REPORT OF THE
JOINT COMMISSION ON HEALTH CARE

Various Responses to Medical Errors

TO THE GOVERNOR AND
THE GENERAL ASSEMBLY OF VIRGINIA

REPORT DOCUMENT NO. 109

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Code of Virginia § 30-168.

The Joint Commission on Health Care (the Commission) is established in the legislative branch of state government. The purpose of the Commission is to study, report and make recommendations on all areas of health care provision, regulation, insurance, liability, licensing, and delivery of services. In so doing, the Commission shall endeavor to ensure that the Commonwealth as provider, financier, and regulator adopts the most cost-effective and efficacious means of delivery of health care services so that the greatest number of Virginians receive quality health care. Further, the Commission shall encourage the development of uniform policies and services to ensure the availability of quality, affordable and accessible health services and provide a forum for continuing the review and study of programs and services.

The Commission may make recommendations and coordinate the proposals and recommendations of all commissions and agencies as to legislation affecting the provision and delivery of health care.

For the purposes of this chapter, "health care" shall include behavioral health care.

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Preface

House Joint Resolution 101, introduced by Delegate John O'Bannon, III during the 2008 General Assembly Session, directed the Joint Commission on Health Care (JCHC) to "study the use of disclosure, apologies, alternative dispute resolution, and other measures in the case of medical errors and adverse medical outcomes and the impact of such measures on the cost and quality of care, patient confidence, and the medical malpractice system." HJR 101 was not reported by House Rules, with the understanding that JCHC could complete the study without the resolution.

A study committee was formed that included representatives of defense and plaintiffs' attorneys, physicians, hospitals, insurers, mediators, the Virginia Bar Association, and the Office of the Attorney General. While significant work was completed during the 10 meetings held in 2008, the study committee concluded that additional information and work was needed. The committee reached consensus on the following recommendation:

> JCHC should convene a Task Force consisting of representatives of the primary stakeholders in this subject area…[and] charge this task force with:
>
> - developing agreed-upon working definitions of key terms such as adverse outcome, medical error, and disclosures, to facilitate discussions in Virginia of the issues;
> - tracking results and developments in disclosure and resolution programs now operational in Virginia and other states, and federal developments in this area;
> - crafting a model or models for disclosure and early resolution programs that could be offered to Virginia health care providers, insurers and attorneys for their use;
> - should such a model or models be developed, considering ways to incentivize health care providers to try use of such models and to report outcomes of their use with regard to several factors, including cost, claims experience, impact on quality/patient safety efforts and reported patient/provider satisfaction;
> - should the Task Force decide not to offer such model(s), explaining the reasons.

On behalf of the Joint Commission and staff, I would like to thank the numerous individuals who served on and consulted with the study committee.

Kim Snead
Executive Director
March 2009

Table of Contents

Various Reponses to Medical Errors

Executive Summary

The 101 Study Committee was formed by the Virginia Bar Association and the Joint Commission on Health Care (JCHC) to study issues raised in House Joint Resolution 101 (HJR 101).[1] Those issues are: (a) disclosure discussions between health care providers and their patients in cases of so-called adverse medical events, and (b) evaluating alternatives in addition to litigation for providers and patients (or their representatives) to reach resolution agreements for compensation of injured patients. The study subject proved to be a complex one, with multiple concerns at play, significant literature written about the issues, and occurring within the larger context of the highly regulated, evolving health care system. In its formative stages, the Steering Committee of the Study Committee agreed that pacing must be an important value, so that we could develop accurate and good information to support valid analysis. In the four months during which the Committee worked, much ground has been was covered and information was compiled and analyzed.

Based on that work, the 101 Study Committee was unable to conclude at this time that Virginia should take action to mandate or foster disclosure conversation programs or alternative programs for compensation resolution; more information and work is needed. However the work done was sufficient for the Committee to reach **consensus** on the following recommendation:

The Joint Commission on Health Care should convene a Task Force consisting of representatives of the primary stakeholders in this subject area – to include the Medical Society of Virginia, the Virginia Hospital and Healthcare Association, Department of Health, Department of Health Professions, Board of Medicine, the Virginia Trial Lawyers Association, the Virginia Association of Defense Attorneys, the medical malpractice insurance industry, and broader physician, health care provider and consumer representation. We recommend that JCHC charge this task force with:

- **developing agreed-upon working definitions of key terms such as adverse outcome, medical error, and disclosures, to facilitate discussions in Virginia of the issues;**

[1] See *Attachment A*, "House Joint Resolution 101 (2008)." [HJR 101, introduced by Delegate John O'Bannon, III during the 2008 General Assembly Session, directed the Joint Commission on Health Care to "study the use of disclosure, apologies, alternative dispute resolution, and other measures in the case of medical errors and adverse medical outcomes and the impact of such measures on the cost and quality of care, patient confidence, and the medical malpractice system." HJR 101 was not reported by House Rules, with the understanding that JCHC could complete the study without the resolution.]

- **tracking results and developments in disclosure and resolution programs now operational in Virginia and other states, and federal developments in this area;**
- **crafting a model or models for disclosure and early resolution programs that could be offered to Virginia health care providers, insurers and attorneys for their use;**
- **should such a model or models be developed, considering ways to incentivize health care providers to try use of such models and to report outcomes of their use with regard to several factors, including cost, claims experience, impact on quality/patient safety efforts and reported patient/provider satisfaction;**
- **should the Task Force decide not to offer such model(s), explaining the reasons.**

The Task Force should build upon the work already done by the 101 Study Committee.

The following report provides a record of the Committee's work, as well as the bases for its recommendation.

Various Reponses to Medical Errors

Report of the HJR 101 Study Committee

I. Introduction: Study Process, Goals and Focus

The 101 Study Committee was formed by the Virginia Bar Association and the Joint Commission on Health Care (JCHC) to study issues raised in House Joint Resolution 101 (HJR 101).[2] A Steering Committee was first appointed with responsibility to define the study parameters, process, and timetables and to identify Committee membership.[3] Because the subject of the 101 Study Resolution was so broad, the Steering Committee framed the study focus as follows:

"This study will consider and advise the Joint Commission on Health Care as to the advisability of fostering disclosures and fostering dispute resolution discussions with patients and their families in instances when an adverse event has occurred. The questions of advisability will be considered in light of goals for the healthcare system of (a) improving the quality of care; (b) increasing provider and patient satisfaction; (c) achieving fair and timely economic resolutions and (d) improving trust and confidence in the system."

A full Committee was then appointed by the Steering Committee to bring in persons with skills or experience in areas pertinent to the study. It was considered that each member of the full Committee would have a voice in any recommendation under consideration; unanimity would not be required in order to make recommendations to the JCHC. In addition to the full Committee, while maintaining the Committee in a manageable size, other persons or groups were identified who were willing to serve as consultants to the Committee when need for further information or advice might be identified.

Goals of the full Committee were to develop sound information and some action options to consider recommending to the JCHC and to write a report that would inform the JCHC about the subject and the issues.

During the course of the study, the full Committee broke into two work groups, one focused on disclosures and the other on resolution models. Although the continuum of resolution interventions or options includes a broad array of possibilities, the study largely focused on early intervention options, that is, before a written demand for compensation or a legal claim is filed.

[2] See *Attachment A*, "House Joint Resolution 101 (2008)."
[3] See *Attachment B*, "HJR 101 Study Committee and Steering Committee Membership."

Information was compiled, reviewed, and memoranda were prepared to facilitate discussions.[4] A total of ten meetings, either by phone conference or in person was held during the course of the study including Steering Committee, work group and full Committee meetings.

II. Background: Statement of Problem

Since the 1970's health care policy including medical malpractice claims has been the subject of much controversy and debate. In undertaking a study of the issues raised by HJR 101 the Study Committee reviewed and analyzed a plethora of literature written specifically about the handling of medical error and compensation of patients injured.[5] At the outset this report will attempt to summarize the issues that are said to be involved in this complex matter:

When there is medical error, needs or concerns arise for both the patient and the health care provider (HCP) be it a facility or individual practitioners:

- The injured patient may need but does not receive an explanation of what happened or an apology from the person or persons responsible for the injury; may need additional treatment; may not receive adequate compensation; and may not be reassured that steps have been or will be taken to assure that this error is not repeated
- The individual HCP may feel powerless to talk openly with the injured patient about what happened and to express an apology; may be concerned about being sued, about increased insurance premiums and continued coverage; may be concerned about loss of face among peers as well as fear of being unfairly branded as negligent; may be fearful about continued participation in managed care plans and other provider panels, and about credentialing consequences, and possible Board of Medicine (BoM) investigations.

For both patient and HCP an important personal relationship has been broken – a relationship that is often intensely personal, involving trust, confidence and vulnerability.

Efforts that have been made over the years to deal with these problems include:

- American Medical Association medical ethics requirement for physicians to disclose medical error, and Joint Commission on the Accreditation of Health Care Organizations (Joint Commission) requirements for accredited health care organizations to disclose certain medical errors

[4] To facilitate Committee discussions, JCHC staff, as well as Committee members, Jeanne Franklin, Larry Hoover, Susan Ward and Michael Goodman prepared various memoranda summarizing and analyzing the broad range of policy and legal issues. For one example see *Attachment C*, "Reflection on Attorney Roles."
[5] See *Attachment D*, "Resource Bank."

- Virginia BoM requirements for physicians to provide patient information about health and care
- Virginia Rules of Professional Conduct requirement for attorneys as adviser/counselor to help injured patient consider a negotiated compensation process (Alternative Dispute Resolution "ADR")
- Virginia Principles of Cooperation between Physicians and Attorneys which encourage creating the opportunity for improved communication between physician and patient within the context of an ADR process
- Legislation creating (a)Medical panels for resolving medical malpractice claims, (b)Setting limits on recoverable damages and (c)Providing privilege for expressions of benevolence

III. Findings: What the Study Committee Has Learned from the Literature and Other Resources

A. Disclosure

An estimated 44,000 to 98,000 people die unnecessarily in hospitals each year as a result of allegedly preventable medical errors.[6] Besides loss of life or serious injury, annual costs of medical errors, including the expense of additional care, lost income and disability were estimated to be between $17 and $29 billion. Furthermore, health care providers face increasing malpractice insurance costs.[7]

What happens to patients or their families when a patient is injured in an adverse medical event? What is disclosed to them? Are they adequately informed of the facts and circumstances and implications for health and future treatment? Unfortunately there are significant disincentives or downsides to the development and use by health care facilities and medical staff of disclosure programs to help patients and their families come to terms with what happened. These are:[8]

- reporting requirements that may trigger government investigations;
- compromise of relations with the responsible insurance company, including the triggering of the cooperation clause (insurer refuses to defend), raised premiums, and discontinued coverage;[9]
- possible waiver of peer review privileges;[10]

[6] Institute of Medicine, "To Err is Human: Building a Safer Health System" (1999).
[7] Michael E. Ornoff, "Why Hospitals Should Undertake Early Disclosure of Adverse Events Coupled with Mediation of Potential Malpractice Claims," (July, 2007); Thomas H. Gallagher, *Disclosing Unanticipated Outcomes to Patients: The Art and Practice*, 3 Journal of Patient Safety 158 (2007).
[8] Institute of Medicine, "To Err is Human: Building a Safer Health System" (1999).
[9] Lee Taft, *Disclosure Danger: The Overlooked Case of the Cooperation Clause*, Harvard Health Policy Review, Vol. 8, No. 2, (Fall 2007). A cooperation clause is a standard clause in most medical liability insurance policies that prohibits the insured physician from admitting liability without the insurance company's written authorization.

- suggestion advanced that precipitous full disclosure before the information is confirmed, and prior to the disclosure being carefully customized to the individual, is not in the patient's best interest;[11]
- prediction that defense costs could rise due to an increased number of claims;[12]
- fear of lawsuit; and,
- loss of professional reputation.

Fear of lawsuits and loss of reputation remain the biggest barriers to disclosure of medical errors. Contributing to this fear is a "deny and defend" culture, where providers are counseled to remain silent out of a belief that silence will protect their reputation and career and protect them from large malpractice claims.[13]

These disincentives have a cost besides inhibiting disclosure programs. Evidence indicates a majority of patients sue, not because of injury but because they believe they are not treated with respect, not told the truth, and believe the health care provider has not taken responsibility for his/her actions.[14] Literature indicates the silence of the "deny and defend" culture breeds anger, and is a major determining factor in a patient's decision to sue. Many studies suggest that silence harms both patient and physician.[15]

A movement promoting disclosure programs in the medical setting is taking root. The process we are talking about when referring to disclosure and disclosure programs involves reconstructing the events that led up to an adverse outcome and relating those events to the patient and/or the patient's family as appropriate.[16] But there are not yet universal standards applicable to disclosure programs. There are varying definitions of the event that should trigger disclosure. For example, disclosure can be triggered by preventable or non-preventable harm or no harm at all, such as a near-miss.[17] Or, some programs determine need for disclosure based on the severity of the harm.[18] It can be

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[10] American Society for Healthcare Risk Management of the American Hospital Association, "Perspective on Disclosure of Unanticipated Outcome Information." (April, 2001).
[11] *Id.*
[12] Allen Kachalia, et al. *Does Full Disclosure of Medical Errors Affect Malpractice Liability? The Jury is Still Out*, Joint Commission on Accreditation of Healthcare Organizations, Vol. 29, No. 10 (October 2003); David M. Studdert, et. Al., *Disclosure of Medical Injury to Patients: An Improbable Risk Management Strategy*, 26 Health Affairs 215 (2007).
[13] Jonathan R. Cohen, *The Culture of Legal Denial*, 84 NE. L. REV. 247 (2005); Lee Taft, J.D. *Disclosing Unanticipated Outcomes: A Challenge to Providers and Their Lawyers* (May 2008).
[14] Michael S. Woods. *Healing Words: The Power of Apology in Medicine* (2004).
[15] Lee Taft, J.D. *Disclosing Unanticipated Outcomes: A Challenge to Providers and Their Lawyers*.
[16] Ellen L. Barton, J.D., CPCU and Mark A. Kadzielski, Esq. "Tell Me Now and Tell Me Later: Disclosure and Reporting of Medical Errors," American Health Lawyers Association, (June 2007), p. 42
[17] *Id.*
[18] A "sentinel event" is an unexpected occurrence involving death or serious injury, or one of the 10 events deemed as such by the Joint Commission, even if death or serious injury does not occur." It can also include events that have caused serious harm, such as death, disability, or additional or prolonged

triggered by medical error,[19] or simply an adverse event,[20] that was the fault of no one. The amount and timing of information disclosed also varies from one program to another. Disclosure can also be mandatory or voluntary.

A full disclosure includes an apology.[21] Yet, as with disclosure itself, the definition of apology varies, and physicians and patients often have differing views as to what constitutes an apology. Many disclosure programs, as well as many state laws, define apology as an expression of benevolence, remorse or sorrow. This more narrow definition differs from one more commonly understood by the general population, i.e. patients. They would define an apology as an expression of remorse and sorrow coupled with an admission of wrongdoing and taking of responsibility.[22] This variation highlights the lack of communication and conflicting expectations between patient and physician at the heart of the problem at issue.

Regardless of how specific disclosure policies are defined, and in addition to ethical and legal requirements to disclose (discussed below), arguments have been made that disclosure of medical errors rebuilds trust and solidifies the provider/patient relationship, thereby decreasing malpractice litigation and reducing overall costs.[23] Furthermore, a culture of transparency and accountability fosters an environment where medical errors are identified and corrected, thereby buttressing the patient safety movement. Acknowledging an error gives an institution the freedom to correct the mistakes and theoretically prevent future harm and improve patient safety. As a result, patients can gain increased confidence in the integrity of the health care system.[24] Disclosure

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treatment. Or, it can be defined as an unexpected occurrence involving death or serious physical or psychological injury or the risk thereof. Serious injury specifically includes loss of limb or function. "Or the risk thereof" includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome.

[19] A "medical error" can generically be defined as a commission or omission with potentially negative consequences for the patient that would have been judged wrong by skilled and knowledgeable peers at the time it occurred, independent of whether there were negative consequences. "Medical Error" can also include preventable systemic problems rather than a problem resulting from poor performance by a health care provider.

[20] An "adverse event" can be generically defined as an unanticipated medical injury resulting from medical testing, treatment or surgical intervention and not disease process, irrespective of whether it was the result of a medical error.

[21] Errors. Teaching Module: Talking About Harmful Medical Errors With Patients, http://depts.washington.edu/toolbox/errors.html.

[22] Lee Taft, J.D. *Disclosing Unanticipated Outcomes: A Challenge to Providers and Their Lawyers* (May 2008).

[23] Jonathan R. Cohen, *Apology and Organizations: Exploring an Example from Medical Practice*, Fordham Urban Law Journal, Vol. XXVII, (2000), at 1458.

[24] Allen Kachalia, et al. *Does Full Disclosure of Medical Errors Affect Malpractice Liability? The Jury is Still Out*, Joint Commission on Accreditation of Healthcare Organizations, Vol. 29 No. 10 (October 2003); Jonathan R. Cohen, *Apology and Organizations: Exploring an Example from Medical Practice*, Fordham Urban Law Journal, Vol. XXVII, (2000), at 1464.

returns the focus to the patient and encourages care to be patient-centered, not based on the protection of the organization.[25]

Currently, there are a variety of federal and state authorities creating standards or requirements for healthcare providers to disclose or health care organizations to have disclosure programs. On a national level, the AMA states that physicians have a fundamental ethical duty to communicate openly and honestly with patients and to keep the patient informed.[26] Likewise, The Joint Commission requires disclosure of medical errors and unanticipated outcomes to patients and their family members by accredited facilities when it is appropriate.[27] This requirement for disclosure includes the disclosure of both positive and negative outcomes, including those unanticipated adverse outcomes that were preventable.[28] Turning to Virginia, the Virginia BoM regulations require practitioners keep their patients accurately informed.[29]

Additionally, seven states mandate disclosure of serious adverse events.[30] Pennsylvania and Rhode Island require written notification of the patient. Key developments are likely to continue taking place at the institutional level.[31]

In an effort to encourage disclosure conversations and apology, 35 states have adopted so-called "apology laws" to create an evidentiary privilege in any subsequent judicial or administrative proceeding.[32] But twenty-five of these states, including Virginia,[33] create a privilege for an "expression of benevolence, remorse, or sorrow" only. Six states protect an expression of benevolence, remorse or sorrow, plus an explanation, and four states protect the entire disclosure statement, which would also include an acceptance of responsibility.[34]

Reporting requirements are distinguishable from disclosure requirements and standards but play a role in whether providers disclose, and how they disclose. For instance, the Health Care Quality Improvement Act (HCQIA) created the

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[25] American Society for Healthcare Risk Management of the American Hospital Association, "Disclosure of Unanticipated Events: The Next Step in Better Communication With Patients." (May 2003).
[26] American Medical Association, Code of Medical Ethics, Ethical Opinions, E-8.12 (1994).
[27] Joint Commission on Accreditation of Healthcare Organizations, "Comprehensive Accreditation Manual for Hospitals: Standard RI 2.90," (2008).
[28] Lee Taft, J.D. *Disclosing Unanticipated Outcomes: A Challenge to Providers and Their Lawyers*. *Citing* Rae M. Lamb, et al., *Hospital Disclosure Practices: Results of a National Survey*, 22 Health Affairs 73, 74 (2003).
[29] 18 VAC 85-20-28.
[30] Thomas H. Gallagher, "Disclosing Medical Errors to Patients: recent Developments and Future Directions," Presentation to VIPIC&S (April, 2008); Lee Taft, *Disclosure Danger: The Overlooked Case of the Cooperation Clause*, Harvard Health Policy Review, Vol. 8, No. 2, (Fall 2007). These states include: Pennsylvania, Nevada, New Jersey, Florida, Oregon, California, and Vermont.
[31]Thomas H. Gallagher, "Disclosing Medical Errors to Patients: Recent Developments and Future Directions," Presentation to VIPIC&S (April, 2008)
[32] See *Attachment E*, "State Apology Laws."
[33] VA. CODE ANN. § 8.01-581.20.1 (2006).
[34] Thomas H. Gallagher, "Disclosing Medical Errors to Patients: Recent Developments and Future Directions," Presentation to VIPIC&S (April, 2008).

National Practitioner Data Bank (NPDB).[35] The NPDB intends to improve the quality of health care by using an alert or flagging system that would help identify incompetent physicians, facilitate a comprehensive review of their professional credentials, and inhibit the ability of incompetent physicians to move from state to state unnoticed. Information on the NPDB is available to certain entities, such as the BoM, but is not available to the general public. This Act requires that medical malpractice payments, adverse actions related to licensure, clinical privileges and professional society membership be reported to the NPDB. Any payment, in any amount, made for the benefit of any type of licensed health care practitioner is reportable.

Virginia law includes several reporting requirements. Directly relevant to the medical error issue and taken together, these laws require that reports must be made to the BoM of:

- any disciplinary action taken against a practitioner if such action "is a result of conduct involving intentional or negligent conduct that causes or is likely to cause injury";
- any malpractice judgment;
- any settlement of a malpractice claim;
- any evidence that indicates a reasonable probability of professional incompetence or intentional or negligent conduct that causes or is likely to cause injury to a patient or patients or unprofessional conduct.

The entity must also report this information to the NPDB.[36] Reporting requirements apply to professional societies, health care institutions, health care practitioners, malpractice insurance carriers and HMOs.[37] The BoM posts any final orders which imposed disciplinary action on its website and posts medical malpractice claim payments and settlements as well.[38]

The foregoing summary highlights crosscurrents in the disclosure program debate. Somehow providers have to balance their ethical and legal responsibilities, as well as their personal, professional and financial liability, when they decide what and how to disclose. However, often what feels like disclosure to a provider (considering the balancing act that takes place) does not

[35] 42 U.S.C. § 11131.
[36] VA. CODE ANN. § 54.1-2909.
[37] VA. CODE ANN. §§ 54.1-2400.6, 54.1-2908, 54.1-2909.
[38] VA. CODE ANN. § 54.1-2910.2.

always meet the expectations of patients.[39] Work is ongoing in the disclosure program movement.[40]

B. Resolution

There are various processes for resolving medical error conflict, including litigation. The most frequently used voluntary process is mediation, where an impartial third party facilitates a private, confidential negotiation between the parties to the dispute. In Virginia it is likely that most medical error conflicts are mediated after a formal claim has been filed in court, pre-trial discovery process has taken place and the parties have been unable to reach a negotiated settlement.

A mediated monetary settlement can avoid the risk of an adverse jury verdict and can save the additional expenses of trial. But it does not alleviate the cost of hostility-creating discovery and a HCP's apology in that context is likely to be interpreted as nothing but an empty gesture; nor does it recognize or respect the fact that parties are often concerned about more than money.[41]

Early, Interest-Based Mediation. The decision to engage in mediation should be made as soon as the parties have adequate information to evaluate the event. For the HCP this means a thorough investigation of the incident and for the patient it means receiving a full disclosure of the facts surrounding the incident.[42]

Entering into mediation before or in the early stages of litigation has numerous advantages. First, this initiative gets the relevant facts on the table from the outset. Too frequently, litigation creates a system in which parties don't know all the facts for many months after initiation of a lawsuit. If both parties enter into mediation shortly after a medical error disclosure, there is a clear message that each side is motivated to resolve the matter. And if the patient enters mediation before a formal claim is made, no report of a settlement is required to be made to the NPDB.

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[39] Studies indicate that patients want and expect the following elements to be included in a disclosure: (1). An explicit statement that an error occurred; (2). What happened and implications for their health; (3). Why it happened; and, (4). How will recurrences be prevented. Providers also report the desire for such conversations, and have further need to move forward in learning how the errors happened and can be prevented.

[40] Thomas H. Gallagher, et. al, *Patients and Physicians' Attitudes Regarding the Disclosure of Medical Errors*, JAMA, 289 (8) (February 26, 2003).

[41] Carol B. Liebman and Chris Stern Hyman, *Medical Error Disclosure, Mediation Skills, and Malpractice Litigation: A Demonstration Project in Pennsylvania*, The Project on Medical Liability in Pennsylvania funded by The Pew Charitable Trusts, (2005); Edward A. Dauer, *Alternatives to Litigation for Health Care Conflicts and Claims: Alternative Dispute Resolution in Medicine*, Hematology/ Oncology Clinics of North America (2002); Michael E. Ornoff, "A Mediation Model for Early Malpractice Claim Resolution in Virginia," (May, 2007).

[42] Carol B. Liebman and Chris Stern Hyman, *Medical Error Disclosure, Mediation Skills, and Malpractice Litigation: A Demonstration Project in Pennsylvania*, The Project on Medical Liability in Pennsylvania funded by The Pew Charitable Trusts, (2005).

Hospitals, unlike individual physicians or physician groups, are well suited to implement early mediation programs because they are often self-insured, or have large self-insured retentions, giving them some ability to control their indemnity payments. Also, hospitals frequently know about potential claims before an adversely affected patient obtains legal counsel; thus potential claims can be handled proactively.

Unlike litigation, mediation offers the opportunity to consider non-monetary needs and interests of both parties, such as staff education or changes in procedures, measures that are not only in the interest of the HCP but may also meet the patient's need to see that the error will never happen to anyone again and that corrective actions will be taken. It also offers the opportunity for a full apology and relational healing between provider and patient and overall satisfaction of both provider and patient by fully participating in the process.[43]

Collaborative Law. An emerging ADR resolution process is Collaborative Law (CL). In this process all parties and their counsel work collaboratively toward a resolution of the issues, and are not limited to legal or monetary remedies. One hundred per cent of the effort is put toward settlement of issues as opposed to preparation for trial. Before the process begins all parties and their attorneys meet and review a "CL participation agreement" which describes the process in detail.

Key provisions of the agreement that distinguish the CL process from both negotiation and mediation include a commitment to complete transparency by parties and their counsel, to all negotiations taking place with all parties present, to neutral experts or consultants chosen jointly by the parties, to no court intervention at any stage of the process, and to withdrawal of counsel of both parties if either party chooses court intervention. Reports of a monetary settlement need not be reported to the NPDB, absent a formal claim or written demand.[44]

The CL process, developed in the late 90's, was used first in the family law setting, where relational and non-monetary issues are obviously in play. More recently it has been adapted for use in business, employment and estate administration disputes, and is now suggested in medical error disputes, where relational and non-monetary issues are also important. Although there is now a

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[43] Carol B. Liebman and Chris Stern Hyman, *Medical Error Disclosure, Mediation Skills, and Malpractice Litigation: A Demonstration Project in Pennsylvania*, The Project on Medical Liability in Pennsylvania funded by The Pew Charitable Trusts (2005); Edward A. Dauer, *Alternatives to Litigation for Health Care Conflicts and Claims: Alternative Dispute Resolution in Medicine*, Hematology/ Oncology Clinics of North America (2002); Michael E. Ornoff, "A Mediation Model for Early Malpractice Claim Resolution in Virginia," (May, 2007).

[44] Fasler, Karen S., *A Niche Of Its Own– Collaborative Law in Medical Malpractice Cases* at 4; Kathleen Clark, *The Use of Collaborative Law in Medical Error Situations*, The Health Lawyer, Vol. 19, No. 6 (June 2007).

state-wide CL organization, the CL process is not widely understood and there are only several hundred qualified CL practitioners in Virginia.

Malpractice Review Panels. This process permits any party to medical malpractice litigation to request a review panel within 30 days from the filing of responsive pleadings. The Virginia Supreme Court selects two doctors and two lawyers from lists provided by the Board of Medicine and Virginia State Bar to sit on the panel. The parties engage in a process very similar to the litigation discovery process, including depositions and written discovery. The panel either conducts a hearing in which evidence is heard or reviews the evidence in an executive session. If the panel finds that the defendant breached the standard of care and that the breach proximately caused damages, the panel may determine the degree and extent of damages, but there is no authority for the panel to assess damages against a party.

The review panel is seldom used by patients or health care providers. To become a viable resolution process, several changes were offered in Committee discussion:

- Both parties must agree to enter the process.
- The panel's decision must be binding.
- The panel must be permitted to make a binding award of damages. (Va. Code Section 8.01- 581.1)

There was no conclusion reached with regard to malpractice review panels or changes to them.

Mediation and other collaborative options would presumably be included in the recommended Task Force consideration of model compensation resolution programs. If early (pre-claim) efforts to resolve compensation of injured patients are not successful, or if a legal claim has simply been filed against a health care provider without an early attempt at resolution, mediation and collaborative law are still available as well as other ADR options that may be considered by the parties to resolve the dispute.

C. Examples of Disclosure/Early Resolution Programs[45]

Across the country, including in Virginia, hospitals have been implementing disclosure/early resolution programs. Many of these programs in existence, however, are not self-promoting. This report will highlight some of the programs about which we know, and who have publicized and touted their success. This success may be accurate, but is difficult to measure. A direct causal connection cannot yet be proven between the implementation of a disclosure/early resolution program and increased patient safety, or a decrease in lawsuits and

[45] See *Attachment F*, "Comparison of Disclosure/Early Resolution Programs: Initial Survey Results."

overall costs. Still the examples and claims of headway in these areas are worth noting.

Even though each of the following disclosure/early resolution programs has a unique approach, some consistent characteristics permeate. For example, all of the disclosure programs focus on early resolution (pre-claim) of the issues. Additionally, each of the disclosure/early resolution programs has transparency and accountability as its intended purpose for implementation, not a decrease in medical malpractice costs. However, before a disclosure conversation is initiated, each of the programs has procedures in place to determine if and how an adverse event has occurred. At that point, they have clear policies as to who makes the initial disclosure, as well as future disclosure conversations. Because these programs require a marked shift in behavior, each employs a strong education/training/support element for all involved. Finally, most often education outreach began with the stakeholders before any programs were implemented.

Although these programs are developing program by program across the country, efforts have been made on the federal level to require disclosure programs in all health care settings. In 2005, the National Medical Error Disclosure and Compensation (MEDiC) Bill was introduced.[46] Although not enacted, it would have promoted the confidential disclosure to patients of medical errors in an effort to improve patient-safety and reduce the number of medical malpractice lawsuits. The legislation specified that at the time of disclosure, compensation for the patient or family would be negotiated, and procedures would be implemented to prevent a recurrence.[47] We do not know if legislative efforts in this direction will be renewed on the federal level. We do know that Medicare Quality Improvement Organizations are enjoined by the federal government to make use of mediation to resolve patient grievances; the most recently announced Scope of Work indicates that the QIOs will be evaluated on their performance in this regard.

Federal Programs. The VA Hospital in Kentucky has probably received the most publicity and acclaim for its disclosure/early resolution program. This approach involves full disclosure and apology. After an adverse event occurs, through case and peer review, the VA determines whether any standard of care violations, medical errors, or patient injuries or deaths occurred in the provision of care. Consensus is reached regarding the need for disclosure of an incident. Physicians and other health care personnel identify potentially compensable events, which would be instances where there has been a breach in the standard of care. If it is determined that disclosure is necessary, a meeting with the patient and family is convened. VA staff members make disclosure and apologize,

[46] S. 1784, 109th Cong. (2005).
[47] Hillary Rodham Clinton, Barack Obama. "Making Patient Safety the Centerpiece of Medical Liability Reform" NEJM Vol 354:2205-2208 No. 21 (May 25, 2006)

accept full responsibility for any unanticipated outcome, and describe what steps are being taken by the hospital to prevent such negative outcomes from occurring in the future. Fair compensation options are offered during the meeting. It should be noted however there is less risk for an individual physician to take part in a disclosure program at the VA hospital than in other settings because the individual physician can never be held personally liable. In any suit against the VA, the United States is the only named defendant.[48]

Nevertheless, the results of this program have been positive. Between 1987 and 2000, this VA hospital negotiated more than 170 settlements, going to trial only three times. The largest payout was $341,000 for a wrongful death, and the average settlement was $16,000. These numbers contrast starkly to amounts paid in VA malpractice suits nationwide.[49]

Academic Health Centers. The University of Michigan Health System has a similar program in place, but it all began with state law encouraging such behavior. Michigan has a compulsory 6 - month pre-suit notice period. Before a malpractice suit may be filed against any health care practitioner or facility in Michigan, the patient or patient's family is required, by law, to present details of the claims in writing. Once this notice is served, a suit cannot be filed for 182 days. This pre-suit notice period allows prospective defendants time to investigate the claim, gives them the opportunity to meet with the patient or family, and offers patients and families time to reconsider their decision to sue.

The University of Michigan Health System's Full Disclosure Program strives to thoroughly review the required written claims within 3 months or less. Each case undergoes internal and sometimes external expert reviews. The patient care at issue is submitted to the Medical Liability Review Committee, which determines reasonableness of care and impact on the patient's outcome. This Committee also considers every submitted case for peer review, clinical quality improvement, and educational opportunities. Furthermore, they study all adverse events to determine how procedures could be improved.

Once the issues are clarified, the hospital's policy requires staff to disclose cases of harmful error, and open discussion with the patient and his lawyer ensues. Physicians provide factual information of the outcome that occurred. If it has been determined that the University of Michigan Health System provided unreasonable care, they compensate patients quickly and fairly. However, if the hospital determines that the care was reasonable and the case is without merit, it will aggressively defend against any claims. Again, it should be noted that there is more incentive for physicians to participate in a disclosure program at this

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[48] Lee Taft, *Disclosure Danger: The Overlooked Case of the Cooperation Clause*, Harvard Health Policy Review, Vol. 8, No. 2, (Fall 2007); Jonathan R. Cohen, *Apology and Organizations: Exploring an Example from Medical Practice*, Fordham Urban Law Journal, Vol XXVII, (2000).

[49] Eve Shapiro. "Disclosing Medical errors: Best Practices from the 'Leading Edge'" (2008).

hospital than in other settings. Although the physician may be individually named in a malpractice suit, the University of Michigan will wholly indemnify all its doctors for damages.[50]

The program has had positive results in the five years since implementation. The annual litigation costs have gone from $3 million to $1 million, and the number of claims and lawsuits has gone from 262 to 114. The average time to resolution of claims has gone from 20.7 months to 9.5 months. The disclosure/early resolution program has led to an unprecedented exchange and flow of information, where staff reports more close calls and patient injuries.[51]

The University of Illinois Medical Center disclosure program includes a hotline that allows for reporting of an error and also provides support for the clinician as he goes through the disclosure steps. Once an error is reported, a rapid investigation team determines whether it is a clear error. If it is a clear error, the case meets criteria for an apology with full disclosure, where the remedy of compensation is considered. At that point, a liaison is created between the patient and family and the claims department to manage the process of financial compensation. Contemporaneous with the steps involving remedy, the organization also decides how to implement process improvements to prevent future error.

The program has had positive results. Patients who have experienced an error or adverse outcome continue to seek care there at the hospital. Furthermore, patient safety has improved, as well as employee attitudes, although no direct link can be made.

Private Health Systems. The Geisinger Health System, a physician-led integrated health system, also implemented a disclosure program based on state law. Pennsylvania passed the Medical Care Availability and Reduction of Error (MCARE) Act, which states that "A person who has sustained injury or death as a result of medical negligence by a health care provider must be afforded a prompt determination and fair compensation. Every effort must be made to reduce and eliminate medical errors by identifying problems and implementing solutions that promote patient safety."[52] This law provided the framework to make disclosure routine and the Geisinger Health System implemented a disclosure program.

As part of the program, the system tells patients and families about serious or sentinel events as soon as they are discovered and follows up the disclosure conversation in writing within seven days. The disclosure conversation includes an explanation of the circumstances under which the serious or sentinel event

[50] Lee Taft, *Disclosure Danger: The Overlooked Case of the Cooperation Clause*, Harvard Health Policy Review, Vol. 8, No. 2, (Fall 2007), (citing conversation between Rick Boothman and author, March, 2006).
[51] Eve Shapiro. "Disclosing Medical errors: Best Practices from the 'Leading Edge'" (2008).
[52] 40 PA. STAT. ANN. § 1303.

occurred and identifies systems issues that contributed to the adverse outcome and the ramifications to the patient. Hospital staff assures patients and families that a complete investigation will take place. In an effort to manage expectations, they also provide the patient or family with the names of those who will manage communication between them and the hospital.

The program has led to a significant increase in reporting of serious events, sentinel events and near misses, and an increase in number of conversations physicians have had with patients about those events. They have had fewer claims filed than the national average. State law provided some protection for the disclosure, or at least peer review coverage, so they could do the right thing while minimizing the effect of lawsuits.[53]

The Kaiser Permanente[54] Program is another example of a private health system implementing a voluntary disclosure program. Although the facilities are private, Kaiser employs its physicians and insures them in the same program with its hospitals, which is a distinct advantage.[55] The Kaiser program has operated since 2003. It is located in California where the hospitals, doctors, nurses are all under the Kaiser mantle, with no independent providers. Kaiser operates a disclosure program in Ohio with the involvement of some independent hospitals and physicians.

The program provides guidance steps for physicians to disclose in the aftermath of an adverse outcome. As with the other programs, they provide training and support for physicians. The Kaiser model employs a Healthcare Ombudsman/Mediator who handles all aspects of preparation for the disclosure and who maintains open communication with the patient. The program is unique in that it is based on total transparency, in real time. During the disclosure conversation, they will discuss with patients information gleaned from root analyses and peer review, but do not actually turn over peer review or Quality Assurance documents, as they are privileged.[56]

Insurance Company Programs. The environment in Colorado also encouraged a reported successful implementation of a disclosure program within the Colorado Physicians Insurance Company (COPIC), which insures physicians in private practice. Colorado has historically good tort reform with a cap on non-economic and global damages, and has a strong apology statute that gave physicians greater confidence to participate in a disclosure program. Additionally, stakeholders had collaborative relationships, which also eased implementation.

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[53] Eve Shapiro. "Disclosing Medical errors: Best Practices from the 'Leading Edge,'" (2008).
[54] *Id.*
[55] Ellen L. Barton, J.D., CPCU and Mark A. Kadzielski, Esq. "Tell Me Now and Tell Me Later: Disclosure and Reporting of Medical Errors, " American Health Lawyers Association, (June 2007), p. 54.
[56] Carole S. Houk, JD, LLM, et.al, *Apology and Disclosure: How a Medical Ombuds Can Help Bring A Policy to Life*, Patient Safety & Quality Healthcare (May/June 2008).

COPIC developed the "3Rs" Program in 1998, which involves: 1). recognizing an unanticipated event, 2). responding soon after the event and, 3). resolving related issues. Once an event is reported, the physician and COPIC are in accord as to intervention. The doctor engages in the disclosure process, tells the patient about the program, and puts the patient in touch with the 3Rs administrator. The 3Rs administrator then reimburses the patient, upon obtaining receipts for out-of-pocket expenses and lost time, up to $30,000. This program seeks to promote disclosure and an early offer following unanticipated outcomes in smaller cases. The Program is "no-fault." The patient is not asked to sign a waiver. Payments are not reportable to NPBD. The COPIC program, however, excludes claims in instances of patient death, attorney involvement or a complaint to the BME.

General. Virginia Mason Patient Safety Alert System's disclosure program focuses on transparency and visibility and also employs a reporting/patient safety mechanism. Within the program, every person is a safety inspector. If *any* employee sees a patient safety issue, he reports it and the process stops immediately. Alerts are color coded, based on actual or potential harm. Before any safety alert can be closed (all go to Board for closure), the hospital must demonstrate something has been done to ensure no reoccurrence of the error. The hospital provides continuous training on communication to physicians. The system has led to increased reporting of actual as well as potential errors. They have had fewer malpractice claims, but refuse to draw a link between the two.

Finally, some hospitals in Virginia currently have disclosure programs in place. One example is the Prince William Hospital in Virginia which implements a disclosure policy that includes apology. Since implementation of the program they have seen no increase in claims. They have shared stories of the positive response with their Board of Trustees, which has been helping to move the hospital and providers from a culture of silence to a culture of transparency. The Board reviews random chart audits for harm and identifies ways to decrease harm from medical error. The Board and medical staff leaders continue to collaborate on best practice strategies.

Pilot Programs. Whereas some states have provided a fertile environment for hospitals to implement their own disclosure programs, other states, such as Vermont, have instituted pilot programs.[57] Vermont's pilot program requires an oral apology or explanation of how medical error occurred, made within 30 days. The oral apology and explanation may not be used to prove liability, are not admissible, and cannot serve as the subject of questioning in administrative or civil proceedings. Of course, information obtained through other channels is not barred from use.

[57] 2005 Adj. Sess., No. 142, Sec 2 (provisions are in the package of state laws distributed on July 1) The program sunsets June 30, 2009 but the Department [of banking, insurance, securities and health care administration] must report to General Assembly in January 2009.

This pilot establishes a voluntary program run by the Vermont Department of Banking, Insurance, Securities & Health Care Administration (BISHCA), in which physicians and hospitals promptly acknowledge and apologize for mistakes in patient care that result in harm and promptly offer fair settlements. Negotiations under the program are confidential, and the statute of limitations is tolled during negotiations. Settlement bars further litigation. If settlement is not reached, the patient still may bring a civil action, having the same options as he did prior to entering into the disclosure program.

Additionally, as part of the program, hospitals will report medical malpractice costs to BISHCA for the department to analyze any cost savings resulting from use of the program. They will report to the general assembly in January 2009, and the program will sunset.

Pennsylvania also implemented a pilot program for early resolution of medical malpractice cases, at the urging of the State Supreme Court.[58] State leaders from the bar and medical society were convened and identified a county in which a program might be situated, based on finding a hospital/health system that was willing and able to participate in such a program.[59] Once the county (Montgomery) was identified, a task force was established of county leaders including physicians, lawyers, and hospital representatives. Ultimately, the task force decided to hire a mediation consulting service to help the task force design a format.[60]

The model includes a first level which focuses on facilitating direct communication with patients about the patient's care and attempts to resolve matters to everyone's satisfaction including possible compensation of the patient. The patient is told about this first level program upon admission to the hospital and is told whom the patient can contact within the hospital should anything arise and the patient wants to initiate that level. It is an ombuds-type program within the hospital and works with a patient safety committee (PSC). If the HCP decides to offer compensation, the PSC or Ombudsmen discusses arrangements or compensation with the patient after advising the patient of the right to counsel.

If the first level does not satisfy the parties, the model elevates to the offer of an early mediation process in which lawyers would be involved. The mediators would be a specially trained lawyer/physician team. A panel of trained mediators has been created.

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[58] Carol B. Liebman and Chris Stern Hyman, *Medical Error Disclosure, Mediation Skills, and Malpractice Litigation: A Demonstration Project in Pennsylvania*, The Project on Medical Liability in Pennsylvania funded by The Pew Charitable Trusts (2005).

[59] A condition of the hospital/health system's participation was that its insurer had to agree to cooperate.

[60] Funding came from different sources including the bar and the medical society.

The hospital staff is a mixed staff so that some physicians do have their own insurers. The hospital group(s) is covered by the hospital policy. The hospital plan is to try to create a culture around this program so that the medical staff can buy into it. Pennsylvania law might provide an advantage: if the hospital pays the settlement – as a kind of global settlement – on the physician's behalf, there is no duty for the physician or hospital to report the settlement to the Board of Medicine.

IV. Recommendation and Rationale

The Joint Commission on Health Care should convene a Task Force consisting of representatives of the primary stakeholders in this subject area – to include the Medical Society of Virginia, the Virginia Hospital and Healthcare Association, Department of Health, Department of Health Professions, Board of Medicine, the Virginia Trial Lawyers Association, the Virginia Association of Defense Attorneys, the medical malpractice insurance industry, and broader physician, health care provider and consumer representation. We recommend that JCHC charge this task force with:

- **developing agreed-upon working definitions of key terms such as adverse outcome, medical error, and disclosures, to facilitate discussions in Virginia of the issues;**
- **tracking results and developments in disclosure and resolution programs now operational in Virginia and other states, and federal developments in this area;**
- **crafting a model or models for disclosure and early resolution programs that could be offered to Virginia health care providers, insurers and attorneys for their use;**
- **should such a model or models be developed, considering ways to incentivize health care providers to try use of such models and to report outcomes of their use with regard to several factors, including cost, claims experience, impact on quality/patient safety efforts and reported patient/provider satisfaction;**
- **should the Task Force decide not to offer such model(s), explaining the reasons.**

The Task Force should build upon the work of the 101 Study Committee.

It is important to note that the 101 Study Committee does not assume that the model program to be developed by the recommended Task Force will be created or protected by legislation. That question is left to the Task Force when it considers ways to incentivize provider engagement in disclosure/early resolution programs. It is equally important to note that this recommendation is not intended to consign the subject to "death by committee" as though the subject is unimportant or too difficult as a political matter to resolve.

Rather, our study recommendation reflects the strong interest of the Committee in finding ways to resolve the tension between on the one hand patient/provider needs and concerns, and on the other hand the reasons why those needs/concerns are not consistently met or addressed. We learned that the tension is commonly perceived around the country and that specific efforts listed in Section II. above have actually done little to reduce it. This tension has resulted in a kind of status quo that the players in both the healthcare and litigation systems have learned to operate within, if not accept.

In instances of medical error, some of the needs of some of the players are being met. Added to that fact, argument was advanced and noted that the current system works well enough, and that educating the professions about possible collaborative solutions and ethical obligations will provide an adequate enhancement of the current system. Education about ethical responsibilities and the effective use of effectively is a good idea in any case. But the Committee did not agree that it is all that might be done to provide options, other than the status quo, for patients and providers to use in cases of adverse medical outcomes and medical error.

The fact remains that not all patient and provider needs/concerns are being met or addressed. Added to that are newer demands upon health care providers by government and payers to make better, more effective effort to root out causes of medical error.[61] If the status quo doesn't now satisfy all concerns of patients and providers, it will also likely stifle 21st century Best Practices for quality improvement and patient safety measures. Hence confronting the subject would seem all the more important. But importance does not make for ease in finding solutions. That is why the Committee believes that a collaborative effort supported by continued state interest in the stakeholders' finding solutions will assist the search.

Numerous publications extol disclosure, apology and early settlement conversations as the solution – the key to containing costs, even while compensating patients appropriately, and almost magically making everyone happier. (At the outset we found that key terms such as medical error, adverse event, unanticipated outcome and disclosure are being used with widely

[61] Information about the evolution of the quality assurance movement over the last 30 or so years and its current iterations is beyond the scope of this study report. But quality improvement work is an important context for the subject of our study. As an example, the enactment of the federal Health Care Quality Improvement Act created the National Practitioner Data Bank with required reporting to it of malpractice case decisions and settlements, as well as adverse credentialing decisions. The Data Bank was created to allow tracking of problem physicians so that they could not "skip town" and set up shop in a new location exposing more patients to their consistently below standard practice. Now the federal government and some private payers also will not reimburse hospitals for care they deem to be caused by medical errors. The Data Bank reporting requirement is a factor inhibiting how health care practitioners and institutions respond in cases of questionable care because it is felt that a lot more than "problem physicians" can be caught up and branded in the Data Bank.

different definitions. The term "medical error" alone is a critical term because it may capture the standard for triggering offers of compensation or entitlement to compensation. Hence our recommendation that the Task Force must settle upon working, universal definitions of key terms for use in Virginia.)

We also found resources that contain detailed information and scholarly analysis of such solutions. And we are hopeful and intrigued that the claims by facilities implementing such approaches are:

- satisfying patient needs/concerns;
- supporting health care providers;
- respecting all the parties and preserving relationships;
- moving the ball forward to create transparency and cooperative learning within health care institutions.

They are also reporting reduced numbers of claims and lower defense and settlement figures although they are more modulated in the last year or so about claiming a direct correlation.

The Committee is uncertain about the future sustainability of cost outcomes when more patients are fairly compensated. The Committee is also mindful of additional factors that would need to be considered when embracing the disclosure/apology/resolution solution.

- It was believed that we did not have enough reliable empirical data available to us to support the alleged cost and claims benefits of an early disclosure or early disclosure/resolution program.
- It was noted that most of the data supporting claims of cost reduction were from programs that are self-insured. The ability of the program to function well likely rests on the fact that the facilities are self insured with captive medical staff - only one or perhaps two insurers are involved. It will be more difficult and complex for health care institutions with independent medical staff and thus multiple insurers to manage the process satisfactorily.
- For all players to cooperate in a program, it seems obvious that insurers must be supportive of it because medical practitioners cannot risk rising premiums, discontinued coverage, or refusal by the insurer to defend a claim following a disclosure.
- A January 2007 study posits an economic model in which the number of "prompted claims" (arising from patients having better information) would exceed "deterred claims" (from patients feeling better satisfied by explanations they receive, acknowledgement of their loss and early offers of compensation), such that costs would actually increase. But that report

does not argue against the value of creating disclosure and early compensation programs.[62]

- With regard to the affordability of alternative, proactive early resolution programs, a theory should also be noted that while there may be some period of increased claims and cost, it would eventually come back around to manageable numbers; greater transparency and efficacy of quality assurance initiatives should bring down the error rate and therefore numbers of persons injured who would merit fair compensation.
- Change in interpretations of Virginia's peer review privilege has created an uncertain environment that is exacerbating the tension noted in this report and serves as a disincentive to embracing voluntary disclosure and early resolution programs.
- Virginia reporting requirements and BoM procedures can be seen as possibly inspiring fear and reluctance rather than open self-examination and correction in cases of medical error.
- The polarization of attitudes about the medical error issue and the need for reform support the status quo.

We noted that programs claiming some cost successes seem to share a common factor besides self-insurance; something created a field ripe for experimentation. In a few instances, voluntary programs are apparently initiated in response to state disclosure requirements, expanded or clarified privilege or to an unacceptable malpractice claim and cost situation. As stated in the preceding Section III.A. of this report, one state has a "cooling off period" that was fertile ground for inserting an alternative resolution program. Some programs are starting up because their state has encouraged or created the framework for pilot programs combining disclosure, apology and early offers of compensation settlement discussions. In one state the impetus for a voluntary program came from the strong interest expressed by that state's Supreme Court in seeing alternative processes tested, together with attorney interest in more expeditious resolution of cases.

In short, leaving the subject to voluntary creation of disclosure programs and access to earlier, less costly and less contentious avenues for compensation may not be adequate as a general matter when measured against existing hurdles. Some form of state policy may be in order to facilitate the stakeholders moving forward. As of this time, Virginia does not have a clear policy on this subject. If anything, Virginia may have an unintended or default policy stemming from existing Virginia law and regulations that have the unintended effect of deterring voluntary disclosure and early resolution programs. In light of all the

[62] David M. Studdert, et. al., *Disclosure of Medical Injury to Patients: An Improbable Risk Management Strategy*, 26 Health Affairs 215 (2007).

information amassed and consideration paid to it, the Committee concluded that its recommendation is a responsible next step with potential for producing innovative, positive developments for Virginia's health care system.

Respectfully Submitted,
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Attachments

Attachment A:	House Joint Resolution 101 (2008)
Attachment B:	HJR 101 Study Committee and Steering Committee Membership
Attachment C:	Reflection on Attorney Roles
Attachment D:	Resource Bank
Attachment E:	Comparison of State Apology Laws
Attachment F:	Comparison of Disclosure/Early Resolution Programs: Initial Survey Results

Attachment A

HOUSE JOINT RESOLUTION NO. 101

Offered January 9, 2008

Prefiled January 8, 2008

Directing the Joint Commission on Health Care to study the use of disclosure, apologies, alternative dispute resolution, and other measures in the case of medical errors and adverse medical outcomes and the impact of such measures on the cost and quality of care, patient confidence, and the medical malpractice system. Report.

Patron-- O'Bannon

Referred to Committee on Rules

WHEREAS, much has been written recently about the incidence of medical errors, the need to disclose medical errors and adverse medical outcomes to patients and their families, and the medical malpractice crisis; and

WHEREAS, the American Medical Association's Code of Medical Ethics provides at E-8.12 that "it is a fundamental ethical requirement that a physician should at all times deal openly and honestly with patients" and that where "a patient suffers significant medical complications that may have resulted from the physician's mistake or judgment...the physician is ethically required to inform the patient of all the facts necessary to ensure understanding of what has occurred"; and

WHEREAS, the Joint Commission on Accreditation of Healthcare Organizations requires certain disclosure by hospitals of medical errors and unanticipated outcomes to patients and their families and the initiation of efforts to prevent future medical errors; and

WHEREAS, § 8.01-581.20:1 of the Code of Virginia permits certain gestures and statements of sympathy or benevolence to be made by providers to patients and family members in connection with a medical error or adverse medical outcome without the gesture or statement being admissible as evidence of liability, but does not make a statement of fault under such circumstances admissible; and

WHEREAS, many studies and demonstration projects in other jurisdictions have suggested that prompt and candid disclosure of medical errors and adverse medical outcomes by providers to patients and their families and the voluntary use of creative alternative dispute resolution techniques may have a number of benefits to the health care system, including improved consumer and provider confidence in and satisfaction with the system, prompt and fair resolution of

possible claims, enhanced reporting of medical errors and adverse medical outcomes and improved procedures to reduce the likelihood of recurrence, improved quality of care, a reduction in the volume and cost of litigation, better patient-provider relationships, and substantial cost savings for the health care system; and

WHEREAS, it would be beneficial to patients, providers, malpractice insurers, and the health care system to study whether and how to implement such measures in the Commonwealth; and

WHEREAS, the Health Law Section of the Virginia Bar Association has volunteered to assist the Joint Commission on Health Care with any aspect of such a study if requested; now, therefore, be it

RESOLVED by the House of Delegates, the Senate concurring, That the Joint Commission on Health Care be directed to study the use of disclosure, apologies, alternative dispute resolution, and other measures in the case of medical errors and adverse medical outcomes and the impact of such measures on the cost and quality of care, patient confidence, and the medical malpractice system.

In conducting its study, the Commission shall review legislation and initiatives in other jurisdictions, consider the need for change to existing Virginia law, and recommend appropriate ways to implement measures in Virginia to achieve these ends, whether on a demonstration basis or for the entire system.

Technical assistance shall be provided to the Commission by the Department of Health and the Department of Health Professions. All agencies of the Commonwealth shall provide assistance to the Commission for this study, upon request.

The Commission shall complete its meetings by November 30, 2008, and the Director shall submit to the Division of Legislative Automated Systems an executive summary of its findings and recommendations no later than the first day of the 2009 Regular Session of the General Assembly. The executive summary shall state whether the Commission intends to submit to the General Assembly and the Governor a report of its findings and recommendations for publication as a House or Senate document. The executive summary and report shall be submitted as provided in the procedures of the Division of Legislative Automated Systems for the processing of legislative documents and reports and shall be posted on the General Assembly's website.

Attachment B
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HJR 101 Study Committee

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Attachment C

Reflection on Attorney Roles:
(9/08/08 Draft by Jeanne and Larry)

A theme emerging from literature review and discussion is that the legal profession plays an important role in how providers and patients respond to unanticipated adverse outcomes.

The Principles of Cooperation adopted by the MSV, VSB, VBA contain principles which encourage attorneys and physicians to create opportunities for healing and closure; Principle 14 urges facilitation of informal, healing conversations between physicians and patients when something is wrong, and Principle 15 urges use of adr to try to resolve disputes, recommending a lawyer/physician mediator team as one approach.

The VSB Rules of Professional Conduct (1.2(a) and Comment 1 thereto) also requires attorneys to counsel clients about the use of dispute resolution processes (in addition to litigation) in line with discussed objectives and means of representation. Rule 2.1 and Comment 2 describe the lawyer's role as counselor/advisor and includes reference to other considerations, such as moral, economic, social and political factors that may be relevant to the client's situation and may include the use of adr processes.

These duties continue throughout the course of representation.

But attorneys, providers and patients seem caught up in a kind of cycle of fear – deny – distrust - blame – shame –fear - deny…... (Anger probably figures in the cycle.) Besides human instincts, an institutional memory may be at work. It's not just the effects of the litigation process. Other factors such as consequences to the physician's career and self - confidence, some of which are triggered by a written demand or filing of a claim, intensify the cycle.

Right now, it would be hard to argue that these principles and ethical rules are having real impact on the cycle.

Yet attention to them could help shift the focus from win/lose in monetary terms to the needs and interests of both provider and patient and the need to provide an opportunity for learning from mistakes. The article by Cris Currie reflects the notion that cooperative learning is a more effective change agent than blame or punishment. (That is not to suggest that fairly compensating an injured patient is punishment but the process for getting there might be perceived as such.)

So the question arises as to how the legal profession can influence events towards such ends.

What options might there be?

1. Background – A Pilot Program

In Pennsylvania, a pilot program between the Montgomery County Bar Association, Montgomery County Medical Society and the Abington Memorial Hospital has been initiated to test an alternative pathway to resolution of patient disputes about care.

Two lawyers from the county bar were interviewed by Larry and Jeanne; they provided illuminating information (but putting our notes together we realize that we may have to go back for more specific information).

The program is the only one known of its kind however other states may be looking into similar ideas. Also, inquiries from other counties in Pennsylvania (including the one in which Philadelphia is located) have been made to the Montgomery Bar Association about how to set up such a program.

Its genesis:

The State Supreme Court wanted to see a pilot program for early resolution of med/mal cases; a former State Supreme Court Justice convened state leaders from the bar and medical society to discuss how to go about getting one started. That group of state leaders identified a county in which a program might be situated; that identification was based on finding a hospital/health system that was willing and able to participate in such a program. (A condition of the hospital/health system's participation was that its insurer had to agree to play.)

Once the county (Montgomery) was identified, a task force was established of county leaders including physicians, lawyers, hospital reps. (and perhaps others). After several discussions, the task force decided to hire a mediation consulting service to help the task force design a format**. [**and] **F**unding **[**for that**]** came from different sources including the bar and the medical society.

The Model:

The model includes a first level which focuses on facilitating direct communication with patients about the patient's care and attempts to resolve matters to everyone's satisfaction including possible compensation of the patient. It is an ombuds type program within the hospital and works with a patient safety committee (PSC). If the HCP decides to offer compensation, the PSC or Ombudsmen discusses arrangements or compensation with the patient after advising the patient of the right to counsel. (We need more precise information about this).

If the first level does not satisfy the parties, the model elevates to the offer of an early mediation process in which lawyers would be involved. The mediators would be a specially trained lawyer/physician team. A panel of trained mediators has been created.

The patient is told about this first level program upon admission to the hospital and is told whom the patient can contact within the hospital should anything arise and the patient wants to initiate that level.

The task force did not create a particular disclosure protocol, e.g. how much the patient is told, whether an apology is included or not, and there was no discussion of requiring disclosure to patients or sharing of peer review or quality assurance privileged information.

The program was launched only a few months ago and at present one matter is moving into the formal mediation process. Bob Slota from the Montgomery County Bar Association who has been directly involved with the program is not aware whether compensation has been paid out as a result of 1st level discussion.

He said that both levels are "early early" (our term) resolution efforts, i.e. prior to filing of a claim or written demand. That removes the data bank issue.

Factors

Pennsylvania law does not have an apology privilege but it does have a privilege for offers of compromise and settlement and Bob Slota believes that the discussion on the first level and transitioning to second level would be covered by that. There was no sense of HCP obligation to disclose privileged information (e.g. QA information).

This model did not create any new privilege.

The hospital staff is a mixed staff so that some physicians do have their own insurers. The hospital group(s) are covered by the hospital policy. The hospital plan is to try to create a culture around this program so that the medical staff can buy into it. Bob thinks they have an advantage in Pennsylvania law: if the hospital pays the settlement – as a kind of global settlement – on the physician's behalf, there is no duty for the physician or hospital to report the settlement to the Board of Medicine.

Getting It off The Ground

The bar association did engage in some PR and conduct outreach to members of its bar. They've not received feedback indicating lawyer reluctance to play but litigation experience within their county makes lawyers desirous of alternatives to litigation. The litigation process moves very slowly in Montgomery County.

Bob Slota's Closing Tips

Be patient.

The process of setting it up and launching it moves slowly.

A key factor in getting their program launched was that the task force had some people on it who were good at and committed to moving it forward.

Referring back to the question, "What might Virginia attorneys do to influence how players respond in cases of unanticipated adverse outcomes?" this type of program seems consistent with the Virginia Principles of Cooperation for Attorneys and Physicians. It also gives Virginia attorneys representing both sides the opportunity to help shift the response to such cases from win/lose in strictly monetary terms to the needs and interests of all parties, including fair compensation for patient.

(Thanks to Michael Ornoff of Mediation Solutions of Virginia in Norfolk, who has consulted to the study co-chairs and alerted us to this program.)

Attachment D

House Joint Resolution 101
Resource Bank

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"Perspective on Disclosure of Unanticipated Outcome Information," American Society for Healthcare Risk Management of the American Hospital Association, (April, 2001).

Ellen L. Barton, J.D., CPCU and Mark A. Kadzielski, Esq., "Tell Me Now and Tell Me Later: Disclosure and Reporting of Medical Errors," American Health Lawyers Association, (June 2007).

Steve Berlin, M.D. and Louis Halikman, M.D. "Communicating Unanticipated Outcomes to Patients" under auspices of Professionals Advocate Insurance Company.

Sean P. Byrne. "Patient Communication and Disclosure of Adverse Events", Presentation to Medical Society of Virginia, Women's Physicians' Conference. (September 28, 2007)

Jonathan R. Cohen, *Apology and Organizations: Exploring an Example From Medical Practice*, Fordham Urban Law Journal, 27:1447-1482 (2000).

Jonathan R. Cohen, *Legislating Apology: The Pros and Cons*, The University of Cincinnati Law Review, 70:819-872 (2002).

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Kathleen Clark, *The Use of Collaborative Law in Medical Error Situations,* The Health Lawyer, Vol. 19, No. 6, June 2007.

Cris M. Currie, *Mediation and Medical Practice Disputes*, Mediation Quarterly (1998).

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N. Beth Dorsey, *Disclosure and apology: medical errors, unanticipated outcomes,* 4 M.L.R. 59 (July 2007).

Scott Forehand, "Helping the Medicine Go Down: How a Spoonful of Mediation Can Alleviate the Problems of Medical Malpractice Litigation" Ohio State Journal on Dispute Resolution (1999).

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Chris Stern Hyman and Carol B. Liebman, "Disclosure of Medical Errors and Events: Effective Communication" and same authors, "A Mediation Skills Model to Manage Disclosure of Errors and Adverse Events to Patients: A Quicker, Less Alienating Route to Closure than Malpractice Litigation," American Bar Association CLE (2006).

Institute of Medicine, *To Err is Human: Building a Safer Health System* (1999)
Allen Kachalia, M.D., J.D., et al. *Does Full Disclosure of Medical Errors Affect Malpractice Liability? The Jury is Still Out,* Joint Commission Journal on Quality and Safety, Vol. 29, No. 10 (October 2003).

Ann J. Kellett, *Healing Angry Wounds: The Roles of Apology and Mediation in Disputes between Physicians and Patients*, Missouri Journal of Dispute Resolution, (1987).

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David M. Studdert, et. al., *Disclosure of Medical Injury to Patients: An Improbable Risk Management Strategy*, 26 Health Affairs 215 (2007).

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Lee Taft, *Disclosing Unanticipated Outcomes: A Challenge to Providers and Their Lawyers,* AHLA Health Lawyers News, (May 2008).

The Health Care Quality Improvement Act, 42 U.S.C 11131.

The National Medical Error Disclosure and Compensation Act of 2005, S. 1784, 109th Cong. (2005).

The Fair and Reliable Medical Justice Act, S. 1337, 109th Cong. (2005).

University of Michigan Hospitals and Health Centers, "Guidelines on How to Disclose Errors."

VA. CODE ANN. § 8.01-576.9

VA. CODE ANN. § 8.01-576.10

VA. CODE ANN. § 8.01-581.20.1

VA. CODE ANN. § 54.1-2909

Albert W. Wu, *Handling Hospital Errors: Is Disclosure the Best Defense?* Annals of Internal Medicine 131, no. 12 (1999).

Attachment E
Comparison of State Apology Laws

State	Arizona	California
Code Section	A.R.S. § 12-2605	West's Ann. Cal. Evid. Code § 1160
Protects:		
Statements	x	x
Affirmations	x	
Gestures	x	x
Writings		x
Conduct	x	
Expressing Apology	x	
Expressing Responsibility	x	
Expressing Liability	x	
Expressing Grief		
Expressing regret		
Expressing fault		
Expressing mistake		
Expressing Error		
Expressing sympathy	x	x
Expressing commiseration	x	
Expressing condolence	x	
Expressing Compassion	x	
Explanation		
Describes sequence of events or significance of events		
Activity constituting voluntary offers of assistance		
General sense of benevolence	x	x
Remedial actions that may be taken		
Made by:		
Health Care Provider	x	
Employee of Health Care Provider	x	
Agent of Health Care Provider		
Person licensed by Medical Board		
Made to:		
alleged victim	x	x
relative of alleged victim	x	x
representative of alleged victim	x	
Time Frame:		
Related to:		
result of unanticipated outcome	x	
accident		x
alleged professional negligence		
adverse outcome		
inadequate treatment		
medical error		
Inadmissible in any wrongful death action:		
Inadmissible in any civil action:	x	x

Inadmissible in any related arbitration:	x	
Inadmissible in any related medical malpractice review:		
Inadmissible in any related mediation:		
State	Colorado	Connecticut
Code Section	C.R.S.A. § 13-25-135	C.G.S.A. § 52-184d
Protects:		
Statements	x	x
Affirmations	x	x
Gestures	x	x
Writings		
Conduct	x	x
Expressing Apology	x	x
Expressing Responsibility		
Expressing Liability		
Expressing Grief		
Expressing regret		
Expressing fault	x	x
Expressing mistake		
Expressing Error		
Expressing sympathy	x	x
Expressing commiseration	x	x
Expressing condolence	x	x
Expressing Compassion	x	x
Explanation		
Describes sequence of events or significance of events		
Activity constituting voluntary offers of assistance		
General sense of benevolence	x	x
Remedial actions that may be taken		
Made by:		
Health Care Provider	x	x
Employee of Health Care Provider	x	x
Agent of Health Care Provider		
Person licensed by Medical Board		
Made to:		
alleged victim	x	x
relative of alleged victim	x	x
representative of alleged victim	x	x
Time Frame:		
Related to:		
result of unanticipated outcome	x	x
Accident		
alleged professional negligence		
adverse outcome		
inadequate treatment		
medical error		
Inadmissible in any wrongful death action:		
Inadmissible in any civil action:	x	x

Inadmissible in any related arbitration:	x	x
Inadmissible in any related medical malpractice review:		
Inadmissible in any related mediation:		
State	Delaware	Florida
Code Section	Del.C. § 4318	West's F.S. A. § 90.4026
Protects:		
Statements	x	x
Affirmations	x	
Gestures	x	x
Writings	x	x
Conduct		
Expressing Apology	x	
Expressing Responsibility		
Expressing Liability		
Expressing Grief		
Expressing regret		
Expressing fault		
Expressing mistake		
Expressing Error		
Expressing sympathy	x	x
Expressing commiseration		x
Expressing condolence	x	
Expressing Compassion	x	x
Explanation		
Describes sequence of events or significance of events		
Activity constituting voluntary offers of assistance		
General sense of benevolence	x	x
Remedial actions that may be taken		
Made by:		
Health Care Provider	x	
Employee of Health Care Provider	x	
Agent of Health Care Provider		
Person licensed by Medical Board		
Made to:		
alleged victim	x	x
relative of alleged victim	x	x
representative of alleged victim	x	
Time Frame:		
Related to:		
result of unanticipated outcome	x	
Accident		
alleged professional negligence		
adverse outcome		
inadequate treatment		
medical error		
Inadmissible in any wrongful death action:		
Inadmissible in any civil action:	x	x

Inadmissible in any related arbitration:		
Inadmissible in any related medical malpractice review:		
Inadmissible in any related mediation:		
State	Georgia	Hawaii
Code Section	Ga. Code Ann. § 24-3-37.1	HRS § 626-1, Rule 409.5
Protects:		
Statements	x	x
Affirmations	x	
Gestures	x	x
Writings		
Conduct	x	
Expressing Apology	x	
Expressing Responsibility		
Expressing Liability		
Expressing Grief		
Expressing regret	x	
Expressing fault		
Expressing mistake	x	
Expressing Error	x	
Expressing sympathy	x	x
Expressing commiseration	x	x
Expressing condolence	x	x
Expressing Compassion	x	
Explanation		
Describes sequence of events or significance of events		
Activity constituting voluntary offers of assistance	x	
General sense of benevolence	x	
Remedial actions that may be taken		
Made by:		
Health Care Provider	x	
Employee of Health Care Provider	x	
Agent of Health Care Provider	x	
Person licensed by Medical Board		
Made to:		
alleged victim	x	
relative of alleged victim	x	
representative of alleged victim	x	
Time Frame:		
Related to:		
result of unanticipated outcome	x	
Accident		
alleged professional negligence		
adverse outcome		
inadequate treatment		
medical error		
Inadmissible in any wrongful death action:		
Inadmissible in any civil action:	x	x

Inadmissible in any related arbitration:		
Inadmissible in any related medical malpractice review:		
Inadmissible in any related mediation:		
State	Idaho	Illinois
Code Section	I.C. § 9-207	735 ILCS 5/8-1901
Protects:		
Statements	x	
Affirmations	x	
Gestures	x	
Writings	x	
Conduct	x	
Expressing Apology	x	x
Expressing Responsibility		
Expressing Liability		
Expressing Grief		x
Expressing regret		
Expressing fault		
Expressing mistake		
Expressing Error		
Expressing sympathy	x	
Expressing commiseration	x	
Expressing condolence	x	
Expressing Compassion	x	
Explanation	x	x
Describes sequence of events or significance of events		
Activity constituting voluntary offers of assistance		
General sense of benevolence	x	
Remedial actions that may be taken		
Made by:		
Health Care Provider	x	x
Employee of Health Care Provider	x	
Agent of Health Care Provider		
Person licensed by Medical Board		
Made to:		
alleged victim	x	x
relative of alleged victim	x	x
representative of alleged victim		x
Time Frame:		72 hours of when HCP knew/should have known potential cause
Related to:		
result of unanticipated outcome	x	x
Accident		
alleged professional negligence		
adverse outcome		
inadequate treatment		x
medical error		
Inadmissible in any wrongful death action:		
Inadmissible in any civil action:	x	x

Inadmissible in any related arbitration:	x	x
Inadmissible in any related medical malpractice review:		
Inadmissible in any related mediation:		x
State	Indiana	Iowa
Code Section	IC 34-43.5-1.2 - IC 34-43.5-1-5	I.C.A. § 622.31
Protects:		
Statements	x	x
Affirmations		x
Gestures	x	x
Writings	x	
Conduct	x	x
Expressing Apology	x	
Expressing Responsibility		
Expressing Liability		
Expressing Grief		
Expressing regret		
Expressing fault		
Expressing mistake		
Expressing Error		
Expressing sympathy	x	x
Expressing commiseration		x
Expressing condolence		x
Expressing Compassion		
Explanation		
Describes sequence of events or significance of events		
Activity constituting voluntary offers of assistance		
General sense of benevolence	x	x
Remedial actions that may be taken		
Made by:		
Health Care Provider		
Employee of Health Care Provider		
Agent of Health Care Provider		
Person licensed by Medical Board		
Made to:		
alleged victim		x
relative of alleged victim		x
representative of alleged victim		x
Time Frame:		
Related to:		
result of unanticipated outcome		
Accident		
alleged professional negligence		x
adverse outcome		
inadequate treatment		
medical error		
Inadmissible in any wrongful death action:		x
Inadmissible in any civil action:	x	x

Inadmissible in any related arbitration:		x
Inadmissible in any related medical malpractice review:	x	x
Inadmissible in any related mediation:		
State	Louisiana	Maine
Code Section	LSA-R.S. 13:3715.5	24 M.R.S.A. § 2907
Protects:		
Statements	x	x
Affirmations		x
Gestures	x	x
Writings	x	
Conduct	x	x
Expressing Apology	x	x
Expressing Responsibility		
Expressing Liability		
Expressing Grief	x	
Expressing regret	x	
Expressing fault		
Expressing mistake		
Expressing Error		
Expressing sympathy	x	x
Expressing commiseration	x	x
Expressing condolence	x	x
Expressing Compassion	x	x
Explanation		
Describes sequence of events or significance of events		
Activity constituting voluntary offers of assistance		
General sense of benevolence	x	x
Remedial actions that may be taken		
Made by:		
Health Care Provider	x	x
Employee of Health Care Provider		x
Agent of Health Care Provider		
Person licensed by Medical Board		
Made to:		
alleged victim	x	x
relative of alleged victim	x	x
representative of alleged victim	x	x
Time Frame:		
Related to:		
result of unanticipated outcome		x
Accident		
alleged professional negligence		
adverse outcome		
inadequate treatment		
medical error		
Inadmissible in any wrongful death action:		
Inadmissible in any civil action:	x	x

Inadmissible in any related arbitration:	x	x
Inadmissible in any related medical malpractice review:		
Inadmissible in any related mediation:		
State	Maryland	Massachusetts
Code Section	MD Code, Courts and Judicial Proceedings § 10-920	M.G.L.A. 233 § 23D
Protects:		
Statements	x	x
Affirmations		
Gestures		x
Writings	x	x
Conduct	x	
Expressing Apology	x	
Expressing Responsibility		
Expressing Liability		
Expressing Grief		
Expressing regret	x	
Expressing fault		
Expressing mistake		
Expressing Error		
Expressing sympathy		x
Expressing commiseration		x
Expressing condolence		
Expressing Compassion		x
Explanation		
Describes sequence of events or significance of events		
Activity constituting voluntary offers of assistance		
General sense of benevolence		x
Remedial actions that may be taken		
Made by:		
Health Care Provider	x	
Employee of Health Care Provider		
Agent of Health Care Provider		
Person licensed by Medical Board		
Made to:		
alleged victim		x
relative of alleged victim		x
representative of alleged victim		
Time Frame:		
Related to:		
result of unanticipated outcome		
Accident		x
alleged professional negligence		
adverse outcome		
inadequate treatment		
medical error		
Inadmissible in any wrongful death action:		

Inadmissible in any civil action:	x	x
Inadmissible in any related arbitration:	x	
Inadmissible in any related medical malpractice review:		
Inadmissible in any related mediation:		
State	Missouri	Montana
Code Section	V.A.M.S. 538.229	MT ST 26-1-814
Protects:		
Statements	x	x
Affirmations		x
Gestures	x	x
Writings	x	x
Conduct		x
Expressing Apology		x
Expressing Responsibility		
Expressing Liability		
Expressing Grief		
Expressing regret		
Expressing fault		
Expressing mistake		
Expressing Error		
Expressing sympathy	x	x
Expressing commiseration	x	x
Expressing condolence		x
Expressing Compassion	x	x
Explanation		
Describes sequence of events or significance of events		
Activity constituting voluntary offers of assistance		
General sense of benevolence	x	x
Remedial actions that may be taken		
Made by:		
Health Care Provider		
Employee of Health Care Provider		
Agent of Health Care Provider		
Person licensed by Medical Board		
Made to:		
alleged victim	x	x
relative of alleged victim	x	x
representative of alleged victim		x
Time Frame:		
Related to:		
result of unanticipated outcome		
Accident		
alleged professional negligence		
adverse outcome		
inadequate treatment		
medical error		
Inadmissible in any wrongful death action:		

Inadmissible in any civil action:	x	x
Inadmissible in any related arbitration:		
Inadmissible in any related medical malpractice review:		
Inadmissible in any related mediation:		
State	Nebraska	New Hampshire
Code Section	NE ST § 27-1201	N.H. Rev. Stat. § 507-E:4
Protects:		
Statements	x	x
Affirmations	x	
Gestures	x	
Writings		x
Conduct	x	x
Expressing Apology	x	
Expressing Responsibility		
Expressing Liability		
Expressing Grief		
Expressing regret		
Expressing fault		
Expressing mistake		
Expressing Error		
Expressing sympathy	x	x
Expressing commiseration	x	x
Expressing condolence	x	
Expressing Compassion	x	x
Explanation		
Describes sequence of events or significance of events		
Activity constituting voluntary offers of assistance		
General sense of benevolence	x	x
Remedial actions that may be taken		
Made by:		
Health Care Provider	x	
Employee of Health Care Provider	x	
Agent of Health Care Provider		
Person licensed by Medical Board		
Made to:		
alleged victim	x	x
relative of alleged victim	x	x
representative of alleged victim	x	
Time Frame:		
Related to:		
result of unanticipated outcome	x	
Accident		
alleged professional negligence		
adverse outcome		
inadequate treatment		
medical error		
Inadmissible in any wrongful death action:		

Inadmissible in any civil action:	x	x
Inadmissible in any related arbitration:	x	
Inadmissible in any related medical malpractice review:		
Inadmissible in any related mediation:		
State	North Carolina	North Dakota
Code Section	NC ST EV § 8C-1, Rule 413	ND ST 31-04-12
Protects:		
Statements		x
Affirmations		x
Gestures		x
Writings		
Conduct		x
Expressing Apology	x	x
Expressing Responsibility		
Expressing Liability		
Expressing Grief		
Expressing regret		
Expressing fault		
Expressing mistake		
Expressing Error		
Expressing sympathy		x
Expressing commiseration		x
Expressing condolence		x
Expressing Compassion		x
Explanation		
Describes sequence of events or significance of events		
Activity constituting voluntary offers of assistance	x	
General sense of benevolence		x
Remedial actions that may be taken	x	
Made by:		
Health Care Provider	x	x
Employee of Health Care Provider		x
Agent of Health Care Provider		x
Person licensed by Medical Board		
Made to:		
alleged victim		x
relative of alleged victim		x
representative of alleged victim		x
Time Frame:		
Related to:		
result of unanticipated outcome		
Accident		
alleged professional negligence		
adverse outcome	x	
inadequate treatment		
medical error		
Inadmissible in any wrongful death action:		

Inadmissible in any civil action:	x	x
Inadmissible in any related arbitration:		x
Inadmissible in any related medical malpractice review:		x
Inadmissible in any related mediation:		
State	Ohio	Oklahoma
Code Section	R.C. § 2317.43	63 Okl.St.Ann. § 1-1708.1H
Protects:		
Statements	x	x
Affirmations	x	x
Gestures	x	x
Writings		
Conduct	x	x
Expressing Apology	x	x
Expressing Responsibility		
Expressing Liability		
Expressing Grief		
Expressing regret		
Expressing fault		
Expressing mistake		
Expressing Error		
Expressing sympathy	x	x
Expressing commiseration	x	x
Expressing condolence	x	x
Expressing Compassion	x	x
Explanation		
Describes sequence of events or significance of events		
Activity constituting voluntary offers of assistance		
General sense of benevolence	x	x
Remedial actions that may be taken		
Made by:		
Health Care Provider	x	x
Employee of Health Care Provider	x	x
Agent of Health Care Provider		
Person licensed by Medical Board		
Made to:		
alleged victim	x	x
relative of alleged victim	x	x
representative of alleged victim	x	x
Time Frame:		
Related to:		
result of unanticipated outcome	x	x
Accident		
alleged professional negligence		
adverse outcome		
inadequate treatment		
medical error		
Inadmissible in any wrongful death action:		

Inadmissible in any civil action:	x	x
Inadmissible in any related arbitration:	x	
Inadmissible in any related medical malpractice review:		
Inadmissible in any related mediation:		
State	Oregon	South Carolina
Code Section	O.R.S. § 677.082	SC ST § 19-1-190
Protects:		
Statements	x	x
Affirmations		x
Gestures		x
Writings	x	
Conduct	x	x
Expressing Apology	x	x
Expressing Responsibility		
Expressing Liability		
Expressing Grief		
Expressing regret	x	x
Expressing fault		
Expressing mistake		x
Expressing Error		x
Expressing sympathy		x
Expressing commiseration		x
Expressing condolence		x
Expressing Compassion		x
Explanation		
Describes sequence of events or significance of events		
Activity constituting voluntary offers of assistance		
General sense of benevolence		x
Remedial actions that may be taken		
Made by:		
Health Care Provider		x
Employee of Health Care Provider		x
Agent of Health Care Provider		
Person licensed by Medical Board	x	
Made to:		
alleged victim		x
relative of alleged victim		x
representative of alleged victim		x
Time Frame:		
Related to:		
result of unanticipated outcome		x
Accident		
alleged professional negligence		
adverse outcome		
inadequate treatment		
medical error		
Inadmissible in any wrongful death action:		

Inadmissible in any civil action:	x	x
Inadmissible in any related arbitration:		
Inadmissible in any related medical malpractice review:		
Inadmissible in any related mediation:		
State	South Dakota	Tennessee
Code Section	SDCL § 19-12-14	Rules of Evid., Rule 409.1
Protects:		
Statements		x
Affirmations		
Gestures		x
Writings		x
Conduct		
Expressing Apology	x	
Expressing Responsibility		
Expressing Liability		
Expressing Grief		
Expressing regret		
Expressing fault		
Expressing mistake		
Expressing Error		
Expressing sympathy		x
Expressing commiseration		x
Expressing condolence		
Expressing Compassion		x
Explanation		
Describes sequence of events or significance of events		
Activity constituting voluntary offers of assistance	x	
General sense of benevolence		x
Remedial actions that may be taken	x	
Made by:		
Health Care Provider	x	
Employee of Health Care Provider		
Agent of Health Care Provider		
Person licensed by Medical Board		
Made to:		
alleged victim		x
relative of alleged victim		x
representative of alleged victim		
Time Frame:		
Related to:		
result of unanticipated outcome		
Accident		x
alleged professional negligence		
adverse outcome	x	
inadequate treatment		
medical error		
Inadmissible in any wrongful death action:		

Inadmissible in any civil action:	x	x
Inadmissible in any related arbitration:		
Inadmissible in any related medical malpractice review:		
Inadmissible in any related mediation:		
State	Texas	Utah
Code Section	V.T.C.A. § 18.061	U.C.A. 1953 § 78-14-18
Protects:		
Statements	x	x
Affirmations		x
Gestures	x	x
Writings	x	
Conduct		x
Expressing Apology		x
Expressing Responsibility		
Expressing Liability		
Expressing Grief		
Expressing regret		
Expressing fault		
Expressing mistake		
Expressing Error		
Expressing sympathy	x	x
Expressing commiseration	x	x
Expressing condolence		x
Expressing Compassion	x	x
Explanation		
Describes sequence of events or significance of events		x
Activity constituting voluntary offers of assistance		
General sense of benevolence	x	x
Remedial actions that may be taken		
Made by:		
Health Care Provider		
Employee of Health Care Provider		
Agent of Health Care Provider		
Person licensed by Medical Board		
Made to:		
alleged victim	x	
relative of alleged victim	x	
representative of alleged victim		
Time Frame:		
Related to:		
result of unanticipated outcome		x
Accident	x	
alleged professional negligence		
adverse outcome		
inadequate treatment		
medical error		
Inadmissible in any wrongful death action:		

Inadmissible in any civil action:	x	x
Inadmissible in any related arbitration:		x
Inadmissible in any related medical malpractice review:		
Inadmissible in any related mediation:		
State	Vermont	Virginia
Code Section	12 V.S.A. § 1912	Va. Code § 8.01-52.1
Protects:		
Statements	x	x
Affirmations		x
Gestures		x
Writings		x
Conduct		x
Expressing Apology	x	
Expressing Responsibility		
Expressing Liability		
Expressing Grief		
Expressing regret	x	
Expressing fault		
Expressing mistake		
Expressing Error		
Expressing sympathy		x
Expressing commiseration		
Expressing condolence		
Expressing Compassion		
Explanation	x	
Describes sequence of events or significance of events		
Activity constituting voluntary offers of assistance		
General sense of benevolence		x
Remedial actions that may be taken		
Made by:		
Health Care Provider	x	x
Employee of Health Care Provider		
Agent of Health Care Provider	x	x
Person licensed by Medical Board		
Made to:		
alleged victim		
relative of alleged victim		x
representative of alleged victim		x
Time Frame:	30 days from when HCP knew/should have known conseq. of error	
Related to:		
result of unanticipated outcome		x
Accident		
alleged professional negligence		
adverse outcome		
inadequate treatment		
medical error	x	
Inadmissible in any wrongful death action:		x

Inadmissible in any civil action:	x	
Inadmissible in any related arbitration:	x	x
Inadmissible in any related medical malpractice review:	x	x
Inadmissible in any related mediation:	x	

State	Washington	Washington
Code Section	RCWA 5.66.010	RCWA 5.64.010
Protects:		
Statements	x	x
Affirmations		x
Gestures	x	x
Writings	x	
Conduct		x
Expressing Apology		x
Expressing Responsibility		
Expressing Liability		
Expressing Grief		
Expressing regret		
Expressing fault		x
Expressing mistake		
Expressing Error		
Expressing sympathy	x	x
Expressing commiseration		x
Expressing condolence		x
Expressing Compassion		x
Explanation		
Describes sequence of events or significance of events		
Activity constituting voluntary offers of assistance		
General sense of benevolence	x	x
Remedial actions that may be taken		x
Made by:		
Health Care Provider		x
Employee of Health Care Provider		
Agent of Health Care Provider		
Person licensed by Medical Board		
Made to:		
alleged victim	x	x
relative of alleged victim	x	
representative of alleged victim		
Time Frame:		w/in 30 days of act/r omission; or w/in 30 days of HCP discovering
Related to:		
result of unanticipated outcome		
accident	x	
alleged professional negligence		x
adverse outcome		
inadequate treatment		
medical error		

Inadmissible in any wrongful death action:		
Inadmissible in any civil action:	x	
Inadmissible in any related arbitration:		
Inadmissible in any related medical malpractice review:		
Inadmissible in any related mediation:		
State	West Virginia	Wyoming
Code Section	W.Va. Code § 55-7-11a	W.S. 1977 § 1-1-130
Protects:		
Statements	x	x
Affirmations	x	x
Gestures	x	x
Writings		
Conduct	x	x
Expressing Apology	x	x
Expressing Responsibility		
Expressing Liability		
Expressing Grief		
Expressing regret		
Expressing fault		
Expressing mistake		
Expressing Error		
Expressing sympathy	x	x
Expressing commiseration	x	x
Expressing condolence	x	x
Expressing Compassion	x	x
Explanation		
Describes sequence of events or significance of events		
Activity constituting voluntary offers of assistance		
General sense of benevolence	x	x
Remedial actions that may be taken		
Made by:		
Health Care Provider	x	x
Employee of Health Care Provider		x
Agent of Health Care Provider		
Person licensed by Medical Board		
Made to:		
alleged victim	x	x
relative of alleged victim	x	x
representative of alleged victim	x	x
Time Frame:		
Related to:		
result of unanticipated outcome		x
Accident		
alleged professional negligence		
adverse outcome		
inadequate treatment		
medical error		

Inadmissible in any wrongful death action:		
Inadmissible in any civil action:	x	x
Inadmissible in any related arbitration:	x	x
Inadmissible in any related medical malpractice review:		
Inadmissible in any related mediation:	x	

Attachment F
Comparison of Disclosure/Early Resolution Programs: Initial Survey Results
University of Illinois Medical Center

Disclosure Program	**University of Illinois Medical Center**
Location (State) of Disclosure Program	Illinois
What Type of Events Prompt Disclosure?	Upon any event, investigation begins to determine whether further investigation is warranted
Both positive and negative outcomes?	
Preventable or Non-preventable harm?	
Any error?	Clear Error prompts apology with full disclosure; However, anytime there's an adverse event, clinicians can call the Patient Communication Consult Service hotline
Who determines need for disclosure?	If it is a probable error, a rapid investigation team determines whether it's a clear error
Who Discloses?	
Individual or as Team?	Usually Individual
If as team, who comprises team?	
To Whom Do You Disclose?	Patients and families
What Information Is Disclosed?	What occurred, facts
Is Apology Offered as Part of Disclosure?	Yes
If yes, under what circumstances?	If there was a clear error as determined by investigation team
Advice on dealing with the harm/injury?	
Information on what action is being taken to prevent recurrence?	
When Does Disclosure Occur?	As soon as discovered.
Where Does Disclosure Occur?	
How Does Disclosure Occur?	
Is Participation in the Disclosure Program Voluntary or Mandatory?	Voluntary
By Whom?	
What if a physician does not want to participate in the disclosure program?	
What type of training is provided for persons making disclosure?	First, everyone has classroom training. Then, they have Patient Communication Consult Service for on-the-spot training whenever something goes wrong. Monthly symposia on issues related to full disclosure and communication. Have form where staff can evaluate the effectiveness of full disclosure and discuss at monthly group meetings. Also hold seminars and offer employee assistance for the person who made the error.
What support services are offered?	
How is Compensation Determined?	Circumstances
When is Compensation Offered?	Compensation is considered as a remedy anytime an apology is offered with full disclosure
How is Compensation Offered?	
How is the compensation issue presented?	A liaison is created between the patient and family and the claims department, since the doctors and nurses shouldn't

	have to manage the process of financial compensation
By Written Agreement?	
How is Settlement of a Claim Reached?	
Is legal representation suggested?	
And if so, when?	
Would the settlement/compensation have to be reported to the NPDB?	
Does the Patient/Patient's Family Sign a Waiver?	
What are the terms of the waiver?	
What, if any, elements of the disclosure are confidential?	
How does the Disclosure Program interact with peer review and quality control?	
What mechanisms provided to minimize future events of the same kind from occurring?	
Is this included in the disclosure?	
Reasons for Implementing Disclosure Program	Because it's the right thing to do. When they hurt someone through unreasonable care, they need to make it right. When the care of the staff is reasonable, they need to support their staff. They need to learn something from medical errors that will allow them to improve care.
How are the Participants of the Disclosure Program Insured?	
# of Claims Before Implementing Disclosure Program	
# of Claims After Implementing Disclosure Program	
Total amount of compensation before and after implementing disclosure program.	
How does the program measure impact?	
Has the Disclosure Program resulted in increased patient safety?	Yes
If yes, how determined?	Every case has its own associated process improvements and they track them all. Found that failure to supervise residents led to many errors, so they have greater engagement by attendings and education and supervision on patient safety-related issues. Additionally the time it takes for clinicians to receive critical test results and to communicate those results to patients has been reduced.
Has the Disclosure Program resulted in increased provider satisfaction?	Yes
If yes, how determined?	Attitudes have improved.
Has the Disclosure Program resulted in increased patient satisfaction?	Yes
If yes, how determined?	Families who have experienced an error or an adverse outcome continue to seek care there
State's Apology Law	735 ILCS 5/8-1901
Other state laws (malpractice, insurance, etc.) encouraging disclosure	
Effect of Disclosure on Licensure	
Effect of Disclosure on Insurance Coverage	

General Comments	Learned/modeled from University of MI Biggest barrier to full disclosure was defense bar. Disclosure process ends when have assured themselves the likelihood of reoccurrence is nil. Providing full disclosure and rapid settlement, but also learning from errors Best way to successfully manage medical malpractice is through safer care.

University of Michigan Health System

Disclosure Program	**University of Michigan Health System**
Location (State) of Disclosure Program	Michigan
What Type of Events Prompt Disclosure?	
Both positive and negative outcomes?	
Preventable or Non-preventable harm?	
Any error?	Yes
Who determines need for disclosure?	Risk Department: Everything hinges on the question of whether care was reasonable or unreasonable. Strive to thoroughly review written claims within 3 months. Submitted to the Medical Liability Review Committee which determines reasonableness of the care.
Who Discloses?	
Individual or as Team?	Chief Risk Officer or a Risk Management consultant.
If as team, who comprises team?	
To Whom Do You Disclose?	Patient
What Information Is Disclosed?	Explanation of what happened.
Is Apology Offered as Part of Disclosure?	Yes, along with explanation and expression of empathy. No excuses
If yes, under what circumstances?	Anytime there was unreasonable care
Advice on dealing with the harm/injury?	Yes
Information on what action is being taken to prevent recurrence?	Yes
When Does Disclosure Occur?	Once the issues have been clarified; Initially they focus on care of patient and family and give reasonable expectations about when will receive more information
Where Does Disclosure Occur?	Disclosure discussions usually continue over time.
How Does Disclosure Occur?	
Is Participation in the Disclosure Program Voluntary or Mandatory?	Voluntary
By Whom?	
What if a physician does not want to participate in the disclosure program?	

What type of training is provided for persons making disclosure? What support services are offered?	Everyone in the risk management department is trained in mediation.
How is Compensation Determined?	Research, expert reviews.
When is Compensation Offered?	Link compensation to the initial question of whether care was reasonable.
How is Compensation Offered?	If care was unreasonable, risk department has already worked up damages and presents that issue to the patient. If the patient argues, they say, "tell us why we're wrong". Credibility is so high now that it is usually accepted.
How is the compensation issue presented?	
By Written Agreement?	Yes, and if compensation is accepted, then it is by written agreement.
How is Settlement of a Claim Reached?	
Is legal representation suggested?	Sometimes
And if so, when?	Depends on the circumstances
Would the settlement/compensation have to be reported to the NPDB?	Not always. There is a loophole in the law that states that every provider with employed staff, if the compensation is offered by the institution, then no reporting is required. Loophole might be fixed soon.
Does the Patient/Patient's Family Sign a Waiver?	Yes, if compensation is offered.
What are the terms of the waiver?	Say that closure for all is the goal.
What, if any, elements of the disclosure are confidential?	
How does the Disclosure Program interact with peer review and quality control?	The Medical Liability Review Committee also considers every submitted case for peer review, clinical quality improvement and educational opportunities. But the committee's role is restricted to medical issues and quality of care concerns. Its conclusions inform claims management, but does not oversee litigation or involve itself in the financial aspects of claim management. Forwards the issue to Quality Control and Peer Review.
What mechanisms provided to minimize future events of the same kind from occurring?	Once it is determined that an error was unreasonable, the Medical Liability Review Committee sends the issue to a Clinical Quality Improvement and an Educational Opportunities group.
Is this included in the disclosure?	Yes, but not necessarily the outcome.
Reasons for Implementing Disclosure Program	Initially, to save money: "If you knew you made an error and would have to settle anyway, wouldn't it make more sense simply to admit the error and compensate patients, saving hundreds of thousands of dollars in court costs and attorney's fees?" Have found in addition that open disclosure paves the way for clinical improvement because being open with patients starts with being honest with yourself, a necessary prerequisite to any real improvement.
How are the Participants of the Disclosure Program Insured?	Self-insured: Refunded so much money because they aren't seeing losses.
# of Claims Before Implementing Disclosure Program	
# of Claims After Implementing Disclosure Program	Decreased by half and the cost of handling them decreased by 2/3's

Total amount of compensation before and after implementing disclosure program.	
How does the program measure impact?	
Has the Disclosure Program resulted in increased patient safety?	Yes
If yes, how determined?	Energized patient safety efforts because they openly talk about errors and confront the issues on a departmental and institutional level. That is impossible in a deny and defend culture.
Has the Disclosure Program resulted in increased provider satisfaction?	Yes
If yes, how determined?	Docs feel empowered by the policy because they finally have permission to tell the truth, something they intrinsically want to do.
Has the Disclosure Program resulted in increased patient satisfaction?	
If yes, how determined?	
Other state laws (malpractice, insurance, etc.) encouraging disclosure	Compulsory 6 month presuit notice period. Before a malpractice suit may be filed, the patient must present details of the claims in writing. Once this notice is served, a suit cannot be filed for 182 days. This allows prospective defendants time to investigate the claim, gives them the opportunity to meet with the patient, and offers patients time to reconsider their decision to sue.
Effect of Disclosure on Licensure	Not unless a pattern has emerged.
Effect of Disclosure on Insurance Coverage	None
General Comments	They fight to defend themselves when their care was reasonable.
	They fight to defend themselves when their care was reasonable. They systematically use mistakes as tools for learning and for making needed changes to their system.

Virginia Mason Medical Center

Disclosure Program	**Virginia Mason Medical Center**
Location (State) of Disclosure Program	Washington
What Type of Events Prompt Disclosure?	Have a Patient Safety Alert System where anyone in the facility from housekeeping on up, can report a patient safety issue
Both positive and negative outcomes?	
Preventable or Non-preventable harm?	
Any error?	Yes, any patient safety issue/incident
Who determines need for disclosure?	
Who Discloses?	Attending physician or physician with best relationship with patient.
Individual or as Team?	
If as team, who comprises team?	
To Whom Do You Disclose?	Patient
What Information Is Disclosed?	
Is Apology Offered as Part of Disclosure?	Yes

If yes, under what circumstances?	Always offer apology with expression of regret; don't normally give explanation because at time, usually too soon to know
Advice on dealing with the harm/injury?	Focus on current needs of patient
Information on what action is being taken to prevent recurrence?	Not at time of disclosure because too soon. Also, don't get specific about process improvement because of liability issues, so speak in general terms.
When Does Disclosure Occur?	If there was actual harm, they complete an investigation of actual harm to a patient involving permanent or close to permanent damage within 24 hours; If it's a near miss, the investigation can take a week. So disclosure occurs after the investigation.
Where Does Disclosure Occur?	
How Does Disclosure Occur?	
Is Participation in the Disclosure Program Voluntary or Mandatory?	Voluntary
By Whom?	
What if a physician does not want to participate in the disclosure program?	
What type of training is provided for persons making disclosure?	2 and 1/2 hour workshops each year to teach physicians how to communicate medical errors and unanticipated events to patients and families. It is not mandatory.
What support services are offered?	Also developed role of "situation facilitator" - 12 people who have thorough knowledge of how to communicate errors. They undergo 2 full days of training. Physicians then consult them whenever an error needs to be disclosed If there is indication that patient will file a claim, risk department alerts the claims specialist and they fill out potential form. Completely separate from the disclosure process. Always tell the patient to be thinking about what would resolve the issue before speaking with claims.
How is Compensation Determined?	
When is Compensation Offered?	
How is Compensation Offered?	
How is the compensation issue presented?	
By Written Agreement?	
How is Settlement of a Claim Reached?	
Is legal representation suggested?	
And if so, when?	
Would the settlement/compensation have to be reported to the NPDB?	
Does the Patient/Patient's Family Sign a Waiver?	
What are the terms of the waiver?	
What, if any, elements of the disclosure are confidential?	

How does the Disclosure Program interact with peer review and quality control?	
What mechanisms provided to minimize future events of the same kind from occurring?	
Is this included in the disclosure?	
Reasons for Implementing Disclosure Program	Wanted complete transparency
How are the Participants of the Disclosure Program Insured?	Self-insured
# of Claims Before Implementing Disclosure Program	
# of Claims After Implementing Disclosure Program	Decreased; but won't necessarily attribute the cause to Alert System
Total amount of compensation before and after implementing disclosure program.	
How does the program measure impact?	
Has the Disclosure Program resulted in increased patient safety?	
If yes, how determined?	
Has the Disclosure Program resulted in increased provider satisfaction?	
If yes, how determined?	
Has the Disclosure Program resulted in increased patient satisfaction?	
If yes, how determined?	
Other state laws (malpractice, insurance, etc.) encouraging disclosure	
Effect of Disclosure on Licensure	
Effect of Disclosure on Insurance Coverage	
General Comments	Led to increased reporting of actual as well as potential errors. Since introduced Alert System in 2002, went from an average of 3 alerts to well over 300 a month. Goal is total transparency

Kaiser Permanente

Disclosure Program	Kaiser Permanente
Location (State) of Disclosure Program	Various states
What Type of Events Prompt Disclosure?	Unanticipated Adverse outcomes
Both positive and negative outcomes?	
Preventable or Non-preventable harm?	
Any error?	

Who determines need for disclosure?	Before determine need for disclosure, first priority is to address current health needs of patient in wake of adverse outcome
Who Discloses?	Designate a lead coordinator to manage communications with the patient or patient representative. Dr. usually does initial disclosure. However, have Healthcare Ombudsman/Mediator to ensure open and continued dialogue until patient needs are met.
Individual or as Team?	
If as team, who comprises team?	
To Whom Do You Disclose?	Patient/Patient Representative; Additionally report to various people, departments, entities or agencies that an unanticipated adverse outcome has occurred. Internal notification and reporting is conducted in accordance with a facility Situation Management
What Information Is Disclosed?	Ensure that the Medical Record contains complete and accurate information regarding the unanticipated adverse outcome: objective details of the situation, patient's condition immediately prior to event, intervention and patient response, notification of patient
Is Apology Offered as Part of Disclosure?	Yes
If yes, under what circumstances?	Unanticipated Adverse outcomes
Advice on dealing with the harm/injury? **Information on what action is being taken to prevent recurrence?**	Honest communication about what will happen next
When Does Disclosure Occur?	Immediately after meeting patient's immediate needs in aftermath of unanticipated adverse outcome
Where Does Disclosure Occur?	
How Does Disclosure Occur?	After taking care of immediate needs and initial disclosure meeting, have follow-up meetings to convey new information discovered and corrective action taken; Maintain an ongoing dialogue regarding patient care issues; identify and address new concerns
Is Participation in the Disclosure Program Voluntary or Mandatory?	Voluntary
By Whom?	
What if a physician does not want to participate in the disclosure program?	
What type of training is provided for persons making disclosure?	4 hour training for physicians to have open disclosure conversations with patients and families and established guidelines; Created Situation Management Teams with trusted people in the medical center. Dr. can call any of these people for immediate counsel
What support services are offered?	Established peer support groups; Developed ways to foster continuing dialogue until the patient and family feel their needs have been met; Identified individuals or departments that can provide needed support to the staff members involved.
How is Compensation Determined?	
When is Compensation Offered?	

How is Compensation Offered?	
How is the compensation issue presented?	
By Written Agreement?	
How is Settlement of a Claim Reached?	
Is legal representation suggested?	
And if so, when?	
Would the settlement/compensation have to be reported to the NPDB?	
Does the Patient/Patient's Family Sign a Waiver?	
What are the terms of the waiver?	
What, if any, elements of the disclosure are confidential?	The Ombudsman is an internal, neutral, confidential link between the patient and the facility.
How does the Disclosure Program interact with peer review and quality control?	
What mechanisms provided to minimize future events of the same kind from occurring?	
Is this included in the disclosure?	
Reasons for Implementing Disclosure Program	Right thing to do and to reduce the number of medical malpractice suits
How are the Participants of the Disclosure Program Insured?	
# of Claims Before Implementing Disclosure Program	
# of Claims After Implementing Disclosure Program	
Total amount of compensation before and after implementing disclosure program.	
How does the program measure impact?	
Has the Disclosure Program resulted in increased patient safety?	
If yes, how determined?	
Has the Disclosure Program resulted in increased provider satisfaction?	Yes
If yes, how determined?	Surveyed: 96% rated experience excellent or very good
Has the Disclosure Program resulted in increased patient satisfaction?	Yes
If yes, how determined?	Surveyed: 75% strongly agreed that access to ombudsman program was easy, cases kept confidential, would use program again, and would recommend program to others.
Other state laws (malpractice, insurance, etc.) encouraging disclosure	
Effect of Disclosure on Licensure	

Effect of Disclosure on Insurance Coverage	
General Comments	Ombudsman program seems to help patients understand issues and resolve their concerns

Geisinger Health System

Disclosure Program	**Geisinger Health System**
Location (State) of Disclosure Program	Pennsylvania
What Type of Events Prompt Disclosure?	Serious event - causes death or compromises patient safety and results in an unanticipated injury that requires the delivery of additional health care services to the patient. Sentinel event- an unexpected occurrence involving death or serious physical injury
Both positive and negative outcomes?	
Preventable or Non-preventable harm?	
Any error?	
Who determines need for disclosure?	Event. Event can be reported to dept. of quality by either patient or provider. Have hotline for patients to report concerns or problems or can report to patient representatives. If patient rep believes event might be of higher level, then reported to
Who Discloses?	
Individual or as Team?	Team
If as team, who comprises team?	Physician and others specially trained to mentor others through the process, and esp. help physicians through them and to improve their skills.
To Whom Do You Disclose?	Patient
What Information Is Disclosed?	
Is Apology Offered as Part of Disclosure?	Yes
If yes, under what circumstances?	
Advice on dealing with the harm/injury?	
Information on what action is being taken to prevent recurrence?	Conducts root cause analysis to determine what they will change to ensure the error doesn't happen again.
When Does Disclosure Occur?	
Where Does Disclosure Occur?	
How Does Disclosure Occur?	
Is Participation in the Disclosure Program Voluntary or Mandatory?	Mandatory
By Whom?	State law
What if a physician does not want to participate in the disclosure program?	
What type of training is provided for persons making disclosure?	Provided training to teams. Used story-telling and videotaped interviews to help clinicians understand what patients want and deserve. No formal training program, but training opportunities throughout the year. Also have ongoing annual training in service
What support services are offered?	
How is Compensation Determined?	

When is Compensation Offered?	
How is Compensation Offered?	
How is the compensation issue presented?	
By Written Agreement?	
How is Settlement of a Claim Reached?	
Is legal representation suggested?	
And if so, when?	
Would the settlement/compensation have to be reported to the NPDB?	
Does the Patient/Patient's Family Sign a Waiver?	
What are the terms of the waiver?	
What, if any, elements of the disclosure are confidential?	
How does the Disclosure Program interact with peer review and quality control?	
What mechanisms provided to minimize future events of the same kind from occurring?	Once root cause analysis complete, report to performance improvement committee and to patient safety committee. Any change is then directed through the leadership of the facility.
Is this included in the disclosure?	
Reasons for Implementing Disclosure Program	State law. But made it easier to follow ethical instincts
How are the Participants of the Disclosure Program Insured?	
# of Claims Before Implementing Disclosure Program	
# of Claims After Implementing Disclosure Program	Fewer claims filed than national average and number of claims for them has decreased.
Total amount of compensation before and after implementing disclosure program.	
How does the program measure impact?	
Has the Disclosure Program resulted in increased patient safety?	
If yes, how determined?	
Has the Disclosure Program resulted in increased provider satisfaction?	
If yes, how determined?	
Has the Disclosure Program resulted in increased patient satisfaction?	
If yes, how determined?	
Other state laws (malpractice, insurance, etc.) encouraging disclosure	Medical Care Availability and Reduction of Error Act (MCARE): "A person who has sustained injury or death as a result of medical negligence by a health care provider must be afforded a prompt determination and fair compensation. Every effort must be made
Effect of Disclosure on Licensure	

Effect of Disclosure on Insurance Coverage	
General Comments	Felt state law helped stem fear of legal repercussions by protecting peer review coverage so they could do the right thing while minimizing the effect of lawsuits. Experienced significant increase in reporting of events and increase in number of conversations physicians have had with patients about these events. Adopt patient-centered, rather than legalistic, philosophy toward disclosure. Concentrate on ethics

Catholic Health Initiatives

Disclosure Program	**Catholic Health Initiatives**
Location (State) of Disclosure Program	Colorado, various
What Type of Events Prompt Disclosure?	
Both positive and negative outcomes?	adverse outcome
Preventable or Non-preventable harm?	
Any error?	Yes
Who determines need for disclosure?	
Who Discloses?	
Individual or as Team?	
If as team, who comprises team?	
To Whom Do You Disclose?	Patient/family
What Information Is Disclosed?	What happened, what you know
Is Apology Offered as Part of Disclosure?	Yes
If yes, under what circumstances?	All
Advice on dealing with the harm/injury?	
Information on what action is being taken to prevent recurrence?	
When Does Disclosure Occur?	All adverse events reported to risk team within 48 hours. Then it is passed along to key persons within the organization.
Where Does Disclosure Occur?	
How Does Disclosure Occur?	
Is Participation in the Disclosure Program Voluntary or Mandatory?	Voluntary

By Whom?	
What if a physician does not want to participate in the disclosure program?	
What type of training is provided for persons making disclosure?	
What support services are offered?	
How is Compensation Determined?	Discussions
When is Compensation Offered?	If have liability, don't fight. Ask how best to compensate patient
How is Compensation Offered?	Through mediation. Beginning with an apology
How is the compensation issue presented?	
By Written Agreement?	
How is Settlement of a Claim Reached?	
Is legal representation suggested?	
And if so, when?	
Would the settlement/compensation have to be reported to the NPDB?	
Does the Patient/Patient's Family Sign a Waiver?	
What are the terms of the waiver?	
What, if any, elements of the disclosure are confidential?	
How does the Disclosure Program interact with peer review and quality control?	
What mechanisms provided to minimize future events of the same kind from occurring?	
Is this included in the disclosure?	
Reasons for Implementing Disclosure Program	Right thing to do. Gave physicians permission to do what ethically wanted and required to do
How are the Participants of the Disclosure Program Insured?	
# of Claims Before Implementing Disclosure Program	Decreasing
# of Claims After Implementing Disclosure Program	

Total amount of compensation before and after implementing disclosure program.	
How does the program measure impact?	
Has the Disclosure Program resulted in increased patient safety?	
If yes, how determined?	
Has the Disclosure Program resulted in increased provider satisfaction?	
If yes, how determined?	
Has the Disclosure Program resulted in increased patient satisfaction?	
If yes, how determined?	
Other state laws (malpractice, insurance, etc.) encouraging disclosure	
Effect of Disclosure on Licensure	
Effect of Disclosure on Insurance Coverage	
General Comments	Disclose everything, if get sued, so be it. Have to do what's right, not what can get away with. Manage event, not claim Always focus on what is best for patient, over bottom line Must be trained in disclosure. Stick to facts you know. No speculation.

COPIC Insurance Company

Disclosure Program	**COPIC Insurance Company**
Location (State) of Disclosure Program	Colorado
What Type of Events Prompt Disclosure?	Doc calls risk management department to report adverse outcome, injury, or anger about some aspect of care
Both positive and negative outcomes?	
Preventable or Non-preventable harm?	
Any error?	Wrong site surgery, patient death, or obvious negligence is ineligible for program. 3Rs program involves injured patient who has made no written demand for compensation, not issued a complaint to a licensing board, and not involved an attorney.
Who determines need for disclosure?	Risk department
Who Discloses?	Physician
Individual or as Team?	
If as team, who comprises team?	
To Whom Do You Disclose?	Patient
What Information Is Disclosed?	What is known about how injury occurred
Is Apology Offered as Part of Disclosure?	Yes, when appropriate
If yes, under what circumstances?	
Advice on dealing with the harm/injury?	

Information on what action is being taken to prevent recurrence?	Yes, when appropriate
When Does Disclosure Occur?	
Where Does Disclosure Occur?	
How Does Disclosure Occur?	
Is Participation in the Disclosure Program Voluntary or Mandatory?	Voluntary
By Whom?	
What if a physician does not want to participate in the disclosure program?	
What type of training is provided for persons making disclosure?	Physicians trained to communicate with their patients, addressing their needs for information, emotional support, and financial assistance.
What support services are offered?	
How is Compensation Determined?	
When is Compensation Offered?	As part of disclosure
How is Compensation Offered?	Offer to cover expenses not covered by patient's insurance and time lost from work
How is the compensation issue presented?	
By Written Agreement?	
How is Settlement of a Claim Reached?	
Is legal representation suggested?	
And if so, when?	
Would the settlement/compensation have to be reported to the NPDB?	
Does the Patient/Patient's Family Sign a Waiver?	No, free to file a lawsuit after accepting reimbursement
What are the terms of the waiver?	
What, if any, elements of the disclosure are confidential?	
How does the Disclosure Program interact with peer review and quality control?	
What mechanisms provided to minimize future events of the same kind from occurring?	
Is this included in the disclosure?	
Reasons for Implementing Disclosure Program	
How are the Participants of the Disclosure Program Insured?	
# of Claims Before Implementing Disclosure Program	
# of Claims After Implementing Disclosure Program	4100 occurrences in 3Rs program, only 875 resulted in payment
Total amount of compensation before and after implementing disclosure program.	
How does the program measure impact?	
Has the Disclosure Program resulted in increased patient safety?	
If yes, how determined?	

Has the Disclosure Program resulted in increased provider satisfaction?	
If yes, how determined?	
Has the Disclosure Program resulted in increased patient satisfaction?	
If yes, how determined?	
Other state laws (malpractice, insurance, etc.) encouraging disclosure	
Effect of Disclosure on Licensure	
Effect of Disclosure on Insurance Coverage	
General Comments	

Brigham and Women's Hospital

Disclosure Program	**Brigham and Women's Hospital**
Location (State) of Disclosure Program	Massachusetts
What Type of Events Prompt Disclosure?	Adverse events and medical errors
Both positive and negative outcomes?	If obvious to patient
Preventable or Non-preventable harm?	
Any error?	Any medication error
Who determines need for disclosure?	
Who Discloses?	Physician or nurse
Individual or as Team?	
If as team, who comprises team?	
To Whom Do You Disclose?	Patient/patient family
What Information Is Disclosed?	What occurred - what they know
Is Apology Offered as Part of Disclosure?	Yes
If yes, under what circumstances?	
Advice on dealing with the harm/injury?	
Information on what action is being taken to prevent recurrence?	
When Does Disclosure Occur?	
Where Does Disclosure Occur?	
How Does Disclosure Occur?	Risk management department has a patient-family relations department that sets up disclosure conversations with the family and circles back to physician. Investigations and follow-0up very detailed. Disclosure is verbal and it also can be written.
Is Participation in the Disclosure Program Voluntary or Mandatory?	Voluntary
By Whom?	

What if a physician does not want to participate in the disclosure program?

What type of training is provided for persons making disclosure?

What support services are offered?

Physician will call risk department for advice when knows of problem

How is Compensation Determined?

When is Compensation Offered?

How is Compensation Offered?

How is the compensation issue presented?

By Written Agreement?

How is Settlement of a Claim Reached?

Is legal representation suggested?

And if so, when?

Would the settlement/compensation have to be reported to the NPDB?

Does the Patient/Patient's Family Sign a Waiver?

What are the terms of the waiver?

What, if any, elements of the disclosure are confidential?

How does the Disclosure Program interact with peer review and quality control?

What mechanisms provided to minimize future events of the same kind from occurring?

Is this included in the disclosure?

Reasons for Implementing Disclosure Program

Right thing to do. Because of Joint Commission. Now to save the relationship with patients and families

How are the Participants of the Disclosure Program Insured?

# of Claims Before Implementing Disclosure Program

# of Claims After Implementing Disclosure Program

Total amount of compensation before and after implementing disclosure program.

How does the program measure impact?

Has the Disclosure Program resulted in increased patient safety?

If yes, how determined?

Has the Disclosure Program resulted in increased provider satisfaction?

If yes, how determined?

Has the Disclosure Program resulted in increased patient satisfaction?

If yes, how determined?

Other state laws (malpractice, insurance, etc.) encouraging disclosure

Effect of Disclosure on Licensure

Effect of Disclosure on Insurance Coverage

General Comments

Lexington, Kentucky VA Hospital

Disclosure Program	**Lexington VA**
Location (State) of Disclosure Program	Kentucky
What Type of Events Prompt Disclosure?	medical error
Both positive and negative outcomes?	
Preventable or Non-preventable harm?	
Any error?	
Who determines need for disclosure?	
Who Discloses?	Chief of Staff
Individual or as Team?	
If as team, who comprises team?	
To Whom Do You Disclose?	Patient/Family
What Information Is Disclosed?	Acknowledges error or event
Is Apology Offered as Part of Disclosure?	Yes, and includes explanation
If yes, under what circumstances?	Always
Advice on dealing with the harm/injury?	Yes
Information on what action is being taken to prevent recurrence?	Yes
When Does Disclosure Occur?	
Where Does Disclosure Occur?	
How Does Disclosure Occur?	
Is Participation in the Disclosure Program Voluntary or Mandatory?	
By Whom?	
What if a physician does not want to participate in the disclosure program?	
What type of training is provided for persons making disclosure?	
What support services are offered?	
How is Compensation Determined?	
When is Compensation Offered?	As part of Disclosure
How is Compensation Offered?	
How is the compensation issue presented?	
By Written Agreement?	
How is Settlement of a Claim Reached?	
Is legal representation suggested?	Yes
And if so, when?	At time of initial Disclosure
Would the settlement/compensation have to be reported to the NPDB?	
Does the Patient/Patient's Family Sign a Waiver?	
What are the terms of the waiver?	

What, if any, elements of the disclosure are confidential?	
How does the Disclosure Program interact with peer review and quality control?	
What mechanisms provided to minimize future events of the same kind from occurring?	
Is this included in the disclosure?	
Reasons for Implementing Disclosure Program	After losing two medical malpractice suits for large amounts
How are the Participants of the Disclosure Program Insured?	
# of Claims Before Implementing Disclosure Program	
# of Claims After Implementing Disclosure Program	
Total amount of compensation before and after implementing disclosure program.	
How does the program measure impact?	
Has the Disclosure Program resulted in increased patient safety?	
If yes, how determined?	
Has the Disclosure Program resulted in increased provider satisfaction?	
If yes, how determined?	
Has the Disclosure Program resulted in increased patient satisfaction?	
If yes, how determined?	
Other state laws (malpractice, insurance, etc.) encouraging disclosure	
Effect of Disclosure on Licensure	
Effect of Disclosure on Insurance Coverage	
General Comments	Seen sharp increase in settlements and a reduction in the mean malpractice settlement. The savings in litigation costs have been significant. Health Care Providers more promptly report errors

Virginia Joint Commission on Health Care

Various Responses to Medical Errors

HJR 101 (2008) (Patron: Delegate O'Bannon)

Jaime Hoyle
Sr. Staff Attorney/Health Policy Analyst
October 23, 2008

House Joint Resolution 101

- Directs the Joint Commission on Health Care (JCHC) to study, in the case of medical errors and adverse medical outcomes:
  - The use of:
    - disclosure
    - apologies
    - alternative dispute resolution and
    - other measures.
  - The impact of such measures on:
    - the cost and quality of care
    - patient confidence and
    - the medical malpractice system.

Study Process

- Formed a Study Committee consisting of representative stakeholders and individuals with expertise in the subject area.
  - Virginia Bar Association, Office of the Attorney General, a plaintiff's attorney, physicians, hospitals, insurers, mediators and defense attorneys.
- The Study Committee formed a Steering Committee to manage the work, and also broke into two workgroups: Disclosure and Resolution.
- Held a total of 10 meetings.

Study Committee Membership

- Ellen M. Brock, M, MD, MPH
  Associate Professor
  Director, General Obstetrics and Gynecology
  Medical Director, Center for Human Stimulation and Patient Safety, VCU
- Patrick C. Devine, Jr., Esq.
  Williams Mullen
- Jeanne F. Franklin, Co-Chairman
  Mediator and Attorney at Law
- Larry Hoover, Co-Chairman
  Of Counsel, Hoover Penrod PLC
- Heman A. Marshall, III, Esq
  Woods Rogers PLC
- Malcolm "Mic" McConnell, III, Esq.
  Allen Allen Allen & Allen
- Susan C. Ward, Esq.
  Vice President and General Counsel, VHHA
- Virginia Blair
  Vice President, Performance Improvement, Prince William Health System
- Thomas C. Brown, Jr. Esq.
  McGuireWoods LLP
- Michael L. Goodman, Esq.
  Goodman, Allen & Filetti PLLC
- W. Scott Johnson, Esq.
  Medical Society of Virginia
- Devin C. Price, CPCU, CIC
  Colony Group, Allied Medical Division
- Arnie Snukals
  Duane & Shannon
- Rebecca W. West
  Piedmont Liability Trust
- Amy Marschean, Esq.*
  Office of the Attorney General
- Carole Houck*
  Principal, Carole Houck International, LLC
- Michael E. Ornoff*
  Mediation Solutions of Virginia
- Sameul S. Jackson*

*Consultants to the Study Committee

Background

- An estimated 44,000-98,000 people die unnecessarily in hospitals each year as a result of allegedly preventable medical errors.
- Besides loss of life or serious injury, annual costs of medical errors, including the expense of additional care, lost income and disability are estimated to be between $17 and $29 billion.
- Furthermore, health care providers (HCPs) face increasing malpractice insurance costs.

5

When there is medical error, needs and concerns arise for both the patient and the HCP

- The injured patient may need, but not receive:
  - An explanation of what happened or an apology from the person or persons responsible for the injury;
  - Adequate compensation; or
  - Reassurance that steps have been taken to assure that the error is not repeated.
- The HCP may feel:
  - Powerless to talk openly with the injured patient about what happened and to express an apology;
  - Torn between ethical responsibilities and fear of the negative consequences of disclosing inaccurate or incomplete information;
  - It is difficult to determine how to balance their ethical and legal responsibilities, as well as their personal, professional and financial liability when they decide what and how to disclose; and
  - Disclosure does not always meet the expectations of patients.
- Fear of lawsuits and loss of reputation remain the biggest barriers to disclosure of medical errors.

6

Medical Error and Medical Malpractice Lawsuits

- Studies suggest that a majority of patients sue, not because of injury but because they believe:
  - they are not treated with respect,
  - not told the truth,
  - the HCP has not taken responsibility for his/her actions,
- The silence of the "deny and defend" culture breeds anger, and is the major determining factor in a patient's decision to sue.
- About 25% of patient complaints reported to the Virginia Board of Medicine (BoM) are motivated by a patient's lack of knowledge concerning his/her treatment and poor communication by physicians.

7

Disclosure of Adverse Medical Events

- Currently, there are a variety of federal and state authorities requiring HCPs to disclose.
  - The AMA states that physicians have a fundamental ethical duty to communicate openly and honestly with patients and to keep the patient informed.
  - The Joint Commission requires disclosure of medical errors and unanticipated outcomes to patients and their family members.
  - Virginia BoM regulations require practitioners keep their patients accurately informed.
  - 8 states mandate disclosure of serious adverse events and Pennsylvania and Rhode Island require written notification to the patient.

8

Disincentives for Disclosure

- Federal and state reporting requirements which can trigger government investigations;
- Raised premiums and discontinued malpractice coverage if the cooperation clause is triggered;
- Possible waiver of peer review privileges;
- Possibility that defense costs could actually rise due to an increased number of claims;
- Loss of professional reputation; and
- Fear of a lawsuit.

9

Incentives for Disclosure

- Disclosure rebuilds trust and solidifies the provider/patient relationship, thereby decreasing malpractice litigation and reducing overall costs.
- A culture of transparency and accountability fosters an environment where medical errors are identified and corrected, thereby buttressing the patient safety movement.
  - Acknowledging an error gives an institution the freedom to correct the mistakes and theoretically prevent future harm and improve patient safety.
- Patients gain increased confidence in the integrity of the health care system.
- Focus of attention returns to the patient, encouraging care to be patient-centered, not based on the protection of the organization.

10

Disclosure and Disclosure Programs

- A movement promoting disclosure programs in the medical setting is taking root nationwide.
- Generally, disclosure and disclosure programs involve reconstructing the events that led up to an adverse outcome and relating those events to the patient.
- There are no universal standards applicable to disclosure programs.
- There are varying definitions of the event that should trigger disclosure.
  - Disclosure can be triggered by preventable or non-preventable harm or no harm at all, such as a near-miss.
  - Some programs determine the need for disclosure based on the severity of the harm.
  - It can be triggered by medical error, or simply an adverse event, that was the fault of no one.

11

Disclosure and Apology

- Full disclosure includes an apology.
- As with disclosure itself, the definition of apology varies, and physicians and patients often have differing views as to what constitutes an apology.
- Many disclosure programs, as well as many state laws, define apology as an expression of benevolence, remorse or sorrow.
  - This more narrow definition differs from one more commonly understood by the general population – patients.
  - Patients define apology as an expression of remorse and sorrow coupled with an admission of wrongdoing and taking of responsibility.
- This variation highlights the lack of communication and conflicting expectations between patient and physician at the heart of the problem at issue.

12

"Apology" Laws

- In an effort to encourage disclosure conversations and apology, 35 states have adopted apology laws to create an evidentiary privilege in any subsequent judicial or administrative proceeding.
  - 25, including Virginia, create a privilege for an "expression of benevolence, remorse or sorrow" only
  - 6 states protect such an expression plus an explanation, and
  - 4 states protect the entire disclosure statement, which would also include an acceptance of responsibility.

13

Resolution

- There are various processes currently used for resolving medical error conflict, including litigation:
  - Mediation
  - Early, interest-based mediation
  - Collaborative law
  - Malpractice Review Panels
- The most frequently used voluntary process is mediation.

14

Examples of Disclosure/Early Resolution Programs

- Across the country, including in Virginia, hospitals have been voluntarily implementing disclosure/early resolution programs.
  - Each program has a unique approach but some consistent characteristics include:
    - Focusing on early resolution (pre-claim) of the issues.
    - Having transparency and accountability as the intended purpose for implementation, not a decrease in medial malpractice costs.
    - Having procedures in place to determine, before a disclosure conversation is initiated, if and how an adverse event occurred.
    - Having clear policies as to who makes the initial disclosure, as well as future disclosure conversations.
    - Employing a strong education/training/support element for all involved.
  - In most instances, educational outreach began with the stakeholders before any programs were implemented.

15

Veterans Administration Hospital in Kentucky

- Involves full disclosure and apology.
- If it is determined that disclosure is necessary, a meeting with the patient and family is convened and staff members make disclosure and apologize, take full responsibility, and describe steps being taken to prevent reoccurrence, and fair compensation is offered.
- Less risk for an individual physician to take part in a disclosure program at this hospital because he can not be held personally liable. In any suit against the VA, the United States is the only named defendant.
- Results have been positive:
  - Between 1987-2000, negotiated more than 170 settlements, going to trial only 3 times.
  - Largest payout was $341,000 for a wrongful death, and the average settlement was $16,000.

16

The University of Michigan Health System

- Michigan has a compulsory 6-month pre-suit notice period.
  - Before a malpractice suit may be filed against any health care practitioner or facility in Michigan, the patient or patient's family is required, by law, to present details of the claims in writing. Once this notice is served, a suit cannot be filed for 182 days.
  - This pre-suit notice period allows prospective defendants time to investigate the claim, gives them the opportunity to meet with the patient or family, and offers patients and families time to reconsider their decision to sue.
- The University of Michigan Health System's Full Disclosure Program:
  - Was developed as a result of state law.
  - Each case undergoes internal and sometimes external expert reviews.
  - The patient care at issue is submitted to the Medical Liability Review Committee, which determines reasonableness of care and impact on the patient's outcome.
    - This Committee also considers every submitted case for peer review, clinical quality improvement, and educational opportunities. Furthermore, they study all adverse events to determine how procedures could be improved.

17

The University of Michigan Health System

- Once the issues are clarified:
  - Hospital policy requires staff to disclose cases of harmful error, and open discussion with the patient and his lawyer ensues.
  - Physicians provide factual information of the outcome that occurred.
  - If it has been determined that the University of Michigan Health System provided unreasonable care, they compensate patients quickly and fairly.
  - If the hospital determines that the care was reasonable and the case is without merit, it will aggressively defend against any claims.
- The program has had positive results in the 5 years since implementing the program, including:
  - Annual litigation costs decreased from $3 million to $1 million.
  - Annual number of claims and lawsuits decreased from 262 to 114.
  - Average time to resolution of claims declined from 20.7 to 9.5 months.
  - The disclosure/early resolution program has led to an unprecedented exchange and flow of information, where staff reports more close calls and patient injuries.
  - Physicians in this program may be individually named in a malpractice suit, but the University will wholly indemnify all its doctors for damages.

18

Disclosure Programs in Virginia

- Some hospitals in Virginia currently have disclosure programs in place.
- One example is the Prince William Hospital:
  - Has a disclosure policy that includes apology.
  - Since implementation of the program they have seen no increase in claims.
  - They have shared stories of the positive response with their Board of Trustees, which has been helping to move the hospital and providers from a culture of silence to a culture of transparency.
  - The Board reviews random chart audits for harm and identifies ways to decrease harm from medical error.
  - The Board and medical staff leaders continue to collaborate on best practice strategies.

19

Pilot Programs in Other States

- Whereas some states have provided a fertile environment for hospitals to implement their own disclosure programs, other states have instituted pilot programs.
- Vermont's pilot program:
  - Requires an oral apology or explanation of how medical error occurred, made within 30 days. This oral apology and explanation may not be used to prove liability, is not admissible, and cannot serve as the subject of questioning in administrative or civil proceedings. Of course, information obtained through other channels is not barred from use.
- This pilot establishes a voluntary program run by the Vermont Department of Banking, Insurance, Securities & Health Care Administration (BISHCA), in which physicians and hospitals promptly acknowledge and apologize for mistakes in patient care that result in harm and promptly offer fair settlements.
- Negotiations under the program are confidential, and the statute of limitations is tolled during negotiations.
- Settlement bars further litigation.
- If settlement is not reached, the patient still may bring a civil action, having the same options as he did prior to entering into the disclosure program.
- Additionally, as part of the program, hospitals will report medical malpractice costs to BISHCA for the department to analyze any cost savings resulting from use of the program.
- They will report to the general assembly in January 2009, and the program will sunset.

20

Pilot Programs in Other States

- Pennsylvania passed the Medical Care Availability and Reduction of Error (MCARE) Act, which states that "A person who has sustained injury or death as a result of medical negligence by a health care provider must be afforded a prompt determination and fair compensation. Every effort must be made to reduce and eliminate medical errors by identifying problems and implementing solutions that promote patient safety."
- Pennsylvania also implemented a pilot program for early resolution of medical malpractice cases, at the urging of the State Supreme Court.
- Once the county (Montgomery) was identified, a task force was established of county leaders including physicians, lawyers, and hospital representatives to develop a model for Disclosure/Early Resolution. The model:
  - Includes a first level of disclosure/early resolution which focuses on facilitating direct communication with patients about the patients' care and attempts to resolve matters to everyone's satisfaction and includes possible patient compensation.
    - Patients are told about this first level program upon admission to the hospital including whom the patient can contact within the hospital in order to initiate the first level of resolution.
  - Is an ombuds-type program within the hospital that works with a patient safety committee. If the HCP decides to offer compensation, the committee or Ombudsmen discusses arrangements or compensation with the patient after advising the patient of the right to counsel.
  - If the first level of resolution does not satisfy the parties, the model elevates to the offer of an early mediation process in which lawyers would be involved. The mediators would be a specially trained lawyer/physician team. A panel of trained mediators has been created.

Pennsylvania Pilot Program (cont.)

- The hospital staff is a mixed staff so that some physicians do have their own insurers.
- The hospital group(s) is covered by the hospital policy.
- The hospital plan is to try to create a culture around this program so that the medical staff can buy into it.
- Pennsylvania law might provide an advantage: if the hospital pays the settlement – as a kind of global settlement – on the physician's behalf, there is no duty for the physician or hospital to report the settlement to the Board of Medicine.

Study Committee Recommendation

- **The JCHC should convene a Task Force consisting of representatives of the primary stakeholders in this subject area – to include the Medical Society of Virginia, The Virginia Hospital and Healthcare Association, The Department of Health, Department of Health Professions, Board of Medicine, the Virginia Trial Lawyers Association, the Virginia Association of Defense Attorneys, the medical malpractice insurance industry and broader physician, health care provider and consumer representation. We recommend that the JCHC charge this task force with:**
  - **building upon the work already done by the 101 Study Committee;**
  - **developing agreed-upon working definitions of key terms such as adverse outcome, medical error, and disclosures, to facilitate discussions in Virginia of the issues;**
  - **tracking results and developments in disclosure and resolution programs now operational in Virginia and other states, and federal developments in this area;**
  - **crafting a model or models for disclosure and early resolution programs that could be offered to Virginia health care providers, insurers and attorneys for their use;**
    - **should such a model or models be developed, considering ways to incentivize health care providers to try use of such models and to report outcomes of their use with regard to several factors, including cost, claims experience, impact on quality/patient safety efforts and reported patient/provider satisfaction;**
    - **should the Task Force decide not to offer such model(s), explaining the reasons.**

23

Summary of the Rationale for the Study Committee's Recommendation

- Reflects the strong interest of the Committee in finding ways to resolve the tension between patient and provider needs/interests and the reasons why those needs/interests may not be consistently met.
- Argument was advanced and noted that the current system works well enough, and that educating the professions about possible collaborative solutions and ethical obligations will provide an adequate enhancement of it.

24

Rationale for the Study Committee's Recommendation

- Considering that the status quo might work well enough, the Committee was hesitant to make a stronger recommendation for the following reasons:
  - Uncertainty about the future sustainability of cost outcomes when more patients are fairly compensated.
  - More data will be available in the future.
  - Most data supporting claims of cost reduction were from programs that are self-insured.
  - Need consensus of all stakeholders.
  - Need more input from insurers as medical practitioners cannot risk rising premiums, discontinued coverage, or refusal by the insurer to defend a claim following a disclosure.
  - Change in interpretations of Virginia's peer review privilege has created an uncertain environment that is exacerbating the tension noted in this report and serves as a disincentive to embracing voluntary disclosure and early resolution programs.
  - Virginia reporting requirements and BoM procedures can be seen as possibly inspiring fear and reluctance rather than open self-examination and correction in cases of medical error.
  - The polarization of attitudes about the medical error issue and the need for reform support the status quo.

25

Options

- **Option 1:** Take no action.
- **Option 2:** Adopt the consensus recommendation of the Study Committee.

26

Public Comments

- Written public comments on the proposed options may be submitted to JCHC by close of business on November 10, 2008.
- Comments may be submitted via:
  - E-mail: sareid@leg.state.va.us
  - Fax: 804-786-5538
  - Mail: Joint Commission on Health Care
    P.O. Box 1322
    Richmond, Virginia 23218
- Comments will be summarized and presented to JCHC during its November 24th meeting.

Internet Address

Visit the Joint Commission on Health Care website:
http://jchc.state.va.us

Contact Information
ksnead@leg.state.va.us
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Appendix A

HOUSE JOINT RESOLUTION NO. 101

Offered January 9, 2008

Prefiled January 8, 2008

Directing the Joint Commission on Health Care to study the use of disclosure, apologies, alternative dispute resolution, and other measures in the case of medical errors and adverse medical outcomes and the impact of such measures on the cost and quality of care, patient confidence, and the medical malpractice system. Report.

Patron-- O'Bannon

Referred to Committee on Rules

WHEREAS, much has been written recently about the incidence of medical errors, the need to disclose medical errors and adverse medical outcomes to patients and their families, and the medical malpractice crisis; and

WHEREAS, the American Medical Association's Code of Medical Ethics provides at E-8.12 that "it is a fundamental ethical requirement that a physician should at all times deal openly and honestly with patients" and that where "a patient suffers significant medical complications that may have resulted from the physician's mistake or judgment...the physician is ethically required to inform the patient of all the facts necessary to ensure understanding of what has occurred"; and

WHEREAS, the Joint Commission on Accreditation of Healthcare Organizations requires certain disclosure by hospitals of medical errors and unanticipated outcomes to patients and their families and the initiation of efforts to prevent future medical errors; and

WHEREAS, § 8.01-581.20:1 of the Code of Virginia permits certain gestures and statements of sympathy or benevolence to be made by providers to patients and family members in connection with a medical error or adverse medical outcome without the gesture or statement being admissible as evidence of liability, but does not make a statement of fault under such circumstances admissible; and

WHEREAS, many studies and demonstration projects in other jurisdictions have suggested that prompt and candid disclosure of medical errors and adverse medical outcomes by providers to patients and their families and the voluntary use of creative alternative dispute resolution techniques may have a number of benefits to the health care system, including improved consumer and provider

confidence in and satisfaction with the system, prompt and fair resolution of possible claims, enhanced reporting of medical errors and adverse medical outcomes and improved procedures to reduce the likelihood of recurrence, improved quality of care, a reduction in the volume and cost of litigation, better patient-provider relationships, and substantial cost savings for the health care system; and

WHEREAS, it would be beneficial to patients, providers, malpractice insurers, and the health care system to study whether and how to implement such measures in the Commonwealth; and

WHEREAS, the Health Law Section of the Virginia Bar Association has volunteered to assist the Joint Commission on Health Care with any aspect of such a study if requested; now, therefore, be it

RESOLVED by the House of Delegates, the Senate concurring, That the Joint Commission on Health Care be directed to study the use of disclosure, apologies, alternative dispute resolution, and other measures in the case of medical errors and adverse medical outcomes and the impact of such measures on the cost and quality of care, patient confidence, and the medical malpractice system.

In conducting its study, the Commission shall review legislation and initiatives in other jurisdictions, consider the need for change to existing Virginia law, and recommend appropriate ways to implement measures in Virginia to achieve these ends, whether on a demonstration basis or for the entire system.

Technical assistance shall be provided to the Commission by the Department of Health and the Department of Health Professions. All agencies of the Commonwealth shall provide assistance to the Commission for this study, upon request.

The Commission shall complete its meetings by November 30, 2008, and the Director shall submit to the Division of Legislative Automated Systems an executive summary of its findings and recommendations no later than the first day of the 2009 Regular Session of the General Assembly. The executive summary shall state whether the Commission intends to submit to the General Assembly and the Governor a report of its findings and recommendations for publication as a House or Senate document. The executive summary and report shall be submitted as provided in the procedures of the Division of Legislative Automated Systems for the processing of legislative documents and reports and shall be posted on the General Assembly's website.

Appendix B

COMMONWEALTH OF VIRGINIA
HOUSE OF DELEGATES
RICHMOND

JOHN M. O'BANNON, III, M.D.
POST OFFICE BOX 70365
RICHMOND, VIRGINIA 23255-0365

SEVENTY-THIRD DISTRICT

COMMITTEE ASSIGNMENTS:
PRIVILEGES AND ELECTIONS
APPROPRIATIONS
HEALTH, WELFARE AND INSTITUTIONS

February 1, 2008

Mrs. Kim Snead
Executive Director
Virginia's Joint Commission for
Health Care for All Virginians
P. O. Box 1322
Richmond, VA 23218

Re: HJ 101

Dear Kim:

Thank you very much for discussing HJ 101 with me and for agreeing to have this placed on the Joint Commission's work plan. It is extremely important to all Virginians and I think is one of the tangible things we may be able to do to make our citizens safer and healthier.

I want to offer the expertise and support of the Health Law Section to you for support as we study this. The Health Law Section of the Virginia Bar Association has been a real leader and in the forefront of this issue, and I know they would be pleased to participate meaningfully.

Respectfully,

John M. O'Bannon, III, MD
Delegate, 73rd District

cc: Rob Beasley Jones
Patrick C. Devine, Jr.

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