

**STATE COMMISSION ON PATIENT SAFETY  
ROUND ONE RECOMMENDATIONS  
APRIL 28, 2005**

**Category C:** Setting Performance Standards and Expectations

Code: OrgReg –Adoption of patient safety requirements as stipulated by regulatory and/or accreditation requirements by health care organizations.

**Recommendation C.06 (OrgReg).1**

*As it relates to the regulation of healthcare organizations, **an appropriate state-level organization**<sup>1</sup> should work with national and state regulatory, licensing and accreditation organizations to develop and implement mechanisms which hold healthcare organizations accountable for developing, implementing, and evaluating effective patient safety programs.*

*In particular, the **appropriate state-level organization** should work with national and state regulatory, licensing and accreditation organizations to develop and implement mechanisms which hold healthcare organizations accountable to:*

**Recommendation C.06 (OrgReg).1.1** *Comply with existing licensure and accreditation requirements related to full disclosure of unanticipated patient outcomes and errors*<sup>2</sup>;

**Recommendation C.06 (OrgReg).1.2** *Take appropriate corrective action as it relates to reported errors*<sup>3</sup>; and

**Recommendation C.06 (OrgReg).1.3** *Focus reporting requirements on reporting solutions rather than on reporting errors*<sup>4</sup>.

**Rationale:** One of the most powerful mechanisms for stimulating change within healthcare organizations is through accreditation, regulation and licensure mechanisms. Policy options for stimulating change can employ voluntary as well as mandatory mechanisms instituted by a variety of agencies and organizations which may or may not be directly accountable to Michigan policymakers. Attempts to effect change through accreditation, regulation and licensure mechanisms is complex because of the myriad of organizations involved. This section begins with an overview of the various organizations involved in regulation of organizations and ends with providing rationale for adoption of the three specific recommendations as provided by testimony submitters.

Overview of Accreditation, Regulation and Licensure Organizations.

There are national and local non-governmental organizations as well as federal and state governmental agencies involved with accreditation, regulation and

**STATE COMMISSION ON PATIENT SAFETY  
ROUND ONE RECOMMENDATIONS  
APRIL 28, 2005**

licensure of healthcare organizations. An overview of agencies involved in licensure, accreditation and regulation of Michigan healthcare organizations follows. Specifically, a limited set of the activities of national non-governmental, federal and state governmental organizations are reviewed.

*National Non-governmental Organizations.* Perhaps the most prominent organization involved with accreditation of healthcare organizations is the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) whose mission is to improve quality through accreditation. As it relates to hospital licensure, 44 states link hospital licensure to JCAHO accreditation. In Michigan, licensure for psychiatric hospitals in Michigan is linked to accreditation by JCAHO.<sup>5</sup> In contrast, the minimum standards for acute care hospitals does not state that JCAHO accreditation is a requirement for licensure in Michigan.<sup>6</sup> Nonetheless, Michigan, will accept (but does not require) JCAHO evaluation to fulfill the biannual evaluation survey requirements for hospitals.<sup>7</sup>

For health maintenance organizations (HMOs) and other types of managed care organizations, the National Committee for Quality Assurance (NCQA), JCAHO, Accreditation Association for Ambulatory Care (AAHC), and the Utilization Review Accreditation Commission (URAC). In Michigan, the Medicaid managed care contract requires NCQA, JCAHO or URAC accreditation to operate. Non-Medicaid HMOs are also accredited by AAHC.<sup>8</sup> Aside from the legal requirement that Medicaid managed care organizations must have a certificate of authority to operate and be incorporated in Michigan, its not clear whether there are additional state-based licensure standards that HMOs must meet in order to conduct business in Michigan<sup>9</sup>.

*Federal Governmental Organizations.* The Centers for Medicare and Medicaid Services (CMS) sets standards related to payment and conditions of participation for various types of healthcare organizations including hospitals. To participate in CMS programs providers must be certified. CMS tends to rely on state health agencies to certify healthcare organizations through state licensure. In some situations, JCAHO accreditation partly or wholly serves as meeting state licensure requirements.<sup>10</sup>

*State Government Organizations.* State licensure is another mechanism by which change as it relates to improving patient safety can be stimulated. As has been noted, state licensure of healthcare organizations can be based to varying degrees on accreditation by JCAHO and NCQA.

**STATE COMMISSION ON PATIENT SAFETY  
ROUND ONE RECOMMENDATIONS  
APRIL 28, 2005**

In Michigan, the licensing of healthcare organizations is a function undertaken by the Department of Community Health, Bureau of Health Systems (Bureau), Division of Healthcare Facilities and Services. The mission of the Licensing and Certification Division within the Bureau is to:

...protect the health and safety of individuals receiving care in health facilities and agencies such as hospitals and home health agencies, hospice, end stage renal disease facilities, outpatient surgical facilities, laboratories, rural health clinics, physical therapy and rehabilitation services, and substance abuse programs. Protection of individuals using these services is achieved through monitoring, evaluation and enforcement to ensure compliance with licensure and/or certification standards to assure and improve the health facilities' quality of care for patients and other individual users of the healthcare services.<sup>11</sup>

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.<sup>12</sup>

Thus, policies relate to licensure that endeavor to improve patient safety for all these types of healthcare organizations could be pursued under the state's rulemaking authority. Licensure of healthcare organizations in Michigan generally follows the administrative rule process. An administrative rule is an agency's written regulation, statement, standard, policy, ruling, or instruction that *has the effect of law*. A state agency writes rules under authority of state statute, the Michigan Administrative Procedures Act, the Michigan Constitution, and applicable federal law.<sup>13</sup>

Recommendation Rationale.

As previously mentioned, use of the licensure, accreditation and regulation "policy lever" can be an effective mechanism for stimulating change. The rationale for exercising this mechanism is reviewed for each of the specific recommendations as submitted through the testimony. Additional rationale for adoption of these recommendations is provided in the next section which review evidence and other existing programs.

**STATE COMMISSION ON PATIENT SAFETY  
ROUND ONE RECOMMENDATIONS  
APRIL 28, 2005**

***Recommendation C.06 (OrgReg).1.1 Comply with existing licensure and accreditation requirements related to full disclosure of unanticipated patient outcomes and errors.***

The testimony submitted did not provide a clear rationale for this recommendation. Nonetheless, the Institute of Medicine (IOM) noted that JCAHO accreditation standards addresses many aspects that promote patient safety.<sup>14</sup> In particular, Weissman et al. reported that as of 2001, the JCAHO has had a standard on disclosure of unanticipated outcomes and errors.<sup>15</sup> Thus, there is a sound rationale for expecting accredited healthcare organizations to be in compliance with the recommendation. It also suggests that there may be a rational basis for expecting non-accredited healthcare organizations to act accordingly.

***Recommendation C.06 (OrgReg).1.2 Take appropriate corrective action as it relates to reported errors.***

The testimony submitted did not provide a rationale for this recommendation. It is assumed that healthcare organizations are required as a condition of licensure and accreditation to appropriately respond to situations that result in errors. Specific programs and requirements related to error response are reviewed in the next section.

***Recommendation C.06 (OrgReg).1.3 Focus reporting requirements on reporting solutions rather than on reporting errors.***

The testimony submitted reasoned that focusing on solutions highlights what was used and found to be effective<sup>16</sup> and is a more productive endeavor than focusing on errors.<sup>17</sup> The testimony also notes that to engage in focusing on solutions assumes access to information that captures “events.”<sup>18</sup> There is support in the literature for the concept of linking accreditation and a solution-oriented focus. For example, one idea for improving patient safety contained in the future action, research and education section of their book, Rosenthal and Sutcliffe suggested that it would be worthwhile to “consider making the previous actions part of hospital accreditation requirements.”<sup>19</sup> It is assumed that this suggestion applies to previous actions related to identifying, implementing and evaluating solutions to problems.

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

This section of the analysis focuses on use of mechanisms to improve safety that employ the licensure, regulation and accreditation of healthcare organizations to

**STATE COMMISSION ON PATIENT SAFETY  
ROUND ONE RECOMMENDATIONS  
APRIL 28, 2005**

effect change. Where available, evidence and use of initiatives similar to those proposed in the testimony will be highlighted. Within the submitted testimony for all three recommendations, either no evidence of effectiveness of the recommendation provided<sup>20</sup> or the evidence was experiential and proved to be difficult to substantiate in the literature.<sup>21</sup> This section of the analysis reviews activities related to the three specific recommendations and the topic of regulation of organizations as a policy option for improving patient safety. The section begins by reviewing federal and national accreditation organizations, state licensure agencies, federal and state pending legislation, and efforts by various state patient safety coalitions.

Federal and National Accreditation Organizations. There is support at least from the IOM for use of accreditation and licensing authorities to improve the safety of patient care. Specifically, the IOM stated that, "After a reasonable period of time for health care organizations to set up such [patient safety] programs, **regulators and accreditors** [emphasis added] should require patient safety programs as a minimum standard."<sup>22</sup> Furthermore, as recommended by the IOM, "Performance standards and expectation for health care organizations should focus greater attention on patient safety." To that end, "**regulators and accreditors** [emphasis added] should require health care organizations to implement meaningful patient safety programs with defined executive responsibility."<sup>23</sup>

JCAHO has addressed the issue of patient safety improvement through two distinct means. First, it addresses patient safety through a series of annual national patient safety goals for a variety of healthcare organizations. Second, it addresses patient safety through its sentinel event program.

JCAHO's general position on patient safety as it relates to accreditation is noted as follows:

The Joint Commission is committed to improving safety for patients and residents in health care organizations. This commitment is inherent in its mission to continuously improve the safety and quality of care provided to the public through the provision of health care accreditation and related services that support performance improvement in health care organizations. At its heart, accreditation is a risk-reduction activity; compliance with standards is intended to reduce the risk of adverse outcomes.<sup>24</sup>

As detailed below, JCAHO's programs provide rationale and support for the submitted recommendations.

**STATE COMMISSION ON PATIENT SAFETY  
ROUND ONE RECOMMENDATIONS  
APRIL 28, 2005**

As it relates to disclosure of errors as noted in **Recommendation C.06 (OrgReg).1.1** which addresses disclosure to patients and their families, according to Weissman et al. JCAHO has an accreditation standard related to disclosure of errors to patients. Specifically, Standard R.I .1.2.2 addresses disclosure of “unanticipated outcomes and other patient safety incidents to patients and their families.”<sup>25</sup> Additionally, JACHO states that disclosure to itself “and other health care oversight bodies having a legitimate “need to know” [which] must have full and timely access to the data in the reporting system”<sup>26</sup> is an essential element to improving patient safety. Although this statement does not address the aspect of disclosure identified in recommendation, it indicates JCAHO’s support for a policy of disclosure. Moreover, JCAHO provides a bibliography of literature on it’s website that addresses the need to disclose errors to patients.<sup>27</sup>

With respect to recommendation **Recommendation C.06 (OrgReg).1.2**, which addresses the need to take appropriate corrective action as it relates to reported errors, JCAHO has relevant policies through its medical error and sentinel event reporting programs. Specifically, JCAHO’s perspective on medical error reporting is that, “Meaningful improvement in patient safety will eventually be reflected by a significant reduction in the number of medical/health care errors that result in harm to patients.”<sup>28</sup> Achieving this significant reduction is dependent upon:

- Identification of the errors that occur.
- Analysis of each error to determine the underlying factors -- the “root causes” -- that, if eliminated, could reduce the risk of similar errors in the future.
- Compilation of data about error frequency and type and the root causes of these errors.
- Dissemination of information about these errors and their root causes to permit health care organizations, where appropriate, to redesign their systems and processes to reduce the risk of future errors.
- Periodic assessment of the effectiveness of the efforts taken to reduce the risk of errors.<sup>29</sup>

Clearly, the existing policies fully anticipate that accredited organizations will engage in the above activities which are examples of “appropriate corrective action” as noted in the recommendation.

The third recommendation, **Recommendation C.06 (OrgReg).1.3**, requests that reporting efforts focus on reporting solutions rather than on reporting errors.

**STATE COMMISSION ON PATIENT SAFETY  
ROUND ONE RECOMMENDATIONS  
APRIL 28, 2005**

Despite its predominant focus on adverse event reporting, JCAHO does address the need to report (and evaluate) solutions through its sentinel event program. The corrective action plan requirement of the sentinel event program states that an action plan as it relates to sentinel events will be considered **acceptable** if it:

- identifies changes that can be implemented to reduce risk, or formulates a rationale for not undertaking such changes; and
- where improvement actions are planned, identifies who is responsible for implementation, when the action will be implemented (including any pilot testing), and how the effectiveness of the actions will be evaluated.<sup>30</sup>

State Licensing Agencies. As noted in recent Journal of the American Medical Association paper, “In the absence of federal legislation requiring hospitals to report safety events, states find themselves increasingly involved in efforts to monitor hospital safety practices.”<sup>31</sup> For example, the National Academy for State Health Policy indicates that six states passed legislation to create patient safety centers<sup>32</sup> and 21 states have mandatory patient safety reporting.<sup>33</sup> Incidentally, Michigan is not one of the states listed as requiring mandatory reporting nor does it have a statewide patient safety center.

As it relates to **Recommendations C.06 (OrgReg).1.2** and **C.06 (OrgReg).1.3** which deal with regulation of organizations by requiring action in response to error reports and reporting of solutions to errors, it may be of use to evaluate the extent to which these mechanisms are used in other states. The IOM interviewed 13 of the 21 states with a mandatory reporting requirement: California, Colorado, Connecticut, Florida, Kansas, Massachusetts, Mississippi, New Jersey, New York, Ohio, Pennsylvania, Rhode Island, and South Dakota. The IOM identified in an appendix information about each of these programs including what constituted a reportable event, who was required to report, whether reporting was mandatory or voluntary, who had access to the information and how the information was used.<sup>34</sup>

**Recommendation C.06 (OrgReg).1.2** addresses regulation of organizations by requiring appropriate corrective action in response to error reports. According to the IOM’s review of states with reporting systems, there is substantial variability in as to the specific adverse event or error that is reportable, whether reporting is mandatory or voluntary, and the types of healthcare organizations that are required to submit reports.<sup>35</sup> In response to reports, the IOM noted that six states require healthcare organizations to submit an acceptable plan for correction (California, Florida, New Jersey, New York, Rhode Island and South Dakota).<sup>36</sup>

**STATE COMMISSION ON PATIENT SAFETY  
ROUND ONE RECOMMENDATIONS  
APRIL 28, 2005**

Although there was variability among states as to the nature of the required corrective action plans, roughly half of the states required development and implementation of a plan. Thus, through an error reporting program, corrective action plans could be required by the state.

With respect to **Recommendation C.06 (OrgReg).1.3** - reporting requirements focus on reporting solutions rather than on reporting errors - in only one situation did the IOM note that solution-related information was part of an error reporting system. Specifically, Rhode Island hospitals are required to provide “a summary of all actions taken to correct the problems identified to prevent recurrence and/or improve overall patient care.”<sup>37</sup> Although this requirement begins to approach identification of solutions, it is not what would be characterized as a solution-reporting system. Based on this information, it appears that reporting and use of solution-related information is not typical in most states.

Regarding **Recommendation C.06 (OrgReg).1.1** which addresses full disclosure of unanticipated patient outcomes and errors as a condition of licensure, none of the information provided by the IOM on error reporting systems addressed this topic.

Although Michigan was not included in the IOM's review, licensure of its healthcare organizations includes a number of requirements which should be evaluated in relationship to the testimony recommendations. As noted earlier, licensure of healthcare organizations in Michigan is the responsibility of the Michigan Department of Community Health, Bureau of Health Systems, Division of Health Care Facilities and Services. The administrative rules that govern hospitals states that hospitals must comply with a set of minimum standards as specified in administrative rule R 325.1100.<sup>38</sup> In this document, administrative rule R 325.1015 states that hospitals are required to submit a monthly report on Form H-205 to the state health commissioner.<sup>39</sup> The administrative rule does not identify whether hospitals are required to report patient safety problems and whether successful solutions to the problems reported. (Form H-205 was not available for review at the time this analysis was prepared.) At this point, it's not clear whether or not the submitted recommendations are consistent with existing administrative rules that regulate licensure of hospitals and all other relevant healthcare organizations.

State and Federal Pending Legislation. Although there are 141 bills pending in the U.S. Congress that relate to patient safety, there is no pending legislation that addresses the use of licensure, regulation or accreditation of healthcare

**STATE COMMISSION ON PATIENT SAFETY  
ROUND ONE RECOMMENDATIONS  
APRIL 28, 2005**

organizations as mechanisms for improving patient safety.<sup>40</sup> Similarly, a document prepared by the Michigan Health and Hospital Association, indicates that there is no legislation pending in the Michigan House or Senate that address this same topic.<sup>41</sup> Lastly, there are no pending administrative rules within the Department of Community Health related to licensure of healthcare organizations.<sup>42</sup>

State Coalitions. Initiatives related to licensure of healthcare organization and reporting were reviewed for the following state-level patient safety programs: Maryland Patient Safety Center, New York Patient Safety Center, Pennsylvania Patient Safety Authority and the Massachusetts Coalition for Prevention of Medical Errors. Although all require some aspect of reporting, none appear to address the reporting elements as stipulated within the three recommendation under review.<sup>43</sup>

Despite the use of some of the methods contained in the recommendations by JCAHO and various state licensing authorities (and a common sense notion that the methods should be helpful), the literature reviewed to date are not conclusive with respect to effectiveness. A **preliminary** review of the literature did not established a positive association between these recommended elements and patient safety improvement. Specifically, disclosure of errors as stipulated in **Recommendation C.06 (OrgReg).1.**, that taking appropriate corrective action as stipulated in **Recommendation C.06 (OrgReg).1.2**, and that focusing on reporting solutions rather than errors as stipulated in **Recommendation C.06 (OrgReg).1.3** improves patient safety.

**Pros and Barriers by Recommendation:**

**Recommendation C.06 (OrgReg).1.1** *Comply with existing licensure and accreditation requirements related to full disclosure of unanticipated patient outcomes and errors.*

**Pros:**

- The requirement specified in this recommendation is already a JCAHO accreditation standard and as such, there is a platform from which voluntary or mandatory requirements could be developed.
- The requirement may be within the scope of responsibility for the state's administrative rulemaking authority and not require action on the part of the state legislature.

**STATE COMMISSION ON PATIENT SAFETY  
ROUND ONE RECOMMENDATIONS  
APRIL 28, 2005**

- The requirement is likely to have broad public appeal in that patients have a right to know when unanticipated patient outcomes and errors occur as it relates to their care.

**Barriers:**

- The requirement specified in this recommendation is subject to interpretation as it relates to what types of unanticipated patient outcomes and errors are subject to disclosure and exactly how disclosure should occur and be documented.
- Complying with the requirement may leave healthcare organizations open to litigation especially if some degree of peer protection for “system-related” errors is not enhanced/established.
- The relationship between what is subject to engaging in open disclosure and what is subject to institutional “incident reports” is not clear.
- Cost to develop policies, implement procedures and monitor compliance.
- The approach could be viewed by providers as “heavy handed” especially if sanctions related to licensure status (organizational as well as individual professionals) could be invoked.

***Recommendation C.06 (OrgReg).1.2 Take appropriate corrective action as it relates to reported errors.***

**Pros:**

- The requirement specified in this recommendation is already a JCAHO accreditation standard and most likely, a condition of maintaining organizational licensure in some circumstances.
- The requirement is within the scope of responsibility for the state’s administrative rulemaking authority.

**Barriers:**

- The recommendation is vague in that term “error” has to be clearly defined as to what sort of events are included, the term “appropriate corrective action” is subject to interpretation.
- There is a general barrier in that error reporting mechanisms are not well-developed in many circumstances and without data and root cause analysis programs, the most “appropriate action” cannot be determined and implemented.
- Cost to implement and monitor compliance as it relates to all possible reported errors.

**STATE COMMISSION ON PATIENT SAFETY  
ROUND ONE RECOMMENDATIONS  
APRIL 28, 2005**

***Recommendation C.06 (OrgReg).1.3*** Focus reporting requirements on reporting solutions rather than on reporting errors.

**Pros:**

- Reporting successful solutions is an ultimate and desirable outcome of patient safety programs.
- Provides an opportunity to do something pro-active and forward-looking in Michigan that is not being done in most other states.
- The recommendation that patient safety improvement efforts is in line with the direction JCAHO may be moving.
- There is an opportunity to affect the state licensure and monitoring processes perhaps more so than national organizations such as JCAHO.
- There is the potential for introducing the recommendation as part of a voluntary program through the state licensure mechanism or through the Michigan Health and Hospital Association.
- Complying with the recommendation could be enhanced through the use of incentives and implemented at the state-level (does not necessarily require buy-in from national organizations such as JCAHO).

**Barriers:**

- Focusing on solutions may present challenges in that it may be difficult to develop “standard” solutions. Current activity in the field seems to be focused on developing and implementing standards of care. Solutions are may vary across institutions and reflect the unique set of circumstances in individual healthcare organizations. As such, these may prove to be difficult to “standardize” and be used by other healthcare organizations.
- Reporting solutions assumes that many other mechanisms are currently in place including a standardized error taxonomy, error reporting systems, well-developed root cause analysis programs, and data analysis and information systems to name a few. Many organizations are not yet able to engage in these activities and to make such a requirement part of accreditation and licensure requirements may be premature. A standardized taxonomy of solutions does not currently exist.
- Diverts attention from other aspects of patient safety programs in need of development.
- Resistance from healthcare organizations and their associations due to the costs and burden of complying to additional reporting requirements.

**Additional Comment/Concerns:**

Two of the three recommendations reviewed (***Recommendation C.06 (OrgReg).1.2*** and ***Recommendation C.06 (OrgReg).1.3***) are germane to many

**STATE COMMISSION ON PATIENT SAFETY  
ROUND ONE RECOMMENDATIONS  
APRIL 28, 2005**

other recommendations submitted regarding voluntary and mandatory reporting which will be presented to the review committee in the future. They were evaluated here because the testimony suggested use of the licensure and accreditation mechanism for enacting/implementing the recommendations. To some extent, **Recommendation C.06 (OrgReg).1.2**, related to full disclosure of unanticipated patient outcomes and errors, could be viewed as redundant of existing JCAHO standards. Although healthcare organizations could be encouraged to more fully comply with JCAHO's standard, they may be reluctant to do so until there more protections from potential litigation are put in place .

This area (accreditation and licensure of healthcare organizations) is a very complex area that truly requires careful analysis and input by regulatory organizations as well as the associations that represent the healthcare organizations that could be effected. The material in this document barely "scratches the surface" regarding what could be done to improve safety in **all** healthcare organizations. This document primarily focuses on hospitals and there are many other areas that should be considered. Should there ever be a state-level center for patient safety, the topic of regulation of healthcare organizations as a means for stimulating improvement in patient safety could be incorporated in the mandate/mission of the center.

**Implementation Steps: TBD, depends on recommendation(s) supported.**

**Cost: TBD, depends on recommendation(s) supported.**

**Implementation Target Date: TBD, depends on recommendation(s) supported.**

**Grade: TBD**

**STATE COMMISSION ON PATIENT SAFETY  
ROUND ONE RECOMMENDATIONS  
APRIL 28, 2005**

**Reference List**

<sup>1</sup> Testimony 213W:175-183, 8-10 and Testimony 106B:O149-151

<sup>2</sup> Testimony 213W:175-183.

<sup>3</sup> Testimony 106B:O149-151

<sup>4</sup> Testimony 106B:O61-64, O69, O149-151

<sup>5</sup> Department of Labor and Economic Growth, Office of Administrative Hearings and Rules, retrieved 4.18.05. R 330.1223- Application for license [psychiatric hospitals]. Rule 1223. Application for a hospital license shall be filed on forms prescribed by the department and shall contain all of the following: (c) An indication of whether the hospital is accredited by the joint commission on accreditation of hospitals. If it has applied for accreditation and was disapproved, it shall attach to the application a copy of the joint commission on accreditation of hospitals notification of disapproval, including the list of recommendations. If it is already accredited, it shall attach to the application a copy of the joint commission on accreditation of hospitals notification of accreditation, including the list of recommendations.

[http://www.state.mi.us/orr/emi/admincode.asp?AdminCode=Single&Admin\\_Num=33001201&Dpt=CH&RngHigh](http://www.state.mi.us/orr/emi/admincode.asp?AdminCode=Single&Admin_Num=33001201&Dpt=CH&RngHigh)

<sup>6</sup> Department of Labor and Economic Growth, Office of Administrative Hearings and Rules, retrieved 4.18.05. Minimum Standards for Hospitals

[http://www.state.mi.us/orr/emi/admincode.asp?AdminCode=Single&Admin\\_Num=32501001&Dpt=CH&RngHigh](http://www.state.mi.us/orr/emi/admincode.asp?AdminCode=Single&Admin_Num=32501001&Dpt=CH&RngHigh)

<sup>7</sup> Michigan Public Health Code, retrieved 4.19.05. Public Health Code at 333.20155 as specified: The department of consumer and industry services shall make a biennial visit to each hospital for survey and evaluation for the purpose of licensure. Subject to subsection (6), the department may waive the biennial visit required by this subsection if a hospital, as part of a timely application for license renewal, requests a waiver and submits both of the following and if all of the requirements of subsection (5) are met: (a) Evidence that it is currently fully accredited by a body with expertise in hospital accreditation whose hospital accreditations are accepted by the United States department of health and human services for purposes of section 1865 of part C of title XVIII of the social security act, 42 U.S.C. 1395bb. (b) A copy of the most recent accreditation report for the hospital issued by a body described in subdivision (a), and the hospital's responses to the accreditation report. <http://www.legislature.mi.gov/mileg.asp?page=getObject&objName=mcl-333-20155&highlight>

<sup>8</sup> Michigan Insurance Code, retrieved 04.16.05. As noted on the OFIS website per Insurance Code at 500.3580 which requires that Insurance Commissioner publish a "consumer guide to health maintenance organizations" that include the national accreditation status of and any limitation on accreditation for each health maintenance organization. The Insurance Code link that *mandates* an HMO consumer's guide to identify national accreditation status (MCL 55.3580):

<http://www.legislature.mi.gov/mileg.asp?page=getObject&objName=mcl-500-3580> . HMO

Consumer Guide link:

[http://www.michigan.gov/documents/cis\\_ofis\\_hmo\\_consumer\\_guide\\_25371\\_7.pdf](http://www.michigan.gov/documents/cis_ofis_hmo_consumer_guide_25371_7.pdf) . HMOs in Michigan accredited by an accreditation organization (Page in the Consumer's Guide)

[http://www.michigan.gov/cis/0,1607,7-154-10555\\_13222\\_13224-54425--,00.html](http://www.michigan.gov/cis/0,1607,7-154-10555_13222_13224-54425--,00.html) .

<sup>9</sup> Michigan Public Health Code MCL 5000.3505.

<sup>10</sup> Kohn LT, Corrigan JM and Donaldson M (eds.). (2000). *To Err is Human: Building a Safer Health System*. Washington, DC: Institute of Medicine. (pg. 266).

<sup>11</sup> Michigan Department of Community Health, retrieved 4.18.05 at

[http://www.michigan.gov/mdch/0,1607,7-132-27417\\_27655\\_27661-42468--,00.html](http://www.michigan.gov/mdch/0,1607,7-132-27417_27655_27661-42468--,00.html)

**STATE COMMISSION ON PATIENT SAFETY  
ROUND ONE RECOMMENDATIONS  
APRIL 28, 2005**

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<sup>12</sup> Michigan Department of Community Health, retrieved 4.18.05 at

[http://www.michigan.gov/mdch/0,1607,7-132-27417\\_28139\\_28142-92559--,html](http://www.michigan.gov/mdch/0,1607,7-132-27417_28139_28142-92559--,html)

<sup>13</sup> As defined by MCL 24.207, a “rule” means “an agency regulation, statement, standard, policy, ruling, or instruction of general applicability that implements or applies law enforced or administered by the agency, or that prescribes the organization, procedure, or practice of the agency, including the amendment, suspension, or rescission of the law enforced or administered by the agency”. However, the statute identifies exceptions to what is considered a rule, i.e. attorney general opinion, intergovernmental memorandum, etc., including certain actions taken by the certificate of need commission or the statewide health coordinating council as identified under sections 333.22215 or 333.22217 of the public health code.

<sup>14</sup> Kohn, op cit., pg. 140-141.

<sup>15</sup> Weissman JS, Annas CL, Epstein AM, Schneider EC, Clarridge B, Kirle L, Gatsonis C, Feibelmann S, Ridley N. (2005). Error reporting and disclosure systems: views from hospital leaders. *JAMA* 293:1359-1366. (Pg. 1364.)

<sup>16</sup> Testimony 106B:O69

<sup>17</sup> Testimony 106B:O65-69

<sup>18</sup> Testimony 106B:O70-71

<sup>19</sup> Rosenthal MM, Sutcliffe KM (eds.). (2002). *Medical Error: What Do We Know? What Do We Do?* San Francisco, CA: Jossey-Bass.

<sup>20</sup> Testimony 106B

<sup>21</sup> Testimony 213W: 65-69.

<sup>22</sup> Kohn, op cit., pg. 134.

<sup>23</sup> Kohn, op cit., pg. 133.

<sup>24</sup> Joint Commission on Accreditation of Healthcare Organizations (JCAHO), retrieved 4.19.05 at <http://www.jcaho.org/accredited+organizations/patient+safety/facts+about+patient+safety.htm>

<sup>25</sup> Weissman op cit., pg. 1362 citing JCAHO. Patient Rights and Organization Ethics [R.I. 1.2.2]. In: *Hospital Accreditation Standards*. Oak Brook, Ill: Joint Commission Resources Inc; 2003:79-80.

<sup>26</sup> JCAHO, retrieved 4.19.05, at

<http://www.jcaho.org/accredited+organizations/patient+safety/medical+errors+disclosure/index.htm>

<sup>27</sup> JCAHO, retrieved 4.19.05, at

<http://www.jcaho.org/accredited+organizations/patient+safety/medical+errors+disclosure/medical+errors+disclosure.htm>

<sup>28</sup> JCAHO, retrieved 4.19.05, at

<http://www.jcaho.org/accredited+organizations/patient+safety/medical+errors+disclosure/index.htm>

<sup>29</sup> JCAHO, retrieved 4.19.05, at

<http://www.jcaho.org/accredited+organizations/patient+safety/medical+errors+disclosure/index.htm>

<sup>30</sup> JCAHO, retrieved 4.1805, at

[http://www.jcaho.org/accredited+organizations/sentinel+event/se\\_pp.htm](http://www.jcaho.org/accredited+organizations/sentinel+event/se_pp.htm)

<sup>31</sup> Weissman, op cit., pg. 1364.

<sup>32</sup> National Academy for State Health Policy (NASHP), retrieved 4.18.05 at

[http://www.nashp.org/docdisp\\_page.cfm?LID=5D30E15B-5584-4A3D-9F11902952374621](http://www.nashp.org/docdisp_page.cfm?LID=5D30E15B-5584-4A3D-9F11902952374621)

<sup>33</sup> NASHP, retrieved 4.18.05 at [http://www.nashp.org/docdisp\\_page.cfm?LID=F5F19A94-DB2F-4C5B-B05876BE2038E891](http://www.nashp.org/docdisp_page.cfm?LID=F5F19A94-DB2F-4C5B-B05876BE2038E891)

**STATE COMMISSION ON PATIENT SAFETY  
ROUND ONE RECOMMENDATIONS  
APRIL 28, 2005**

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<sup>34</sup> Kohn, op cit., pg. 254-265.

<sup>35</sup> Kohn, ibid.

<sup>36</sup> Kohn, ibid.

<sup>37</sup> Kohn, ibid., pg. 264.

<sup>38</sup> Michigan Public Health Code, retrieved 4.18.05. R 325.1100 Licensing of hospitals. Rule 100. (1) Until such times as rules are promulgated under the authority of section 5 of Act No. 17 of the Public Acts of 1968, licensing of all hospitals shall be based upon compliance with the minimum standards for hospitals set forth in R 325.1001 to R 325.1081 of the Michigan Administrative Code. [http://www.state.mi.us/orr/emi/admincode.asp?AdminCode=Single&Admin\\_Num=32501001&Dpt=CH&RngHigh](http://www.state.mi.us/orr/emi/admincode.asp?AdminCode=Single&Admin_Num=32501001&Dpt=CH&RngHigh)

<sup>39</sup> Michigan Public Health Code, retrieved 4.18.05. R 325.1015 Monthly report. Rule 15. As provided in Act No. 231 of the Public Acts of 1951, each licensed maternity hospital shall make a monthly statistical report on a prescribed form (H-205) to the state health commissioner. [http://www.state.mi.us/orr/emi/admincode.asp?AdminCode=Single&Admin\\_Num=32501001&Dpt=CH&RngHigh](http://www.state.mi.us/orr/emi/admincode.asp?AdminCode=Single&Admin_Num=32501001&Dpt=CH&RngHigh)

<sup>40</sup> GovTrack, retrieved 4.18.05 at <http://www.govtrack.us/congress/billsearch.xpd>

<sup>41</sup> Michigan Health & Hospital Association, retrieved 4.18.05 at <http://www.mha.org/mha/advocacy/Bill%20Tracking%2005-06.pdf>

<sup>42</sup> Department of Labor and Economic Growth, Office of Administrative Hearings and Rules, retrieved 4.18.05 <http://www.state.mi.us/orr/emi/rules.asp?type=dept&id=CH>

<sup>43</sup> Various patient safety centers, retrieved 4.18.05 at: Maryland Patient Safety Center <http://www.marylandpatientsafety.org/>; New York Patient Safety Center <http://www.health.state.ny.us/nysdoh/healthinfo/patientsafety.htm>; Pennsylvania Patient Safety Authority <http://www.psa.state.pa.us/psa/site/default.asp>; and Massachusetts Coalition for Prevention of Medical Errors <http://www.macoalition.org/index.shtml>.