall notify the entity of the acceptance of such certification; or

`(B) an entity's initial certification does not meet such requirements, the Secretary shall notify the entity that such certification is not accepted and the reasons therefore.

`(3) DISCLOSURES REGARDING RELATIONSHIP TO PROVIDERS- The Secretary shall consider any disclosures under subsection (b)(1)(E) by an entity and shall make public findings on whether the entity can fairly and accurately perform the patient safety activities of a patient safety organization. The Secretary shall take those findings into consideration in determining whether to accept the entity's initial certification and any subsequent certification submitted under subsection (a) and, based on those findings, may deny, condition, or revoke acceptance of the entity's certification.

`(d) LISTING- The Secretary shall compile and maintain a listing of entities with respect to which there is an acceptance of a certification pursuant to subsection (c)(2)(A) that has not been revoked under subsection (e) or voluntarily relinquished.

`(e) REVOCATION OF ACCEPTANCE OF CERTIFICATION-

`(1) IN GENERAL- If, after notice of deficiency, an opportunity for a hearing, and a reasonable opportunity for correction, the Secretary determines that a patient safety organization does not meet the certification requirements under subsection (a)(2), including subparagraphs (A) and (B) of such subsection, the Secretary shall revoke the Secretary's acceptance of the certification of such organization.

`(2) SUPPLYING CONFIRMATION OF NOTIFICATION TO PROVIDERS- Within 15 days of a revocation under paragraph (1), a patient safety organization shall submit to the Secretary a confirmation that the organization has taken all reasonable actions to notify each provider whose patient safety work product is collected or analyzed by the organization of such revocation.

`(3) PUBLICATION OF DECISION- If the Secretary revokes the certification of an organization under paragraph (1), the Secretary shall--

`(A) remove the organization from the listing maintained under subsection (d);
and

`(B) publish notice of the revocation in the Federal Register.

`(f) STATUS OF DATA AFTER REMOVAL FROM LISTING-

`(1) NEW DATA- With respect to the privilege and confidentiality protections described in section 922, data submitted to an entity within 30 days after the entity is removed from the listing under subsection (e)(3)(A) shall have the same status as data submitted while the entity was still listed.

`(2) PROTECTION TO CONTINUE TO APPLY- If the privilege and confidentiality protections described in section 922 applied to patient safety work product while an entity was listed, or to data described in paragraph (1), such protections shall continue to apply to such work product or data after the entity is removed from the listing under subsection (e)(3)(A).

`(g) DISPOSITION OF WORK PRODUCT AND DATA- If the Secretary removes a patient safety organization from the listing as provided for in subsection (e)(3)(A), with respect to the patient safety work product or data described in subsection (f)(1) that the patient safety organization received from another entity, such former patient safety organization shall--

`(1) with the approval of the other entity and a patient safety organization, transfer such work product or data to such patient safety organization;

`(2) return such work product or data to the entity that submitted the work product or data; or

`(3) if returning such work product or data to such entity is not practicable, destroy such work product or data.

`SEC. 925. TECHNICAL ASSISTANCE.

`The Secretary, acting through the Director, may provide technical assistance to patient safety organizations, including convening annual meetings for patient safety organizations to discuss methodology, communication, data collection, or privacy concerns.

`SEC. 926. SEVERABILITY.

`If any provision of this part is held to be unconstitutional, the remainder of this part shall not be affected.'

(b) Authorization of Appropriations- Section 937 of the Public Health Service Act (as redesignated by subsection (a)) is amended by adding at the end the following:

`(e) Patient Safety and Quality Improvement- For the purpose of carrying out part C, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2006 through 2010.'

(c) GAO Study on Implementation-

(1) STUDY- The Comptroller General of the United States shall conduct a study on the effectiveness of part C of title IX of the Public Health Service Act (as added by subsection (a)) in accomplishing the purposes of such part.

(2) REPORT- Not later than February 1, 2010, the Comptroller General shall submit a report on the study conducted under paragraph (1). Such report shall include such recommendations for changes in such part as the Comptroller General deems appropriate.

Speaker of the House of Representatives.
Vice President of the United States and
President of the Senate.

**APPENDIX E: WYOMING DEPARTMENT OF HEALTH RULES AND
REGULATIONS FOR HEALTH CARE FACILITY SAFETY EVENT
REPORTING**

State of Wyoming



Department of Health

**Rules and Regulations for
Health Care Facility Safety Event Reporting**

Brent D. Sherard, M.D., M.P.H., Director and State Health Officer

August 2005

State of Wyoming Department of Health

Rules and Regulations for Health Care Facility Safety Event Reporting

Rules and Regulations for
Health Care Facility Safety Event Reporting
is published by the Department of Health
Brent D. Sherard, M.D., M.P.H., Director and State Health Officer

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Statement of Reasons

Health Care Facility Safety Event Reporting Chapter 2

The Wyoming Department of Health proposes the following rules to comply with the provisions of 2005 General Session, Enrolled Act No. 104 (to be codified at W.S. 35-2-912), which authorizes the Department of Health to promulgate rules to establish Healthcare Facility Safety Event Reporting, and the Wyoming Administrative Procedures Act at W.S. 16-3-101 et seq. The proposed rules:

Establish health care facility safety event reporting relating to health care facilities; providing for mandatory reporting of safety events by health care facilities to the Department as specified; requiring an annual report of safety events by the Department; providing for confidentiality; providing for immunity; providing definitions; providing a sunset date; providing an appropriation; and providing for an effective date.

Establish general requirements for health care facilities to designate a patient safety officer and report to the Department of Health, Preventive Health and Safety Division the occurrence of any safety event occurring after June 30, 2005. The Department will develop and implement a reporting system for a health facility to submit timely reports of safety events.

Outline Department authority to require submission of health care facility safety event reports and related information to the Department of Health and to comply with all provisions of the Act.

Establish general requirements for the Department to collect and maintain information on health care facility safety events in this state. The Department will prepare and publish an annual report on or before December 31 of each year all reported safety events for the previous year and provide a trend analysis for systemic improvements to enhance patient safety and health care. Referenced information is to be aggregated so as not to reveal the identity of individuals or health care facilities.

Any act authorized or required herein is subject to the confidentiality, immunity and whistle blowing provisions of W.S. 35-2-910 (a) and (b). Health care information may be disclosed to the Department of Health without the patient's authorization if disclosed pursuant to this Act.

DEPARTMENT OF HEALTH
HEALTH CARE FACILITY SAFETY EVENT REPORTING

CHAPTER 2

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Chapter 2

Health Care Facility Safety Event Reporting Rules

Section 1. Authority.

This Chapter is promulgated by the Department pursuant to the provisions of 2005 General Session, Enrolled Act No. 104 (to be codified at W.S. 35-2-912), which authorizes the Department to promulgate rules to establish Health Care Facility Safety Event Reporting, and the Wyoming Administrative Procedures Act at W.S. 16-3-101 et seq.

Section 2. Purpose and Applicability.

(a) These rules shall apply to and govern Health Care Facility Safety Event Reporting. They shall become effective upon adoption for all health care facilities to report any safety event occurring after June 30, 2005.

(b) The Department may issue Manuals, Bulletins, or both, to interpret the provisions of these rules and regulations. Such Manuals and Bulletins shall be consistent with and reflect the policies contained in these rules and regulations. The provisions contained in Manuals or Bulletins shall be subordinate to the provisions of these rules and regulations.

Section 3. General Provisions.

(a) This Chapter is intended to be read in conjunction with 2005 General Session, Enrolled Act No. 104 (to be codified as W.S. 35-2-912).

(b) The incorporation by reference of any external standard is intended to be the incorporation of that standard as it is in effect on the effective date of this Chapter of these rules and regulations.

Section 4. Definitions.

The following definitions shall apply in the interpretation and enforcement of these rules. Where the context in which words are used in these rules indicates that such is the intent, words in the singular shall include the plural and vice versa. Throughout these rules gender pronouns are used interchangeably, except where the context dictates otherwise. The drafters have attempted to utilize each gender pronoun in equal numbers, in random distribution. Words in each gender shall include individuals of the other gender. Except as otherwise specified in this section, the terminology used in this Chapter is the standard terminology and has the standard meaning used in health care, health insurance, Medicare and Medicaid.

For the purpose of these rules, the following definitions shall apply:

- (a) "Act" means 2005 General Session, Enrolled Act No. 104 (to be codified at W.S. 35-2-912).
- (b) "Department" means the Wyoming Department of Health, Preventive Health and Safety Division, its agent, designee, or successor.
- (c) "Device," includes, but is not limited to, catheters, drains, and other specialized tubes, infusion pumps, and ventilators.
- (d) "Director" means the director of the Department, the director's agent, designee, or successor.
- (e) "Documentation" means written evidence, in the form specified by the Department, to support an assertion or position.
- (f) "Health care facility" means any licensed health care facility in the State of Wyoming.
- (g) "Hospital" means a health care facility where the sick or injured are given medical or surgical care.
- (h) "Hyperbilirubinemia" means bilirubin levels greater than thirty (30) milligrams per deciliter.
- (i) "Patient" means an individual under medical care, treatment or medical Services.
- (j) "Patient safety officer" is an employee of a licensed health care facility located within this state that is designated to receive and pass on reports of patient safety events to the Department.
- (k) "Reporting" means Health Care Facility Safety Event Reporting created by the Act and implemented by this Chapter.
- (l) "Public records" means "Public records" as defined in W.S. 16-4-201(a)(v), which is incorporated by this reference.
- (m) "Safety event" means an unexpected occurrence involving death or serious physical or psychological injury or the risk there of, including:
 - (i) Surgical events as defined at W.S. 35-2-912;
 - (ii) Product or device events as defined at W.S. 35-2-912;
 - (iii) Patient protection events as defined at W.S. 35-2-912;
 - (iv) Care management events as defined at W.S. 35-2-912;
 - (v) Environmental events as defined at W.S. 35-2-912; and
 - (vi) Criminal events as defined at W.S. 35-2-912.

Section 5. Safety Events to be Reported.

(a) The following “safety” events or unexpected occurrences involving death or serious physical or psychological injury or the risk thereof are required to be reported to the Department in the specified report format:

(i) Surgical events including:

(A) Surgery performed on a wrong body part that is not consistent with the documented informed consent for that patient; reportable events do not include situations requiring prompt action that occur in the course of surgery or situation whose urgency precludes obtaining informed consent.

(B) Surgery performed on the wrong patient;

(C) The wrong surgical procedure performed on a patient that is not consistent with the documented informed consent for that patient; Reportable events do not include situations requiring prompt action that occur in the course of surgery or situations whose urgency precludes obtaining informed consent.

(D) Retention of a foreign object in a patient after surgery or other procedure, excluding objects intentionally implanted as part of a planned intervention and objects present prior to surgery that are intentionally retained; and

(E) Death during or immediately after surgery of a normal, healthy patient who has no organic, physiologic, biochemical, or psychiatric disturbance and for whom the pathologic processes for which the operation is to be performed are localized and do not entail a systemic disturbance.

(ii) Product or device events including:

(A) The use of contaminated drugs, devices or biologics provided by the facility when the contamination is the result of generally detectable contaminants in drugs, devices or biologics regardless of the source of the contamination or the product;

(B) The use or function of a device in patient care in which the device is used or functions other than as intended; and

(C) Intravascular air embolism that occurs while being cared for in a facility, excluding deaths associated with neurosurgical procedures known to present a high risk of intravascular air embolism.

(iii) Patient protection events including:

- (D) An infant discharged to the wrong person;
 - (E) Patient death or serious disability associated with patient disappearance for more than four (4) hours, excluding events involving adults who have decision making capacity; and
 - (F) Patient suicide or attempted suicide resulting in serious disability while being cared for in a facility due to patient actions after admission to this facility, excluding deaths resulting from self-inflicted injuries that were the reason for admission to the facility.
- (iv) Care management events including:
- (A) Patient death or serious disability associated with a medication error, including, but not limited to, errors involving the wrong drug, the wrong dose, the wrong patient, the wrong time, the wrong rate, the wrong preparation, or the wrong route of administration, excluding reasonable differences in clinical judgment on drug selection and dose;
 - (B) Patient death or serious disability associated with a hemolytic reaction due to the administration of ABO-incompatible blood or blood products;
 - (C) Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in a facility, including events that occur within forty-two (42) days of post-delivery and excluding deaths from pulmonary or amniotic fluid embolism, acute fatty liver of pregnancy, or cardiomyopathy;
 - (D) Patient death or serious disability directly related to hypoglycemia, the onset of which occurs while the patient is being cared for in a facility;
 - (E) Death or serious disability, including kernicterus, associated with failure to identify and treat hyperbilirubinemia in neonates during the first twenty-eight (28) days of life;
 - (F) Stage three (3) or four (4) pressure ulcers acquired after admission to a facility, excluding progression from stage two (2) to stage three (3) if stage two (2) was recognized upon admission; and
 - (G) Patient death or serious disability due to spinal manipulative therapy.
- (v) Environmental events including:
- (A) Patient death or serious disability associated with an electric shock while being cared for in a facility, excluding events involving planned treatments such as electric counter shock;

- (B) Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by toxic substances;
 - (C) Patient death or serious disability associated with a burn incurred from any source while being cared for in a facility;
 - (D) Patient death or serious injury associated with a fall while being cared for in a facility; and
 - (E) Patient death or serious disability associated with the use or lack of restraints or bedrails while being cared for in a facility.
- (vi) Criminal events including:
- (A) Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed health care provider;
 - (B) Abduction of a patient of any age;
 - (C) Sexual assault on a patient within or on the grounds of a facility; and
 - (D) Death or significant injury of a patient or staff member resulting from a physical assault that occurs within or on the grounds of a facility.

Section 6. Designation of Patient Safety Officers.

- (a) Each licensed health care facility located within this state shall designate a patient safety officer and shall provide the Department with the officer's name and contact information.
- (b) Through the patient safety officer, each facility shall report to the Department the occurrence of any safety event happening after June 30, 2005 as described in Section 5.

Section 7. Procedures for Health Care Facility Safety Event Reporting.

- (a) The health care facility shall submit a report to the Department upon forms approved by the Department.
- (b) A person who is employed by a health care facility shall, within twenty-four (24) hours after becoming aware of a safety event at the health care facility, notify the patient safety officer of the facility of the safety event. The patient safety officer shall, within fifteen (15) days after receiving notification, report the safety event.
- (c) If the patient safety officer of a health care facility personally discovers or becomes aware, in the absence of notification by another employee, of a safety event at

the health care facility, the patient safety officer shall, within fifteen (15) days after discovering or becoming aware of the safety event, report the safety event to the Department.

(d) Safety event reports shall be filed in a format specified by the Department and shall identify the facility but shall not include any identifying information for any of the health care professionals, facility employees or patients involved.

Section 8. Annual Health Care Facility Safety Event Report Prepared by the Department.

(a) Information will be collected and maintained by the Department in the Preventive Health and Safety Division.

(b) On or before December 31 of each year beginning in 2006, the Department shall prepare and publish:

(i) A report and analysis of all reported safety events for the previous year; and

(ii) A trend analysis and recommendations for systemic improvements that are likely to enhance patient safety and health care.

(c) The Department will ensure all referenced information is aggregated so as not to reveal the identity of any specific person or health care facility.

(d) The report shall be made available to the public and copies forwarded to the governor, the health care commission and the joint labor, health and social services interim committee.

Section 9. Confidentiality, Immunity and Whistle Blowing.

(a) Any notice, report, document and any other information compiled or disseminated pursuant to the provisions of this Chapter is confidential, is not discoverable or admissible in evidence in any administrative or legal proceeding conducted in this state and is not a public record.

(b) No contractor, employee or other member of the Department who receives any notice, report, document or any other information compiled or disseminated pursuant to the provisions of this Chapter shall be permitted or required to testify in any civil action as to any evidence or any other matters presented to the Department or as to any findings, recommendations, evaluations, opinions or other actions of the Department or any contractors, employees or other members thereof.

(c) Information, documents or other records otherwise available from original sources are not to be construed as immune from discovery or use in any civil action merely because they were submitted to the Department, nor shall any person who provides information to the Department under this Chapter be prevented from testifying as to

matters within his knowledge, but that person shall not be asked about his testimony or communications with the Department.

(d) Any action authorized or required by this Chapter shall be subject to the confidentiality, immunity and whistle blowing provisions of W.S. 35-2-910 (a) and (b).

(e) The State of Wyoming elects to be covered as of April 1, 2005, by the immunity granted by the Health Care Quality Improvement Act of 1986, P.L. 99-660, Title IV adopted by Congress in 1986, as authorized, for the Department with respect to its duties and responsibilities under this Chapter.

Section 10. Disclosure Without Patient's Authorization.

A hospital may disclose health care information about a patient without the patient's authorization if the disclosure is pursuant to W.S. 35-2-912.

Section 11. Interpretation of Chapter.

(a) The order in which the provisions of this Chapter appear is not to be construed to mean that any one provision is more or less important than any other provision.

(b) The text of this Chapter shall control the titles of its various provisions.

Section 12. Superseding Effect.

When promulgated, this Chapter supersedes all prior rules or policy statements issued by the Department, including Manuals or Bulletins, which are inconsistent with this Chapter.

Section 13. Severability.

If any portion of this Chapter is found to be invalid or unenforceable, the remainder shall continue in full force and effect.