

Recommendations

These recommendations take into consideration testimony originally coded to 06 (OrgReg)¹ and 07 (ProfLic)², as well as other sources, as noted.

- N1. The structure and functions of Michigan's health professions licensing boards should be reviewed and revised through legislation and administrative rule to strengthen the boards' ability to address patient safety issues, promulgate rules, and effectively discharge their responsibilities.³ In particular, boards should:
 - N1a. Be educated on the science of safety so they can identify system-related errors and include such findings in their reports, communicate system issues to the applicable health-care organizations, collect and trend individual-level data related to system issues and communicate trends to applicable health-care organizations.
 - N1b: Be permitted, when appropriate, to use non-disciplinary approaches such as alternative mediation when dealing with health professionals involved in errors attributable to health-care systems rather than individuals.^{4 5}
 - N1c: Be authorized to participate actively in promulgation of administrative rules that support a culture of safety by reviewing, commenting, voting and signing off on proposed rules to ensure that the policy and substance of rules are driven by health-care professionals.⁶
 - N1d: Require criminal background checks on all new health-care professional license applicants.⁷
 - N1e: Develop systems that more quickly and effectively identify and remove from practice unsafe professionals until competence to practice or operate is proven.⁸
- N2. In conjunction with national and state regulatory, licensing and accreditation organizations, state regulatory agencies should more rigorously monitor and hold all licensed health-care organizations accountable for full compliance with licensing and accreditation requirements. As a condition of licensure, all health-care organizations should develop, implement, and evaluate effective patient safety programs that require the organization to:
 - N2a. Pro-actively and fully disclosure to patients unanticipated patient outcomes and errors.⁹
 - N2b. Report all sentinel and adverse events.
 - N2c. Take appropriate corrective action as it relates to sentinel and adverse events as well as errors and near-misses.¹⁰
 - N2d. Investigate patient safety issues or error trends as identified and reported by a licensing board and implement appropriate system changes.
 - N2e. Perform criminal background checks on new employees and on all employees working in home care, long-term care and assisted living facilities.¹¹
- N3. Third-party payers and government sponsored health-care programs should develop patient safety incentives and other programs which reward in a "pay-for-performance" manner, health-care organizations that:
 - N3a. Pro-actively and fully disclosure to patients unanticipated patient outcomes and errors.
 - N3b. Report all sentinel and adverse events.
 - N3c. Take appropriate corrective action as it relates to sentinel and adverse events as well as errors and near misses.

Clarification

In preparing for Round Two, the Analytic Team has minimized overlap between the areas of Professional Education and Regulation and Licensing. All recommendations, rationale and research previously included in Regulation and Licensing that address the education of individual health professionals have been included in the Professional Education report.

Rationale

The licensing of health-care professionals and regulation of health-care organizations is one of the primary tools available to the State of Michigan to assure awareness of patient safety issues and reduce avoidable harm to patients. Moreover, licensing and regulation of professionals and health-care organizations is a legitimate and compelling interest of the State because of its exclusive right to regulate, license, monitor and control the activities of health-care organizations and individuals engaging in health-care practice as a means to protect the health and well-being of its citizens.

The recommendations above aim to reduce avoidable harm by incorporating “culture of safety” principles into the structure and practice of licensing boards. To promote a culture of safety within licensing boards, these bodies must be able to encourage voluntary reporting of errors and address professionals in a non-punitive manner. In Michigan, in contrast to several other states, licensing boards do not have the statutory authority to use non-disciplinary approaches such as “alternative mediation” to deal with professionals involved in system-driven patient safety issues. It will be important that licensing boards, while they incorporate culture of safety principles into their operations, continue to meet their obligation to protect the public from unsafe and incompetent professionals and bar professionals with certain criminal histories from working with vulnerable patients.

The organizational recommendations also aim to reduce harm by requiring all health-care organizations across the continuum of care to comply with patient safety and other requirements. Almost all accrediting and federal regulatory bodies have adopted or are adopting voluntary and/or mandatory patient safety requirements.¹² The requirements vary greatly, however.

A minimum set of safety program requirements should apply to all health-care organizations operating in Michigan, rather than just to some (e.g., hospitals but not outpatient surgery centers). Moreover, high levels of compliance with safety program requirements should be expected. Among JCAHO-accredited hospitals, by contrast, compliance with the disclosure of errors standard is, on average, low and varies a great deal from hospital to hospital. Aside from ethical and legal issues, disclosure of errors to patients is an important part of safety programs because the errors are documented, valuable information is obtained through discussions with the patient and/or family, patients learn from the experience, and a more thorough analysis of the event can be performed.

Modifying the requirements of health-care organization licensure is within the administrative rulemaking authority of the Department of Community Health, Bureau of Health Systems. The Health Systems Bureau (Division of Healthcare Facilities and Services) issues licenses to health-care organizations across the entire continuum of care.¹³

Adoption of patient safety programs by health-care organizations could also be stimulated by government and third-party payer incentive programs.

Evidence for harm reduction

A recent study argues that significant changes in the way licensing boards address issues related to errors and near misses is needed if they are to function as a means for improving

safety. The study found considerable fear that punitive action would result from disclosing a medication error, even if the error was a “near miss” and did not reach the patient. Expectation of punitive action varied by discipline, but was highest among professionals who had served on a licensing board.¹⁴ Failure to change these conditions impedes adoption of a culture of safety throughout the entire health-care industry.

Although the accrediting and regulatory agencies undergo a rigorous vetting process to develop their safety standards and Michigan should hold its licensed health-care organizations to those standards on principle and logic alone, there appears to be little or no empirical evidence compliance with the standards related to disclosure, reporting, and use of corrective action plans reduces harm to patients.

Assessment

Advantages

- The Public Health Code already permits regulatory agencies to monitor health-care organization performance. Thus, some of the recommendations require only changes to administrative rules, a less cumbersome process than statutory changes.
- Improving the knowledge, operations and legal capacity of boards may increase the boards’ ability to operate more efficiently and effectively and reduce potential harm to patients.
- Pharmacists and professionals working in nursing homes are already required to undergo criminal background checks. Expanding the requirement to all disciplines, especially those working with vulnerable populations, has the potential to identify professionals who should not be working among vulnerable patients and may deter such individuals from seeking employment in these areas.
- Wide accountability among all regulated and licensed health-care organizations for meeting established safety standards, such as full disclosure, is likely to have broad public appeal. Additionally, there is some evidence of financial benefits to health-care organizations that engage in pro-active full disclosure programs.
- Incentives programs related to implementing patient safety programs are already in place among some third-party payers.

Barriers

- The licensing boards’ activities are governed by administrative rules specific to each health-care occupational group. Thus, changes to each occupational group’s licensing board’s administrative rules may be required.
- Modifying the licensing boards’ operations to incorporate perspectives related to the science and culture of safety may also require financial and human resources.
- Increased enforcement of systems to identify and remove unsafe professionals should take into account differences between “errors of systems” and “errors of individuals.” Given the amount of distrust between professionals and boards, some degree of public relations work may be needed to convince professionals that it is safe to voluntarily disclose errors to licensing boards.
- Clear and widely agreed upon definitions are needed in order for health-care organizations to engage in full disclosure, reporting adverse and sentinel events and determining an appropriate corrective action plan.
- Other barriers to engaging in full disclosure include fear of litigation and costs related to program development and implementation and compliance monitoring.

Implementation

Further research

- Investigate mechanisms in Michigan and comparable states by which “unsafe” professionals are identified and removed from practice until competence to practice or operate is proven.¹⁵

Legislation and/or administrative rules

Amend the Public Health Code to:

- Revise the structure and functions of licensing boards to strengthen the boards’ ability to promulgate rules, address patient safety issues, and effectively discharge their responsibilities as specified in Recommendation N1a-e.
- Hold health-care organizations accountable for developing, implementing, and evaluating effective patient safety programs and investigating system-related patient safety issues or error trends and implement appropriate system changes if notified by a licensing board as specified in Recommendation N2a-e.

Resources

- Licensing boards will need additional funds and possibly staff to modify their operations.

Incentives

- Third-party payers and government sponsored health-care programs should develop patient safety incentives and other programs which reward in a “pay-for-performance” manner, health-care organizations that engage in pro-active and full disclosure of unanticipated patient outcomes and errors, report all sentinel and adverse events as required, and take appropriate corrective action as it relates to errors and near-misses.

Specific steps and target dates

Following adoption of these recommendations, the following steps will take place.

- Within 12 months, the Department of Community Health will finalize administrative rules to accomplish recommendations N1, N1c, N1d, and N2.
- Within 12 months, the Department of Community Health will inventory mechanisms in Michigan and comparable states by which “unsafe” professionals are identified and removed from practice until competence to practice or operate is proven, an important step toward recommendations N1b and N1e.
- Within 18 months, the Department of Community Health will propose administrative rules and/or legislation to modify the process by which “unsafe” professionals are identified and removed from practice until competence to practice or operate is proven, accomplishing recommendations N1b and N1e.
- Within 18 months the Department of Community Health or the Michigan Partnership for Safe Health Care will convene the first of a series of forums involving third-party payers and sponsors of government health programs. The task force will be charged with developing and promoting “pay for performance” guidelines per recommendation N3.

Testimony overview

Testimony related to regulation and licensing was received from seven informants (one hospital, two health-care professionals, two educators, and two health-care provider organizations).

Summary of additional research

Licensing of professionals

Two national and two state commissions (Missouri and Florida) identified issues regarding the way licensing boards are structured and operate, affecting their ability to protect the public from harm. The Pew Health Professions Commission conducted a review and recommended that states “provide the resources necessary to adequately staff and equip all health professions boards to meet their responsibilities expeditiously, efficiently and effectively.”¹⁶ Licensing boards appear to be hindered by a number of barriers, including inadequate resources and statutory limitations. The Missouri Commission reviewed its health-care boards, found deficiencies and recommended that the legislature allow, when appropriate, licensing boards to improve investigations and take disciplinary action when the professional was found to be reckless, incompetent, impaired, negligent or abusive.¹⁷

The Pew Commission found that ensuring the competence of health-care professionals throughout their careers is a serious problem: continuing education doesn’t guarantee competence, most licensing boards do not require periodic demonstrations of competence for continued licensure, and most legislatures have not allowed or required licensing boards assess continuing competence.¹⁸ The IOM also found that most states do not assess competence after initial licensure.¹⁹ The IOM recommended that performance standards and expectations for health professionals focus greater attention on patient safety. It also recommended that health professional licensing boards develop more effective methods to identify unsafe providers and take action.²⁰

Regulation of organizations

Because federal legislation requiring health-care organizations to implement safety programs and report safety events is limited, states have become more involved in monitoring and ensuring safety.²¹ Accordingly, the IOM recommends that licensing authorities focus on improving patient safety. Specifically, the IOM recommends adoption of safety-oriented performance standards and that regulators and accreditation bodies require health-care organizations to implement meaningful patient safety programs.^{22 23}

Full compliance with accrediting standards, especially standards related to disclosure, reporting, and corrective action, should be expected. JCAHO indicates that reducing harm to patients requires: identification of errors, analysis of error root causes, compiling and analyzing error data, dissemination of lessons learned, re-design systems based on disseminated information, and periodic assessment of effectiveness.^{24 25} These standards are consistent with recommendations N3a-d and should apply to all health-care organizations, not just those that are JCAHO-accredited.

The JCAHO standard for disclosure of errors to patients and their families addresses “unanticipated outcomes” and “other patient safety incidents.”²⁶ JACHO states that disclosure to itself and other health-care oversight bodies with a legitimate “need to know” is essential.²⁷ Despite the fact that several professional societies and credentialing organizations require that medical errors be disclosed to patients, evidence suggests that health-care organizations comply to varying degrees for a number of reasons, despite an ethical obligation, case law precedents, and evidence that the public, patients and physicians support disclosure.^{28 29}

Although evidence is sparse concerning the effects of full disclosure on health-care organizations, patients and professionals,^{30 31} there are other reasons for health-care organizations to comply with the requirement. A study of a Veteran’s Affairs hospital in Lexington, Kentucky, that has required full and pro-active disclosure since 1987 found that the hospital had an average payment per claim of \$15,622, compared to \$720,000 for other VA

facilities and \$1,484,000 for hospitals in the private sector.³² The studied hospital attributed this result to pro-actively admitting error, assisting the patient to file a claim, and offering compensation. These actions may defuse emotions that contribute to the decision to sue, resulting in savings to the hospital on litigation expenses and court judgments. Another study of health plan member attitudes about full disclosure of errors found that full disclosure reduced the likelihood of changing physicians, increased trust and satisfaction, and reduced the likelihood of seeking legal advice in all but one situation.³³ Additional evidence suggests that when litigation is pursued, full disclosure at the time the error was committed may favorably affect jury decisions.³⁴

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 scores for relevant recommendations considered in Round One:

- Professional Licensing: 3.4 (range 2.0 to 5.0)
- Regulation of Organizations: 2.2 (range 1.0 to 3.0)

Notes

There was strong support for all but two of the Round One recommendations related to using licensing of health-care professionals as a mechanism to improve patient safety competence.

- Regarding requests for licensing new groups of health-care professions (technologists who operate ionizing radiation equipment³⁵ and registered dieticians who provide medical nutritional therapy³⁶), the Panel recommended that such groups follow established procedures by submitting to the Department of Community Health clear and compelling empirical evidence that restricting practice through licensing is required to reduce errors and harm to patients and that the lack of licensing poses a threat to public health.
- The Panel was generally opposed to the recommendation requesting that Executive Order 96-2 be rescinded because it would create gaps, inconsistencies and inequities among licensing boards. The Panel was, however, supportive of modifying the administrative rulemaking process to strengthen the role of licensing boards as it relates to rule promulgation as noted in Recommendation Na-e.³⁷

During its deliberations, the Review Panel identified two additional opportunities use licensure as a mechanism to improve patient safety.

- The Panel recommended that criminal background checks be required of specific health-care employees as noted in Recommendations N1d and N3e.
- The Panel also recommended that licensing boards be educated in the science of safety and that they collect, trend and report system-related safety issues to appropriate health-care organizations.

There was only moderate support for Round One recommendations related to regulation of organizations, partly because recommendations related to development of a statewide error-reporting system had not yet been presented.

- The Panel raised a number of concerns about Recommendations N3a-d, which originally did not extend to non-JCAHO accredited and ambulatory health-care organizations. Concerns were also raised about pervasive under-reporting of sentinel events and that

requiring compliance with existing licensing and accreditation requirements was redundant of existing regulations. Recommendations N3a-e have been modified to address these concerns and suggestions.

- The Review Panel suggested that participation in the voluntary reporting system could be a condition of licensure. This recommendation was not added to Round Two recommendations because making participation in the voluntary reporting system a condition of licensure essentially makes participation in the system mandatory. In follow-up meetings, there was little support for a mandatory error reporting system.
- Round One recommendation related to reporting solutions and identifying and sharing practices were transferred to other more appropriate recommendation areas.

Endnotes

¹ Code 06 (Organization Regulation) was used to identify testimony recommending adoption of patient safety requirements as stipulated by regulatory and/or accreditation requirements by health-care organizations.

² Code 07 (Professional Licensing) was used to identify testimony recommending improvement of patient safety through licensing and/or certification of professionals working in the health-care field, including the specific inclusion of content related to patient safety in licensing and certification requirements.

³ Testimony 302O:141-143.

⁴ Testimony 302O:130-133, 302W:404-406.

⁵ Testimony 213W:8-10, 175-183.

⁶ Testimony 302O:144-146.

⁷ Centers for Medicare and Medicaid Services, retrieved 7.12.05 at <http://www.cms.hhs.gov/medicaid/survey-cert/bcp.asp>

⁸ Although this recommendation was not submitted through the testimony, it was an important strategy for improving safety through the professional licensure and disciplinary mechanism as identified by the Institute of Medicine, Missouri Commission on Patient Safety, and the Florida Commission on Excellence in Health Care among others.

⁹ Testimony 213W:175-183.

¹⁰ Testimony 106O:149-151.

¹¹ Centers for Medicare and Medicaid Services, retrieved 7.12.05 at <http://www.cms.hhs.gov/medicaid/survey-cert/bcp.asp>

¹² The Joint Commission on Accreditation of Healthcare Organizations, National Committee for Quality Assurance, Accreditation Association for Ambulatory Care, Utilization Review Accreditation Commission, and the Centers for Medicare and Medicaid Services are all involved with accrediting and to varying extents, regulating Michigan health-care organizations.

¹³ Michigan Department of Community Health, retrieved 4.18.05 at http://www.michigan.gov/mdch/0,1607,7-132-27417_28139_28142-92559--,html. The Bureau issues licenses and/or certificates for acute care hospitals; clinical laboratories; home health agencies; nursing homes and long-term care units; end stage renal disease facilities; hospices and hospice residences; psychiatric hospitals, units, and partial hospitalization programs; substance abuse centers; ambulatory surgical centers; comprehensive outpatient rehabilitation facilities; freestanding outpatient surgical facilities; outpatient physical therapy/occupational therapy and/or speech pathology services; portable x-ray services; rural health clinics; and county medical care facilities.

¹⁴ Institute for Safe Medication Practices, retrieved 7.8.05, at <http://www.ismp.org/msarticles/20050519Print.html>. May 19, 2005, Practitioners anticipate punitive action from licensing bodies. ISMP Medication Safety Alert!

¹⁵ Testimony 826W:149-152.

¹⁶ Finnocchio, L.J., Dower, C.M., Blick, N.T., & Gragnola, C.M. (1998). *Taskforce on health care Workforce Regulation - Strengthening Consumer Protection: Priorities for health care Workforce Regulation*. San Francisco: Pew Health Professions Commission.

¹⁷ Missouri Commission on Patient Safety (July 2004). *Missouri Commission on Patient Safety : Report Presented to Governor Bob Holden, July 2004*. Retrieved 7.13.05 at <http://www.insurance.mo.gov/aboutMDI/issues/patsafety/PatientSafety.pdf>. (pp. 26).

¹⁸ Finnocchio, op cit.

- ¹⁹ Kohn LT, Corrigan JM and Donaldson M (eds.). (2000). *To Err is Human: Building a Safer Health System*. Washington, DC: Institute of Medicine. (pg. 135).
- ²⁰ Kohn, *ibid.*, pg. 134.
- ²¹ Weissman JS, Annas CL, Epstein AM, Schneider EC, Clarridge B, Kirle L, Gatsonis C, Feibelman S, Ridley N. (2005). Error reporting and disclosure systems: views from hospital leaders. *JAMA*, 293(11):1359-1366.
- ²² Kohn, *op cit.*, pg. 133.
- ²³ Kohn, *ibid.*, pg. 134.
- ²⁴ JCAHO, retrieved 4.19.05 at <http://www.jcaho.org/accredited+organizations/patient+safety/medical+errors+disclosure/index.htm>
- ²⁵ JCAHO, retrieved 4.19.05 at <http://www.jcaho.org/accredited+organizations/patient+safety/medical+errors+disclosure/index.htm> - Retrieved April 19, 2005.
- ²⁶ Weissman *op cit.*, pg. 1362 citing Joint Commission on Accreditation of Health Care Organizations. (2003). Patient Rights and Organization Ethics [R.I. 1.2.2]. In: *Hospital Accreditation Standards*. Oak Brook, Ill: Joint Commission Resources Inc. pg. 79-80.
- ²⁷ JCAHO, retrieved 4.19.05 at <http://www.jcaho.org/accredited+organizations/patient+safety/medical+errors+disclosure/index.htm> - Retrieved April 19, 2005.
- ²⁸ Mazor KM, Simon SR, Gurwitz JH. (2004). Communicating with patients about medical errors: a review of the literature. *Arch Intern Med*, 164:1690-1697.
- ²⁹ Gallagher TH, Waterman AD, Ebers AG, Fraser VJ, Levinson W. (2003). Patients' and physicians' attitudes regarding the disclosure of medical errors. *JAMA*, 289:1001-7.
- ³⁰ Kachalia A, Shojania KG, Hofer TP, Piotrowski M, Saint S. (2003). Does full disclosure of medical errors affect malpractice liability? The jury is still out. *Jt Comm J Qual Saf*, 29:503-11.
- ³¹ Mazor, *op cit.*
- ³² Kraman SS, Hamm G. (1999). Risk management: extreme honesty may be the best policy. *Annals of Internal Medicine*, 131:963-967.
- ³³ Mazor, *op cit.*
- ³⁴ Popp, P.L. (2003). How will disclosure affect future litigation? *ASHRM Journal of Healthcare Risk Management*, 23:5-9.
- ³⁵ Testimony 829W:30-33.
- ³⁶ Testimony 812W:135-136, 217-218.
- ³⁷ Testimony 302O:144-146.