

## Recommendations

These recommendations take into consideration testimony originally coded to 26 (PeerProtect)<sup>1</sup> as well as other sources, as noted.

- J1: The State legislature should provide statutory protection for patient safety data and reporting activities without denying patients and families access to information through normal channels of discovery when medical errors occur.
  - o J1a: Designate patient safety data as privileged and confidential.
  - o J1b: Protect individuals who report health-care errors, adverse events, and near misses from blame and disciplinary action.
  - o J1c: Protect organizations and staff that collect, analyze, and report the data from litigation pressures.
  - o J1d: Align protection strategies with emerging federal legislative strategies.
  - o J1e: Include a provision for assessing by a specific target date the effectiveness of the statutory protections in (1) protecting J1a–J1c; (2) increasing reporting of medical errors, adverse events and near misses; and (3) achieving any other stated performance goals.

## Rationale

Comprehensive data about errors, adverse events and near misses are essential to preventing patient harm. Collecting and analyzing such data provide a clear picture of what is happening, so appropriate prevention measures can be taken.

To collect complete data, everyone associated with health-care delivery must be willing to provide this crucial information. Individuals will do so only if they feel safe from legal and professional repercussions within their own work settings and in the greater community.<sup>2</sup> Organizations will participate in such reporting only if they will not be subject to a loss of business or damaged reputation.

Thus, to develop a robust database with the potential to point out system conditions that might lead to harm, patient safety data must be protected from unintended uses and health-care practitioners and others working in the health-care arena that, in good faith, report conditions or events that jeopardize patient safety, must be protected from blame and disciplinary actions.<sup>3</sup>

Patient safety data collected for these learning purposes must be expressly protected if the State does not want it disclosed. In the absence of such explicit protections, the data could be accessed via Freedom of Information or Open Records requests, subpoena, legal discovery, or could be admitted into evidence in a civil or administrative proceeding, for instance.<sup>4</sup>

In order to be effective and reliable, protections should be:

- Comprehensive—to cover the many ways that confidentiality can be challenged.
- Statutory—to better withstand legal challenges.
- Specific to the reporting system—to make legislative intent clear.<sup>5</sup>

Such statutory protections are necessary to ensure that “the first response is not to assign blame, censure, or sue but to look at how and why an error occurred and take steps to avoid the error in the future”.<sup>6</sup>

## Assessment

### Advantages

- This legislation would ensure the “safe environment” providers perceive as necessary for identifying and discussing medical errors as a first step to an evidence-based system approach to decreasing harm to patients.
- The increased reporting resulting from providers feeling safe to report medical errors and near misses would place the state and individual organizations in a better position to make needed changes in the health care system overall and their own systems to enhance patient safety and provide useful information to the public.
- Federal efforts to address patient safety legislation appear to have stalled. Legislation at the state level to protect patient safety data, sources, and related activities would allow Michigan to move forward to identify sources of medical error and to change the culture of health-care in the state to one of learning with a systems orientation rather than one of individual blame.
- A state-level approach would allow Michigan to determine what will best meet its needs around protecting patient safety data and those who report it, collect it, analyze it and disseminate the findings as well as deciding what to disclose in what format.

### Barriers

- Lack of a system orientation to the delivery of health care.
- The possibility that any federal patient safety legislation would preempt state laws.

### Additional Comment/Concerns:

- It may be simplistic to assume that reporting will increase if data is protected.
- Statutory provisions, especially with powerful stakeholders, are difficult to repeal. It will be important to link the continuation of statutory protections to evaluation of the reporting strategies and sunset the protections if they do not prove effective in meeting the goal.<sup>7 8</sup>

## Implementation

### Further research

To date, no perceived difference in underreporting has been found between states with strong protections for reporting system data and those with weak or no legal protections. Empirical studies with larger samples and methods for measuring underreporting are needed to determine whether a relationship exists between underreporting of adverse events and strength of legal protections.<sup>9</sup>

### Legislation and/or administrative rules

The following changes to Michigan law were proposed:

- Establish in statute that all records, data, and knowledge collected for or produced solely for or by individuals or committees for patient safety improvement purposes in all health-care settings are confidential and privileged information and are exempt from public disclosure (FOIA) laws.
- Ensure that such protections do not deny patients and families access to information through normal channels of discovery when medical errors occur.

- Protect in statute persons providing information or services related to patient safety reporting from civil liability or charges of violating criminal law unless the information is false and the person knew or had reason to believe the information was false.
- Extend to all health-care employees the protections of Public Health Code MCL 333.20180(1)-(7), which currently provides protection for hospital employees against retaliation for reporting an unsafe practice or condition.

### Resources

- Michigan health professional societies should provide advocacy and lobbying efforts to achieve the necessary tort reform and liability protection within the health-care industry to support patient safety improvement efforts.<sup>10</sup>
- Purchasers of health care should proactively help health-care providers protect the confidentiality of any information disclosed to them for the purpose of improving patient safety through learning from sharing process of care information.<sup>11</sup>

### Incentives

The protections recommended here are an incentive for reporting data on which to base planning and strategies.

### Specific steps and target dates

- By spring 2006, the Department of Community Health (or its designate) will convene a forum of major Michigan health-care stakeholders to develop consensus on the objectives to be achieved through legal protection for patient safety data, sources, and activities and the type of public reporting that should occur.
- By spring 2006, legal counsel should be retained by the convened forum to provide guidance on how patient safety legislation should interface with current other legislation and regulations relevant to patient data disclosure and peer review and to draft legislation to achieve the identified objectives.
- By spring 2006, legal counsel should be retained by the convened forum to provide guidance on the need for protection of patient safety data and other activities and sources when used for patient safety performance measurement and monitoring by individual health-care organizations.
- By fall 2006, legislation will be introduced that designates patient safety data as privileged and confidential, protects individuals who report health-care errors, adverse events, and near misses from blame and disciplinary action, and protects the organizations and staff that collect, analyze, and report the data from litigation pressures.

## Testimony overview

### Summary

Based on 15 recommendations coded 26 (PeerProtect) plus 1 coded 15 (Collaboration) and evidence offered from 13 testimonies representing hospitals, health care providers, educators, consumers, insurers and professional organizations.

### Key findings

- The State of Michigan should establish a medico-legal environment that encourages all health-care organizations and professionals to report patient safety-related information and that supports learning versus punitive approaches to health-care errors, adverse events, and near misses.<sup>12 13 14 15 16 17 18 19</sup>

- All records, data, and knowledge collected for or by individuals or committees for patient safety improvement purposes in all health-care settings should be designated confidential and privileged information and protected accordingly.<sup>20 21 22 23 24 25 26 27</sup>
- Health-care employers should be prevented from taking adverse employment action against any employee who in good faith reports patient safety information, e.g., expand Public Health Code MCL 333.20180(1) – (7) to all health-care employees.<sup>28</sup>
- Purchasers of health care can help promote a non-punitive culture by promoting methods to peer protect information disclosed for their use.<sup>29</sup>
- Michigan health professional societies should provide advocacy and lobbying to achieve tort reform and liability protection to support patient safety improvement efforts.<sup>30</sup>

### Summary of additional research: Michigan

Information from various sources appears to confirm that peer review protection<sup>31</sup> may be inadequate for protecting patient safety information and *all* staff engaging in patient safety data collection and analysis activities.<sup>32</sup>

Effective December 30, 2002, the Public Health Code (333.20180(1)-(7)) provides protection from retaliation against hospital employees who report an unsafe practice or condition beyond the Whistleblower Protection Act.<sup>33</sup> Other health-care employees and professionals are not provided this same protection.

When protections regarding patient safety-related data are developed, the purpose of the reporting must be carefully defined as well as the type of data involved and who is disclosing it to whom. Michigan's Freedom of Information Act, Medical Care Access Act, the federal Health Insurance Portability and Accessibility Act (HIPAA), and the Public Health Code (especially Articles 15 and 17) need careful consideration,<sup>34</sup> including circumstances under which state law takes precedence over federal law. Legal opinion should be obtained regarding the specific aspects to be addressed for voluntary reporting of medical errors, adverse events, and near misses and on the need for protecting the collection and use of any patient safety performance measures/performance monitoring shared with other organizations.

### Summary of additional research: National perspective

#### Federal legislation

In *To Err is Human*, the Institute of Medicine called on Congress to extend peer review protections to data collected and analyzed by health-care organizations for internal use or shared with others solely for purposes of improving safety and quality.<sup>35</sup> However, patient safety legislation at the federal level has stalled while state legislative action is exploding.

The last reported movement on the most current federal bill was March 9, 2005, when the Committee on Health, Education, Labor, and Pensions ordered it to be reported without amendment favorably. If enacted as it stands, this bill would amend the Public Health Service Act to designate patient safety data as privileged and confidential while permitting certain disclosures of such data by a provider or designated patient safety organization (PSO), including:

- Voluntary disclosures of non-identifiable data;
- Disclosures of data containing evidence of a wanton and criminal act to directly harm the patient;
- Disclosures necessary to carry out PSO or research activities; and
- Voluntary disclosures for public health surveillance.

It would prohibit an accrediting body from taking any accrediting action against a provider based on the provider's good faith participation in collecting, developing, reporting, or maintaining patient safety data. It would also prohibit an accrediting body from requiring a provider to reveal its communications with any PSO. Additionally, the bill prevents a provider from taking an adverse employment action against an individual based upon the good faith reporting of information. This legislation is intended to preempt state laws that govern disclosure of information provided to patient safety organizations.<sup>36</sup>

### **Veterans Administration**

In testimony submitted to the State Commission on Patient Safety, the Veteran's Administration noted that since the implementation of confidentiality protections in 1999, "the rate of reporting patient safety information increased 30-fold which has ... sustained to the present day".<sup>37</sup> The testimony also noted that while the VA includes only 4% of all health-care facilities in the United States, it has completed 4,500 root cause analyses, 300 proactive risk analyses, and 140,000 reports since then, as contrasted with JCAHO's 3,500 reports since 1996.<sup>38</sup>

The VA's independent, external reporting system (PSRS – Patient Safety Reporting System), designed to complement its internal reporting system, was rolled out in early 2002. The PSRS was developed by the VA and the National Aeronautics and Space Administration (NASA) and builds on the Aviation Safety Reporting System designed by NASA. The guiding principles of PSRS are voluntary participation, confidentiality of information submitted, and non-punitive reporting. The focus of both voluntary systems (aviation and VA) is on gathering sufficient data regarding errors and near misses to answer the questions "Why did the system fail; why did a human err?" The VA decided to offer more opportunities for confidential reporting to increase the data available, "When individuals feel uncomfortable reporting to the internal systems, they have a safety valve they can use – PSRS," according to the testimony of Dr. James Bagian, Director of the VA National Center for Patient Safety. Reports submitted to PSRS are confidential and privileged quality assurance documents protected under provisions of 38 USC 5705.<sup>39</sup>

### **American Academy of Family Physicians (AAFP)**

A recent report on the voluntary error-reporting system that was developed and tested by AAFP between 2000 and 2004 raised a number of questions about legal and practical constraints to such a system becoming a robust quality improvement tool. The primary legal concern was the lack of legislation to make such a reporting system confidential and non-punitive. In their opinion, this could be addressed by making legal protections complement HIPAA and state and federal peer review laws, striking a balance between patient safety and ensuring accountability. Until federal protections are in place, the AAFP feels that non-anonymous reporting is too risky for family physicians and their offices.

The report also lists several practical barriers to a national reporting system (also relevant to state systems) that need to be addressed. Electronic management of large datasets raises particular data and source protection issues. For example, storage of data electronically where it has "no country of residence" raises questions regarding whose legal code will take precedence and what access third parties might have. There is also the need for enhanced security to preserve anonymity of reporters when data is reported electronically, including removal of "cookies" from reporters' computers.<sup>40</sup>

### **Summary of additional research: Other states**

Most of the action in protecting patient safety data is occurring at the state level. The trend is toward greater protection of data, sources, and the activities related to working with the data. As peer review protection has proved more vulnerable to requests for disclosure through the legal system, more states are moving to include comprehensive protections for patient safety data as

an integral part of their reporting systems and to include these protections in authorizing statutes. As one example, Pennsylvania strengthened its reporting protections when its new system was established in 2002.<sup>41</sup>

### **Missouri**

Missouri's Commission on Patient Safety recommended in its July 2004 report to the governor: Missouri should provide statutory protection for patient safety activities to encourage health-care organizations and professionals to voluntarily report information and participate in the peer review / quality improvement process. Recommendations to the legislature included:

- Create protections for information shared among health-care organizations and professionals that is designed solely for improving patient safety and health-care delivery systems.
- Expand the qualifications of members on peer review/patient safety committees to allow full participation by licensed health-care professionals not listed in the statute plus non-licensed professionals like risk managers and other employees who play key roles in safety improvements.
- Protect patient safety data, documents and information reported to the Missouri Center for Patient Safety from use in civil, judicial and administrative proceedings.
- Protect the job status of health-care professionals and organization employees from reprisal for reporting errors internally and to the Missouri Center for Patient Safety.<sup>42</sup>

### **National Academy for State Health Policy (NASHP)**

NASHP published a number of reports in the early 2000s which addressed protection and disclosure of data related to medical errors and related issues. At the state level, the issue of patient safety data protection has to be considered in the context of medical malpractice concerns.

NASHP counsels that protections in statute and as an integral part of the reporting system will likely provide the most reliable protection. They note that, "Ideally, protection provisions would be sufficient to allay fears of those reporting events that the adverse event information would be used against them, while enabling states to achieve some goals of the reporting system: to spot trends, enhance patient safety through the identification and correction of practices that result in errors or adverse events, provide valuable information to those conducting research on patient safety and evaluation of reporting systems, and inform consumers generally about the safety of their health care system. Thus, while the statutory provisions should be comprehensive and protect data from compulsory disclosure, they should also be explicit about exceptions and allowable uses of the data."<sup>43</sup>

For more detailed information, please see the tables on pages 8 to 13.

## **Review Panel Round One**

### **Scoring summary**

In Round One, the Review Panel was asked to score each recommendation area on a scale of 1 to 5, where 5=extremely viable, 4=very viable, 3=somewhat viable, 2=potentially viable with changes, and 1=not viable for this project. Average score regarding the relevant recommendation considered in Round One:

- Peer Protection: 3.75 (range 2 to 5)

## Notes

Most Review Panel members voting on this recommendation gave it a high level of support (5 of 8 members rating it 4 or 5). Suggestions and concerns raised by the Review Panel or others connected to this initiative have been addressed in this Round 2 presentation.

- Concerns about exceptions and allowable data uses that do not shut out consumers were addressed through added language to the main recommendation and by additional material in the evidence section on recommendations from those who have studied these issues and how other states handle this. Legal guidance will be needed for drafting specific statutory language.
- The sub-recommendation regarding whistleblower protection has been modified. Rather than advocating for education of those covered regarding its provisions, it now recommends expansion of coverage to all health-care employees.
- The specifics of broad protection and any exceptions will need to be worked out as specific language is drafted.
- Alignment with federal legislative strategies has been brought into a sub-recommendation.
- Two of the original sub-recommendations concerning implementation strategies have been moved to the Resources section.
- A provision calling for assessment of statutory protection strategy for effectiveness in achieving desired goals has been added based on recommendations in literature reviewed.<sup>44</sup>
- Concern about assessing the need for legal protection of patient safety performance measurement and monitoring by individual health-care organizations is addressed as a specific step for spring 2006.

Specific feedback (somewhat paraphrased to conserve space) from the Review Panel included:

- [A] “learning” [approach to medical errors] must include some level of public involvement and disclosure of aggregate data. Can’t be overboard and shield intentional or flagrant errors or incidents. Must be explicit about exceptions and allowable data uses. It should not create a blanket shield for data labeled patient safety but not part of established system of patient safety reporting.
- Expand current hospital employee whistleblower protection—MCL 333.20180(1)-(7) related to reporting unsafe practices or conditions to all health-care workers.
- Broad protection important. Make sure reporting does NOT go to regulatory agency. This will...provide additional assurance that the reporting will not be used to discipline the provider/organization submitting the report. If state system/center, then obligation to investigate/report/act would need to be delineated as part of initiating such a system/center/organization.
- Keep legislative language and intent narrowly focused on patient safety.
- Policy statement [State of Michigan should provide statutory protection for patient safety activities...] [and State legislature should establish that all records, data, and knowledge collected...for patient safety improvement purposes...are confidential and privileged information.] Should have broad support from stakeholders. [Other recommendations from Round One]...could be included as possible approaches for a designated state body to review later.

<b>Summary of legal and design options for protecting data</b>	
<p>A 2001 NASHP report addressed legal and system design options for protecting reporting system data.<sup>45</sup> While the report focused primarily on mandatory reporting of medical errors, much of the discussion is relevant for consideration in the development of a voluntary reporting system.</p>	
<b>Issue</b>	<b>Discussion</b>
Foundation assumptions for reporting system	Two basic questions need to be addressed before deciding on type of protection for the data and people and organizations involved: (1) what is the purpose of the reporting system (e.g., public accountability or understanding how and why errors occur); and (2) how will the public's interest in accessing the information be balanced with providers' concerns about possible legal consequences of disclosure.
Reporting system design	Systems designed to de-identify data or use anonymous reporting can make data less useful for discovery. Some data de-identification may already be addressed adequately through other patient data confidentiality protections.
Public disclosure laws	All states have public disclosure laws (e.g., FOIA) that require public officials to make documents and records obtained while conducting official government business available to the public. Public disclosure exemptions for patient safety data and related documents need to be created if the entity housing and working with the data is part of state government. Exemptions alone offer limited disclosure protection but they can be strengthened by either creating or referencing them in confidentiality or peer review laws that protect reporting system information expressing a clear legislative intent that the information not be subject to disclosure under state freedom of information laws.
Confidentiality protections	Confidentiality protections for reporting systems can provide legal protections for data, reporters, or materials produced from working with the data, or all of these. Information may be protected from discovery, subpoena, search warrant, state public disclosure laws, and evidence in civil or administrative proceedings. Protection for reporters may include exclusion from civil and criminal lawsuits, monetary liability, retaliatory lawsuits, state anti-trust lawsuits, compelled testimony, and employer retaliation (i.e., whistleblower protection). Confidentiality statutes and regulations specific to reporting system data can provide strong disclosure protections. However, the decision must be made whether to protect any follow-up information as well as the original reporting.
Peer review protection	While peer review protection typically extends to committee reports, records, proceedings, testimony, and participants, the specific protection offered varies among states. Depending on how broadly these statutes are worded, they can provide strong legal protections for reporting system data if their language includes (or may be interpreted to include) documents, records, and other information shared for purposes of quality assurance or improvement. To reduce ambiguity, both statutes should include language that makes it clear that reporting system activities are to enjoy peer review protected status. The strongest protections also preclude the people from volunteering information or being compelled to testify about information from the reporting system.

<b>Strengths and weaknesses of legal protections</b>		
The same NASHP 2001 report also summarizes the strengths and weaknesses of the various protection strategies in protecting those who report the data. This table is reproduced here. <sup>46</sup>		
<b>Approach to Protecting Data</b>	<b>Strengths</b>	<b>Weaknesses</b>
System design features (de-identify data; anonymous reporting)	Reduce need for legal protections for reporters & providers by not collecting &/or maintaining identifying information. May encourage reporting by minimizing threat of legal exposure for reporters and providers.	Do not protect incidents from disclosure & the legal process, only protects identifying information. Thus, data can be used as general similar occurrence evidence. Anonymous reports make it impossible for state officials to conduct F/U activities or issue institution specific reports to the public. Do not hold institutions publicly accountable through threat of public exposure. Do not provide consumers with information to inform provider choice.
Exemptions from public disclosure laws	May be used to strengthen legal protections provided by special confidentiality statutes for mandatory reporting system data. May be used to strengthen legal protections for mandatory reporting system data provided by states' peer review laws.	Their application may be limited by the courts. May not provide protection from legal compulsion. Statutory language may allow state officials to release exempted information at their discretion.
Confidentiality protections	Specifically designed to protect information in reporting systems & thus not susceptible to court interpretation as to whether the protections apply to reporting systems. May encourage reporting by minimizing threat of legal exposure for reporters & providers.	May not protect information obtained during F/U investigations unless protective statute drafted to extend protections to F/U activities.
Statutory peer review protections	May provide very strong protections for reports & reporters depending upon scope of protections. May be protected from varying court interpretations by providing clear language of legislative intent.	Subject to limited application depending upon how badly prospective litigants need the information & whether, on balance. A court determines that justice would be served by making the information available. Certain documents & records related to reportable incidents (e.g., documents created by, as opposed to for, the committee process may be excluded from the protection by the courts. May not protect information produced by the state (e.g., notes from investigations or final reports) in response to a report.

**Protection of reporting within state patient safety centers**

Patient safety centers in existence when the Flood Tide Forum completed its report did not handle mandatory reporting systems for patient safety data. Five of six (FL, MD, MA, NY, and PA) housed mandatory systems for reporting serious adverse events separately within state regulatory agencies. Oregon has no mandatory reporting system and the Oregon Patient Safety Commission is creating a voluntary reporting system for serious adverse events as part of its mission (discussed further under Oregon in the following table). The table reproduced below describes the reporting system within each of the six patient safety centers and how it is protected.<sup>47</sup>

State	Characteristics
Florida	Confidential, voluntary reporting system for near misses.
Maryland	Confidential, voluntary reporting system for near misses and adverse events that do not cause harm.
Massachusetts	Is pursuing the possibility of a voluntary, confidential reporting system for near misses and complications in order to provide hospitals information to help in establishing best practices.
New York	Has legislative authority to implement a confidential, voluntary system but has not done so yet. Plans are under development for a <i>Hospital Report Card</i> .
Oregon	Confidential, voluntary system for serious adverse events
Pennsylvania	Mandatory, confidential web-based system for serious events, near misses, and infrastructure failures, with no identifiable patient or provider information. All licensed hospitals, birthing centers, and ambulatory surgical facilities are required to submit reports through a single portal. There is a statutory provision for submission of “anonymous reports” by health care workers who can demonstrate a facility’s failure to submit a required report. The reporting system automatically directs reports of serious events and incidents to the Patient Safety Authority and reports of serious events and infrastructure failures to the Department of Health. The system contains integral, facility-specific analytical and statistical tools for use by facilities to promote internal quality improvement and patient safety activities.

<b>Comparison of Pennsylvania and Oregon patient safety-related protections</b>		
Detailed information on protection of patient safety data, sources, and activities related to use is presented in table format for two states of particular interest, Pennsylvania because it is using a combination of legal protection and incentives (possibility of medical malpractice liability insurance premium discount if a reduction in serious events can be shown following adoption of recommendations by the state's patient safety center) to increase reporting and Oregon because it is using a voluntary approach to adverse event reporting. This is presented to allow a comparison of current protection approaches in a state with mandatory reporting and one in the process of developing a voluntary reporting system.		
	<b>Pennsylvania<sup>48</sup></b>	<b>Oregon<sup>49</sup></b>
Description of responsible agency	Patient Safety Authority, an independent state agency; established 2002	Oregon Patient Safety Commission, a semi-independent state agency; established 2003
Type of reporting system	Mandatory	Voluntary
Who reports	All state-licensed hospitals, birthing centers, and ambulatory surgical centers	Hospitals, long-term care facilities, ambulatory surgical centers, outpatient renal dialysis facilities, and freestanding birthing centers as defined in state law; pharmacies licensed by state; and independent professional health-care societies or associations
What is reported	Serious adverse events and incidents (near misses)	Serious adverse events, root cause analysis, actions plans established to prevent similar serious adverse events and patient safety plans
Number of reports received	70,851 reports of serious events and incidents in 2004; 95% incidents	NA
<b>Approach to Protecting Data</b>		
System design features	All reports are de-identified and do not contain any patient or provider names; anonymous reporting possible for individual health-care workers.	All reports or other information developed and disseminated by the Program may not contain or reveal the names or other identifiable information with respect to participants providing information to the Commission for the purposes of the 2003 Act.
Exemptions from public disclosure laws	Any documents, materials or information made confidential by the Act are not subject to the Right-to-Know Law.	Oregon Public Records Law does not apply to public records containing patient safety data or reports that are created or maintained by the Commission and the Public Meetings Law does not apply to portions of meetings (or minutes of those portions) of the Commission Board of Directors, subcommittees, or advisory committees that consider information that identifies a participant or patient.
Confidentiality protections	Any documents, materials or information received from the medical facility, health-care worker, patient safety committee or governing board of a medical facility that is solely prepared or created for	Patient safety data and reports obtained by a patient safety reporting program from participants are confidential and privileged and are not admissible in evidence in any civil action, including but not limited to a judicial,

	<p>compliance with the Act, is not discoverable or admissible as evidence in any civil or administrative action or proceeding. No person who performs responsibilities for or participates in meetings of the patient safety committee or governing board of a medical facility pursuant to the Act shall be allowed to testify related to knowledge gained by this participation. Any documents, materials, records or information that would otherwise be available from original sources is not to be construed as immune from disclosure or use in a civil or administrative action or proceeding merely because they were presented to the patient safety committee or governing board of a medical facility.</p>	<p>administrative, arbitration or mediation proceeding. Patient safety data, patient safety activities and reports are not subject to: civil or administrative subpoena; discovery in connection with a civil action, including but not limited to a judicial, administrative, arbitration, or mediation proceeding; or disclosure under state public records law pursuant to section 2 (3) of this 2003 Act and, if permissible, federal public records laws. The privilege established under this section does not apply to records of a patient's medical diagnosis and treatment and to records of a participant created in the ordinary course of business.</p>
<p>Sources &amp; user protection</p>	<p>Persons providing information or services to the patient safety committee, governing board of a medical facility, authority, or department are protected from civil liability or charges of violating criminal law unless the information is false and the person knew or had reason to believe the information was false.</p> <p>Act states that medical facility patient safety plans shall "Prohibit any retaliatory action against a health care worker for reporting a serious event or incident in accordance with the act of December 12, 1986 (P.L. 1559, No.169), known as the Whistleblower Law."<sup>50</sup> House attempting to pass further legislation in 2004 specific to health-care practitioners who report poor patient care or unsafe conditions. Current status unclear.</p>	<p>Persons serving on the Patient Safety Commission Board of Directors, on a committee established by the board, communicating information to the Reporting Program or conducting a study or investigation on behalf of the Program are not subject to an action for civil damages for affirmative actions taken, acts of omission, or statements made in good faith. Participants or representatives of the Reporting Program cannot be examined in any civil action as to whether a communication of any kind has been made or shared with another participant or with the Program regarding patient safety data, activities, reports, records, memos, analyses, deliberative work, statements or root cause analyses, provided the communication was made with the intent of making a disclosure to or preparing a report to be submitted to the Commission.</p> <p>Reports or other information developed and disseminated by the Program may not contain or reveal the names or other identifiable information with respect to participants providing information to the Commission for the purposes of the 2003 Act, or to any individual identified in the report or information, and upon whose patient safety data, patient safety activities and reports the Commission has relied in developing and disseminating information.</p> <p>It is explicitly stated that notification to patients of a serious adverse event may not be construed as admission of liability in a civil action.</p> <p>No specific mention of whistle-blower protection for health-care employees noted in legislation.</p>

Statutory peer review protections and patient safety	Not discussed.	Other privileges under state or federal law that provide greater peer review or confidentiality protections are still available.
<b>Uses of Data</b>		
Uses of data	Reporting system automatically directs reports of serious events and infrastructure failures to the Department of Health.	The board may not use or disclose patient safety data for purposes of any enforcement or regulatory action in relation to a participant.
<b>Reports</b>		
Reports	Initiated 2004: Electronically distributed quarterly <i>Patient Safety Advisories</i> (clinical analysis of reports submitted plus lit search about process improvements for improving patient safety) for health-care professionals & administrators	Section 4 of 2003 law: The program shall include: "Distributing written reports using aggregate, de-identified data from the program to describe statewide serious adverse event patterns and maintaining a website to facilitate public access to reports, as well as a list of names of participants. The reports shall include but are not limited to: (A) the types and frequencies of serious adverse events; (B) yearly serious adverse event totals and trends; (C) clusters of serious adverse events; (D) demographics of patients involved in serious adverse events, including the frequency and types of serious adverse events associated with language barriers or ethnicity; (E) systems' factors associated with particular serious adverse events; (F) interventions to prevent frequent or high severity serious adverse events; and (G) appropriate consumer information regarding prevention of serious adverse events.

## Endnotes

<sup>1</sup> Code 26 (PeerProtect). The submitted testimony recommends development of an environment that provides legal protection for health care organizations and clinical practitioners when using data for improvement of patient safety practices.

<sup>2</sup> Testimony 608W:154-157, insurer.

<sup>3</sup> See Research Overview: Michigan for discussion of whistleblower protection in Michigan. Per Review Panel this is recommended for expansion to all health-care employees.

<sup>4</sup> See Summary of legal and design options for protecting data, p. 8 and Strengths and weaknesses of legal protections, p. 9 this document.

<sup>5</sup> Marchev, M., Rosenthal, J. & Booth, M. (October 2003). *How states report medical errors to the public: Issues and barriers*. Retrieved 4/30/05 from [http://www.nashp.org/Files/GNL52\\_medical\\_errors\\_reporting\\_for\\_the\\_web.pdf](http://www.nashp.org/Files/GNL52_medical_errors_reporting_for_the_web.pdf)

<sup>6</sup> Testimony 213W:131-133, health-care provider.

<sup>7</sup> Marchev, M. (December 2003). *Medical malpractice and medical error disclosure: Balancing facts and fears*. Retrieved 5/1/05 from [http://www.nash.org/files/medical\\_malpractice\\_and\\_medical\\_error\\_disclosure.pdf](http://www.nash.org/files/medical_malpractice_and_medical_error_disclosure.pdf)

<sup>8</sup> Example of state legislation approach to assessing effectiveness of statutory protection of patient safety data for a voluntary reporting system: Oregon Patient Safety Commission Legislation – “The Oregon Patient Safety Commission Board of Directors shall report: (4) No later than September 30, 2007, to an interim committee of the Seventy-fourth Legislative Assembly regarding reporting results and whether performance goals have been met. The board shall offer recommendations for any changes to the system, including possible implementation of a mandatory serious event reporting system.” Retrieved 7.07.05 from [www.theoma.org/Files/OREGON\\_PATIENT\\_SAFETY\\_COMMISSION\\_LEGISLATION.doc](http://www.theoma.org/Files/OREGON_PATIENT_SAFETY_COMMISSION_LEGISLATION.doc)

<sup>9</sup> Flowers, L. & Riley, T. (March 2001). *State-based mandatory reporting of medical errors: An analysis of the legal and policy issues*. Portland, ME: National Academy for State Health Policy.

<sup>10</sup> Testimony 110W:102-121; 1229-131; 103-104, hospital.

<sup>11</sup> Testimony 110W:55-56; 60-62; 45-48, hospital.

<sup>12</sup> Testimony 213W:8-10; 136-137; 168-174; 128-133, health-care provider.

<sup>13</sup> Testimony 103O:38-46, hospital.

<sup>14</sup> Testimony 204W:83-84, health-care provider.

<sup>15</sup> Testimony 608W:40; 149-153, insurer.

<sup>16</sup> Testimony 212W:119-121, health-care provider.

<sup>17</sup> Testimony 826W:----, professional organization.

<sup>18</sup> Testimony 202O:57-59; 60-63.

<sup>19</sup> Testimony 213W:8-10; 136-137; 175-183; 128-133, health-care provider.

<sup>20</sup> Testimony 205W:163-165; 179-180, health-care provider.

<sup>21</sup> Testimony 808O:175-184; 189-191; W:336-338, professional organization.

<sup>22</sup> Testimony 826W:144-147, professional organization.

<sup>23</sup> Testimony 302W:453-457; O:167-185, educator.

<sup>24</sup> Testimony 828W:98-101, professional organization.

<sup>25</sup> Testimony 110W:102-121; 129-131; 103-104, hospital.

<sup>26</sup> Testimony 608W:40; 149-153, insurer.

<sup>27</sup> Testimony 110W:55-56; 60-62; 45-48, hospital.

<sup>28</sup> Testimony 404W:19-21; 339-344; 32-36; 51-52; 384-385, consumer.

<sup>29</sup> Testimony 110W:55-56;60-62; 45-48, hospital.

<sup>30</sup> Testimony 110W:102-121;129-131; 103-104, hospital.

<sup>31</sup> (Public Health Code 333.20175(8) “The records, data, and knowledge collected for or by individuals or committees assigned a professional review function in a health facility or agency, or an institution of higher education in this state that has colleges of osteopathic and human medicine, are confidential, shall be used only for the purposes provided in this article, are not public records, and are not subject to court subpoena.” Retrieved 5/2/05 from <http://www.legislature.mi.gov/mileg.asp?page=getObject&objName=mcl-333-20175>

<sup>32</sup> Examples: 1) the Michigan Appellate Digest (12/6/02) regarding MCL 333.20175(8) "A statutory privilege should be narrowly construed consistent with its purpose." Hospitals: "The purpose of the privilege granted to medical facility peer review records in the PHC is to assure that honest assessment and review of performance is undertaken by peer review committees." Michigan Appellate Digest. Retrieved 5/2/05 from <http://courtofappeals.mijud.net/Digest/newHTML/22536321.htm>.

2) DykemaGossett Health Law Developments – January 2005: [Based on *Feyz vs. Mercy Memorial Hospital*] The Michigan peer review statute protects only action taken by a person or committee that has been assigned a peer review function. [This] illustrates the benefits of listing in Medical Staff and Corporate Bylaws the various committees and individuals who are assigned a practice review function. Retrieved 5/2/05 from <http://www.dykema.com/healthcare/news/hlthlawdev0105.pdf>

3) Public Health Code 333.21513 - The owner, operator, and governing body of a hospital licensed under this article: (d) Shall assure that physicians and dentists admitted to practice in the hospital are organized into a medical staff to enable an effective review of the professional practices in the hospital for the purpose of reducing morbidity and mortality and improving the care provided in the hospital for patients. The review shall include the quality and necessity of the care provided and the preventability of complications and deaths occurring in the hospital. Retrieved 5/3/05 from <http://www.legislature.mi.gov/mileg.asp?page=getObject&objName=mcl-333-21513>

<sup>33</sup> A person employed by or under contract to a hospital shall not be discharged, threatened, or otherwise discriminated against by the hospital regarding that person's compensation or the terms, conditions, location or privileges of that person's employment if that person reports an unsafe practice or condition. This protection is in addition to the protection for reporting a violation of the law under the Whistleblower Protection Act (WPA). If the unsafe practice or condition also violates the law, the person making the report will already be protected under the WPA and can follow the requirements for reporting the issue as noted above. If the unsafe practice or condition is not also a violation of law, the new amendment to the Public Health Code provides the protection for the person reporting the issue (note that the amendment does not define "unsafe practice or condition"). This distinction is important because there are some conditions that the hospital employee must follow in order to be entitled to the protection the new amendment provides. Under the new amendment, the hospital employee must give written notice of the unsafe practice or condition to the hospital, and allow the hospital 60 days to address the matter. The hospital is required to provide a response in writing to the person who provided the written notice within the 60 day period. Once the 60 days have expired, the hospital employee may only report the unsafe practice or condition to the Department of Consumer and Industry Services if the employee has no reasonable expectation that the hospital has taken or would take timely action to address the issue. The hospital employee is protected from retaliation for reporting the issue both before and after the report is submitted to the DCIS, including the 60 day period. Therefore, the protection starts as soon as the hospital employee provides the written notice to the hospital. Retrieved 5/3/05 from <http://www.minurses.org/Labor/handbook.shtml>

<sup>34</sup> Personnel communication, Denise Chrysler, MDCH, June 29, 2005.

<sup>35</sup> Kohn, L. T., Corrigan, J. M., & Donaldson, M. S. (Eds). Committee on Quality of Health Care in American, Institute of Medicine. (2001). *To err is human: Building a safer health system*. Washington, D.C.: National Academies Press, 1999.

<sup>36</sup> S544 Patient Safety and Quality Improvement Act of 2005

Retrieved 5/5/05 from <http://thomas.loc.gov/cgi-bin/bdquery/z?d109:SN00544:@@D&summ2=m&>

<sup>37</sup> Testimony 205W:77-80, health-care provider.

<sup>38</sup> Testimony 205W:82-91, 106-108; O:692-704, health-care provider.

<sup>39</sup> NCPS Tips – May/June 2002. Retrieved 5/3/05 from [http://www.index.va.gov/search/va/va\\_search.jsp](http://www.index.va.gov/search/va/va_search.jsp)

<sup>40</sup> Phillips, R, L., Dovey, S. M., Hickner, J. S., Graham, D. & Johnson, M. (2005). The AAFP patient safety reporting system: Development and legal issues pertinent to medical error tracking and analysis. *Advances in Patient Safety, Volume 3*. Retrieved 7/11/05 from <http://www.ahrq.gov/downloads/pub/advances/vol3/phillips.pdf>. Several other important to consider barriers to developing patient safety reporting systems that are not directly related to protecting data and sources were also listed: (1) volume of reports per year – this could be up to 5 million near misses annually, 15 to 50 time the number submitted to the Aviation Safety Reporting System (ASRS); (2) cost of processing the reports – ASRS spent around \$70 per case in 2002; and (3) coding of narrative data – this raises issues of reliability in a tedious task and how to link data to other databases.

- <sup>41</sup> Marchev, M., Rosenthal, J., & Booth, M. (October 2003). *How states report medical errors to the public: Issues and barriers*. Retrieved 4/30/05 from [http://www.nashp.org/Files/GNL52\\_medical\\_errors\\_reporting\\_for\\_the\\_web.pdf](http://www.nashp.org/Files/GNL52_medical_errors_reporting_for_the_web.pdf)
- <sup>42</sup> Missouri Commission on Patient Safety. (2004, July). *Report presented to Governor Bob Holden*. Retrieved 4/13/05 from <http://insurance.mo.gov/aboutMD/issues/patsafety/PatientSafety.pdf>
- <sup>43</sup> A sample data protection statute is included in Marchev, P9. Marchev, M. (December 2003). *Medical malpractice and medical error disclosure: Balancing facts and fears*. Retrieved 5/1/05 from [http://www.nashp.org/files/medical\\_malpractice\\_and\\_medical\\_error\\_disclosure.pdf](http://www.nashp.org/files/medical_malpractice_and_medical_error_disclosure.pdf)
- <sup>44</sup> Marchev, M. (December 2003). *Medical malpractice and medical error disclosure: Balancing facts and fears*. Retrieved 5/1/05 from [http://www.nashp.org/files/medical\\_malpractice\\_and\\_medical\\_error\\_disclosure.pdf](http://www.nashp.org/files/medical_malpractice_and_medical_error_disclosure.pdf)
- <sup>45</sup> Flowers, L. & Riley, T. (March 2001). *State-based mandatory reporting of medical errors: An analysis of the legal and policy issues*. Portland, ME: National Academy for State Health Policy. Pp. 38-53.
- <sup>46</sup> Flowers, L. & Riley, T. (March 2001). *State-based mandatory reporting of medical errors: An analysis of the legal and policy issues*. Portland, ME: National Academy for State Health Policy. Pp. 59-60.
- <sup>47</sup> Rosenthal, J. & Booth, M. (2004, October). *Flood Tide Forum: State patient safety centers: A new approach to promote patient safety*. P. 19. Retrieved 3/28/05 from [http://www.nashp.org/Files/final\\_web\\_report\\_11.01.04.pdf](http://www.nashp.org/Files/final_web_report_11.01.04.pdf)
- <sup>48</sup> Pennsylvania Patient Safety Authority. Retrieved 6/24/07 from <http://www.psa.state.pa.us/psa/cwp/view.asp?a...>
- <sup>49</sup> Oregon Patient Safety Commission Legislation. Retrieved 7.07.05 from [www.theoma.org/Files/OREGON\\_PATIENT\\_SAFETY\\_COMMISSION\\_LEGISLATION.doc](http://www.theoma.org/Files/OREGON_PATIENT_SAFETY_COMMISSION_LEGISLATION.doc) –
- <sup>50</sup> Pennsylvania Act 13 (Medical Care Availability and Reduction of Error Act). Retrieved 6/24/07 from <http://www.mcare.state.pa.us/mclf/lib/mclf/hb1802.pdf>