

**STATE COMMISSION ON PATIENT SAFETY
ROUND ONE RECOMMENDATIONS
June 8, 2005**

Category A: Leadership and Knowledge

Code 11 (GuidePrin) – Guiding Principle: Strong, clear, and visible attention to patient safety that permeates “how an organization conducts its business” (its practices and methods) so that there is no question that patient safety is a goal of the organization and is strongly embraced and used as a guiding principle.

Code 12 (Ldrship) – Leadership: Enhancement of leadership within an organization to foster, develop, and implement patient safety systems.

Recommendation A2:¹ In order to improve their ability to prevent harm to patients, all organizations and practitioners concerned with the delivery of health care services must act to transform the state’s dominant health care culture from one of individual, professional autonomy to one that acknowledges the complex interdependence of people and processes through a systems orientation.

Recommendation A2a:² To assist them in successfully completing the transformation to a systems-oriented culture and to institutionalize this culture, organizations and practitioners should employ principles known to support the institution of innovations in other industries.³ They are also encouraged to use these principles in specific patient safety initiatives as a way to initiate transformation of their care delivery processes.⁴

Recommendation A2b:⁵ Because there is currently no systematic body of empirical evidence to support the use of specific organizational strategies (e.g., teams or culture change) to decrease medical errors or enhance patient safety, health care organizations should clearly specify their desired outcomes and build in timely evaluation of interventions.^{6 7 8}

Rationale: While the majority of health care organizations are now involved to some degree in efforts to improve patient safety and to create cultures of safety, progress is slow. Two major barriers to progress are rooted in the long-standing dominant health care culture of individual, professional autonomy: 1) the need to change the behaviors of individuals and 2) the need to change organization behavior to a non-blaming systems-oriented approach and to establish new lines of accountability. Both of these desired changes can be perceived as threats to the authority and autonomy of professionals.⁹

Informants at the State Patient Safety Commission hearings during fall 2004 provided a number of recommendations for improving patient safety in Michigan that would require significant changes in the ways that health care organizations and individual practitioners do things. These recommendations and their associated concerns fit well into a framework (slightly modified) used by the Pennsylvania Patient Safety Collaborative to present their thoughts on the

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elements of a culture of safety.¹⁰ When organized in this manner, these recommendations support a call for transforming the long-standing dominant culture in Michigan's health care field (a culture based on individual, professional autonomy) to one that is based on a systems approach. The following elements are addressed by a systems-oriented culture:

- State leadership for state-wide change in patient safety across the continuum of care^{11 12 13 14 15 16 17 18 19 20 21 22}
- Pervasive commitment to patient safety by organization leaders both clinical and administrative^{23 24 25 26 27 28 29 30 31 32 33}
- Open communication about patient safety at all levels of an organization with inclusion of patients and their families as active participants in their care and in the assessment of safety issues^{34 35 36 37}
- Creation of an organizational environment that supports learning from errors and near misses through rewarding those who report patient safety concerns, analysis of reported data to understand the underlying reasons for errors and near misses, use of a systems approach to assess patient safety problems and develop solutions, feedback of the outcomes of reports and analyses, and celebration of success in increasing reports of patient safety concerns and errors as well as in the use of data to make improvements to prevent future errors^{38 39 40 41 42 43 44 45 46 47 48 49 50}
- Safety design^{51 52 53}
- All persons involved in the care giving process, regardless of level, are engaged in and accountable for patient safety^{54 55 56 57 58 59}

Evidence and/or information on comparable initiatives being carried out in other states:

Culture is the set of values, guiding beliefs, understandings, and ways of thinking that is shared by members of an organization and is taught to new members as correct. Its critical functions are to:

1. Integrate organizational members so they know how to relate to one another. It guides day-to-day working relationships and communication between people.
2. Help the organization adapt to the external environment. It guides how an organization meets goals and how it deals with outsiders.⁶⁰

Not everyone agrees that culture can be changed but even those who feel it can be changed do not offer it as a quick and easy process.⁶¹ Regardless, there is a good deal of talk within patient safety circles about "creating the culture change" to make patient care safe. Various instruments have been used to assist organizations to assess their safety culture or climate and new ones are

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appearing (e.g., AHRQ's new Hospital Survey on Patient Safety and the SAQ set – Safety Attitudes Questionnaires currently used as part of the Keystone ICU project). JCAHO stimulated activity around safety culture creation in 2001 when its new patient safety accreditation standards for health care facilities required HCO leaders to ensure the implementation of an integrated patient safety program throughout the organization. In 2003, JCAHO also began requiring accredited organizations to meet annually specified patient safety goals. Each year the goals and associated recommendations are re-evaluated to determine whether they should be continued or replaced.⁶²

IOM Reports:

The IOM report *To Err is Human* stated that it would be hard to overestimate the underlying, critical importance to medical error reduction efforts of developing a systems-oriented culture of safety. This movement from the focus on blaming the individual for errors and accidents to acknowledging the complex interactive nature of people and processes in today's health care ties directly into the need to establish nonpunitive environments and systems for reporting errors so that adequate data can be collected to assess what is actually happening related to errors. The report is also clear about the necessity of making patient safety an explicit organizational goal clearly supported by top organizational leaders.⁶³

Keeping Patients Safe: Transforming the Work Environment of Nurses provides a more lengthy discussion of creating and sustaining a culture of safety including potential barriers (health care professional unrealistic expectations of clinical perfection, litigation, and regulatory barriers) and perspective on the long-term commitment nature of creating such cultures.⁶⁴

AHRQ Reports:

The recently available web-based four volume series on *Advances in Patient Safety* contains a number of articles that address various aspects of organizational culture and climate from model development (e.g., relationships between organizational elements such as leadership and outcomes) to implementation (e.g., cultural barriers to learning cultures in residency settings) to systems thinking and patient safety.

Two of particular interest:

- 1) A review of literature that concluded that there is no systematic body of empirical evidence currently available to support the proposition that organizational variables such as teams, culture change, or leadership make a difference in decreasing medical errors or in enhancing patient safety. This appears to be primarily related to inadequacy of reported detail on linkages between the organizational variables studied and the patient safety dependent variables in the published studies as well as the small number of published studies on anything other than medication

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errors. In addition, most of the studies did not take a systems perspective but examined single variables without considering interconnected organizational dynamics that may have been taking place.

The important issue here is that there is a lack of evidence to guide program development and other interventions. This indicates the importance of clearly defining goals and carrying out evaluation of interventions in a timely manner.⁶⁵

- 2) Presentation of an organizational model that highlights change management issues critical for sustained success of patient safety initiatives. Four implications for health care organizations are offered: 1) Change must consistently target multiple organization components (e.g., not just clinical or just technological). 2) Participants in the delivery process must play distinct roles in managing change (e.g., especially important for senior management to play an active role in establishing patient safety as an important and urgent priority). 3) Change must be implemented using support structures and multiple tactics integrated in a long-term plan (important that tactics are consistent with each other and aligned with the purpose of change). 4) Change must be institutionalized by providing health care workers with the capabilities and opportunities to engage in continuous safety improvement (e.g., role redesignment and retraining for these roles).⁶⁶

Other States:

Of 6 state patient safety centers, most plan to foster creation of a culture of safety. Florida and Oregon include such statements in their mission statements. Maryland and Pennsylvania include them in their “planned activities”. The group recommends beginning patient safety efforts by focusing on creating a culture of safety.⁶⁷

Missouri’s report to the governor includes the recommendation to “Create a culture of safety focusing on a system-oriented approach to reducing patient harm.”⁶⁸

Pros:

System-oriented health care culture:

- Would provide the foundation for all patient safety initiatives
- Could be expected to speed up improvement of patient safety indicators.

Barriers:

Culture change:

- Is hard work and takes long-term commitment to the goal

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- Would require careful planning using principles known to support the institution of innovations in other industries to achieve it and then to sustain it
 - Would require specific attention from top leadership
- Socialized professional expectations would also serve as a barrier.

Additional Comments/Concerns:

Implementation Steps:

- Decision that change to a culture supportive of patient safety efforts is a priority
- Assess readiness of organization / state to change
 - Why hasn't this happened before?
 - What needs to change for this to happen?
 - What will keep this change going after the initial effort has ended?
 - How can the change be institutionalized?
- Action plan for achieving change
- Plan for sustaining change
- Identify champions
- Roll out for the long run

Cost: TBD

Implementation Target Date: TBD

Grade: TBD

¹ This recommendation developed from 5 of 6 recommendations (5 informants) coded Leadership, 29 of 33 coded GuidePrin (19 informants), and 4 published documents. These materials are referenced in Endnotes related to information in the Rationale section.

² This recommendation developed from one published document referenced in Endnotes.

³ See for example: Rogers, E. M. (1995). *Diffusion of innovations (4th edition)*. New York: The Free Press. Kotter, J. P. (1996). *Leading change*. Boston, MA: Harvard Business School Press.

⁴ Ramanujam, R., Keyser, D. J., & Sirio, C. A. (2005). Making a case for organizational change in patient safety initiatives. *Advances in patient safety, Vol. 2*. Retrieved 5.31.05 from <http://www.ahrq.gov/downloads/pub/advances/vol2/Ramanujam.pdf>

⁵ This recommendation developed from 1 recommendation of 34 coded GuidPrin and 2 published documents referenced in Endnotes.

⁶ Hoff, T., Jameson, L., Hannan, E., & Flink, E. (2004). A review of the literature examining linkages between organizational factors, medical errors, and patient safety. *Medical care research and review, 61(1)*, 3-37. Retrieved 6.01.05 from <http://mcr.sagepub.com/cgi/reprint/61/1/3> Evidence does exist in aviation and nuclear safety

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regarding the worth of addressing individual, group, or structural aspects of organizations; it is evidence specific to the patient safety arena that is lacking.

⁷ Recommendation – Testimony 906-W (other) We must also build a body of evidence to support the wholesale transformation of the industry. Building capacity includes development of a non-punitive reporting system so we can learn where mistakes are happening, where patients are at greatest risk of harm. That knowledge will provide a platform for the second dimension of progress [development of clear national patient safety goals and implementation of related measures]. [W 159-164]

⁸ Leape, L. L. (2005). Prologue: Where the rubber meets the road. *Advances in patient safety, Vol 3*. Retrieved 5.22.05 from <http://www.ahrq.gov/downloads/pub/advances/vol3/Leape.pdf>

⁹ Leape, L. L. & Berwick, D. M. (2005). Five years after *To Err is Human* what have we learned? *Journal of the American Medical Association, 293*, 2384-2390.

¹⁰ Pennsylvania Patient Safety Collaborative. (2001). *Elements of a culture of safety*. Retrieved 5.23.05 from

http://www.haponline.org/downloads/1_Elements%20of%20a%20Culture%20of%20Safety.pdf

State leadership for state-wide change in patient safety across the continuum of care is added here. Expansion of the system perspective to include the state as a whole is justified by the Michigan State Patient Safety Coalition's concern with safety in any health care service delivery setting.

¹¹ Recommendation – Testimony 204-B (provider) Create a statewide culture of safety. [W70]

¹² Recommendation – Testimony 204-B (provider) First, the Commission should establish a definition of patient safety that health care practitioners willingly embrace. [W70-71]

¹³ Recommendation – Testimony 204-B (provider) Seventh, identify trends or other significant opportunities to make care safer and share that information in a meaningful way with potentially similar impacted practitioners or institutions. [W91-94]

¹⁴ Recommendation – Testimony 213-W (provider) I will argue in my testimony that developing a “culture of safety” in hospitals, state regulatory agencies, third-party payers, and our legal system can help to reduce medical errors better in the long term, ... [W 8-10] I can make some recommendations, based on my personal experiences. [W 136-137] 1. As in most hospitals, Providence has a process in place, where all serious errors are reviewed. The focus of this team is not to place blame, but to look at all factors to discover the “root causes” of the error. The leader of this team begins by explaining this to the involved individuals, to encourage their participation and honest sharing of information. This attitude needs to be adopted across the state. [W 138-144] We need to promote an environment in which the first response is not to assign blame, censure, or sue, but to look at how and why and an error occurred, and take steps to avoid the error in the future.” [W 131-133]

¹⁵ Recommendation – Testimony 213-W (provider) I will argue in my testimony that developing a “culture of safety” in hospitals, state regulatory agencies, third-party payers, and our legal system can help to reduce medical errors better in the long term, ... [W 8-10] I can make some recommendations, based on my personal experiences. [W 136-137] 4. Healthcare organizations need to continue to focus on developing “just” cultures, and do a better job of communicating and educating the public. [W 165-167] You may have heard the term “blame-free” culture used. This is not an appropriate phrase to use, since it implies that there is no accountability. The overwhelming majority of healthcare workers do not come to work to harm or injure a patient. In rare instances, an individual may cause harm to a patient due to gross negligence, or criminal actions. In these cases, blame is appropriate and necessary. However, in the majority of cases, medical errors are not totally due to an individual's error. There is frequently a system or process component that contributes to the error. The better term to use would be “just” culture ... [W 116-123] Effective change is never easy, and in order to continue to provide safer care to the patients we serve, we need to cultivate a “just” culture across our state. [W 201-202] [I]n order to improve patient safety, we need to promote an environment where healthcare providers feel safe to report actual errors, whether or not harm is caused to patients, in addition to “near misses,” where an

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error is prevented from reaching the patient. We need to promote an environment in which the first response is not to assign blame, censure, or sue, but to look at how and why and an error occurred, and take steps to avoid the error in the future. [W 128-133]

¹⁶ Recommendation – Testimony 302-B (educator) We must change the culture surrounding healthcare regulation in Michigan to recognize that “to err is human.” At the present time, our system is punitive (W399-400). First, as you've heard from others, we have to change the culture to recognize the fact that to err is human.[O 112-114]

¹⁷ Recommendation – Testimony 605-B (insurer) [For] (implementation of high technology tools) There is also a required need for a change in the culture of safety in these settings (hospitals, physician offices, and community pharmacies, and other settings), as well as substantial training and re-engineering of clinical processes, which represent additional costs for providers [P3, L30-31]

¹⁸ Recommendation – Testimony 827-W (professional organization) Patient safety should be a multi-faceted concept, including participation with patients, their families, health care providers, third party payers, government agencies, employers, and consumer groups, that is embraced before an individual enters the health care system and then followed throughout the system with them. [W70-73] Creating a culture of safety goes beyond implementing an organizational concept. It should entail prevention before entry into the health care system and follow-up after hospitalization. Organizations should develop meaningful patient safety programs that actively involve patients, their families, and staff before, during, and after the need for hospitalization. [W80-84] Patient safety training should be required as part of an organizations annual staff competency program. This will foster an environment that emphasizes the importance of patient safety. Part of this type of program should provide an opportunity for patients to comment on safety issues. This information can be used to improve the patient safety program as needed. [W101-105]

¹⁹ Recommendation – Testimony 828-W (professional organization) Regulation and legislation must support collaborative approaches among hospitals, physicians, hospital employees, and health plans to stimulate and improve patient safety and must be non-punitive (W 96-98).

²⁰ Recommendation – Testimony 830-W (professional organization) We urge the State Commission on Patient Safety to give significant attention to the multitude of patient safety concerns faced by the state's approximately 40,000 nursing home residents (W23-25). We therefore urge the Commission to pay careful attention to the plethora of urgent patient safety issues facing the state's vulnerable nursing home residents and to make recommendations for addressing these shameful and unnecessary conditions (W106-110).

²¹ Recommendation – Testimony 906-W (other) The science of safety can be summarized in four points: (1) We will make mistakes. (2) We need to create a culture where mistakes are identified. (3) To maximize learning we must focus on systems rather than people. (4) Leaders control the potential to change systems. State leadership is needed to create an environment where clinicians can learn from mistakes. [W 133-136]

There are two goals for safety education. One is to have caregivers become comfortable saying "I'm fallible. I'm going to make mistakes. That's just part of the human condition." Having acknowledged that, we need to strive to make our care harm-free rather error-free. The second is to get them to understand the idea of systems. [W 138-141]

²² Recommendation – Testimony 906-W (Other) *Michigan has a strong tradition of voluntary hospital reporting, a leadership track record for collaboration ... , an enviable assembly of healthcare stakeholders that are members of the Michigan Health and Safety Coalition, and a major insurer (Blue Cross Blue Shield of Michigan) with a progressive vision of how to support quality and safety improvements. That combination of forces with a shared vision could position the state to aggressively innovate and add to the body of knowledge necessary to demonstrate definitively, year after year, that healthcare is indeed safer. ... We encourage the patient safety commission to recommend this level of state leadership.* [W 230-241]

An overarching opportunity is for states like Michigan to call for and support coordinated

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leadership from all of these different major stakeholders [Fed, State (incl licensing), health professional ed, health care delivery systems, practitioners – see W 198-203] rather than developing one more unique, state specific set of expectations for healthcare quality and safety. [W 211-213]

Leadership for reform, then, really needs to come from several different sources. In Crossing the Quality Chasm the IOM called for fundamental change at many different levels. We need to see change at the Federal level and we also need change at the state level. We need change in the health profession education, training and licensure. We also need change in the healthcare delivery system at the community level and the local level and in the micro-systems of care: individual care units in hospitals, physician's offices, clinics etc. [W 198-203]

²³ Pennsylvania Patient Safety Collaborative. P. 3

²⁴ Page, A. (ed). (2004). *Keeping patients safe*. Washington, D. C.: The National Academies Press. P. 282

²⁵ Recommendation – Testimony 103-O (hospital) The patient safety culture is I believe fundamental to truly achieving the safe environment of care. And there is a long tradition of punitive response to clinical errors and adverse outcomes in healthcare. I think these issues [patient safety culture and tradition of punitive response to clinical errors and adverse outcomes] have to be overcome by leadership, by education, and by an infrastructure of organizational policies that support a nonpunitive reporting of errors. Organizations absolutely must learn from these events. These events are inevitable. Human error is inevitable. And no system is going to be absolutely perfect and eliminate entirely errors and adverse events. [O 22-37]

²⁶ Recommendation – Testimony 104-O (hospital) I'd like to provide a summary of the nine initiatives which have assisted and supported our patient safety journey and hopefully this can be processed in other hospitals, these recommendations. [O 9-13] Leadership is the key for the organization to move towards a culture of safety. The direction for the patient safety begins with the board and begins with the president, the CEO, the COO, and the top leadership group. [O 32-36]

The president needs to be the leader of the Patient Safety Committee. This gives the organization the message that patient safety is the number one priority. [O 48-51] An active Patient Safety Committee can be the pulse for the organization for patient safety success. We have employees and managers at all levels in the organization as part of our Patient Safety Committee, which is led by the president. Data and measurement drive the agenda. They have reviewed the occurrences, they look at near misses, they look at the actions, and they make recommendations. They give the direction to the organization, the people down in the ranks who know what's going on about what needs to be done and what resources need to be provided to the organization. [O 99-112]

²⁷ Recommendation – Testimony 807-B (professional organization) I am submitting in written testimony today with references to illustrate that the promotion of a safety culture in healthcare facilities, regular feedback of our findings from the surveillance, education of direct care providers on practices to prevent infection, and organizational leadership support all can be brought to bear in enhancing patient safety. (O 60-69).

²⁸ Recommendation – Testimony 906-W (other) *Michigan has a strong tradition of voluntary hospital reporting, a leadership track record for collaboration ... , an enviable assembly of healthcare stakeholders that are members of the Michigan Health and Safety Coalition, and a major insurer (Blue Cross Blue Shield of Michigan) with a progressive vision of how to support quality and safety improvements. That combination of forces with a shared vision could position the state to aggressively innovate and add to the body of knowledge necessary to demonstrate definitively, year after year, that healthcare is indeed safer. ... We encourage the patient safety commission to recommend this level of state leadership. [W 230-241]*

An overarching opportunity is for states like Michigan to call for and support coordinated leadership from all of these different major stakeholders [Fed, State (incl licensing), health professional ed, health care delivery systems, practitioners – see W 198-203] rather than

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²⁹ Reinertsen, J. L., Pugh, M. D., & Bisognano, M. (2005). *Seven leadership leverage points for organization-level improvement in health care*. Retrieved 5.16.05 from

<http://www.ihl.org/IHI/Products/WhitePapers/SevenLeadershipLeveragePointsWhitePaper.htm>

Seven Leadership Leverage Points: 1) Establish and oversee system-level aims for improvement at the highest board and leadership level; 2) Align system measures, strategy, and projects in a leadership learning system; 3) Channel leadership attention to system-level improvement; 4) Get the right team on the bus; 5) Make the chief financial officer a quality champion; 6) Engage physicians; and 7) Build improvement capability

³⁰ Recommendation – Testimony 205-B (provider) Encourage Chief Executive Officers of Michigan health systems to invest in patient safety organizational structure by committing human and fiscal resources to operationalize a robust patient safety program in their respective institutions (e.g. patient safety manager/officer, medical director of safety, patient safety line item budget) [W168-172].

³¹ Recommendation – Testimony 213-W (provider) I will argue in my testimony that developing a “culture of safety” in hospitals, state regulatory agencies, third-party payers, and our legal system can help to reduce medical errors better in the long term, ... [W 8-10] I can make some recommendations, based on my personal experiences. [W 136-137] 2. We have various multidisciplinary patient safety committees that I facilitate, or participate in. During these meetings, we review all errors, and near misses related to medication [assume medication] use, and patient identification. We identify trends, and develop action plans to deal with them, and the information is filtered up to our governing board. All healthcare organizations need to share this kind of information with their governing boards. Additionally, the fact that these processes exist needs to be shared with the public. [W 145-153]

³² Recommendation – Testimony 606-W (insurer) CALL TO ACTION HAP has pledged to implement programs of this type [that support and promote bedrock principles of patient safety; W27] – recommended by The Leapfrog Group, the Institute for Healthcare Improvement and other patient safety organizations – and we urge other Michigan organizations to adopt them as well. [W37-40; also W245-248] Refocus on specific quality “leaps.” ...Therefore, HAP urges a renewed focus on specific, discrete improvements in quality and safety designed to yield the largest safety gains. These include:... [W249-252] a. CPOE implementation, in which physicians enter prescriptions and treatments into a computer rather than manual transcription. An alignment of government, health plans, coalitions and purchasers to implement CPOE by 2007-2008 in high-volume hospitals would have a huge impact on quality care and patient safety. [W253-256] b. Evidence-based hospital referral, in which elective treatment is guided by referrals to hospitals and clinical teams with superior outcomes and/or procedures linked with minimum patient volumes [W257-259] c. ICU physician staffing, in which hospital intensive care units are managed by physicians certified in critical care medicine [W260-261] Leverage purchasing power. [W279]

³³ Kohn, L. T., Corrigan, J. M., & Donaldson, M. S. (Eds). Committee on Quality of Health Care in America, Institute of Medicine. (2001). Chapter 8: Creating safety systems in health care organizations. *To err is human: Building a safer health system*. Washington, D.C.: National Academies Press. Retrieved 3.28.05 <http://www.iom.edu/topic.asp?id=3718>

³⁴ Pennsylvania Patient Safety Collaborative. P. 5

³⁵ Page, A. (ed). P. 289

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³⁶ Recommendation – Testimony 213-W (provider) I will argue in my testimony that developing a “culture of safety” in hospitals, state regulatory agencies, third-party payers, and our legal system can help to reduce medical errors better in the long term, ... [W 8-10] I can make some recommendations, based on my personal experiences. [W 136-137] 2. We have various multidisciplinary patient safety committees that I facilitate, or participate in. During these meetings, we review all errors, and near misses related to medication [assume medication] use, and patient identification. We identify trends, and develop action plans to deal with them, and the information is filtered up to our governing board. All healthcare organizations need to share this kind of information with their governing boards. Additionally, the fact that these processes exist needs to be shared with the public. [W 145-153] 4. Healthcare organizations need to continue to focus on developing “just” cultures, and do a better job of communicating and educating the public. [W 165-167] You may have heard the term “blame-free” culture used. This is not an appropriate phrase to use, since it implies that there is no accountability. The overwhelming majority of healthcare workers do not come to work to harm or injure a patient. In rare instances, an individual may cause harm to a patient due to gross negligence, or criminal actions. In these cases, blame is appropriate and necessary. However, in the majority of cases, medical errors are not totally due to an individual's error. There is frequently a system or process component that contributes to the error. The better term to use would be “just” culture ... [W 116-123] Effective change is never easy, and in order to continue to provide safer care to the patients we serve, we need to cultivate a “just” culture across our state. [W 201-202]

[I]n order to improve patient safety, we need to promote an environment where healthcare providers feel safe to report actual errors, whether or not harm is caused to patients, in addition to “near misses,” where an error is prevented from reaching the patient. We need to promote an environment in which 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. [W 128-133]

³⁷ Recommendation – Testimony 906-W (other) By far the most cost-effective opportunity to improve care in this country is not from discovering new therapies but in learning how to deliver those therapies that we know work safely and cost-effectively. We need a more balanced health care research portfolio, to help with those efforts. We know, through research on organizational behaviors, that we need to focus on “systems” to truly impact change. [W 46-50] The third dimension [to the work that lies ahead] is improving communication, which is at the core of culture change. IT infrastructure including an electronic medical record is part of that because it is not a tool to just help link us better, but a tool that has to be coupled with culture change and enhancing our ability to work together as human beings. The transparency needed to create a seamless system of care cannot be accomplished without standardizationof IT [W 174-178]

³⁸ Recommendation – Testimony 105-B (hospital) I am going to share with you what we have experienced in our microcosm at Munson because I believe that it could serve as the source for other initiatives that if implemented at the macro or State level, would result in fewer deaths and less harm to patients in the State of Michigan. [W 16-19; O 24-29] Secondly, mandatory nonpunitive reporting systems. This should be instituted for errors and near misses occurring in healthcare. We must create a learning environment so that care providers are not operating in a vacuum, unaware of errors their colleagues are making. The data elements must have easily understood definitions that can be operationalized in a consistent manner across settings. In time, I would suggest these results be made public by organization [written “should be publicly made available”] so that informed decisions can be made as to where people choose [want replaces choose in written] to receive their healthcare. We should be able to benchmark our results on a multitude of measures, including [oral: “patient” added] falls, nosocomial skin breakdown, medication errors causing harm, pneumonia and shock rates and other patient satisfaction measures [last phrase in written: “and general patient satisfaction with pain control to name a few”]. If we measure it, we can [written: “better”] understand it and then improve -- create (written: “implement” replaces “improve – create”) solutions to improve it. [O 220-240; W 123-132] Creating a culture of patient safety is needed. This involves: Non-punitive error reporting[;]

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Follow-up on errors when they happen[;] Making system changes so errors are not repeated [W 160-163]

³⁹ Recommendation – Testimony 106-B (hospital) We would echo Dr. Bagian's comments that all reporting is voluntary, and we have to make it safe for people to do that type of reporting [voluntary reporting], to tell the stories. [O 146-149] We have found that people want to tell us what is going on but they must have it safe. [O 117-118] It's [error reporting is] more about the culture than the economic cost. [O 164-165] It's the culture. It's how do you create an environment where the people that work in it day in, day out, are willing to say I think this went wrong. Here's another interesting fact. Most of our reports are self-identified reports. In other words, it's Paul talking about what Paul's experience of what he did or almost did in his role and participation in an error. What we are finding is that this whole system that we have had in the past of human vigilance of watching for mistakes doesn't work and we have to develop systems in place to make that obsolete, and that's what we're talking about.

We want to create an environment where it's safer -- we want to create an environment where people feel safe to report but they also see the benefit of that reporting. Benefit is we are implementing systems that make it safer for them to do their job. [O 172-191] And here's the other important point: We are celebrating the fact that our reports are going up. That's a cultural issue and sometimes it's hard for people to understand. But if you don't celebrate that you've got an open environment to hear more about the events, and this what I'm deeply concerned about mandatory reporting, if we're going to go out there and say look at all these bad things that occurred at St. Elsewhere Hospital, if we do that we're going to drive our reporting underground. [O 243-253]

⁴⁰ Recommendation – Testimony 106-B (hospital) We would echo Dr. Bagian's comments that all reporting is voluntary, and we have to make it safe for people to do that type of reporting [voluntary reporting], to tell the stories. The Commission should be holding healthcare organizations accountable to take action upon the stories [told through voluntary reporting]. [O 149-151] The Commission should be asking organizations not what problems that they have had but what solutions they have generated. What solutions are now present? [O 61-64] A focus should be on that [what type of solutions are being effective and utilized]. [O 69]

⁴¹ Recommendation – Testimony 213-W (provider) I will argue in my testimony that developing a “culture of safety” in hospitals, state regulatory agencies, third-party payers, and our legal system can help to reduce medical errors better in the long term, ... [W 8-10] I can make some recommendations, based on my personal experiences. [W 136-137] 4. Healthcare organizations need to continue to focus on developing “just” cultures, and do a better job of communicating and educating the public. [W 165-167] You may have heard the term “blame-free” culture used. This is not an appropriate phrase to use, since it implies that there is no accountability. The overwhelming majority of healthcare workers do not come to work to harm or injure a patient. In rare instances, an individual may cause harm to a patient due to gross negligence, or criminal actions. In these cases, blame is appropriate and necessary. However, in the majority of cases, medical errors are not totally due to an individual's error. There is frequently a system or process component that contributes to the error. The better term to use would be “just” culture ... [W 116-123] Effective change is never easy, and in order to continue to provide safer care to the patients we serve, we need to cultivate a “just” culture across our state. [W 201-202] [I]n order to improve patient safety, we need to promote an environment where healthcare providers feel safe to report actual errors, whether or not harm is caused to patients, in addition to “near misses,” where an error is prevented from reaching the patient. We need to promote an environment in which the first response is not to assign blame, censure, or sue, but to look at how and why and an error occurred, and take steps to avoid the error in the future. [W 128-133] 7. Performance improvement (PI) processes such as Six Sigma, LEAN, Failure Mode Effects Analysis (FMEA), and traditional PI tools are being integrated throughout the organization. We are seeing positive results from the use of these processes, and are beginning to see a change in our culture.

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Encourage healthcare organizations to integrate business improvement strategies that have proven successful in other businesses. [W 184-190]

⁴² Recommendation – Testimony 807-B (professional organization) I am submitting in written testimony today with references to illustrate that the promotion of a safety culture in healthcare facilities, regular feedback of our findings from the surveillance, education of direct care providers on practices to prevent infection, and organizational leadership support all can be brought to bear in enhancing patient safety. [O 60-69]

⁴³ Recommendation – Testimony 816-W (professional organization) A culture of safety must be developed in which mental health providers can provide data about psychiatric/psychological medical errors. [W 72-74]

⁴⁴ Pennsylvania Patient Safety Collaborative. P. 5

⁴⁵ Recommendation – Testimony 103-O (hospital) The patient safety culture is I believe fundamental to truly achieving the safe environment of care. And there is a long tradition of punitive response to clinical errors and adverse outcomes in healthcare. I think these issues have to be overcome by leadership, by education, and by an infrastructure of organizational policies that support a nonpunitive reporting of errors. Organizations absolutely must learn from these events. These events are inevitable. Human error is inevitable. And no system is going to be absolutely perfect and eliminate entirely errors and adverse events. It's absolutely essential that when these events occur people are comfortable to report them openly, to participate in very detailed in-depth root cause analysis of the underlying reasons for the event. I would like to suggest as one part of this that the medical-legal climate is a barrier to this open reporting and would urge that to be one focus of many. [O 22-46]

⁴⁶ Recommendation – Testimony 104-O (hospital) I'd like to provide a summary of the nine initiatives which have assisted and supported our patient safety journey and hopefully this can be processed in other hospitals, these recommendations. [O 9-13] I'd like to start first with the patient safety needs to be an organizational goal. [O 12-15] Organizations need to develop a culture of safety. [O 52-55] Part of this culture is a nonpunitive culture. That means that employees can report without having any penalties. They don't have to be fearful for their jobs, for themselves, or for their peers. It promotes reporting, and we usually find in our organization that this has truly increased those occurrence reporting and those near misses. This allows us to put our emphasis on systems and on processes and not on people. [O 67-75] We need to tell our stories. We use story-telling. We talk about "It Happens Here." [O 174-175]

⁴⁷ Recommendation – Testimony 106-B (hospital) We would echo Dr. Bagian's comments that all reporting is voluntary, and we have to make it safe for people to do that type of reporting [voluntary reporting], to tell the stories. [O 146-149] We have found that people want to tell us what is going on but they must have it safe. [O 117-118] It's [error reporting is] more about the culture than the economic cost. [O 164-165] It's the culture. It's how do you create an environment where the people that work in it day in, day out, are willing to say I think this went wrong. Here's another interesting fact. Most of our reports are self-identified reports. In other words, it's Paul talking about what Paul's experience of what he did or almost did in his role and participation in an error. What we are finding is that this whole system that we have had in the past of human vigilance of watching for mistakes doesn't work and we have to develop systems in place to make that obsolete, and that's what we're talking about.

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⁴⁸ Recommendation – Testimony 608-W (insurer) To that end, [to prevent future harm [W32]] we need to develop a process that would not only encourage reporting of medical errors but would enhance the reporters comfort in reporting. A process that creates further fear of retribution is useless. An environment that encourages reporting of medical errors, whether facility specific, state wide or national basis should be created in the spirit of a “just culture”. (A just culture is a shared understanding of how the acceptability of individual behavior is to be determined and how accountability/culpability is evaluated. Ultimately a just culture is shared accountability.) [W32-39]

⁴⁹ Recommendation – Testimony 204-O (provider) Eighth, publicly celebrate identified safety improvement ideas generated.

⁵⁰ Kohn, L. T., Corrigan, J. M., & Donaldson, M. S. (Eds).

⁵¹ This topic is addressed under the Team and Human Design and Facility Design recommendations.

⁵² Pennsylvania Patient Safety Collaborative. P. 7

⁵³ Kohn, L. T., Corrigan, J. M., & Donaldson, M. S. (Eds).

⁵⁴ Recommendation – Testimony 213-W (provider) I will argue in my testimony that developing a “culture of safety” in hospitals, state regulatory agencies, third-party payers, and our legal system can help to reduce medical errors better in the long term, ... [W 8-10] I can make some recommendations, based on my personal experiences. [W 136-137]

4. Healthcare organizations need to continue to focus on developing “just” cultures, and do a better job of communicating and educating the public. [W 165-167] You may have heard the term “blame-free” culture used. This is not an appropriate phrase to use, since it implies that there is no accountability. The overwhelming majority of healthcare workers do not come to work to harm or injure a patient. In rare instances, an individual may cause harm to a patient due to gross negligence, or criminal actions. In these cases, blame is appropriate and necessary. However, in the majority of cases, medical errors are not totally due to an individual’s error. There is frequently a system or process component that contributes to the error. The better term to use would be “just” culture ... [W 116-123] Effective change is never easy, and in order to continue to provide safer care to the patients we serve, we need to cultivate a “just” culture across our state. [W 201-202]

⁵⁵ Recommendation – Testimony 303-O (educator) ...respect for patients, families, nurses and all healthcare workers must be so fundamental that jobs and hospital privileges are at risk if standards are not met (O171-174).

⁵⁶ Recommendation – Testimony 606-W (insurer) To that end, [to prevent future harm [W32]] we need to develop a process that would not only encourage reporting of medical errors but would enhance the reporters comfort in reporting. A process that creates further fear of retribution is useless. An environment that encourages reporting of medical errors, whether facility specific, state wide or national basis should be created in the spirit of a “just culture”. (A just culture is a shared understanding of how the acceptability of individual behavior is to be determined and how accountability/culpability is evaluated. Ultimately a just culture is shared accountability.) [W32-39]

⁵⁷ Recommendation – Testimony 419-W (consumer) Another critical factor to improving patient safety is to allow for health care workers to have a stronger voice and more involvement in decision-making in health care facilities. [W300-302]

⁵⁸ Pennsylvania Patient Safety Collaborative. P. 8.

⁵⁹ Page, A. (ed). P. 288.

⁶⁰ Daft, R. L. (1995). *Organization Theory and Design 5th edition*. Minneapolis/St. Paul, MN: West Publishing Co.

⁶¹ Kotter, J. P. “Culture changes only after you have successfully altered people’s actions, after the new behavior produces some group benefit for a period of time, and after people see the connection between the new actions and the performance improvement. P. 156

⁶² Page, A. P. 303.

⁶³ Kohn, L. T., Corrigan, J. M., & Donaldson, M. S. (Eds). Chapter 8: Creating safety systems in health care organizations.

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⁶⁴ Page, A. Chapter 7: Creating and sustaining a culture of safety.

⁶⁵ Hoff, T., Jameson, L., Hannan, E. et al

⁶⁶ Ramanujam, R., Keyser, D. J., & Sirio, C. A.

⁶⁷ Rosenthal, J. & Booth, M. (2004, October). *Flood Tide Forum: State patient safety centers: A new approach to promote patient safety*. Retrieved 3/28/05 from http://www.nashp.org/Files/final_web_report_11.01.04.pdf

⁶⁸ 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>