

**FEATURE**

**A National Survey of Medical Error Reporting Laws**

The *Journal's* Editorial Staff

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## INTRODUCTION

A. *The Institute of Medicine Report*

In 1999, the Institute of Medicine (IOM) released a landmark report on medical errors, *To Err is Human*.<sup>1</sup> On the basis of studies in New York, Colorado, and Utah, the IOM estimated that between 44,000 and 98,000 Americans died in hospital settings in 1997 as a result of preventable medical errors.<sup>2</sup> These errors occurred at every phase of the medical system, including preventive care, diagnosis, treatment, and follow-up; errors with serious consequences were most frequent in settings where patients were most vulnerable.<sup>3</sup> If the rate of serious medical errors has remained constant since the IOM study, these events could have been responsible for between 49,000 and 109,000 deaths in 2006.<sup>4</sup> Researchers continue to publish alarming estimates of specific types of medical errors, which range from transfusion of incompatible blood products, to medication errors, to foreign objects left in bodies, to equipment failures, to mistaken identities of patients or body parts. For example, a recent study found that over the course of their careers, orthopedic hand surgeons had a one in five chance of performing a surgery on the wrong side of a

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1. See INST. OF MED., *TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM* (Linda T. Kohn, Janet M. Corrigan & Molla S. Donaldson eds., 1999) [hereinafter *TO ERR IS HUMAN*]; see also Robert Pear, *Group Asking U.S. for New Vigilance in Patient Safety*, N.Y. TIMES, Nov. 30, 1999, at A1.

2. *TO ERR IS HUMAN*, *supra* note 1, at 26. The IOM defined an error as “the failure of a planned action to be completed as intended (i.e., an error of execution) or the use of a wrong plan to achieve an aim (i.e., an error of planning).” *Id.* at 28. Although this estimate already exceeds the number of Americans who died in 1997 from traffic fatalities, breast cancer, or AIDS, it may still be conservative. *Id.* The studies upon which the IOM relied only considered errors documented in patient records and for which two reviewers agreed that the adverse event was “preventable or negligent.” *Id.* at 31. Moreover, deaths from health care-associated infections were not included in the overall estimate.

3. The IOM report concluded that “high error rates with serious consequences are most likely to occur in intensive care units, operating rooms, and emergency departments.” *Id.* at 36.

4. *Journal* staff calculations are based on hospital admissions data reported in Am. Hosp. Ass’n, *Fast Facts on US Hospitals 1-2*, Oct. 22, 2007, <http://www.aha.org/aha/content/2007/pdf/fastfacts2007.pdf>. Calculations reflect eleven percent growth in hospital admissions between 1997 and 2006 and assume that the rate of medical errors has remained constant during this time period.

patient's body.<sup>5</sup> Health care-associated (nosocomial) infections are the most common complications among hospitalized patients, and they may now result in 90,000 to 100,000 patient deaths each year in the United States.<sup>6</sup>

Rather than ascribing these thousands of adverse events to errant individuals, the IOM argued that the scope of medical errors demanded change from health care systems. The report stressed that “although some of these cases [of preventable adverse events] may stem from incompetent or impaired providers, the committee believes that many could likely have been avoided had better systems of care been in place.”<sup>7</sup> Health care delivery for any one patient involves a variety of complex interlinked systems. Different individual providers and teams of providers are often involved in the care of a single patient; those providers are governed by interwoven regulations emanating from provider groups, facilities, states and the federal government. Factors at every level of these systems affect the incidence of medical errors and the responses that they provoke. From this perspective, it is clear that preventing errors does not entail simply “getting rid of bad apples.” Rather, “improving safety for patients require[s] a systems approach in order to modify the conditions that contribute to errors.”<sup>8</sup> After reviewing the successful systems-based safety improvements in the airline industry and in workplace safety, the IOM noted, “[A]ccidents can be prevented through good organizational design and management.”<sup>9</sup>

Policymakers and health care administrators need accurate data on the types, frequencies, and root causes of medical errors before they will be able to implement systemic reforms. In order to gather the information necessary to implement a systems approach, the IOM recommended that each state create a dual reporting system. First, the IOM encouraged Congress to establish a national system operated by the National Forum for Health Care Quality Measurement and Reporting to collect reports from individual states concerning the most

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5. Sameul C. Seiden & Paul Barach, *Wrong-Side/Wrong-Site, Wrong-Procedure, and Wrong-Patient Adverse Events: Are They Preventable?*, 141 ARCHIVES OF SURGERY 931, 932 (2006) (citing Eric G. Meinberg & Peter J. Stern, *Incidence of Wrong-Site Surgery Among Hand Surgeons*, 85-A J. BONE & JOINT SURGERY 193, 193-97 (2003)).

6. See John P. Burke, *Infection Control – A Problem for Patient Safety*, 348 N. ENG. J. MED. 651, 651 (2003) (estimating that nosocomial infections result in 90,000 deaths per year); R. Monina Klevens et al., *Estimating Health Care-Associated Infections and Deaths in U.S. Hospitals, 2002*, 122 PUB. HEALTH REPORTS 160, 160 (2007) (estimating that health care-associated infections resulted in 98,987 deaths in 2002). In conducting this survey, *Journal* staff focused exclusively on hospital-acquired infections. Certain states may operate error reporting programs that cover health care-associated infections outside of the hospital setting.

7. TO ERR IS HUMAN, *supra* note 1, at 30.

8. *Id.* at 49.

9. *Id.* at 57. See *id.* at 71-74.

serious errors taking place in hospitals and other health care settings.<sup>10</sup> An underlying premise of the proposed mandatory reporting system was that serious adverse events are “easy to identify,”<sup>11</sup> enabling state departments of health to detect such errors, to hold facilities accountable, and to assist facilities in developing protocols to reduce future errors. The IOM also recommended that analyses of the root causes of these adverse events be available to the public,<sup>12</sup> thereby reinforcing facilities’ incentives to minimize errors and invest in patient safety. Second, the IOM recommended that the Center for Patient Safety should develop a voluntary reporting mechanism for less serious medical errors. In contrast to the mandatory system, the IOM envisioned that reports under the voluntary system would receive legal protection from data discovery.<sup>13</sup> This confidentiality would enable monitors to collect sufficient data to “analyz[e] and understand[] the causes of errors in order to make improvements.”<sup>14</sup>

### *B. Progress Since the IOM Report*

The IOM report propelled a number of state governments to institute medical error reporting systems. At the time of the report’s release in 1999, the IOM reviewed programs in thirteen states that collected medical error data.<sup>15</sup> By early 2008, programs in twenty-seven states were operational.<sup>16</sup> In addition to gathering data on medical errors, state departments of health have worked with hospitals and other care facilities on root cause investigations, protocols to address known errors, and the implementation of best practices to prevent future errors. Many of these state efforts have utilized a list of serious reportable events created by the National Quality Forum (NQF),<sup>17</sup> a nonprofit organization that

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10. *Id.* at 86.

11. *Id.* at 88.

12. *Id.* at 86-87.

13. *Id.* at 87-89.

14. *Id.* at 87.

15. *Id.* at 91. As of 2000, fifteen states had authorized adverse event reporting systems. JILL ROSENTHAL & MARY TAKACH, NAT’L ACAD. FOR STATE HEALTH POLICY, 2007 GUIDE TO STATE ADVERSE EVENT REPORTING SYSTEMS 4 (2007), available at [http://www.nashp.org/Files/shpsurveyreport\\_adverse2007.pdf](http://www.nashp.org/Files/shpsurveyreport_adverse2007.pdf).

16. Using the methodology described *infra*, *Journal* staff identified twenty-four states operating medical error reporting programs. This list of twenty-four states was supplemented with three additional states (Colorado, Kansas, and South Carolina) identified in ROSENTHAL & TAKACH, *supra* note 15. A fourth state, Georgia, was also identified by the same authors, but *Journal* staff omitted it from this analysis since the statutes cited pertained to committees conducting peer review, rather than government or non-profit entities conducting external oversight. For the purpose of this survey, we refer to the District of Columbia as a state.

17. These events have been labeled “never events” because they should never occur; they include errors such as unintended retention of a foreign object or patient death associated with a fall

promotes system-wide quality improvement in health care.<sup>18</sup> The NQF first issued a list of twenty-seven serious events in 2002, then added artificial insemination with the wrong donor sperm or egg in 2006 to reach its current total of twenty-eight “never” events.<sup>19</sup> State Medicaid programs in at least four states have attempted to create incentives for improving patient safety by publicly announcing that they will no longer reimburse providers for some or all of the events on the NQF list.<sup>20</sup>

The federal government has also encouraged efforts to promote patient safety. As of October 2008, Medicare will no longer pay for ten “reasonably preventable” conditions caused by medical errors, such as bed sores, injuries from falls, and some hospital-associated infections.<sup>21</sup> The Centers for Medicare and Medicaid Services also require hospitals to report forty-two measures of quality, including some measures of medical errors, in order to receive a full payment update to rates in the following fiscal year.<sup>22</sup> The Agency for Healthcare Research and Quality (AHRQ), part of the Department of Health and Human Services, is the focal point for patient safety at the federal level; in 2001, this agency established the Center for Quality Improvement and Patient Safety<sup>23</sup> to gather and disseminate information on health care quality measurement and to

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during care. See NAT’L QUALITY FORUM, SERIOUS REPORTABLE EVENTS IN HEALTHCARE – 2006 UPDATE: A CONSENSUS REPORT [hereinafter NQF LIST]. For the updated list of twenty-eight events issued in 2006, see Press Release, Nat’l Quality Forum, National Quality Forum Updates Endorsement of Serious Reportable Events in Healthcare (Nov. 15, 2006), <http://www.qualityforum.org/pdf/news/prSeriousReportableEvents10-15-06.pdf>.

18. See Nat’l Quality Forum, About Us, <http://www.qualityforum.org/about> (last visited Nov. 15, 2008).

19. Press Release, Nat’l Quality Forum, *supra* note 17. See *infra* Appendix for the list of NQF “serious reportable events.”

20. Kevin Sack, *Medicare Won’t Pay for Medical Errors*, N.Y. TIMES, Sept. 30, 2008, at A1, available at <http://www.nytimes.com/2008/10/01/us/01mistakes.html>.

21. *Id.*; see also Press Release, Ctrs. for Medicare & Medicaid Servs., Office of Pub. Affairs, Medicare and Medicaid Move Aggressively To Encourage Greater Patient Safety in Hospitals and Reduce Never Events (July 31, 2008) (on file with journal).

22. CTRS. FOR MEDICARE & MEDICAID SERVS., FISCAL YEAR 2009 QUALITY MEASURE REPORTING FOR 2010 PAYMENT UPDATE (2008), <http://www.cms.hhs.gov/HospitalQualityInits/Downloads/HospitalRHQDAPU200808.pdf>; see also Sack, *supra* note 20.

23. AGENCY FOR HEALTHCARE RESEARCH & QUALITY, AHRQ’S PATIENT SAFETY INITIATIVE: BUILDING FOUNDATIONS, REDUCING RISK ch. 3 (2003), available at <http://www.ahrq.gov/qual/pscongrpt/psini3.htm>. The Center for Quality Improvement and Patient Safety was the successor organization to the Center for Quality Measurement and Improvement. This transformation was an “initial step in a series of efforts to re-focus and concentrate in one organizational unit activities designed to improve the safety of the health care Americans receive.” *Id.*

implement evidence-based preventive practices.<sup>24</sup> In December 2000, Congress allocated \$50 million to AHRQ for research on ways to reduce medical errors.<sup>25</sup> By 2004, nearly all of this funding was earmarked for information technology development rather than error prevention research, but the first three years of funding established medical error research as a legitimate, critical, and underdeveloped academic field.<sup>26</sup> In July 2005, Congress reinforced its support for error monitoring with the Patient Safety and Quality Improvement Act, which encouraged voluntary and confidential reporting of adverse events and created a certification process for patient safety organizations to collect and analyze patient safety information.<sup>27</sup>

Executive federal efforts to monitor the incidence of health care-associated infections remain focused in the Centers for Disease Control and Prevention (CDC). The CDC have operated a National Nosocomial Infections Surveillance System since the early 1970s, which as of 2005 included at least 300 hospitals.<sup>28</sup> In 2005, the National Nosocomial Infections Surveillance System was replaced by the National Healthcare Safety Network (NHSN), which also incorporates surveillance data from the Dialysis Surveillance Network and the National Surveillance of Healthcare Workers.<sup>29</sup> The NHSN issued its first report on health care-associated infections in 2007.<sup>30</sup> To date, however, no “comprehensive nationwide monitoring system” exists for medical error reporting, and recent attempts to estimate error rates show little movement in actual error incidence

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24. See Agency for Healthcare Research & Quality, Center for Quality Improvement and Patient Safety: Mission Statement, <http://www.ahrq.gov/about/cquips/cquipsmiss.htm> (last visited Nov. 15, 2008).

25. H.R. REP. NO. 106-1033, at 40 (2000) (Conf. Rep.); see also INST. OF MED., TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM 5 (1999), <http://www.iom.edu/Object.File/Master/4/117/ToErr-8pager.pdf> (official summary of full report); Press Release, Agency for Healthcare Research & Quality, HHS Announces \$50 Million Investment to Improve Patient Safety (Oct. 11, 2001), <http://www.ahrq.gov/news/press/pr2001/patsafpr.htm>.

26. See Lucian L. Leape & Donald M. Berwick, *Five Years After To Err Is Human: What Have We Learned?*, 293 JAMA 2384, 2385 (2005).

27. Patient Safety and Quality Improvement Act of 2005, Pub. L. No. 109-41, 119 Stat. 424 (codified at 42 U.S.C. § 299b-24 (Supp. 2005)); see also Agency for Healthcare Research & Quality, Patient Safety Organization Overview, <http://www.pso.ahrq.gov/psos/overview.htm> (last visited Nov. 15, 2008); Agency for Healthcare Research & Quality, Welcome to AHRQ's Patient Safety Organization Web Site, <http://www.pso.ahrq.gov> (last visited Nov. 15, 2008).

28. Ctrs. for Disease Control & Prevention, National Nosocomial Infections Surveillance System, <http://www.cdc.gov/ncidod/dhqp/nnis.html> (last visited Nov. 15, 2008).

29. Jonathan R. Edwards et al., *National Healthcare Safety Network (NHSN) Report, Data Summary for 2006*, 35 AM. J. INFECTION CONTROL 290, 290 (2007), available at [http://www.cdc.gov/ncidod/dhqp/pdf/nhsn/2006\\_NHSN\\_Report.pdf](http://www.cdc.gov/ncidod/dhqp/pdf/nhsn/2006_NHSN_Report.pdf).

30. *Id.*

nationwide.<sup>31</sup>

In the years since the IOM report, non-governmental actors have also been at the forefront of efforts to document and prevent medical errors. Professional associations such as the Joint Commission on Accreditation of Healthcare Organizations, the American Hospital Association, and the American College of Physicians have reinforced state and federal efforts to improve patient safety standards, and the NQF has played a critical role in classifying medical errors and promoting best practices to avoid them.<sup>32</sup> Under the Patient Safety and Quality Improvement Act, non-governmental organizations are eligible to become Patient Safety Organizations, which are authorized to gather medical error reports protected from legal disclosure.<sup>33</sup> At least three states (Florida, Nebraska, and Pennsylvania) rely on non-governmental organizations to analyze reports of medical errors at facilities statewide.<sup>34</sup> Private insurers in seven states, including WellPoint, Aetna, Cigna, and Blue Cross Blue Shield, have ceased to provide coverage for procedures to correct medical errors.<sup>35</sup> Further, many state hospital associations have entered voluntary agreements to refrain from billing for medical errors. Government-run programs such as Medicare and Medicaid have followed in the footsteps of these private arrangements, aiming to create financial incentives for safeguards on patient safety.<sup>36</sup>

## I. OBJECTIVE

Given the progress to date in promoting best practices and research on patient safety, as well as the growing involvement of federal actors and health care payers in addressing medical errors, it is a propitious time to reexamine state efforts to gather the data on which system reforms are based. As the IOM acknowledged in its original report, state monitoring systems are uniquely poised to collect the data necessary to sustain system-level reform efforts.

The objective of this survey is to catalogue and describe the medical error reporting regimes established in the twenty-seven jurisdictions with reporting systems. State reporting procedures vary dramatically with regard to the types of incidents that must be reported, the speed with which those incidents must be reported, the penalties imposed for failures to report, and the level of protection

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31. See Leape & Berwick, *supra* note 26, at 2384 (citing AGENCY FOR HEALTHCARE RESEARCH & QUALITY, 2004 NATIONAL HEALTHCARE QUALITY REPORT, <http://www.ahrq.gov/qual/nhqr04/nhqr2004.pdf>).

32. See *id.* at 2386.

33. Agency for Healthcare Research & Quality, Patient Safety Organization Overview, *supra* note 27.

34. See *infra* Table.

35. Sack, *supra* note 20.

36. *Id.*

offered from legal discovery. By describing these various systems, the staff of the *Yale Journal of Health Policy, Law, and Ethics* hopes to provide valuable information to those states considering the institution of reporting programs, to aid policymakers from states refining their current systems, and to assist practitioners and non-governmental entities working towards patient safety improvements.

After the completion of research for this survey, our staff became aware of a similar study by the National Academy for State Health Policy (NASHP) published in December 2007, which collected data current through October 2007.<sup>37</sup> Given the brisk pace of reporting system reforms,<sup>38</sup> our study provides a timely update, with current information on state reporting systems as of September 2008. We also used the opportunity to cross-reference our findings with the earlier survey as an added check on accuracy.

Overall, we aimed for our survey to be uniquely responsive to the concerns of clinicians, policymakers, advocates, and legal practitioners by updating statutory and regulatory citations, clarifying separate requirements where states have more than one reporting program, and adding Internet citations to program descriptions where available. We also report specific information on state-by-state deadlines for reporting, penalties for failures to report, regimes for reporting health care-associated infection incidence, and enactment of pay-for-performance programs. Finally, we have included an explicit description of our methodology for transparency and to ensure that any other research teams seeking to update this report can replicate our study.

## II. METHODOLOGY

Research for this project proceeded in four stages: 1) a systematic literature review of state statutes; 2) a systematic literature review of state regulations, with supplementary literature searches using Google and individual state department of health websites; 3) data extraction using standardized extraction forms; and 4) verification of results with state program administrators. The *Journal* received no external support or funding for the survey.

### *A. Systematic Review of State Statutes*

In the first stage of our analysis, *Journal* staff designed a single, highly sensitive search strategy to locate state statutes related to medical error reporting. The staff then replicated this search strategy within each of the individual state

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37. ROSENTHAL & TAKACH, *supra* note 15.

38. *Id.* at 1 (noting that between 2005 and 2007, fifteen states and the District of Columbia enacted or revised their reporting systems).

statutory databases maintained electronically by Westlaw.<sup>39</sup> We did not filter search results by date or any other restriction. If these searches yielded more than one hundred search results, we used Boolean operators to narrow the search to occurrences of the terms within the same paragraph.<sup>40</sup> *Journal* staff then reviewed the content of every search result for relevance. If any reviewer believed that a specific statute was relevant, that reviewer downloaded and examined the statute in its entirety. As an external check on these results, we then compared our list of retrieved statutes to the statutes listed in the Thomson/West publication, *50 State Statutory Surveys: Patient Safety and Medical Errors Reforms* (2007).<sup>41</sup> If a potentially relevant statute listed in the West publication had not been retrieved in the course of our initial search, we downloaded it for review in its entirety and scanned it for additional relevant citations.

We completed the first stage of this study in February 2008; therefore, this national survey represents the state of the law as it was published on February 1, 2008. The statutes retrieved by this literature search are current through at least the close of the 2007 legislative session in each state.<sup>42</sup>

#### *B. Systematic Review of State Regulations with Supplementary Internet Research*

The second stage of research was a systematic literature search and review of state regulations pertaining to medical error reporting. The *Journal* staff jointly designed a single replicable search strategy to retrieve administrative regulations<sup>43</sup> and then executed this search strategy within each of the individual state administrative code databases maintained electronically by Westlaw or

39. Specifically, we conducted “Terms and Connectors” searches of the following form, aiming to maximize sensitivity: 1) healthcare & quality & report\*; 2) error & report\* & health\*; and 3) adverse & health\* & report\*.

40. That is, we used “/p” instead of “&” in the search strategies described *supra*.

41. While the Thomson/West survey is relatively recent, it is not comprehensive, includes a number of statutes that do not govern medical error reporting, and does not provide summary information regarding those statutes.

42. In early September 2008, in order to apprise ourselves of major legislative changes, *Journal* staff also established an automated alert on LexisNexis to monitor any additional publications in NCSL LegisBriefs, NCSL State Legislatures Magazine, and NCSL State Legislative Reports. This alert used the following search string: (healthcare & quality & report\*) or (error & report\* & health\*) or (adverse & health\* & report\*). We also set an alert from the “Combined State & Federal Code Archives” database to report new results from the following search string: (“adverse event” or “sentinel event”) & report\* & health. Finally, we set an alert from the “State Administrative Codes” database to report new results from the following search string: (“adverse event” or “sentinel event” or error) & report\* & health.

43. Specifically, we conducted “Terms and Connectors” searches of the following form: 1) health & adverse & report!; and 2) health & report! & quality.

LexisNexis.<sup>44</sup> Again, to maximize sensitivity, we placed no restrictions on our search results by date or any other criterion. We reviewed the content of the first one hundred search results for each state. If any reviewer considered a regulation to be relevant, the reviewer downloaded the full text of the regulation and reviewed it in its entirety. If we had previously retrieved a statute that contained distinctive terms for a given state (e.g., “sentinel event” or “Patient Safety Center”), we conducted additional searches of the administrative code database utilizing those terms. The second stage of this study was also complete as of February 2008, and we verified data with state departments of health as of September 2008.

To supplement the results of our Westlaw and LexisNexis searches, we conducted a web-based search using the Internet search engine Google.<sup>45</sup> We reviewed the content of the first twenty results and extracted relevant data. Finally, we searched the website of each state department of health for any information regarding medical error reporting.

During the first two stages of this study, we recovered a number of statutes and regulations that appeared relevant but that upon closer inspection did not apply to medical error reporting. Based on the scope and objective of our survey, we excluded statutes, rules, and regulations that required practitioners to report adverse medical malpractice settlements or claims to an external body. We also excluded any statute, rule, or regulation that required the reporting of data related to “quality,” but did not 1) indicate specific categories of incidents, events, or errors that must be reported or 2) provide an operational definition of incidents, events, or errors that must be reported.

### *C. Data Extraction*

After we reviewed the results of our searches, we created a common data extraction form to organize the data from relevant statutes and regulations. The staff members jointly agreed to organize and gather data according to the following sixteen prompts:

- 1) Provide a general description of the error reporting program;
- 2) Specify whether error reports are mandatory or voluntary;
- 3) List the specified recipient of error reports;

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44. At the time of our research, Westlaw did not maintain separate administrative code databases for all states, so we used LexisNexis databases for the remaining states.

45. Specifically, for each state, we conducted the following two searches: 1) health <state name> quality report; and 2) health <state name> adverse report.

- 4) Specify whether error reports are submitted electronically (i.e., through secure transmission over the Internet);
- 5) Specify which facilities must provide reports of medical errors;
- 6) Explain which medical errors, adverse events, and/or incidents must be reported;
- 7) Specify whether hospital-acquired infections are reportable as a separate category;
- 8) Specify the allowable duration of time for a health care provider to submit an initial report and any additional reports, including a root cause analysis and a corrective action plan;
- 9) Describe what penalties, if any, health care providers may face for noncompliance with the reporting regime:
  - (a) Specify whether the report recipient has the authority to revoke, suspend, or alter the license of a health care provider for noncompliance;
  - (b) Record whether the report recipient conducts audits (random or announced) of medical records to ensure compliance with reporting requirements;
- 10) State whether any of the data collected under the reporting regime are made available to the public;
- 11) Indicate whether reports of medical errors, adverse events, or other incidents are protected from legal discovery;
- 12) Specify whether the applicable statutes and regulations provide civil immunity for health care employees that report medical errors;
- 13) Indicate whether the state has implemented any positive financial incentives for health care providers that reduce their rate of medical errors or adverse events;
- 14) List all statutes and regulations directly relating to medical error reporting programs;
- 15) Specify any secondary resources encountered in the course of our

research; and

16) List the date the medical error reporting program started.

When we were unable to discern the answer from the retrieved information, we marked the answer as “Unclear from statutes and regulations.”

We selected these sixteen categories based on two considerations. First, our initial review of all the retrieved statutes helped us determine the types of data that we could feasibly extract. We paid particular attention to categories that would be of interest to medical and legal practitioners, such as reporting deadlines, penalties, and resources for further information. Second, we supplemented our list of data fields with categories from similar surveys conducted by NASHP in 2000 and 2001.<sup>46</sup>

Our initial review of available data shaped our data extraction process most visibly in the area of defining which events must be reported. Initially, we had planned to inquire whether a reporting program required each of the twenty-eight “serious reportable events” listed by the NQF.<sup>47</sup> However, a brief review of the statutes revealed that many states featured broad definitions of “adverse events” that did not map onto the NQF categories.<sup>48</sup> Moreover, we encountered several states with additional, discrete categories of events not encompassed by the lengthy NQF list.<sup>49</sup> As a result, we decided to summarize the types of medical errors, adverse events, and incidents that must be reported under each state program. We have specifically noted those states that have adopted a reporting regime encompassing all or most of the NQF list.

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46. JILL ROSENTHAL, MAUREEN BOOTH & ANNE BARRY, NAT’L ACAD. FOR STATE HEALTH POLICY, COST IMPLICATIONS OF STATE MEDICAL ERROR REPORTING PROGRAMS: A BRIEFING PAPER (2001), *available at* [http://www.nashp.org/Files/GNL\\_38\\_Cost\\_Implications.pdf](http://www.nashp.org/Files/GNL_38_Cost_Implications.pdf); JILL ROSENTHAL, TRISH RILEY & MAUREEN BOOTH, NAT’L ACAD. FOR STATE HEALTH POLICY, STATE REPORTING OF MEDICAL ERRORS AND ADVERSE EVENTS: RESULTS OF A 50-STATE SURVEY (2000), *available at* [http://www.nashp.org/Files/GNL\\_31\\_Reprint.pdf](http://www.nashp.org/Files/GNL_31_Reprint.pdf).

47. For the NQF list of “serious reportable events,” see *infra* Appendix.

48. *See, e.g.*, NEV. REV. STAT. § 439.830 (2007) (requiring reporting of any sentinel event, which is broadly defined as “an unexpected occurrence involving facility-acquired infection, death or serious physical or psychological injury or the risk thereof, including, without limitation, any process variation for which a recurrence would carry a significant chance of a serious adverse outcome. The term includes loss of limb or function.”).

49. *See, e.g.*, UTAH ADMIN. CODE. r. 380-200-3(1)(d) (2008) (Utah regulations include four additional events not found in the National Quality Forum list: “(iv) unanticipated death of a full-term newborn; . . . (ix) Prolonged fluoroscopy with cumulative dose greater than 1500 rads to a single field; (x) Radiotherapy to the wrong body region; (xi) Radiotherapy greater than 25% above the prescribed radiotherapy dose; and (xii) Death or major permanent loss of function related to a health care acquired infection.”).

#### *D. Personal Communication and Verification*

After data extraction, *Journal* staff personally contacted the relevant government agency or department of health in each state to verify our results. In September 2008, we contacted each of these administrative bodies using the mailing address posted on its website. Our mailing enclosed either our summary of the state program for medical error reporting or a letter indicating that we were unable to locate any evidence of a statewide reporting program. We requested that administrators in each state verify the accuracy of information we provided, and if we had made errors, provide corrections or clarification. As this issue went to press, agencies in nineteen states had responded to our requests.<sup>50</sup> The majority of responses came from states actually operating medical error reporting programs.

### III. RESULTS AND SELECTED TRENDS

Twenty-seven states have instituted medical error reporting systems as of September 2008, and each of these regimes is described in detail in the Table below. Although there is extensive variability across state systems, we discerned several trends that may interest policymakers and practitioners: the persistence of underreporting despite reporting deadlines, licensing penalties, and restrictions protecting reported information from legal discovery; a shift toward requiring the reporting of health care-associated infections; and the influence of pay-for-performance programs in several pioneering states.

#### *A. Underreporting*

The IOM recognized that practitioners might be reluctant to voluntarily report medical mistakes. At the time of the IOM report, underreporting was known to be a serious problem for error reporting programs. The IOM noted that “[u]nderreporting is believed to plague all programs, especially in their early years of operation. Colorado’s program received seventeen reports in its first two years of operation, but ten years later, received more than 1000 reports. On the other hand, New York’s program receives approximately 20,000 reports annually.”<sup>51</sup> However, the IOM hoped that safeguards on the confidentiality of data would resolve the underreporting problem, writing that “[p]atient safety is also hindered through the liability system and the threat of malpractice, which discourages the disclosure of errors. The discoverability of data under legal

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50. The states that responded to our inquiries were Arizona, Connecticut, the District of Columbia, Illinois, Kentucky, Massachusetts, Michigan, Montana, Nebraska, Nevada, New Jersey, New Mexico, North Dakota, Ohio, Oregon, Pennsylvania, Tennessee, Utah, and Washington.

51. TO ERR IS HUMAN, *supra* note 1, at 92.

proceedings encourages silence about errors committed or observed. Most errors and safety issues go undetected and unreported, both externally and within health care organizations.”<sup>52</sup> The IOM also believed that serious errors would be difficult for practitioners to conceal.<sup>53</sup>

Twenty-one of the twenty-seven state reporting programs presently in operation contain explicit protections against legal discoverability of error reports in civil actions.<sup>54</sup> Whether confidentiality protections are extended to error reports could not be determined for five additional states.<sup>55</sup> Only the state of Washington explicitly refuses to protect error reports from legal discovery.<sup>56</sup> Despite the ubiquity of confidentiality protections, underreporting appears to affect numerous state systems. In Figure 1, we compare the number of “serious reportable events” submitted by hospitals in a given state to the number of residents in that state.<sup>57</sup> For this illustration, we rely exclusively on states that

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52. *Id.* at 43.

53. *Id.* at 88.

54. Colorado’s reporting program only provides protection from legal discovery to reports of hospital-acquired infections. COLO. REV. STAT. § 25-3-605 (2008). Reports of other types of occurrences are not protected from use in regulatory proceedings. *Id.* § 25-1-124(4).

55. These states are California, New York, Oregon, Rhode Island, and South Carolina.

56. WASH. REV. CODE § 70.56.050 (2007). In Tennessee, “[t]he affected patient and/or the patient’s family, as may be appropriate, shall also be notified of the event or incident by the facility.” TENN. COMP. R. & REGS. 1200-8-1.11(8)(j) (2007). In Florida, victims of adverse events have the right to their records and adverse event reports. Patient’s Right-to-Know About Adverse Medical Incidents Act, FLA. STAT. § 381.028 (2007). It remains unclear how the patient and family notification provisions for Tennessee and Florida can reasonably coexist with protections against data discoverability.

57. See CONN. DEP’T OF PUB. HEALTH, LEGISLATIVE REPORT TO THE GENERAL ASSEMBLY: ADVERSE EVENT REPORTING 7-10 (2007), available at <http://www.ct.gov/dph/lib/dph/hisr/hcqsar/healthcare/pdf/adverseeventreportoct2007.pdf> (reporting 176 adverse events from July 1, 2006 to June 30, 2007, 91 percent of which we assume occurred in a hospital setting); IND. STATE DEP’T OF HEALTH, INDIANA MEDICAL ERROR REPORTING SYSTEM: REPORT FOR 2007 (2008), at 2, available at [http://www.in.gov/isdh/files/2007\\_MERS\\_Report.pdf](http://www.in.gov/isdh/files/2007_MERS_Report.pdf) (reporting 101 adverse events in hospitals in calendar year 2007); MINN. DEP’T OF HEALTH, ADVERSE HEALTH EVENTS IN MINNESOTA 5, 9, 40, 41, 59, 63 (2008), available at <http://www.health.state.mn.us/patientsafety/ae/aereport0108.pdf> (reporting 121 adverse events in hospitals and four events in ambulatory surgical centers from October 7, 2006 to October 6, 2007); N.J. DEP’T OF HEALTH & SENIOR SERVS., PATIENT SAFETY INITIATIVE: 2006 SUMMARY REPORT 6 (2007), available at [http://www.state.nj.us/health/ps/documents/ps\\_report\\_2006.pdf](http://www.state.nj.us/health/ps/documents/ps_report_2006.pdf) (reporting 450 adverse events in hospitals in calendar year 2006); POPULATION DIV., U.S. CENSUS BUREAU, ANNUAL ESTIMATES OF THE POPULATION FOR THE UNITED STATES, REGIONS, STATES, AND PUERTO RICO: APRIL 1, 2000 TO JULY 1, 2007 (2007), available at <http://www.census.gov/popest/states/tables/NST-EST2007-01.xls> (estimating the population of relevant states as of July 1, 2007); WASH. STATE DEP’T OF HEALTH, SERIOUS REPORTABLE EVENTS REPORTS, available at [http://www.doh.wa.gov/hsqa/ocrh/video\\_conf/2007\\_8\\_15/Handouts/](http://www.doh.wa.gov/hsqa/ocrh/video_conf/2007_8_15/Handouts/)

have adopted or adapted the NQF list of serious reportable events in order to compare states with roughly similar reporting requirements. At least twelve states have incorporated all or most of the items on the NQF's list of serious reportable events.<sup>58</sup> However, one state (California) does not issue public reports, two states (the District of Columbia and Massachusetts) started collecting data on NQF events very recently, and three states (Illinois, Utah, and Vermont) do not appear to post public reports in an easily accessible location. As such, Figure 1 contains data for only six states.

For the six states included in the figure, the estimated rates of preventable medical errors vary dramatically. Indeed, the number of reported errors per 100,000 residents in New Jersey and Connecticut exceeds the number of reported errors per 100,000 residents in Indiana by an implausible factor of three.<sup>59</sup> We obtain qualitatively similar results when comparing the number of serious reportable events to the estimated number of hospital admissions in a given state in 2006.<sup>60</sup>

It is unlikely that the actual rates of medical error vary this dramatically across states; some segment of the variation is almost certainly due to lower rates of reporting in particular states. In exploring how to address underreporting, four facets of current states systems warrant attention: 1) differences in whether underreporting is penalized, 2) differences in the probability that underreporting

SummaryAdverseEvents.pdf (reporting 180 serious reportable events in hospitals from June 2, 2006 to July 13, 2007); WYO. DEP'T OF HEALTH, ADVERSE HEALTH EVENTS IN WYOMING HEALTHCARE FACILITIES: SECOND ANNUAL REPORT 2006-2007 (2007), at 7, available at <http://wdh.state.wy.us/Media.aspx?mediaId=3248> (reporting 14 adverse events in hospitals from mid-2006 to mid-2007).

58. These states are California, Connecticut, the District of Columbia, Illinois, Indiana, Massachusetts (started August 2008), Minnesota, New Jersey, Utah, Vermont, Washington, and Wyoming. Note that Connecticut's list of "serious reportable events" includes several additional items not found on the NQF list.

59. The Connecticut data has been adjusted to include only reports of events included in the NQF list. Reports of "[p]erforations during open, laparoscopic and/or endoscopic procedures resulting in death or serious disability," "[o]bstetrical events resulting in death or serious disability to the neonate," "[s]ignificant medication reactions resulting in death or serious disability," "[l]aboratory or radiologic test results not reported to the treating practitioner or reported incorrectly which result in death or serious disability due to incorrect or missed diagnosis in the emergency department," and "[n]osocomial infections resulting in death or serious injury" were omitted from this analysis. CONN. DEP'T OF PUB. HEALTH, *supra* note 57.

60. Specifically, we compare the number of events reported by a state to an estimate of the number of hospital admissions in that state in that year. See Kaiser Family Foundation, Hospital Admissions per 1,000 Population: 2006, <http://www.statehealthfacts.org/compareraw.jsp?ind=386&cat=8&sub=94&yr=61&typ=1&sort=a&o=a> (last visited Dec. 13, 2008) (reporting data from American Hospital Association survey).

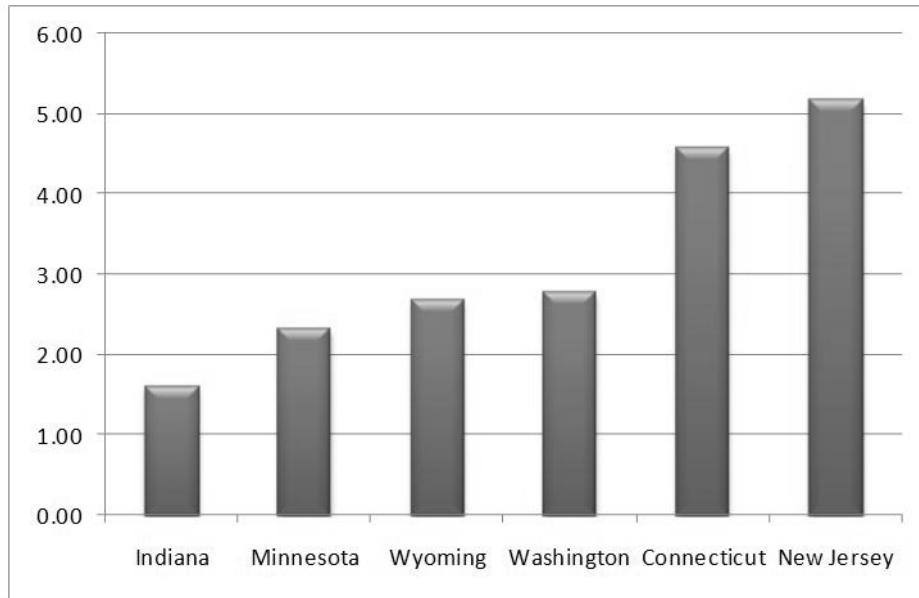


FIGURE 1. Number of “Serious Reportable Events” in Hospitals per 100,000 Residents (2006-2007)

will be detected by the regulating agency, 3) variation in facility acceptance of the reporting mechanism, and 4) variation in the extent to which physicians perceive that the reporting mechanism is designed to gather information rather than punish adverse events.

First, states differ with regard to the penalties for non-reporting. At least thirteen states have statutory or regulatory authority to impose financial penalties for failure to comply with reporting requirements.<sup>61</sup> In New Jersey, hospitals owe \$1000 per day for failure to report a serious reportable adverse event, with a maximum penalty of \$100,000 per event.<sup>62</sup> Similarly, facilities in Pennsylvania that fail to report a serious event may be subject to a \$1000 per day administrative penalty, although this penalty may be adjusted at the discretion of the Department of Health.<sup>63</sup> Other jurisdictions impose far smaller financial penalties; for example, the District of Columbia imposes fines of \$500 to \$2500 for failure to report an adverse event.<sup>64</sup> In theory, states that routinely exercise their authority to impose financial penalties for failure to report should enjoy

61. These states are Colorado, the District of Columbia, Florida, Maine, Maryland, Massachusetts, New Jersey, Oregon, Pennsylvania, South Carolina, Utah, Vermont, and Wyoming.

62. N.J. ADMIN. CODE § 8:43E-3.4(a)(14) (2008).

63. 40 PA. CONS. STAT. § 1303.313 (2008).

64. D.C. CODE § 7-161(d)(2) (2008).

higher rates of compliance than states lacking such authority.<sup>65</sup>

Second, states differ with regard to whether they conduct audits of the records kept by the target medical facilities. Seven states provide at least limited statutory or regulatory authority for the governing agency to audit the records of facilities required to report medical errors.<sup>66</sup> Unfortunately, the extent to which such authority is employed is heavily contingent upon state appropriations, which lie beyond the scope of this study.<sup>67</sup> Anecdotal reports regarding the practices of leading states, however, may prove illuminating. A 2001 analysis by NASHP of medical error programs in New York and Florida found that “both states validate data by following up on media reports, identifying reportable incidents through the complaint process, conducting random on-site chart reviews, and attempting to match incident reports to hospital discharge data records.”<sup>68</sup> The most recent report of the New York Patient Occurrence Reporting and Tracking System indicates that the New York Department of Health engages in “surveillance activities” and “retrospective chart review” to ensure that reporting occurs. “The Department [of Health] does impose citations and in some instances, fines for non-reporting or late reporting of statutorily mandated codes.”<sup>69</sup> Although New York’s definition of an adverse event is broader and far from synonymous with the NQF list of serious preventable events, it remains instructive that an impressive 31,154 reports were filed in 2004.<sup>70</sup> Most recently, in 2007, New York underwent a pilot phase of its program for hospital-acquired infection reporting. To assess whether hospitals were properly complying with the self-reporting requirements, Department of Health staff audited samples of medical records in onsite visits to ninety-five percent of New York hospitals from July 2007 to January 2008.<sup>71</sup>

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65. Certain states appear to financially penalize medical providers for lapses in safety, which may further reduce the willingness of providers to share information regarding preventable adverse events. California imposes a penalty of up to \$50,000 for any situation “in which the licensee’s noncompliance with one or more requirements of licensure has caused, or is likely to cause, serious injury or death to the patient.” CAL. HEALTH & SAFETY CODE § 1280.3 (2008).

66. These states are Florida, Massachusetts, Minnesota, New Jersey, New York, Pennsylvania, and Vermont.

67. Although the magnitude of appropriations for various state adverse event reporting systems are not comprehensively catalogued in any single publication, the 2007 study by NASHP provides information regarding the funding source for each system. See ROSENTHAL & TAKACH, *supra* note 15.

68. ROSENTHAL, BOOTH & BARRY, *supra* note 46, at 13.

69. STATE OF N.Y. DEP’T OF HEALTH, NEW YORK PATIENT OCCURRENCE REPORTING AND TRACKING SYSTEM REPORT 14 (2005), available at [http://www.health.state.ny.us/nysdoh/hospital/nyports/annual\\_report/2002-2004/docs/2002-2004\\_nyports\\_annual\\_report.pdf](http://www.health.state.ny.us/nysdoh/hospital/nyports/annual_report/2002-2004/docs/2002-2004_nyports_annual_report.pdf).

70. *Id.* at 2.

71. N.Y. STATE DEP’T OF HEALTH, HOSPITAL-ACQUIRED INFECTION REPORTING SYSTEM: PILOT

Third, health care facilities in different states may differ in the willingness of their staff to participate in the applicable reporting program. A facility's willingness to invest resources to consistently report all covered incidents may depend on the structure of the program. For instance, states that require facilities to report an incident within a short time span may foster a culture of compliance, whereas states that only require reporting on a semi-annual or annual basis may signal to participating facilities that the data generated are far from critical. Figure 2 provides an illustration of the disparities across states in deadlines for reporting incidents.<sup>72</sup> Moreover, medical providers may be more likely to comply with state reporting regimes that require the generation of "root cause analyses" that are actually reviewed and aggregated into useful reports that reveal trends and offer advice.<sup>73</sup> Indeed, a recent survey of physicians in Washington and Missouri revealed that "[p]hysicians [in the sample] were more likely to discuss serious errors, minor errors, and near misses with their colleagues than to report them to risk management or to a patient safety program."<sup>74</sup> Physicians in this survey offered several suggestions on how to increase their willingness to formally report error information: they generally desired a system that was confidential, nondiscoverable, and nonpunitive, and that did not require a substantial time commitment.<sup>75</sup> However, eighty-five percent of physicians surveyed also stressed the need for the information they submitted to be actually "used for system improvements."<sup>76</sup>

Fourth, despite the widespread availability of confidentiality provisions and protections against data discoverability, health care providers may remain fearful that liability will result from participation in an error reporting regime. This fear may stem from the origins of mandatory adverse event reporting programs, which were originally designed to shine a harsh light on poorly performing doctors and hospitals.<sup>77</sup> One method for allaying these fears is the use of

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YEAR – 2007, at 8 (2008), available at [http://www.health.state.ny.us/nysdoh/hospital/reports/hospital\\_acquired\\_infections/2007/docs/hospital-acquired\\_infection-full\\_report.pdf](http://www.health.state.ny.us/nysdoh/hospital/reports/hospital_acquired_infections/2007/docs/hospital-acquired_infection-full_report.pdf).

72. Figure 2 only includes those states with deadlines of forty-five days or less.

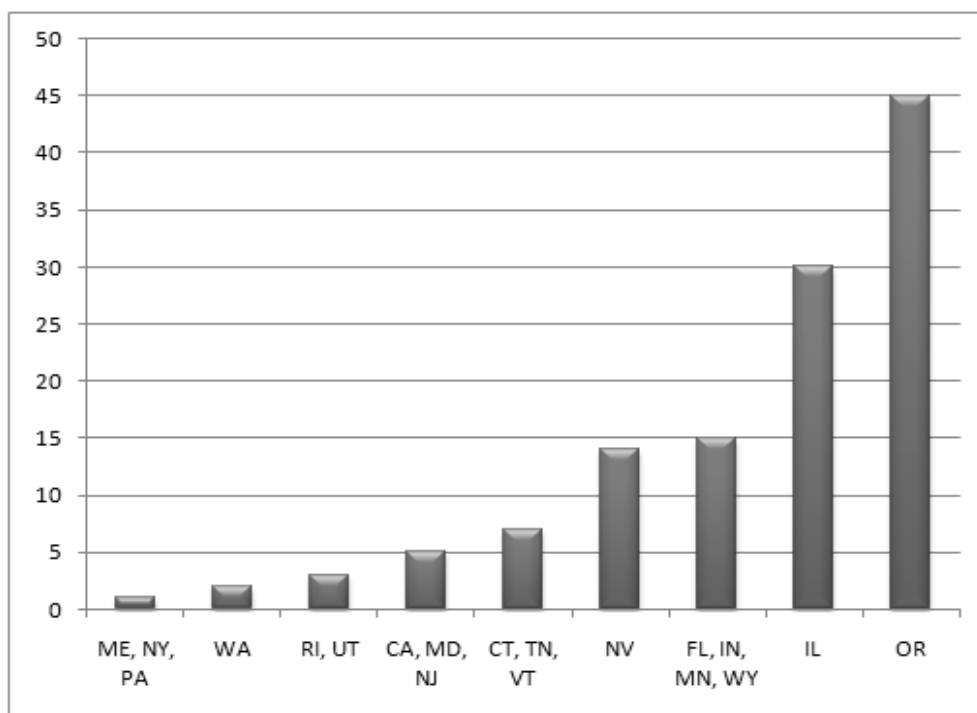
73. Minnesota provides exemplary feedback to participating institutions. See MINN. STAT. § 144.7065(8) (2008) (requiring facilities to submit root cause analyses of reported events and plans of corrective action); MINN. DEP'T OF HEALTH, *supra* note 57 (providing summary information on common root causes of preventable adverse events and offering recommendations for the prevention of future adverse events, particularly wrong-site surgery and pressure ulcers).

74. Jane Garbutt et al., *Lost Opportunities: How Physicians Communicate About Medical Errors*, 27 HEALTH AFF. 246, 250 (2008).

75. *Id.* at 251.

76. *Id.*

77. See Kathryn E. Wood & David B. Nash, *Mandatory State-Based Error-Reporting Systems: Current and Future Prospects*, 20 AM. J. MED. QUALITY 298, 299 (2005).



**FIGURE 2. Maximum Number of Days for Reporting Facilities to File Incident Reports**

Note: Figure only includes those states with deadlines of forty-five days or less following the incident or its discovery.

nonprofit “Patient Safety Organizations” for data collection, rather than a government body.<sup>78</sup> As mentioned above, our study reveals that at least three states (Florida, Nebraska, and Pennsylvania) rely on nonprofit organizations to receive and analyze at least some adverse event data.

### *B. Hospital-Acquired Infection Reporting*

States are gradually converging on a set of serious, preventable adverse occurrences that must be reported. As noted above, twelve states have adopted or slightly altered the NQF’s list of “serious reportable events.” In addition, twelve states now require the reporting of certain health care-associated or hospital-acquired infections, and one state provides for optional reporting of hospital-acquired and health care-associated infections (HAIs).<sup>79</sup> Among medical errors,

<sup>78</sup> *Id.*

<sup>79</sup> The states requiring the reporting of hospital-acquired infections are Colorado, Connecticut, the District of Columbia, Illinois, Massachusetts, Nevada, New Jersey, New York, Oregon, Pennsylvania, Utah, and Washington. Indiana allows for optional reporting of hospital-

HAIs are likely the leading cause of injury and death; in a 2007 report, the CDC “estimated that 1.7 million hospital patients—4.5 of every 100 admissions—become infected each year, causing or contributing to the deaths of nearly 100,000 people.”<sup>80</sup> However, given the preventability of HAIs, they may be low-hanging fruit in the response to preventable adverse events.

The Institute for Healthcare Improvement has addressed HAIs squarely in its ongoing “5 Million Lives Campaign,” which advocates for hospitals to adopt twelve specific care improvements shown to reduce patient injury and death (including practices to prevent staph infections, central line infections, surgical site infections, and ventilator-associated pneumonia).<sup>81</sup>

### *C. Leading Edge: Pay-for-Performance Programs*

Health care providers have seen increasing interest in pay-for-performance programs, which attempt to create financial incentives for the provision of higher-quality care and may impose financial penalties for medical errors. Our survey discovered that at least two states have established pilot programs based on pay-for-performance principles. Recent legislation in New York under the title of “Pay for Performance” expressed the state legislature’s intent “to encourage and support regional demonstration projects involving multiple payors utilizing such metrics as the basis for providing financial incentives to providers to achieve increased quality and cost effectiveness.”<sup>82</sup> The statute authorizes the Commissioner of Health to select up to five demonstration projects for state support, and one selection criterion is the “use of . . . metrics to measure and reward physician, clinic and hospital performance . . . .”<sup>83</sup> According to a 2008 statute, Pennsylvania will also institute a pay-for-performance program in

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acquired infections.

80. Inst. for Healthcare Improvement, *What Zero Looks Like: Eliminating Hospital-Acquired Infections*, <http://www.ihl.org/IHI/Topics/PatientSafety/SafetyGeneral/ImprovementStories/WhatZeroLooksLikeEliminatingHospitalAcquiredInfections.htm> (last visited Nov. 15, 2008) (citing Klevens et al., *supra* note 6).

81. *See* Press Release, Inst. for Healthcare Improvement, *IHI Launches National Campaign To Reduce Medical Harm in U.S. Hospitals, Building on Its Landmark 100,000 Lives Campaign* (Dec. 12, 2006), *available at* <http://www.ihl.org/NR/rdonlyres/A96E0639-A979-44F6-A0FF-20329E492F44/4230/5MillionLivespressreleaseupdatedDec26FINALFINAL.pdf>; *see also* Inst. for Healthcare Improvement, *Doing Better Spending Less*, <http://www.ihl.org/IHI/Topics/CriticalCare/IntensiveCare/ImprovementStories/DoingBetterSpendingLess.htm> (last visited Nov. 15, 2008) (chronicling stories of improvements in intensive care); Inst. for Healthcare Improvement, *Protecting Five Million Lives from Harm*, <http://www.ihl.org/IHI/Programs/Campaign> (last visited Nov. 15, 2008).

82. N.Y. PUB. HEALTH LAW § 2999-b (2007).

83. *Id.* § 2999-c(1).

January 2009; the Department of Public Welfare will make a quality improvement payment to health care facilities that achieve at least a ten percent reduction in health care-associated infections relative to the preceding year.<sup>84</sup>

There is some evidence that pay-for-performance programs combined with reporting programs may make headway towards improving the quality of care. A 2007 study in the *New England Journal of Medicine* reported that among hospitals already engaged in voluntary public reporting of quality, those enrolled in a pay-for-performance demonstration project funded by CMS showed greater improvement on measures of quality over a two-year period.<sup>85</sup> Although the difference between the two groups was modest, the study provides some support for the idea that “financial incentives are capable of catalyzing quality-improvement efforts among hospitals already engaged in public reporting.”<sup>86</sup> The IOM has heralded interest in pay-for-performance programs as a desirable trend for system-level change, noting in 2007 that “[a]lthough the magnitude of incentives necessary to achieve significant and sustainable change while avoiding adverse consequences is uncertain, steps can be taken now to begin to address the deficiencies of current payment systems and encourage progress toward significant quality improvement.”<sup>87</sup> Notably, successful pay-for-performance regimes require confidence that underreporting can be kept at bay, even after the introduction of financial rewards that increase the incentives for underreporting.

#### IV. SURVEY LIMITATIONS

The results of this survey have several limitations. First, it was not possible to ensure that statutory or regulatory developments after September 2008 would be included. Second, in states where administrators from state agencies or departments of health did not respond to our requests for information, our results are limited to the detail provided in published sources. Third, it was not within the scope of this study to search for information beyond a formal description of the systems in place. For example, we did not have the capacity to contact health providers directly to learn how reporting systems are actually enforced in practice. Further, with some exceptions from states with publicly released data, we were not able to collect the actual number of reported errors for each state.

Despite these limitations, however, this survey is a timely and uniquely practice-oriented view of statewide medical error reporting systems, and we

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84. 40 PA. CONS. STAT. § 1303.407 (2008).

85. Peter K. Lindenauer et al., *Public Reporting and Pay for Performance in Hospital Quality Improvement*, 356 NEW ENG. J. MED. 486 (2007).

86. *Id.* at 494.

87. INST. OF MED., *REWARDING PROVIDER PERFORMANCE: ALIGNING INCENTIVES IN MEDICARE* 2 (2007).

anticipate that practitioners, policymakers, patient safety advocates, and researchers alike will find these program descriptions useful.

#### CONCLUSION

Progress towards improved patient safety has continued apace since the IOM report, but continuing efforts to reform health systems must be based on solid data regarding the types of medical errors, the frequencies of such mistakes, and the steps being taken to address them. Statewide collection of medical error data could have far-reaching effects; however, the quality of the data will depend heavily on the systems that states use to gather this information. This survey provides an up-to-date look at the systems currently in use, with the hope that this comparison will aid all those working towards improvements in patient safety.

**APPENDIX. NATIONAL QUALITY FORUM LIST OF “SERIOUS REPORTABLE EVENTS”<sup>88</sup>**

1) Surgical Events:

- A. Surgery performed on the wrong body part;
- B. Surgery performed on the wrong patient;
- C. Wrong surgical procedure performed on a patient;
- D. Unintended retention of a foreign object in a patient after surgery or other procedure;
- E. Intraoperative or immediately postoperative death in an ASA Class I [i.e., healthy] patient.

2) Product or Device Events:

- A. Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the healthcare facility;
- B. Patient death or serious disability associated with the use or function of a device in patient care in which the device is used or functions other than as intended;
- C. Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in a healthcare facility.

3) Patient Protection Events:

- A. Infant discharged to the wrong person;
- B. Patient death or serious disability associated with patient elopement (disappearance);
- C. Patient suicide, or attempted suicide, resulting in serious disability while being cared for in a healthcare facility.

4) Care Management Events:

- A. Patient death or serious disability associated with a medication error (e.g., errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation, or wrong route of administration);
- B. Patient death or serious disability associated with a hemolytic reaction due to the administration of ABO/HLA-incompatible blood or blood products;
- C. Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in a healthcare facility;

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88. NQF LIST, *supra* note 17, at 7-16.

- D. Patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for in a healthcare facility;
- E. Death or serious disability (kernicterus) associated with failure to identify and treat hyperbilirubinemia in neonates;
- F. Stage 3 or 4 pressure ulcers acquired after admission to a healthcare facility;
- G. Patient death or serious disability due to spinal manipulative therapy;
- H. Artificial insemination with the wrong donor sperm or wrong egg.

5) Environmental Events:

- A. Patient death or serious disability associated with an electric shock while being cared for in a healthcare facility;
- B. Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by toxic substances;
- C. Patient death or serious disability associated with a burn incurred from any source while being cared for in a healthcare facility;
- D. Patient death or serious disability associated with a fall while being cared for in a healthcare facility;
- E. Patient death or serious disability associated with the use of restraints or bedrails while being cared for in a healthcare facility.

6) Criminal Events:

- A. Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider;
- B. Abduction of a patient of any age;
- C. Sexual assault on a patient within or on the grounds of a healthcare facility;
- D. Death or significant injury of a patient or staff member resulting from a physical assault (i.e., battery) that occurs within or on the grounds of a healthcare facility.

**TABLE: NATIONAL SURVEY OF LAWS**

<b>ALABAMA</b>
A medical error reporting regime does not appear to exist for this state.
<b>ALASKA</b>
A medical error reporting regime does not appear to exist for this state.
<b>ARIZONA</b>
A medical error reporting regime does not exist for this state. <sup>89</sup>
<b>ARKANSAS</b>
A medical error reporting regime does not appear to exist for this state.
<b>CALIFORNIA</b>
<p><b>1. GENERAL DESCRIPTION:</b> Hospitals are required to report most of the “serious reportable events” listed by the NQF.</p> <p><b>2. IS REPORTING MANDATORY?</b> Yes.<sup>90</sup></p> <p><b>3. REPORT RECIPIENT(S):</b> Department of Health Services.</p> <p><b>4. IS REPORTING CONDUCTED ELECTRONICALLY?</b> Unclear from statutes and regulations.</p> <p><b>5. WHAT FACILITIES MUST PROVIDE REPORTS?</b> General acute care hospitals, acute psychiatric hospitals, and special hospitals.<sup>91</sup></p> <p><b>6. WHAT INCIDENTS MUST BE REPORTED?</b> “Adverse events” must be reported. Adverse events are defined to include twenty-seven of the twenty-eight “serious reportable events” listed by the NQF.<sup>92</sup></p> <p><b>7. MUST HOSPITAL-ACQUIRED INFECTIONS BE REPORTED?</b> Infections acquired in hospitals are not explicitly listed as a separate category, but could result from other “adverse events” (e.g., the use of contaminated drugs, devices, or biologics).</p>

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89. E-mail from Edward Welsh, Manager, Cost Reporting & Discharge Data, Ariz. Dep’t of Health Servs., to Jeffrey M. Tebbs, Executive Editor, Yale Journal of Health Policy, Law, & Ethics (Sept. 19, 2008, 19:31 EST) (on file with journal).

90. CAL. HEALTH & SAFETY CODE § 1279.1 (2008).

91. *Id.*

92. *See id.* § 1279.1(b)(1)-(6); *supra* Appendix. The National Quality Forum and California lists are nearly identical, with the exception that the California statute does not specifically include the event of artificial insemination with the wrong donor sperm or wrong egg as a reportable event.

**8. DEADLINES:** Hospitals must report adverse events within five days of the event.<sup>93</sup> If the error has produced an ongoing threat, hospitals must report the event within twenty-four hours.<sup>94</sup>

**9. PENALTIES AND/OR ENFORCEMENT MECHANISMS:** If a patient is in imminent danger, then the Department of Health Services will inspect the facility within forty-eight hours after receiving the report of an adverse event. If no imminent threat exists, then the investigation and report must be completed within forty-five days.<sup>95</sup> For any violation that causes an immediate threat to a patient, the Department of Health Services can assess a penalty of up to \$50,000 per violation upon the facility. The Department can assess up to \$17,500 per violation that does not lead to an immediate threat.<sup>96</sup> If a facility fails to report an adverse event, the Department may assess \$100 per day for the failure to report within the five day period following the event.<sup>97</sup>

**(a) Revocation of license?** Yes. The Department of Health Services may provide consulting services for a facility to develop a corrective plan. If the facility does not implement the plan, the facility's license may be revoked. Additionally, if the facility and the Department of Health Services cannot agree on a corrective plan and safety remains an issue, the Department can order the closure of the facility or a reduction in its patient numbers.<sup>98</sup>

**(b) Audits?** Unclear from statutes and regulations.

**10. ARE PUBLIC REPORTS ISSUED?** By 2009, information regarding reports of substantiated adverse events will be available to the public via non-electronic means.<sup>99</sup> By 2015, the Department of Health Services shall provide this information on its website.<sup>100</sup>

**11. ARE ERROR REPORTS PROTECTED FROM LEGAL DISCOVERY?** Unclear from statutes and regulations. Note that "[a]ll inspection reports and lists of deficiencies shall be open to public inspection when the state department has received verification that the health facility has received the report from the state department. All plans of correction shall be open to public inspection upon receipt by the state department."<sup>101</sup>

**12. IMMUNITY FOR REPORTERS?** Unclear from statutes and regulations.

**13. ANY PAY-FOR-PERFORMANCE PROGRAMS IMPLEMENTED?** No.

93. CAL. HEALTH & SAFETY CODE § 1279.1 (2008).

94. *Id.*

95. *Id.* § 1279.2.

96. *Id.* § 1280.3.

97. *Id.* § 1280.4.

98. *Id.* § 1280.

99. *Id.* § 1279.3.

100. California Department of Public Health, <http://www.cdph.ca.gov> (last visited Nov. 15, 2008).

101. CAL. HEALTH & SAFETY CODE § 1280(e) (2008).

**14. RELEVANT STATUTES AND REGULATIONS:** CAL. HEALTH & SAFETY CODE §§ 1279-1280 (2008).

**15. OTHER RESOURCES:** N/A.

**16. DATE REPORTING STARTED:** Unknown.

**COLORADO**

**1. GENERAL DESCRIPTION:** Health care facilities must report listed occurrences to the Department of Public Health and Environment, which then investigates each report, summarizes its findings, and makes those summaries available to the public.<sup>102</sup> Health care facilities must also report hospital-acquired infections to the National Healthcare Safety Network and allow those data to be released to the Department of Public Health and Environment.<sup>103</sup>

**2. IS REPORTING MANDATORY?** Yes, for both listed occurrences and hospital-acquired infections.<sup>104</sup>

**3. REPORT RECIPIENT(S):** All health care facilities must report listed occurrences directly to the Department of Public Health and Environment.<sup>105</sup> A smaller group of health care facilities must report hospital-acquired infections to the National Healthcare Safety Network, and must also authorize the Department of Public Health and Environment “to have access to health-facility-specific data contained in the [N]ational [H]ealthcare [S]afety [N]etwork database.”<sup>106</sup>

**4. IS REPORTING CONDUCTED ELECTRONICALLY?** For the reporting of listed occurrences, “[t]he board [of the Department of Health] by rule shall specify the manner, time period, and form in which the reports . . . shall be made.”<sup>107</sup> Currently, occurrences must be reported within one business day by phone, followed by a written report to be returned by fax within five business days.<sup>108</sup> For the reporting of hospital-acquired infections, health facilities must report “in

102. COLO. REV. STAT. § 25-1-124 (2008).

103. *Id.* § 25-3-601 to -607.

104. *Id.* § 25-1-124(2) (“Each health care facility . . . shall report to the department the following occurrences.”); *id.* § 25-3-602(1)(a), (3)(a) (“A health facility shall collect data on hospital acquired infection rates . . . [and] shall routinely submit its hospital-acquired infection data to the [N]ational [H]ealthcare [S]afety [N]etwork”).

105. *Id.* § 25-1-124(2) (for listed occurrences). Within the department, it appears that reports are made to the Health Facilities and Emergency Medical Services Division. *See* Colo. Dep’t of Pub. Health & Env’t, Occurrence Reporting Program: Health Facilities, <http://www.cdphe.state.co.us/hf/static/occforms.htm> (last visited Nov. 15, 2008) [hereinafter CDPHE, Occurrence Reporting Program].

106. COLO. REV. STAT. § 25-3-602(3)(a)-(c) (2008); *id.* § 25-3-601(2) (defining “department”); *id.* § 25-3-601(3) (defining “[h]ealth facility”).

107. *Id.* § 25-1-124(3).

108. *See* COLO. DEP’T OF PUB. HEALTH & ENV’T, OCCURRENCE REPORTING MANUAL 7 (2007), available at <http://www.cdphe.state.co.us/hf/download/occman.pdf> [hereinafter CDPHE, OCCURRENCE REPORTING MANUAL]; CDPHE, Occurrence Reporting Program, *supra* note 105.

accordance with [N]ational [H]ealthcare [S]afety [N]etwork requirements and procedures.”<sup>109</sup> The National Healthcare Safety Network surveillance system is electronic.<sup>110</sup>

**5. WHAT FACILITIES MUST PROVIDE REPORTS?** “Each health care facility licensed pursuant to [Colo. Rev. Stat. § 25-3-101] or certified pursuant to [Colo. Rev. Stat. § 25-1.5-103(1)(a)]” must report listed occurrences.<sup>111</sup> “Health care facilities” include any “general hospital, hospital unit . . . psychiatric hospital, community clinic, rehabilitation center, convalescent center, community mental health center, acute treatment unit, facility for persons with developmental disabilities, habilitation center for brain-damaged children, chiropractic center and hospital, maternity hospital, nursing care facility, pilot project rehabilitative nursing facility, hospice care, assisted living residence . . . , dialysis treatment clinic, ambulatory surgical center, birthing center, or other facility of a like nature . . . .”<sup>112</sup>

“[I]f the Colorado attorney general, the division for developmental disabilities in the department of human services, a community centered board, an adult protection service, or a law enforcement agency” makes a report of any of the listed occurrences in a licensed long-term care facility, that report must also be provided to the department.<sup>113</sup> A “licensed long-term care facility” is defined as “a licensed community residential or group home, a licensed intermediate care facility for the mentally retarded, and a licensed facility for persons with developmental disabilities.”<sup>114</sup>

Health care facilities must also report hospital-acquired infections to the National Healthcare Safety Network.<sup>115</sup> This reporting statute defines a “health care facility” as “a hospital, a hospital unit, an ambulatory surgical center, or a dialysis treatment clinic currently licensed or certified by the department pursuant to the department’s authority . . . .”<sup>116</sup>

**6. WHAT INCIDENTS MUST BE REPORTED?** The statute requires reporting of the following events: “(a) Any occurrence that results in the death of a patient or resident of the facility and is required to be reported to the coroner pursuant to [Colo. Rev. Stat. § 30-10-606], as arising from an unexplained cause or under suspicious circumstances; (b) Any occurrence that results in any of the following serious injuries to a patient or resident: (I) Brain or spinal cord injuries; (II) Life-

109. COLO. REV. STAT. § 25-3-602(3)(a) (2008).

110. See Nat’l Healthcare Safety Network, Overview, <http://www.cdc.gov/ncidod/dhqp/nhsn.html> (last visited Nov. 15, 2008).

111. COLO. REV. STAT. § 25-1-124(2) (2008).

112. *Id.* § 25-3-101; see also *id.* § 25-1.5-103 (listing the same facility types with additional clarification).

113. *Id.* § 25-1-124(2.5).

114. *Id.*

115. *Id.* § 25-3-602(3)(a).

116. *Id.* § 25-3-601(3).

threatening complications of anesthesia or life-threatening transfusion errors or reactions; (III) Second- or third-degree burns involving twenty percent or more of the body surface area of an adult patient or resident or fifteen percent or more of the body surface area of a child patient or resident; (c) Any time that a resident or patient of the facility cannot be located following a search of the facility, the facility grounds, and the area surrounding the facility and there are circumstances that place the resident's health, safety, or welfare at risk or, regardless of whether such circumstances exist, the patient or resident has been missing for eight hours; (d) Any occurrence involving physical, sexual, or verbal abuse of a patient or resident . . . or . . . by another patient or resident, an employee of the facility, or a visitor to the facility; (e) Any occurrence involving neglect of a patient or resident . . . ; (f) Any occurrence involving . . . a pattern of or deliberately misplacing, exploiting, or wrongfully using, either temporarily or permanently, a patient's or resident's belongings or money without the patient's or resident's consent[;] (g) Any occurrence in which drugs intended for use by patients or residents are diverted to use by other persons; and (h) Any occurrence involving the malfunction or intentional or accidental misuse of patient or resident care equipment that occurs during treatment or diagnosis of a patient or resident and that significantly adversely affects or if not averted would have significantly adversely affected a patient or resident of the facility.”<sup>117</sup>

A “hospital-acquired infection” is “a localized or systemic condition that results from an adverse reaction to the presence of an infectious agent or its toxins that was not present or incubating at the time of admission to the health facility.”<sup>118</sup> An “infection” is “the invasion of the body by pathogenic microorganisms that reproduce and multiply, causing disease by local cellular injury, secretion of a toxin, or antigen-antibody reaction in the host.”<sup>119</sup> Health care facilities must report hospital-acquired infections in each of the following categories: “(I) Cardiac surgical site infections; (II) Orthopedic surgical site infections; and (III) Central line-related bloodstream infections.”<sup>120</sup> Individuals who collect data on hospital-acquired infections must be certified according to national certification standards, unless they are at hospitals with fifty or fewer beds.<sup>121</sup>

**7. MUST HOSPITAL-ACQUIRED INFECTIONS BE REPORTED?** Yes, as defined above.<sup>122</sup>

**8. DEADLINES:** For listed occurrences, “[t]he board by rule shall specify the manner, time period, and form in which the reports required . . . shall be

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117. *Id.* § 25-1-124(2).

118. *Id.* § 25-3-601(4).

119. *Id.* § 25-3-601(5).

120. *Id.* § 25-3-602(1)(a).

121. *Id.* § 25-3-602(1)(c).

122. *Id.* § 25-3-601 to -607.

made.”<sup>123</sup> Currently, facilities must initially report occurrences within one business day, followed by a written report within five business days.<sup>124</sup> Health care facilities must report hospital-acquired infections “routinely” and “in accordance with [N]ational [S]afety [N]etwork requirements and procedures.”<sup>125</sup>

**9. PENALTIES AND ENFORCEMENT MECHANISMS:** For the reporting of occurrences, “Effective December 1, 2001, if [a facility] report[s] late, [it] will receive one letter of warning. After that, any late report will result in a deficiency under State Licensure [R]egulation 3.2.”<sup>126</sup> Failure to report hospital-acquired infections can result in “termination of licensure or other sanctions related to licensure” or “a civil penalty of up to one thousand dollars per violation for each day the health facility is in violation.”<sup>127</sup>

(a) **Revocation of license?** Yes, for the failure to report hospital-acquired infections.<sup>128</sup> Late reports of occurrences constitute “deficiencies” under state licensure requirements.<sup>129</sup>

(b) **Audits?** Unclear from statutes and regulations.

**10. ARE PUBLIC REPORTS ISSUED?** Yes, for both listed occurrences and hospital-acquired infections. For occurrence reporting, “[t]he department shall investigate each report . . . . For each report investigated, the department shall prepare a summary of its findings, including the department's conclusions and whether there was a violation of licensing standards or a deficiency or whether the facility acted appropriately in response to the occurrence . . . . The department shall make the following information available to the public: (I) Any investigation summaries prepared . . . . (II) Any complaints against a health care facility that have been filed with the department and that the department has investigated . . . ; and (III) A listing of any deficiency citations issued against each health care facility . . . . The information released . . . shall not identify the patient or resident or the health care professional involved in the report.”<sup>130</sup> Additionally, the department will report “to a law enforcement agency” any reports “involving physical, sexual, or verbal abuse of a patient or resident.”<sup>131</sup>

For hospital-acquired infections, “the department shall [annually] submit to the health and human services committees of the house of representatives and of the senate a report summarizing the risk-adjusted health-facility data. The department shall post the report on its website . . . . The department shall issue

123. *Id.* § 25-1-124(3).

124. *See* CDPHE, OCCURRENCE REPORTING MANUAL, *supra* note 108, at 7; CDPHE, Occurrence Reporting Program, *supra* note 105.

125. COLO. REV. STAT. § 25-3-602(3)(a) (2008).

126. *See* CDPHE, OCCURRENCE REPORTING MANUAL, *supra* note 108, at 5.

127. COLO. REV. STAT. § 25-3-606 (2008).

128. *Id.*

129. *See* CDPHE, OCCURRENCE REPORTING MANUAL, *supra* note 108, at 5.

130. COLO. REV. STAT. § 25-1-124(5)-(6) (2008).

131. *Id.* § 25-1-124(8).

semi-annual informational bulletins summarizing all or part of the information submitted in the health-facility reports . . . . The annual report shall compare the risk-adjusted, hospital-acquired infection rates . . . for each individual health facility in the state . . . . A health-facility report or department disclosure may not contain information identifying a patient, employee, or licensed health care professional in connection with a specific infection incident.”<sup>132</sup>

**11. ARE ERROR REPORTS PROTECTED FROM LEGAL DISCOVERY?** Reports of occurrences are not protected from use in regulatory proceedings. “Any report submitted . . . shall be strictly confidential; except that information in any such report may be transmitted to an appropriate regulatory agency having jurisdiction for disciplinary or license sanctions. The information in such reports shall not be made public upon subpoena, search warrant, discovery proceedings, or otherwise, except as provided in [the subsection on public reporting].”<sup>133</sup>

Hospital-acquired infection reports are protected from legal discovery.<sup>134</sup> “[A]ll information and materials obtained and compiled . . . are confidential; are not subject to disclosure, discovery, subpoena, or other means of legal compulsion for release to any person . . . and may not be admitted as evidence or otherwise disclosed in a civil, criminal, or administrative proceeding.”<sup>135</sup>

**12. IMMUNITY FOR REPORTERS?** Unclear from statutes and regulations for occurrence reporting. However, there is immunity for individuals who contribute to the state’s medical quality reporting program, which suggests that individuals who report medical errors may also be protected.<sup>136</sup> It appears that health care facility employees have immunity for reporting hospital-acquired infections. “Information reported by a health facility . . . and all related information and materials are subject to an absolute privilege and shall not be used in any form against the health facility, its agents, employees, partners, assignees, or independent contractors in any civil, criminal, or administrative proceeding, regardless of the means by which a person came into possession of the information . . . .”<sup>137</sup>

**13. ANY PAY-FOR-PERFORMANCE PROGRAMS IMPLEMENTED?** Colorado has established a commission to create a comprehensive hospital information system for the management of hospital-related data and statistics.<sup>138</sup> The commissioners instituted a hospital report card survey in November 2007.<sup>139</sup> There is no evidence that payment systems are linked to quality reports.

132. *Id.* § 25-3-603.

133. *Id.* § 25-1-124(4).

134. *Id.* § 25-3-605.

135. *Id.*

136. *See id.* § 25-3-109(6).

137. *Id.* § 25-6-605.

138. *Id.* § 25-3-702.

139. *Id.* § 25-3-703; Colorado Hospital Report Card, <http://www.cohospitalquality.org/index.php> (last visited Nov. 15, 2008).

**14. RELEVANT STATUTES AND REGULATIONS:** COLO. REV. STAT. § 25-1-124 (2008); COLO. REV. STAT. § 25-3-601 to -607 (2008).

**15. OTHER RESOURCES:** COLO. DEP'T OF PUB. HEALTH & ENV'T, OCCURRENCE REPORTING MANUAL (2007), *available at* <http://www.cdphe.state.co.us/hf/download/occmn.pdf>.

**16. DATE REPORTING STARTED:** Occurrence reporting started April 24, 1997.<sup>140</sup> Reporting of hospital-acquired infections started July 31, 2007.<sup>141</sup>

#### CONNECTICUT

**1. GENERAL DESCRIPTION:** Hospitals and outpatient surgical facilities must report any “serious reportable event” as defined by the NQF, as well as several supplementary events defined by the Commissioner of Public Health.

**2. IS REPORTING MANDATORY?** Yes.<sup>142</sup>

**3. REPORT RECIPIENT(S):** Department of Public Health.<sup>143</sup>

**4. IS REPORTING CONDUCTED ELECTRONICALLY?** No. Initial reports are submitted in writing. However, if an adverse event is deemed “emergent,” it must be reported immediately by telephone, followed by a written report.<sup>144</sup>

**5. WHAT FACILITIES MUST PROVIDE REPORTS?** Hospitals and outpatient surgical facilities.<sup>145</sup>

**6. WHAT INCIDENTS MUST BE REPORTED?** Connecticut requires facilities to report all of the twenty-eight “serious reportable events” listed by the NQF.<sup>146</sup> A list of additional reportable adverse events is also compiled by the Commissioner of Public Health and adopted as regulations.<sup>147</sup> That list includes the following occurrences: “(1) Perforations during open, laparoscopic and/or endoscopic procedures resulting in death or serious disability; (2) Obstetrical events resulting in death or serious disability to the neonate; (3) Significant medication reactions resulting in death or serious disability; (4) Laboratory or radiologic test results not reported to the treating practitioner or reported incorrectly which result in death or serious disability due to incorrect or missed diagnosis in the emergency

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140. COLO. REV. STAT. § 25-1-124 (2008).

141. *Id.* § 25-3-602(3)(a).

142. CONN. GEN. STAT. § 19a-127n(b) (Supp. 2008).

143. *Id.*

144. CONN. AGENCIES REGS. § 19a-127n-2(c) (2008). An emergent report is “the report of an unexpected situation or sudden occurrence of a serious and urgent nature which requires immediate remedial action on the part of the facility to protect the health and safety of its patient population, or an event which is unusually serious in nature and has resulted in a patient’s death or injury.” *Id.* § 19a-127n-1(6).

145. CONN. GEN. STAT. § 19a-127n(b) (Supp. 2008).

146. *See id.* § 19a-127n(a)(1); *supra* Appendix.

147. CONN. GEN. STAT. § 19a-127n(a)(1) (Supp. 2008).

department; and (5) Nosocomial infections defined as reportable sentinel events by the Joint Commission on Accreditation of Healthcare Organizations.”<sup>148</sup>

**7. MUST HOSPITAL-ACQUIRED INFECTIONS BE REPORTED?** Yes. “Nosocomial infections defined as reportable sentinel events by the Joint Commission on Accreditation of Healthcare Organizations” are included in the Department of Public Health’s supplemental list of reportable adverse events.<sup>149</sup>

**8. DEADLINES:** Facilities have seven days to report an adverse event to the Department of Public Health; facilities have thirty days to file a corrective action plan. Facilities may be investigated after a report is filed.<sup>150</sup>

**9. PENALTIES AND ENFORCEMENT MECHANISMS:** For violations, the Commissioner of Public Health can revoke a facility’s license, subject it to suspension or censure, issue a letter of reprimand, place a facility on probation, and/or issue an order to compel compliance.<sup>151</sup>

(a) **Revocation of license?** Yes.<sup>152</sup>

(b) **Audits?** No.

**10. ARE PUBLIC REPORTS ISSUED?** No. The Department of Public Health investigates reports but does not disclose the results to the public. The Commissioner of Public Health shall report annually to the joint standing committee of the General Assembly “having cognizance on matters relating to public health.”<sup>153</sup>

**11. ARE ERROR REPORTS PROTECTED FROM LEGAL DISCOVERY?** Yes. Any information collected for adverse event reports is confidential and not discoverable for a civil suit.<sup>154</sup>

**12. IMMUNITY FOR REPORTERS?** Unclear from statutes and regulations.

**13. ANY PAY-FOR-PERFORMANCE PROGRAMS IMPLEMENTED?** No.

**14. RELEVANT STATUTES AND REGULATIONS:** CONN. GEN. STAT. § 19a-127n (2007); CONN. GEN. STAT. § 19a-494 (2007); CONN. AGENCIES REGS. § 19a-127n-2 (2008).

**15. OTHER RESOURCES:** N/A.

**16. DATE REPORTING STARTED:** October 1, 2002.<sup>155</sup>

**DELAWARE**

A medical error reporting regime does not appear to exist for this state.

148. CONN. AGENCIES REGS. § 19a-127n-2(i) (2008).

149. *Id.*

150. CONN. GEN. STAT. § 19a-127n (Supp. 2008); CONN. AGENCIES REGS. § 19a-127n-2(c), 19a-127n-2(f) (2008).

151. CONN. GEN. STAT. § 19a-494 (Supp. 2008).

152. *Id.*

153. *Id.* § 19a-127n(d).

154. *Id.* § 19a-127n(e).

155. *Id.* § 19a-127n(b).

<b>DISTRICT OF COLUMBIA</b>
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- 1. GENERAL DESCRIPTION:** Health care facilities must report “adverse events” to the Department of Health on a semi-annual basis.
- 2. IS REPORTING MANDATORY?** Yes.
- 3. REPORT RECIPIENT(S):** The Department of Health; specifically the Senior Deputy for Health Regulation and Licensing Administration.<sup>156</sup>
- 4. IS REPORTING CONDUCTED ELECTRONICALLY?** No, although the Department of Health expects to have “an interactive [w]eb-based reporting system” by 2009.<sup>157</sup>
- 5. WHAT FACILITIES MUST PROVIDE REPORTS?** An individual or entity licensed or otherwise authorized under District of Columbia law to provide health care services, including “a hospital, nursing facility, comprehensive outpatient rehabilitation facility, home health agency, hospice program, renal dialysis facility, ambulatory surgical center, pharmacy, physician or health care practitioner’s office, long-term care facility, behavioral health residential treatment facility, health clinic, clinical laboratory, health center, physician, physician assistant, nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse midwife, psychologist, certified social worker, registered dietitian or nutrition professional, physical or occupational therapist, pharmacist, or other individual health care practitioner.”<sup>158</sup>
- 6. WHAT INCIDENTS MUST BE REPORTED?** “Adverse events” must be reported. The D.C. Code defines an “adverse event” as “an event, occurrence, or situation involving the medical care of a patient by a health care provider that results in death or an unanticipated injury to the patient.”<sup>159</sup> The Board of Medicine has “defined the statutory term ‘adverse event’ as the [twenty-eight] Never Events set forth by the National Quality Forum and one [Hospital-Acquired Infection].”<sup>160</sup>
- 7. MUST HOSPITAL-ACQUIRED INFECTIONS BE REPORTED?** One type of hospital-acquired infection must be reported: “[n]osocomial infection defined as a central catheter associated laboratory confirmed primary bloodstream infection.”<sup>161</sup>

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156. E-mail from John Greenhaugh, Senior Assistant Attorney Gen., Health Regulation & Licensing Admin., D.C. Dep’t of Health, to Jeffrey M. Tebbs, Executive Editor, Yale Journal of Health Policy, Law, & Ethics (Nov. 6, 2008, 14:42 EST) [hereinafter E-mail from Greenhaugh] (on file with journal).

157. *Id.*

158. D.C. CODE § 7-161(a)(2) (2008).

159. *Id.* § 7-161(a)(1).

160. E-mail from Greenhaugh, *supra* note 156.

161. D.C. Dep’t of Health, Adverse Event Reporting Form, at 8, [http://hpla.doh.dc.gov/hpla/frames.asp?doc=/hpla/lib/hpla/dc\\_adverse\\_event\\_reporting\\_form.pdf](http://hpla.doh.dc.gov/hpla/frames.asp?doc=/hpla/lib/hpla/dc_adverse_event_reporting_form.pdf) (last visited Nov. 15, 2008); see also E-mail from Greenhaugh, *supra* note 156.

**8. DEADLINES:** Health care facilities are required to provide reports regarding adverse events by January 1 and July 1 of each year.<sup>162</sup>

**9. PENALTIES AND ENFORCEMENT MECHANISMS:** If facilities fail to file reports, they are subject to fines ranging from \$500 to \$2500.<sup>163</sup>

(a) **Revocation of license?** Unclear from statutes and regulations.

(b) **Audits?** Unclear from statutes and regulations.

**10. ARE PUBLIC REPORTS ISSUED?** Yes, the Department of Health issues an annual report.<sup>164</sup>

**11. ARE ERROR REPORTS PROTECTED FROM LEGAL DISCOVERY?** Yes.<sup>165</sup>

**12. IMMUNITY FOR REPORTERS?** Unclear from statutes and regulations.

**13. ANY PAY-FOR-PERFORMANCE PROGRAMS IMPLEMENTED?** No.

**14. RELEVANT STATUTES AND REGULATIONS:** D.C. CODE § 7-161 (2008); 17-40 D.C. CODE MUN. REGS. § 4017.40 (Weil 2008).

**15. OTHER RESOURCES:** D.C. Dep't of Health, Adverse Event Reporting Form, [http://hpla.doh.dc.gov/hpla/frames.asp?doc=/hpla/lib/hpla/dc\\_adverse\\_event\\_reporting\\_form.pdf](http://hpla.doh.dc.gov/hpla/frames.asp?doc=/hpla/lib/hpla/dc_adverse_event_reporting_form.pdf) (last visited Nov. 15, 2008).

**16. DATE REPORTING STARTED:** July 1, 2007.<sup>166</sup>

## FLORIDA

**1. GENERAL DESCRIPTION:** Licensed health care facilities are required to establish internal risk management programs that include an investigation of the frequency and causes of specific types of adverse incidents. Certain adverse incidents must then be reported to the Agency for Health Care Administration and the Department of Health.

**2. IS REPORTING MANDATORY?** Yes.<sup>167</sup>

**3. REPORT RECIPIENT(S):** The Agency for Health Care Administration and the Department of Health. The Florida Patient Safety Corporation, a nonprofit entity, then reviews these adverse event reports in order to recommend “changes in practices and procedures . . . to improve health care quality and to prevent future adverse incidents.”<sup>168</sup>

**4. IS REPORTING CONDUCTED ELECTRONICALLY?** Unclear from statutes and regulations.

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162. D.C. CODE § 7-161(d)(1) (2008).

163. *Id.* § 7-161(d)(2) (2008).

164. *Id.* § 7-161(e)(8); 17-40 D.C. CODE MUN. REGS. § 4017.40 (Weil 2008); E-mail from Greenhaugh, *supra* note 156.

165. D.C. CODE § 7-161(e)(1) (2008).

166. E-mail from Greenhaugh, *supra* note 156.

167. FLA. STAT. § 395.0197(4)(e) (2006); *id.* § 395.0197(7).

168. *Id.* § 381.0271(7)(a)(2).

**5. WHAT FACILITIES MUST PROVIDE REPORTS?** All licensed facilities must provide reports.<sup>169</sup> These facilities include the office practices of medical doctors<sup>170</sup> and osteopathic practitioners.<sup>171</sup>

**6. WHAT INCIDENTS MUST BE REPORTED?** “Adverse incidents” must be reported. The Florida statute defines an “adverse incident” as “an event over which health care personnel could exercise control and which is associated in whole or in part with medical intervention, rather than the condition for which such intervention occurred,” and which falls into one of four categories. The first are incidents that result in one of the following injuries: “(1) Death; (2) Brain or spinal damage; (3) Permanent disfigurement; (4) Fracture or dislocation of bones or joints; (5) A resulting limitation of neurological, physical, or sensory function which continues after discharge from the facility; (6) Any condition that required specialized medical attention or surgical intervention resulting from nonemergency medical intervention, other than an emergency medical condition, to which the patient has not given his or her informed consent; or (7) Any condition that required the transfer of the patient, within or outside the facility, to a unit providing a more acute level of care due to the adverse incident, rather than the patient’s condition prior to the adverse incident.” The second category of incidents includes “the performance of a surgical procedure on the wrong patient, a wrong surgical procedure, a wrong-site surgical procedure, or a surgical procedure otherwise unrelated to the patient’s diagnosis or medical condition.” The third category of incidents “require[s] the surgical repair of damage resulting to a patient from a planned surgical procedure, where the damage was not a recognized specific risk, as disclosed to the patient and documented through the informed-consent process.” The fourth type of adverse incidents results from “a procedure to remove unplanned foreign objects remaining from a surgical procedure.”<sup>172</sup> Internal risk managers at licensed facilities must also investigate allegations of sexual misconduct.<sup>173</sup>

**7. MUST HOSPITAL-ACQUIRED INFECTIONS BE REPORTED?** No.

**8. DEADLINES:** Facilities have three business days to report adverse incidents to their own internal risk management programs.<sup>174</sup> Certain adverse events must then be reported to the Department of Health within fifteen days.<sup>175</sup>

**9. PENALTIES AND ENFORCEMENT MECHANISMS:** For non-willful violations of the reporting requirements, the Agency for Health Care Administration first seeks corrective action by the facility. If the facility fails to demonstrate this

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169. *Id.* § 395.0197(1).

170. *Id.* § 458.351(1)-(2).

171. *Id.* § 459.026(1)-(2).

172. *Id.* § 395.0197(5).

173. *Id.* § 395.0197(9).

174. *Id.* § 395.0197(4)(e).

175. *Id.* § 395.0197(7) (listing which adverse incidents must be reported to the Agency for Health Care Administration).

correction within the timeframe established by the Agency, or if the Agency discovers a pattern of non-willful violations, the Agency may impose administrative fines, not to exceed \$5000 for any individual violation. Penalties for repeated non-willful violations may not exceed \$10,000 per violation. Penalties for intentional and willful violations may not exceed \$25,000 per violation, per day, and may not exceed \$250,000 total.<sup>176</sup>

**(a) Revocation of license?** Unclear from statutes and regulations.

**(b) Audits?** As part of its licensure process, the Agency for Health Care Administration is directed to review the internal risk management program at each licensed facility to determine whether the program is appropriately reporting adverse incidents.<sup>177</sup>

**10. ARE PUBLIC REPORTS ISSUED?** Each licensed facility must submit an annual report summarizing its adverse incident reports for the prior year. This annual report is confidential and is not available to the public.<sup>178</sup> However, on at least a quarterly basis, the Agency for Health Care Administration must publish “a summary and trend analysis of adverse incident reports . . . .”<sup>179</sup> These reports shall not include information that would identify the reporting facility or the practitioners involved.<sup>180</sup> Victims of adverse events have the right to their records and adverse event reports.<sup>181</sup>

**11. ARE ERROR REPORTS PROTECTED FROM LEGAL DISCOVERY?** Yes.<sup>182</sup>

**12. IMMUNITY FOR REPORTERS?** Yes.<sup>183</sup>

**13. ANY PAY-FOR-PERFORMANCE PROGRAMS IMPLEMENTED?** No.

**14. RELEVANT STATUTES AND REGULATIONS:** FLA. STAT. § 381.0271 (2006); FLA. STAT. § 381.028 (2006); FLA. STAT. § 395.0197 (2006); FLA. STAT. § 458.351 (2006); FLA. STAT. § 459.026 (2006).

**15. OTHER RESOURCES:** N/A.

**16. DATE REPORTING STARTED:** Unknown.

## GEORGIA

A medical error reporting regime does not appear to exist for this state.

176. *Id.* § 395.0197(12).

177. *Id.* § 395.0197(15).

178. *Id.* § 395.0197(5)(c); *id.* § 395.0197(6)(2).

179. *Id.* § 395.0197(8).

180. *Id.*

181. Patient’s Right-to-Know About Adverse Medical Incidents Act, FLA. STAT. § 381.028 (2006).

182. FLA. STAT. § 395.0197(6)(c) (2006); FLA. STAT. § 395.0197(7)(h) (2006); *id.* § 395.0197(13)-(14).

183. *Id.* § 395.0197(4).

**HAWAII**

A medical error reporting regime does not appear to exist for this state.

**IDAHO**

A medical error reporting regime does not appear to exist for this state.

**ILLINOIS**

**1. GENERAL DESCRIPTION:** Hospitals and ambulatory surgical treatment centers are required to report twenty-four different “adverse health care event[s]” to the Department of Public Health. The reporting system “shall not be designed . . . to punish errors or to investigate or take disciplinary action against health care facilities, health care practitioners, or health care facility employees.”<sup>184</sup>

**2. IS REPORTING MANDATORY?** Yes.<sup>185</sup>

**3. REPORT RECIPIENT(S):** Department of Public Health.<sup>186</sup>

**4. IS REPORTING CONDUCTED ELECTRONICALLY?** An electronic filing option is available,<sup>187</sup> and the Department of Public Health “will be strongly encouraging facilities to report electronically.”<sup>188</sup>

**5. WHAT FACILITIES MUST PROVIDE REPORTS?** Any “health care facility,” which is defined to include state hospitals, university hospitals, hospitals licensed under the Hospital Licensing Act or the University of Illinois Hospital Act, and ambulatory surgical treatment centers.<sup>189</sup>

**6. WHAT INCIDENTS MUST BE REPORTED?** The Illinois Adverse Health Care Reporting Act of 2005 requires facilities to report twenty-four of the twenty-eight “serious reportable events” listed by the NQF.<sup>190</sup> The four adverse events from the NQF list that have not been adopted by Illinois are 1) death or serious disability associated with failure to identify and treat hyperbilirubinemia in neonates, 2) stage 3 or 4 pressure ulcers acquired after admission to a health care facility, 3) patient death or serious disability due to spinal manipulative therapy, and 4) artificial insemination with the wrong donor sperm or egg.

**7. MUST HOSPITAL-ACQUIRED INFECTIONS BE REPORTED?** Pursuant to the Hospital Report Card Act, hospitals must prepare a quarterly report of

184. 410 ILL. COMP. STAT. 522/10-5 (2005).

185. *Id.* 522/10-15(a).

186. *Id.* 522/10-10 (defining “department”).

187. *Id.* 522/10-30(d).

188. Facsimile from Mary Driscoll, Div. Chief of Patient Safety & Quality, Div. of Health Policy, Ill. Dep’t of Pub. Health, to Jeffrey M. Tebbs, Executive Editor, Yale Journal of Health Policy, Law, & Ethics (Sept. 22, 2008) [hereinafter Facsimile from Driscoll] (on file with journal).

189. 410 ILL. COMP. STAT. 522/10-10 (2005) (defining “health care facility”).

190. *Id.* 522/10-15(b)-(g).

“[i]nfection-related measures for the facility,”<sup>191</sup> which includes “central line blood [s]tream infections.”<sup>192</sup>

**8. DEADLINES:** Health care facilities must report adverse health care events within thirty days of discovery to the Department of Public Health.<sup>193</sup> Facilities must then conduct a root cause analysis and implement a corrective action plan within ninety days of the initial submission of the adverse event report.<sup>194</sup>

**9. PENALTIES AND ENFORCEMENT MECHANISMS:** The statute directs the Department of Public Health to impose sanctions against health care facilities that fail to comply with reporting system requirements.<sup>195</sup> The pending approval of an associated administrative rule will clarify the nature of those sanctions.<sup>196</sup>

**(a) Revocation of license?** Yes. If a hospital fails to comply with the Adverse Health Care Reporting Act of 2005, its license may be revoked.<sup>197</sup>

**(b) Audits?** Unclear from statutes and regulations.

**10. ARE PUBLIC REPORTS ISSUED?** Yes. The Department of Health issues an annual report with aggregate data.<sup>198</sup>

**11. ARE ERROR REPORTS PROTECTED FROM LEGAL DISCOVERY?** Yes.<sup>199</sup>

**12. IMMUNITY FOR REPORTERS?** Unclear from statutes and regulations.

**13. ANY PAY-FOR-PERFORMANCE PROGRAMS IMPLEMENTED?** No.

**14. RELEVANT STATUTES AND REGULATIONS:** Adverse Health Care Reporting Act of 2005, 410 ILL. COMP. STAT. 522/10-5 to 522/10-50 (2005); Hospital Report Card Act, 210 ILL. COMP. STAT. 86/25(a)(2) (2008); ILL. ADMIN. CODE 255, §§ 250, 280 (2008).

**15. OTHER RESOURCES:** N/A.

**16. DATE REPORTING STARTED:** January 1, 2008.<sup>200</sup>

## INDIANA

**1. GENERAL DESCRIPTION:** Administrative regulations require hospitals to implement a quality assessment and improvement program that includes the reporting of serious adverse events to the Indiana Department of Health.

**2. IS REPORTING MANDATORY?** Yes.<sup>201</sup>

191. 210 *id.* 86/25(a)(2) (2008).

192. Facsimile from Driscoll, *supra* note 188.

193. 410 ILL. COMP. STAT. 522/10-15(a) (2005).

194. *Id.* 522/10-20.

195. *Id.* 522/10-30(b)(4).

196. Facsimile from Driscoll, *supra* note 188.

197. ILL. ADMIN. CODE tit. 255, § 280 (2008).

198. 410 ILL. COMP. STAT. 522/10-25 (2005); *id.* 522/10-35(4).

199. *Id.* 522/10-25.

200. *Id.* 522/10-30.

201. 410 IND. ADMIN. CODE 15-1.4-2 (2008); *Id.* 15-1.4-2.2(a).

- 3. REPORT RECIPIENT(S):** Department of Health.<sup>202</sup>
- 4. IS REPORTING CONDUCTED ELECTRONICALLY?** Unclear from statutes and regulations.
- 5. WHAT FACILITIES MUST PROVIDE REPORTS?** Hospitals.<sup>203</sup>
- 6. WHAT INCIDENTS MUST BE REPORTED?** “Serious adverse events” must be reported. Adverse events are defined to include twenty-seven of the twenty-eight “serious reportable events” listed by the NQF.<sup>204</sup> The hospital must also have a “plan to address the internal review and reporting of unusual occurrences and disasters.”<sup>205</sup>
- 7. MUST HOSPITAL-ACQUIRED INFECTIONS BE REPORTED?** No. The reporting of hospital-acquired infections is optional.<sup>206</sup>
- 8. DEADLINES:** Hospitals must submit reports to the Department of Health within fifteen days after the hospital quality assurance and improvement program becomes aware of the incident.<sup>207</sup>
- 9. PENALTIES AND ENFORCEMENT MECHANISMS:** Unclear from statutes and regulations.
- (a) Revocation of license?** Unclear from statutes and regulations.
- (b) Audits?** Unclear from statutes and regulations.
- 10. ARE PUBLIC REPORTS ISSUED?** Yes. The Department of Health issues an annual report.<sup>208</sup>
- 11. ARE ERROR REPORTS PROTECTED FROM LEGAL DISCOVERY?** Yes.<sup>209</sup>
- 12. IMMUNITY FOR REPORTERS?** Unclear from statutes and regulations.
- 13. ANY PAY-FOR-PERFORMANCE PROGRAMS IMPLEMENTED?** No.
- 14. RELEVANT STATUTES AND REGULATIONS:** IND. CODE § 16-40-5-4 to § 16-40-5-6 (Supp. 2008); 410 IND. ADMIN. CODE 15-1.2-1 (2008); 410 IND. ADMIN. CODE 15-1.4-2 (2008); 410 IND. ADMIN. CODE 15-1.4-2.2 (2008).
- 15. OTHER RESOURCES:** N/A.
- 16. DATE REPORTING STARTED:** Unknown.

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202. *Id.* 15-1.4-2; *Id.* 15-1.4-2.2(a).

203. *Id.* 15-1.4-2; *Id.* 15-1.4-2.2.

204. *See id.* 15-1.4-2.2(a); *supra* Appendix. The National Quality Forum and Indiana lists are nearly identical, with the exception that the Indiana regulation does not specifically include the event of artificial insemination with the wrong donor sperm or wrong egg as a reportable event.

205. 410 IND. ADMIN. CODE 15-1.2-1 (2008) (listing examples of unusual occurrences and disasters).

206. IND. CODE § 16-40-5-5(2) (Supp. 2008) (stating that health care facilities, health care professionals, and individuals may file reports of infections that were acquired in the health care facility).

207. 410 IND. ADMIN. CODE 15-1.4-2.2(c)(1)(B) (2008).

208. *Id.* 15-1.4-2.2(d).

209. IND. CODE § 16-40-5-6 (Supp. 2008).

**IOWA**

A medical error reporting regime does not appear to exist for this state.

**KANSAS**

**1. GENERAL DESCRIPTION:** Health care providers, medical care facility agents, and medical care facility employees must report incidents in which an action by a health care provider “(1) [i]s or may be below the applicable standard of care and has a reasonable probability of causing injury to a patient; or (2) may be grounds for disciplinary action by the appropriate licensing agency.”<sup>210</sup> Reports are first filed internally for review and then sent to the appropriate state licensing agency for “appropriate disciplinary measures.”<sup>211</sup>

**2. IS REPORTING MANDATORY?** Yes.<sup>212</sup>

**3. REPORT RECIPIENT(S):** Health care providers, medical care facility agents, and medical care facility employees report incidents directly to “the chief of the medical staff, chief administrative officer or risk manager of the facility.”<sup>213</sup> This individual then “refer[s] the report to the appropriate executive committee or professional practices peer review committee . . . .”<sup>214</sup> After investigating the report, the applicable committee must “report to the appropriate state licensing agency any finding by the committee that a health care provider acted below the applicable standard of care which action had a reasonable probability of causing injury to a patient, or in a manner which may be grounds for disciplinary action by the appropriate licensing agency, so that the agency may take appropriate disciplinary measures.”<sup>215</sup>

**4. IS REPORTING CONDUCTED ELECTRONICALLY?** No.<sup>216</sup>

**5. WHAT FACILITIES MUST PROVIDE REPORTS?** Licensed medical care facilities, private psychiatric hospitals, state psychiatric hospitals, and certain state institutions for the mentally retarded.<sup>217</sup>

210. KAN. STAT. ANN. § 65-4921(f) (2007); *id.* § 65-4923(a)(2).

211. *Id.* § 65-4923(a)(2).

212. *Id.* § 65-4923(a) (“If a health care provider, or a medical care facility agent or employee who is directly involved in the delivery of health care services, has knowledge that a health care provider has committed a reportable incident, such health care provider, agent or employee shall report such knowledge . . .”).

213. *Id.* § 65-4923(a)(2).

214. *Id.*

215. *Id.*

216. KAN. ADMIN. REGS. § 28-52-2(a) (2008) (“Each medical care facility shall identify a written form on which employees and health care providers shall report clinical care concerns to the risk manager, chief of staff, or administrator.”).

217. KAN. STAT. ANN. § 65-4921(e) (2007) (defining “[m]edical care facility”).

**6. WHAT INCIDENTS MUST BE REPORTED?** A “[r]eportable incident” is defined as “an act by a health care provider which: (1) Is or may be below the applicable standard of care and has a reasonable probability of causing injury to a patient; or (2) may be grounds for disciplinary action by the appropriate licensing agency.”<sup>218</sup>

**7. MUST HOSPITAL-ACQUIRED INFECTIONS BE REPORTED?** Unclear from statutes and regulations.

**8. DEADLINES:** At least once every three months, the review and executive committee of the medical facility must submit a report to the secretary of health and environment “summarizing the reports received” for the applicable time period.<sup>219</sup> “The report shall include the number of reportable incidents reported, whether an investigation was conducted and any action taken.”<sup>220</sup>

**9. PENALTIES AND ENFORCEMENT MECHANISMS:** “No person or entity shall be subject to liability in a civil action for failure to report as required” under the reporting program.<sup>221</sup>

**(a) Revocation of license?** Yes. “The license of a person or entity required to report . . . may be revoked, suspended or limited, or the licensee subjected to public or private censure, by the appropriate state licensing agency if the licensee is found . . . to have willfully and knowingly failed to make any [required] report.”<sup>222</sup>

**(b) Audits?** Unclear from statutes and regulations.

**10. ARE PUBLIC REPORTS ISSUED?** Yes. Annual reports are issued.<sup>223</sup>

**11. ARE ERROR REPORTS PROTECTED FROM LEGAL DISCOVERY?** Yes. “The reports and records made pursuant to [this reporting program] . . . shall be confidential and privileged.”<sup>224</sup> “Such reports and records shall not be subject to discovery, subpoena or other means of legal compulsion for their release to any person or entity and shall not be admissible in any civil or administrative action other than a disciplinary proceeding by the appropriate state licensing agency.”<sup>225</sup>

Witnesses or participants in meetings of the executive or review committees of affected medical facilities shall not “be compelled to testify in any civil, criminal or administrative action, other than a disciplinary proceeding by the appropriate licensing agency, as to any committee discussions or proceedings.”<sup>226</sup>

**12. IMMUNITY FOR REPORTERS?** Yes. “No employer shall discharge or otherwise discriminate against any employee for making any report” required by

218. *Id.* § 65-4921(f).

219. *Id.* § 65-4923(d).

220. *Id.*

221. *Id.* § 65-4927(a).

222. *Id.* § 65-4927(b).

223. ROSENTHAL AND TAKACH, *supra* note 15, at 14.

224. KAN. STAT. ANN. § 65-4925(a) (2007).

225. *Id.*

226. *Id.* § 65-4925(b).

the applicable statute.<sup>227</sup> The statute provides for the recovery of damages by aggrieved employees for monetary losses attributable to wrongful discharge.<sup>228</sup> Further, “[a]ny person or entity which, in good faith, reports or provides information or investigates any health care provider [under this reporting program] . . . shall not be liable in a civil action for damages or other relief arising from the reporting.”<sup>229</sup>

**13. ANY PAY-FOR-PERFORMANCE PROGRAMS IMPLEMENTED?** No.

**14. RELEVANT STATUTES AND REGULATIONS:** KAN. STAT. ANN. § 65-4921 to -4929 (2007); KAN. ADMIN. REGS. § 28-52-1 to -4 (2008).

**15. OTHER RESOURCES:** N/A.

**16. DATE REPORTING STARTED:** 1986.<sup>230</sup>

**KENTUCKY**

A medical error reporting regime does not exist for this state.<sup>231</sup>

**LOUISIANA**

A medical error reporting regime does not appear to exist for this state.

**MAINE**

**1. GENERAL DESCRIPTION:** Health care facilities must notify the Division of Licensing and Certification within the Bureau of Medical Services of the occurrence of any “sentinel event.”

**2. IS REPORTING MANDATORY?** Yes. Sentinel event reporting is mandatory.

**3. REPORT RECIPIENT(S):** The Division of Licensing and Certification within the Bureau of Medical Services.<sup>232</sup>

**4. IS REPORTING CONDUCTED ELECTRONICALLY?** Yes.<sup>233</sup>

**5. WHAT FACILITIES MUST PROVIDE REPORTS?** All health care facilities “defined under Title 34-B, chapter 1 or a health care facility licensed by the division,” except for facilities “licensed as a nursing facility or licensed under chapter 1665.”<sup>234</sup> This includes general and specialty hospitals, ambulatory

227. *Id.* § 65-4928(a).

228. *Id.* § 65-4928(b).

229. *Id.* § 65-4926.

230. *Id.* §§ 65-4921 to -4929.

231. Letter from J. Thomas Badgett, Chief Med. Officer, Ky. Cabinet for Health & Family Servs., to Jeffrey M. Tebbs, Executive Editor, *Yale Journal of Health Policy, Law, & Ethics* (Oct. 21, 2008) (on file with journal).

232. ME. REV. STAT. ANN. tit. 22 §§ 8752(2), 8753 (2008).

233. *Id.* § 8754(2).

234. *Id.* §§ 8752(2), 8753 (defining “health care facility”).

surgical centers, end-stage renal disease facilities or units, and intermediate care facilities for persons with mental retardation.<sup>235</sup>

**6. WHAT INCIDENTS MUST BE REPORTED?** Any of the following sentinel events that are “determined to be unrelated to the natural course of the patient’s illness or underlying condition or proper treatment of that illness or underlying condition or that results from the elopement of a hospitalized inpatient who lacks the capacity . . . to make decisions:” 1) an “unanticipated death” or “a major permanent loss of function that is not present when the patient is admitted to the health care facility;” 2) “[s]urgery on the wrong patient or wrong body part;” 3) “[h]emolytic transfusion reaction involving administration of blood or blood products having major blood group incompatibilities;” 4) “[s]uicide of a patient in a health care facility where the patient receives inpatient care;” 5) “[i]nfant abduction or discharge to the wrong family;” 6) “[r]ape of a patient.”<sup>236</sup>

**7. MUST HOSPITAL-ACQUIRED INFECTIONS BE REPORTED?** Hospital-acquired infections are not explicitly listed as a separate category of sentinel events, but could qualify as “adverse events” in instances where the infection results in unanticipated death or a major permanent loss of function.

**8. DEADLINES:** The Division of Licensing and Certification must be notified the next business day after the sentinel event or its discovery. The health care facility then files a written report within forty-five days of the occurrence.<sup>237</sup>

**9. PENALTIES AND ENFORCEMENT MECHANISMS:** If a health care facility knowingly violates reporting requirements, it is subject to a civil penalty of up to \$5000 per unreported episode. That fine must be recovered in a civil action. Fines are deposited in a special account to support sentinel event reporting and education.<sup>238</sup>

(a) **Revocation of license?** Unclear from statutes and regulations.

(b) **Audits?** Unclear from statutes and regulations.

**10. ARE PUBLIC REPORTS ISSUED?** Yes. The Division of Licensing and Certification develops an annual report for the legislature, health care facilities, and the public. The annual report includes summary data of the number and types of sentinel events of the prior calendar year by type of health care facility, rates of change, other analyses, and an outline of areas to be addressed for the upcoming year.<sup>239</sup>

**11. ARE ERROR REPORTS PROTECTED FROM LEGAL DISCOVERY?** Yes.<sup>240</sup>

**12. IMMUNITY FOR REPORTERS?** Yes.<sup>241</sup>

235. ME. DEP’T OF HEALTH & HUMAN SERVS., SENTINEL EVENT ANNUAL REPORT TO THE LEGISLATURE: CY 2006 (2007), [http://maine.gov/dhhs/dlrs/medical\\_facilities/archive/SE\\_Annual\\_Report\\_2007.doc](http://maine.gov/dhhs/dlrs/medical_facilities/archive/SE_Annual_Report_2007.doc).

236. ME. REV. STAT. ANN. 22 tit. §§ 8752(4), 8753 (2008) (defining “sentinel events”).

237. *Id.* § 8753(2).

238. *Id.* § 8755.

239. *Id.* § 8754(4).

240. *Id.* § 8754(3).

**13. ANY PAY-FOR-PERFORMANCE PROGRAMS IMPLEMENTED?** Unclear from statutes and regulations.

**14. RELEVANT STATUTES AND REGULATIONS:** ME. REV. STAT. ANN. tit. 22, §§ 8751-8756 (2008); 10-144-112 ME. CODE R. § VI (Weil 2008); 10-144-118 ME. CODE R. § 5.C.7 (Weil 2008); 10-144-125 ME. CODE R. § 4.B. (Weil 2008); 10-144-126 ME. CODE R. § 4.F. (Weil 2008).

**15. OTHER RESOURCES:** NAT'L ACAD. FOR STATE HEALTH POLICY, AN ACT TO REDUCE MEDICAL ERRORS AND IMPROVE PATIENT HEALTH: A CASE STUDY FROM MAINE (2002), [http://www.nashp.org/Files/Mandatory\\_reporting\\_ME.pdf](http://www.nashp.org/Files/Mandatory_reporting_ME.pdf); ME. DEP'T OF HEALTH & HUMAN SERVS., SENTINEL EVENT ANNUAL REPORT TO THE LEGISLATURE: CY 2006 (2007), [http://maine.gov/dhhs/dlrs/medical\\_facilities/archive/SE\\_Annual\\_Report\\_2007.doc](http://maine.gov/dhhs/dlrs/medical_facilities/archive/SE_Annual_Report_2007.doc).

**16. DATE REPORTING STARTED:** May 2003.<sup>242</sup>

## MARYLAND

**1. GENERAL DESCRIPTION:** Hospitals must report all “level 1 adverse events” to the Department of Health and Mental Hygiene<sup>243</sup> and conduct root cause analyses of these events.

**2. IS REPORTING MANDATORY?** Reporting is only mandatory for “level 1” events, as defined below.

**3. REPORT RECIPIENT(S):** Department of Health and Mental Hygiene.<sup>244</sup>

**4. IS REPORTING CONDUCTED ELECTRONICALLY?** Unclear from statutes and regulations.

**5. WHAT FACILITIES MUST PROVIDE REPORTS?** Hospitals.<sup>245</sup>

**6. WHAT INCIDENTS MUST BE REPORTED?** Hospitals must report “level 1 adverse event[s]” to the Department of Health and Mental Hygiene. An “adverse event” is an “unexpected occurrence related to an individual’s medical treatment and not related to the natural course of the patient’s illness or underlying disease condition.”<sup>246</sup> A “[l]evel 1 adverse event” means “an adverse event that results in death or serious disability,”<sup>247</sup> and hospitals must report these events to the Department of Health and Mental Hygiene. A “[l]evel 2 adverse event” is “an adverse event that requires a medical intervention to prevent death or serious disability.”<sup>248</sup> A “[n]ear-miss” is a “situation that could have resulted in an

241. *Id.* § 8753(4).

242. *Id.* § 8751.

243. MD. CODE REGS. 10.07.06.04(B)(1) (2008); *id.* 10.07.06.09.

244. *Id.* 10.07.06.02(3) (defining “department”); *id.* 10.07.06.09.

245. *Id.* 10.07.06.01.

246. *Id.* 10.07.06.02(2).

247. *Id.* 10.07.06.02(4).

248. *Id.* 10.07.06.02(5). A “[l]evel 3 adverse event” is “an adverse event that does not result in death or serious disability and does not require any medical intervention to prevent death or serious

adverse event but did not, either by chance or through timely intervention”; hospitals are encouraged to report “near-misses.”<sup>249</sup> In addition to identifying “any immediate corrective action to prevent reoccurrence,” the hospital is also required to complete a root cause analysis for any level 1 or 2 adverse event (or near-miss that warrants a root cause analysis).<sup>250</sup> Root cause analyses for level 1 adverse events must be submitted to the Department of Health and Mental Hygiene.

**7. MUST HOSPITAL-ACQUIRED INFECTIONS BE REPORTED?** Hospital-acquired infections are not explicitly listed as a separate category, but could qualify as “level 1 adverse events” if they result in death or serious disability.

**8. DEADLINES:** Hospitals must report level 1 adverse events within five days of the hospital’s knowledge of the event. The hospital is then required to submit a root cause analysis and action plan within sixty days of its knowledge of the event.<sup>251</sup>

**9. PENALTIES AND ENFORCEMENT MECHANISMS:** If a hospital fails to implement a patient safety program that fulfills the requirements of the applicable regulations, then the Secretary of Health and Mental Hygiene may revoke the hospital’s license or assess a fine of \$500 per day.<sup>252</sup>

(a) **Revocation of license?** Yes.<sup>253</sup>

(b) **Audits?** Unclear from statutes and regulations.

**10. ARE PUBLIC REPORTS ISSUED?** Yes, an annual report is produced by the Hospital Patient Safety Program that provides aggregate data on level 1 adverse events in Maryland hospitals.<sup>254</sup>

**11. ARE ERROR REPORTS PROTECTED FROM LEGAL DISCOVERY?** Yes.<sup>255</sup>

**12. IMMUNITY FOR REPORTERS?** Unclear from statutes and regulations.

**13. ANY PAY-FOR-PERFORMANCE PROGRAMS IMPLEMENTED?** No.

**14. RELEVANT STATUTES AND REGULATIONS:** MD. CODE ANN., HEALTH-GEN. § 19-304 (2005); MD. CODE REGS. 10.07.06.01-16 (2008) (Hospital Patient Safety Program); *see also* MD. CODE ANN., HEALTH-GEN. § 19-305 (2005) (requiring residential treatment centers to notify a resident’s family or guardian of adverse events and changes in condition).

disability.” *Id.* 10.07.06.02(6).

249. *Id.* 10.07.06.02(8).

250. *Id.* 10.07.06.05. Level 3 adverse events and certain near-misses should still be evaluated by the hospital to determine any patterns or trends, although they need not be reported to the Department of Health and Mental Hygiene. *Id.* 10.07.06.07.

251. *Id.* 10.07.06.09(A-B).

252. MD. CODE ANN., HEALTH-GEN. § 19-304 (2005); MD. CODE REGS. 10.07.06.16 (2008).

253. MD. CODE REGS. 10.07.06.16(A) (2008).

254. *See, e.g.*, MD. DEP’T OF HEALTH & MENTAL HYGIENE, MARYLAND HOSPITAL PATIENT SAFETY PROGRAM ANNUAL REPORT: FISCAL YEAR 2007, [http://www.dhmh.state.md.us/ohcq/download/reports/mhpsp\\_07\\_report.pdf](http://www.dhmh.state.md.us/ohcq/download/reports/mhpsp_07_report.pdf).

255. MD. CODE REGS. 10.07.06.09(C) (2008).

**15. OTHER RESOURCES:** MD. DEP'T OF HEALTH & MENTAL HYGIENE, MARYLAND HOSPITAL PATIENT SAFETY PROGRAM ANNUAL REPORT: FISCAL YEAR 2007, [http://www.dhmv.state.md.us/ohcq/download/reports/mhpsp\\_07\\_report.pdf](http://www.dhmv.state.md.us/ohcq/download/reports/mhpsp_07_report.pdf).

**16. DATE REPORTING STARTED:** March 15, 2004.<sup>256</sup>

**MASSACHUSETTS**

**1. GENERAL DESCRIPTION:** Health care facilities must report “major incidents” to the Board of Registration in Medicine.<sup>257</sup> Health care facilities must also report “serious incidents” to the Division of Health Care Quality within the Department of Public Health’s Bureau of Health Care Safety and Quality.<sup>258</sup> Starting on August 10, 2008, hospitals and ambulatory surgical centers are also required to report the NQF’s “serious reportable events”<sup>259</sup> and hospital-acquired infections to the Health Care Quality and Cost Council within the Executive Office of Health and Human Services.<sup>260</sup>

In January 2004, Massachusetts launched the Betsy Lehman Center for Patient Safety and Medical Error Reduction. The center is meant to serve as a clearinghouse for the development and dissemination of best practices for patient safety. The Massachusetts General Laws mandate that the Center “coordinate state participation in any appropriate state or federal reports or data collection efforts relative to patient safety and medical error reduction. The center shall analyze available data, research and reports for information that would improve education and training programs that promote patient safety.”<sup>261</sup>

**2. IS REPORTING MANDATORY?** Yes.

**3. REPORT RECIPIENT(S):** Board of Registration in Medicine; Department of Public Health; Health Care Quality and Cost Council.

**4. IS REPORTING CONDUCTED ELECTRONICALLY?** Unclear from statutes and regulations.<sup>262</sup>

256. *Id.* 10.07.06.03(A) (specifying date on which “patient safety program” associated with reporting of Level 1 adverse events must be implemented).

257. 243 MASS. CODE REGS. 3.08(2) (2008). The regulation alternates between the terms “major accident” and “major incident.” The Division of Health Care Quality of the Massachusetts Department of Public Health indicated that “major incident” is the proper term. Letter from Nancy Murphy, Policy Analyst, Div. of Health Care Quality, Mass. Dep’t of Pub. Health, to Jeffrey M. Tebbs, Executive Editor, *Yale Journal of Health Policy, Law, & Ethics* (Sept. 17, 2008) [hereinafter Letter from Murphy] (on file with journal).

258. 105 MASS. CODE REGS. 130.331(2008); Letter from Murphy, *supra* note 257.

259. *See supra* Appendix.

260. 2008 Mass. Legis. Serv. ch. 305 (West); Letter from Murphy, *supra* note 257.

261. MASS. GEN. LAWS ch. 6A, § 16E (2006).

262. 243 MASS. CODE REGS. 3.08(3) (2008) (“When reporting a major incident, health care facilities shall use the Board’s form prescribed for that purpose.”).

**5. WHAT FACILITIES MUST PROVIDE REPORTS?** “Health care facilit[ies]” must report “major incidents.” A health care facility is defined as “any entity licensed pursuant to [Mass. Gen. Laws ch. 111, § 51 (2006) (Hospitals, institutions for unwed mothers, or clinics)]; any nursing home, within the meaning of [Mass. Gen. Laws ch. 111, § 203(d) (2006)]; any state, county or municipal hospital; any entity maintaining more than one primary or episodic walk-in center; and any health maintenance organization within the meaning of [Mass. Gen. Laws ch. 176G, § 1 (2006)].”<sup>263</sup> Hospitals must report “serious incidents” in addition to major incidents.<sup>264</sup>

**6. WHAT INCIDENTS MUST BE REPORTED?** Health care facilities must report “major incidents” to the Board of Registration in Medicine. Major incidents are defined as “(a) Maternal deaths that are related to delivery”; “(b) Death in the course of, or resulting from, elective ambulatory procedures”; “(c) Any invasive diagnostic procedure or surgical intervention performed on the wrong organ, extremity or body part”; and “(d) All deaths or major or permanent impairments of bodily functions . . . that are not ordinarily expected as a result of the patient’s condition on presentation.”<sup>265</sup> Major incidents of type (d) are not necessarily errors. The regulation seeks to identify any outcomes that are rare relative to the normal progression of a disease or condition.<sup>266</sup>

In addition, hospitals must report “serious incidents” to the Department of Public Health, which are defined as: “(1) Fire; (2) Suicide; (3) Serious criminal acts; (4) Pending or actual strike action by its employees, and contingency plans for operation of the hospital; (5) Serious physical injury to a patient resulting from an accident or unknown cause.”<sup>267</sup>

**7. MUST HOSPITAL-ACQUIRED INFECTIONS BE REPORTED?** “Beginning in July 2008, pursuant to hospital licensure regulatory amendments, hospitals must participate in and report healthcare-associated infections to the Centers for Disease Control and Prevention’s (CDC) National Healthcare Safety Network (NHSN). The Department [of Public Health] will have access to certain data for the purposes of monitoring and public reporting. Public reports will be available on the Health Care Quality and Cost Council’s consumer health information website beginning in March 2009. The Betsy Lehman Center will have access to certain data for review and development of recommendations regarding future public reporting.”<sup>268</sup>

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263. *Id.* 3.02.

264. 105 *id.* 130.331.

265. 243 *id.* 3.08(2).

266. *Id.* 3.08(2)(d).

267. 105 *id.* 130.331(A).

268. Letter from Murphy, *supra* note 257; *see also* 2008 Mass. Legis. Serv. ch. 305 (West).

**8. DEADLINES:** Health care facilities must file “major incident” reports with the Board of Registration in Medicine on a quarterly basis.<sup>269</sup> Hospitals must immediately report via telephone any “serious incident” to the Department of Public Health. A hospital must also file written reports within one week for “any other serious incidents occurring on the premises covered by its license . . . which seriously affect the health and safety of its patients.”<sup>270</sup>

**9. PENALTIES AND ENFORCEMENT MECHANISMS:** “If any insurer or health care provider fails to submit required data to the [Health Care Quality and Cost Council] on a timely basis, the council shall provide written notice to the insurer or health care provider. An insurer or health care provider that fails, without just cause, to provide the required information within [two] weeks following receipt of the written notice may be required to pay a penalty of \$1,000 for each week of delay; provided, however, that the maximum annual penalty under this section shall be \$50,000.”<sup>271</sup>

**(a) Revocation of license?** Participation in the Patient Care Assessment (PCA) program operated by the Board of Registration in Medicine is a condition of both hospital and physician licensure. However, the “PCA Committee is not punitive or adversarial in nature; it does not discipline physicians or regulate their licensure.”<sup>272</sup>

**(b) Audits?** The Board of Registration in Medicine and the Department of Public Health have “access and audit authority over Qualified Patient Care Assessment Program information and records during normal business hours.”<sup>273</sup> The Board’s authority to conduct external audits is limited to “all incident reports, patient complaints, employee training materials, credentialing items, Patient Care Assessment Coordinator reports, and other items [the hospitals] are charged with generating.”<sup>274</sup> The Board is not, however, entitled to “access and audit authority” over a hospital’s Peer Review Committee “proceedings, reports, and records” unless necessary for the Board during its “investigation of a complaint [regarding a physician] . . . .”<sup>275</sup> Health care facilities are also required to conduct internal reviews of “a percentage of patients’ medical records . . . shortly after discharge” to “reveal . . . adverse or potentially adverse patient occurrences that might not otherwise be evident.”<sup>276</sup> The “Patient Care Assessment Coordinator” at the health care facility, who is

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269. 243 MASS. CODE REGS. 3.08(3) (2008).

270. 105 *id.* 130.331.

271. 2008 Mass. Legis. Serv. ch. 305 (West).

272. Commonwealth of Mass., Bd. of Registration in Med., Patient Care Assessment, <http://www.massmedboard.org/pca> (last visited Nov. 15, 2008).

273. 243 MASS. CODE REGS. 3.07(3)(k) (2008).

274. Beth Israel Hosp. Ass’n v. Bd. of Registration in Med., 515 N.E.2d 574, 580 (Mass. 1987).

275. *Id.* at 579 n.11.

276. 243 MASS. CODE REGS. 3.07(3)(c) (2008).

charged with “implement[ing] . . . a facility’s Qualified Patient Care Assessment Program,” is also responsible for creating “a random chart audit system to assure compliance with the incident reporting requirements.”<sup>277</sup>

**10. ARE PUBLIC REPORTS ISSUED?** Yes, the Board of Registration in Medicine releases an annual report regarding “major incidents” reported to its Patient Care Assessment Division.<sup>278</sup> Serious “incident reports (with protected health information redacted) are public information once a review is completed and the case is closed.”<sup>279</sup>

**11. ARE ERROR REPORTS PROTECTED FROM LEGAL DISCOVERY?** Yes.<sup>280</sup>

**12. IMMUNITY FOR REPORTERS?** Yes. “No person filing a complaint [against a licensed physician] or . . . assisting the [Board of Registration in Medicine] at its request in any manner in discharging its duties and functions shall be liable in any cause of action arising out of the receiving of such information or assistance, provided the person making the complaint or reporting or providing such information or assistance does so in good faith and without malice.”<sup>281</sup>

**13. ANY PAY-FOR-PERFORMANCE PROGRAMS IMPLEMENTED?** Unclear from statutes and regulations.

**14. RELEVANT STATUTES AND REGULATIONS:** MASS. GEN. LAWS ch. 111, §§ 203-205 (West 2003 & Supp. 2008); MASS. GEN. LAWS ch. 112, § 5 (Supp. 2008); 243 MASS. CODE REGS. 3.07-3.08 (2008).

**15. OTHER RESOURCES:** COMMONWEALTH OF MASS., BD. OF REGISTRATION IN MED., PATIENT CARE ASSESSMENT DIVISION ANNUAL REPORT (2005), [http://www.massmedboard.org/pca/pdf/pca\\_annual\\_report\\_2005.pdf](http://www.massmedboard.org/pca/pdf/pca_annual_report_2005.pdf).

**16. DATE REPORTING STARTED:** 1987.<sup>282</sup>

### MICHIGAN

“Michigan does not require the mandatory reporting of medical errors, nor [is] information as to near misses or potential adverse events systematically gathered by [the] Department [of Community Health].”<sup>283</sup> Nevertheless, “the concerns of medical errors have and will continue to receive attention across Michigan’s

277. *Id.* 3.07(3)(d)(3).

278. *See, e.g.*, COMMONWEALTH OF MASS., BD. OF REGISTRATION IN MED., PATIENT CARE ASSESSMENT DIVISION ANNUAL REPORT (2005), [http://www.massmedboard.org/pca/pdf/pca\\_annual\\_report\\_2005.pdf](http://www.massmedboard.org/pca/pdf/pca_annual_report_2005.pdf).

279. Letter from Murphy, *supra* note 257.

280. MASS. GEN. LAWS ANN. ch. 111, § 204 (West 2003 & Supp. 2008); *id.* § 205 (West 2003).

281. *Id.* ch. 112, § 5 (Supp. 2008).

282. 243 MASS. CODE REGS. 3.07(3) (2008); *see also* COMMONWEALTH OF MASS., BD. OF REGISTRATION IN MED., *supra* note 278.

283. Letter from Janet Olszewski, Dir., Mich. Dep’t of Cmty. Health, to Jeffrey M. Tebbs, Executive Editor, Yale Journal of Health Policy, Law, & Ethics (Oct. 8, 2008) [hereinafter Letter from Olszewski] (on file with journal).

entire continuum of health care. In 2006, the Michigan State Commission on Patient Safety recommended to the Governor a statewide voluntary, confidential, non-punitive health care error and near-miss reporting system. In response to the federal Patient Safety and Quality Improvement Act of 2005, the Michigan Health & Hospital Association recently established a new Patient Safety Organization . . . that will collect and analyze data about medical errors and near misses in Michigan hospitals.<sup>284</sup> Finally, 108 hospitals have voluntarily committed to participating in a project organized by the Health & Hospital Association to reduce hospital-acquired infections that will entail the collection of data on hospital-acquired infections.<sup>285</sup>

**MINNESOTA**

- 1. GENERAL DESCRIPTION:** Minnesota has implemented a comprehensive reporting regime that requires all hospitals and outpatient surgical centers to report the occurrence of any of the twenty-eight “serious reportable events” designated by the NQF.
- 2. IS REPORTING MANDATORY?** Yes.<sup>286</sup>
- 3. REPORT RECIPIENT(S):** Commissioner of Health.
- 4. IS REPORTING CONDUCTED ELECTRONICALLY?** Electronic reporting is available but not required.<sup>287</sup>
- 5. WHAT FACILITIES MUST PROVIDE REPORTS?** Hospitals and outpatient surgical centers.<sup>288</sup>
- 6. WHAT INCIDENTS MUST BE REPORTED?** The Minnesota Adverse Health Care Events Reporting Act requires the reporting of all of the twenty-eight “serious reportable events” listed by the NQF.<sup>289</sup> The Commissioner of Health is directed to monitor implementation efforts in other states and offer recommendations to the legislature for the modification of this list in order to keep the reporting system “as . . . uniform as possible with similar systems in other states.”<sup>290</sup>
- 7. MUST HOSPITAL-ACQUIRED INFECTIONS BE REPORTED?** Hospital-acquired infections are not explicitly listed as a separate category, but could result from other “adverse events” (e.g., the use of contaminated drugs, devices, or biologics).

284. *Id.*

285. Mich. Health & Hosp. Ass’n, Keystone: HAI, [http://www.mhakeystonecenter.org/hai\\_overview.htm](http://www.mhakeystonecenter.org/hai_overview.htm) (last visited Nov. 15, 2008); *see also* Letter from Olszewski, *supra* note 283.

286. MINN. STAT. § 144.7065 (Supp. 2008) (detailing “facility requirements to report, analyze, and correct”).

287. *Id.* § 144.7065(9).

288. *Id.* § 144.7063(3) (defining “facility”).

289. *Id.* § 144.7065(2)-(7); *see also supra* Appendix.

290. MINN. STAT. § 144.7069 (Supp. 2008).

**8. DEADLINES:** Adverse health care events should be reported “as soon as is reasonably and practically possible, but no later than fifteen (15) working days after discovery of the event.”<sup>291</sup> A root cause analysis of the event and a plan of corrective action are due to the Commissioner of Health within sixty days of the event.<sup>292</sup>

**9. PENALTIES AND ENFORCEMENT MECHANISMS:** The reporting system includes “sanctions against facilities for failure to comply with [its] requirements.” Violations of reporting system requirements may entail “failure to file a timely adverse event report,” failure to conduct a root cause analysis,” and failure “to implement a corrective action plan . . . .”<sup>293</sup>

**(a) Revocation of license?** Yes. “If a facility fails to develop and implement a corrective action plan or report to the commissioner why corrective action is not needed, the commissioner may suspend, revoke, fail to renew, or place conditions on the license under which the facility operates.”<sup>294</sup>

**(b) Audits?** While the statute does not indicate whether the Commissioner of Health is authorized to conduct random audits of health care facility records, it does require the Commissioner to review the reports from various licensing boards (e.g., the Board of Medical Practice, the Board of Pharmacy) and determine whether the events listed therein have been previously reported under the Adverse Health Care Events Reporting Act. If an event has not been reported, the facility knew or reasonably should have known about the occurrence of that event, and the event was reportable under section 144.7065, then the facility will be considered out of compliance with the reporting act and will be subject to investigation by the Department of Health under the Vulnerable Adult Act or the Maltreatment of Minors Act.<sup>295</sup> In addition, the Department of Health website indicates that the Department reviews all death records to determine whether deaths were related to reportable adverse events.<sup>296</sup>

**10. ARE PUBLIC REPORTS ISSUED?** Yes. The Commissioner of Health is required to publish an annual report regarding the adverse event reporting system.<sup>297</sup> These annual reports release data at the level of individual facilities.<sup>298</sup>

**11. ARE ERROR REPORTS PROTECTED FROM LEGAL DISCOVERY?** Yes.<sup>299</sup>

291. *Id.* § 144.7065(1).

292. *Id.* § 144.7065(8).

293. *Id.* § 144.7067.

294. *Id.* § 144.7067(3)(b).

295. *Id.* § 144.7068.

296. Minn. Dep’t of Health, Frequently Asked Questions: Adverse Events, <http://www.health.state.mn.us/patientsafety/ae/faq.html> (last visited Nov. 15, 2008).

297. MINN. STAT. § 144.7067(2)(4) (Supp. 2008).

298. *See, e.g.,* MINN. DEP’T OF HEALTH, *supra* note 73.

**12. IMMUNITY FOR REPORTERS?** Unclear from statutes and regulations.

**13. ANY PAY-FOR-PERFORMANCE PROGRAMS IMPLEMENTED?** Unclear from statutes and regulations.

**14. RELEVANT STATUTES AND REGULATIONS:** Minnesota Adverse Health Care Events Reporting Act of 2003, MINN. STAT. §§ 144.7063-144.7069 (Supp. 2008); MINN. STAT. § 145.64 (Supp. 2008).

**15. OTHER RESOURCES:** MINN. DEP'T OF HEALTH, ADVERSE HEALTH EVENTS IN MINNESOTA (2008),

<http://www.health.state.mn.us/patientsafety/ae/aereport0108.pdf>.

**16. DATE REPORTING STARTED:** July 1, 2003.<sup>300</sup>

#### MISSISSIPPI

A medical error reporting regime does not appear to exist for this state.

#### MISSOURI

A medical error reporting regime does not appear to exist for this state.

#### MONTANA

A medical error reporting regime does not exist for this state.<sup>301</sup>

#### NEBRASKA

**1. GENERAL DESCRIPTION:** Nebraska's error reporting regime is set forth in the Patient Safety Improvement Act. The act allows certain nonprofit organizations ("patient safety organizations") to collect data on a host of specified types of medical errors from health care providers that agree to participate. Participating health care providers voluntarily agree to report medical errors, prepare root cause analyses, and implement action plans. The act is "not administered by . . . the Department of Health and Human Services, and such reporting is not required of licensed health professionals."<sup>302</sup>

**2. IS REPORTING MANDATORY?** No. Reporting is voluntary.

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299. MINN. STAT. § 145.64 (Supp. 2008).

300. MINN. DEP'T OF HEALTH, ADVERSE HEALTH EVENTS IN MINNESOTA: FIRST ANNUAL PUBLIC REPORT 3 (2005), <http://www.health.state.mn.us/patientsafety/ae/aereport0105.pdf>.

301. Facsimile from Roy Kemp, Deputy Adm'r (QAP), Mont. Dep't of Pub. Health & Human Servs., to Jeffrey M. Tebbs, Executive Editor, Yale Journal of Health Policy, Law, & Ethics (Oct. 27, 2008) (on file with journal).

302. Letter from Becky Wisell, Adm'r, Office of Med. & Specialized Health, Neb. Dep't of Health & Human Servs., to Jeffrey M. Tebbs, Executive Editor, Yale Journal of Health Policy, Law, & Ethics (Sept. 16, 2008) [hereinafter Letter from Wisell] (on file with journal).

**3. REPORT RECIPIENT(S):** “Patient safety organizations” that are nonprofit as defined by section 501(c)(3) of the Internal Revenue Code.<sup>303</sup> The Act specifies rules for the composition of the board of a patient safety organization.<sup>304</sup>

**4. IS REPORTING CONDUCTED ELECTRONICALLY?** Unclear from statutes and regulations.

**5. WHAT FACILITIES MUST PROVIDE REPORTS?** A provider under the Act is either: “(1) A facility licensed under the Health Care Facility Licensure Act; or (2) A health care professional licensed under the Uniform Credentialing Act.”<sup>305</sup> Providers elect whether to participate.<sup>306</sup>

**6. WHAT INCIDENTS MUST BE REPORTED?** Covered events include the following: “(a) Surgery or procedures performed on the wrong patient or the wrong body part of a patient; (b) Foreign object accidentally left in a patient during a procedure or surgery; (c) Hemolytic transfusion reaction in a patient resulting from the administration of blood or blood products with major blood group incompatibilities; (d) Sexual assault of a patient during treatment or while the patient was on the premises of a facility; (e) Abduction of a newborn infant patient from the hospital or the discharge of a newborn infant patient from the hospital into the custody of an individual in circumstances in which the hospital knew, or in the exercise of ordinary care should have known, that the individual did not have legal custody of the infant; (f) Suicide of a patient in a setting in which the patient received care twenty-four hours a day; (g) Medication error resulting in a patient’s unanticipated death or permanent or temporary loss of bodily function, including (i) [circumstances necessitating] treatment intervention, [resulting in] temporary harm, (ii) [circumstances necessitating] initial-prolonged hospitalization, [resulting in] temporary harm, (iii) permanent patient harm, and (iv) near death event in circumstances unrelated to the natural course of the illness or underlying condition of the patient, including, but not limited to, errors involving the wrong drug, the wrong dose, the wrong patient, the wrong time, the wrong rate, the wrong preparation, or the wrong route of administration, but excluding reasonable differences in clinical judgment on drug selection and dose; (h) Patient death or serious disability associated with the use of adulterated drugs, devices, or biologics provided by the provider; (i) Patient death or serious disability associated with the use or function of a device in patient care in which the device is used or functions other than as intended; and (j) Unanticipated death or major permanent loss of function associated with . . . nosocomial infection.”<sup>307</sup> Patient safety organizations, upon reviewing indicators recommended by the Joint Commission on Accreditation of Healthcare

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303. NEB. REV. STAT. § 71-8714 (Supp. 2007).

304. *Id.* § 71-8715.

305. *Id.* § 71-8709 (defining “provider”).

306. *Id.* § 71-8716(2).

307. *Id.* § 71-8717(1).

Organizations, can add or subtract from the list of reportable patient safety events, and those changes shall be binding on providers who elect to participate.<sup>308</sup> This list shares several elements with the list provided by the NQF, but the lists are not identical.

**7. MUST HOSPITAL-ACQUIRED INFECTIONS BE REPORTED?** Only to the extent that the infection results in death or major permanent loss of function.<sup>309</sup>

**8. DEADLINES:** Providers report aggregate totals of each type of event on an annual basis. For each reported event, a root cause analysis and action plan must be conducted within forty-five days. A copy of that action plan must be sent to the relevant patient safety organization within thirty days of its creation.<sup>310</sup>

**9. PENALTIES AND ENFORCEMENT MECHANISMS:** This voluntary program does not feature penalties or enforcement mechanisms.

(a) **Revocation of license?** N/A.

(b) **Audits?** N/A.

**10. ARE PUBLIC REPORTS ISSUED?** Yes. “A patient safety organization shall release to the public non-identifiable aggregate trend data identifying the number and types of patient safety events that occur. A patient safety organization shall publish educational and evidenced-based information from the summary reports, which shall be available to the public, that can be used by all providers to improve the care they provide.”<sup>311</sup>

**11. ARE ERROR REPORTS PROTECTED FROM LEGAL DISCOVERY?** Yes.<sup>312</sup>

**12. IMMUNITY FOR REPORTERS?** Yes, unless reporting was done “with actual malice, fraudulent intent, or bad faith.”<sup>313</sup>

**13. ANY PAY-FOR-PERFORMANCE PROGRAMS IMPLEMENTED?** No.

**14. RELEVANT STATUTES AND REGULATIONS:** Patient Safety Improvement Act of 2005, NEB. REV. STAT. §§ 71-8701 to -21 (Supp. 2007).

**15. OTHER RESOURCES:** N/A.

**16. DATE REPORTING STARTED:** Unknown.

## NEVADA

**1. GENERAL DESCRIPTION:** Medical facilities, through their “patient safety officers,” report all sentinel events to the State Health Division of the Department of Health and Human Services.<sup>314</sup>

**2. IS REPORTING MANDATORY?** Yes.<sup>315</sup>

308. *Id.* § 71-8717(2).

309. *Id.* § 71-8717(1)(j) (requiring reporting of “[u]nanticipated death or major permanent loss of function associated with health care associated nosocomial infection”).

310. *Id.* § 71-8718.

311. *Id.* § 71-8720.

312. *Id.* §§ 71-8710 to -13.

313. *Id.* § 71-8721.

314. NEV. ADMIN. CODE § 439.902 (2008) (defining “division”).

**3. REPORT RECIPIENT(S):** Medical facility employees report sentinel events to the “patient safety officer” designated by the facility. The patient safety officer then reports the sentinel events to the State Health Division of the Department of Health and Human Services.<sup>316</sup>

**4. IS REPORTING CONDUCTED ELECTRONICALLY?** No. “Reports are submitted via fax and/or [United States Postal Service] Certified Mail. As funds become available, future plans include implementing a web-based system.”<sup>317</sup>

**5. WHAT FACILITIES MUST PROVIDE REPORTS?** Hospitals, obstetric centers, surgical centers for ambulatory patients, and independent centers for emergency medical care.<sup>318</sup>

**6. WHAT INCIDENTS MUST BE REPORTED?** Medical facilities are responsible for reporting the occurrence of all “sentinel events.”<sup>319</sup> A sentinel event is defined as “an unexpected occurrence involving facility-acquired infection, death or serious physical or psychological injury or the risk thereof, including, without limitation, any process variation for which a recurrence would carry a significant chance of a serious adverse outcome. The term includes loss of limb or function.”<sup>320</sup> The reporting form used by medical facilities contains a list of reportable events. “The list is based on the NQF Never Events, Joint Commission [on Accreditation of Healthcare Organizations] reportable sentinel events and statutory requirements.”<sup>321</sup>

**7. MUST HOSPITAL-ACQUIRED INFECTIONS BE REPORTED?** Yes.<sup>322</sup>

**8. DEADLINES:** Any person employed by a medical facility must report sentinel events to the facility’s patient safety officer within twenty-four hours of becoming aware of the event. The patient safety officer then has thirteen days to report the sentinel event to the health division.<sup>323</sup> If the patient safety officer is the individual to discover the sentinel event, that officer has fourteen days to

315. NEV. REV. STAT. § 439.835 (2005 & Supp. 2008).

316. *Id.*

317. E-mail from Lynn O’Mara, Health Planning Program Manager, Bureau of Health Statistics, Planning & Emergency Response, Nev. State Health Div., to Jeffrey M. Tebbs, Executive Editor, Yale Journal of Health Policy, Law, & Ethics (Nov. 7, 2008, 14:56 EST) [hereinafter E-mail from O’Mara] (on file with journal).

318. NEV. REV. STAT. § 439.805 (2005 & Supp. 2008) (defining “medical facility”).

319. *Id.* § 439.835.

320. *Id.* § 439.830 (defining “sentinel event”).

321. E-mail from O’Mara, *supra* note 317.

322. NEV. REV. STAT. § 439.802 (2005 & Supp. 2008) (defining “facility acquired infection”). “Only ‘unexpected occurrences’ of facility acquired events are required to be reported as sentinel events.” Unexpected occurrences are defined as occurrences that are unrelated “to the patients underlying condition or the natural course of the patient’s illness.” E-mail from O’Mara, *supra* note 317.

323. NEV. REV. STAT. § 439.835 (2005 & Supp. 2008).

report its occurrence to the State Health Division.<sup>324</sup> Within forty-five days of becoming aware of a sentinel event, the patient safety officer must submit a second, more detailed report to the division, including an analysis of factors contributing to the event and a description of any corrective actions undertaken by the medical facility.<sup>325</sup> A representative from the medical facility must provide notice to any patient involved in a sentinel event within seven days of “discovering or becoming aware of a sentinel event . . . .”<sup>326</sup>

**9. PENALTIES AND ENFORCEMENT MECHANISMS:** “Currently, there are no penalties for non-reporting . . . .”<sup>327</sup>

**(a) Revocation of license?** No.

**(b) Audits?** No. The Health Division does not currently have the authority to conduct audits.<sup>328</sup>

**10. ARE PUBLIC REPORTS ISSUED?** In the future, public reports will be issued. “[T]o the extent of legislative appropriation and authorization,” the health division is obligated to contract with a “quality improvement organization, as defined in 42 C.F.R. § 400.200,” to produce a quarterly report regarding the “analysis of aggregated trends of sentinel events . . . .”<sup>329</sup> However, “No appropriations have been authorized due to fiscal constraints.”<sup>330</sup> “[T]he Health Division expects to publish a public report that covers Jan. 1, 2005 – Dec. 31, 2007, for the 2009 Legislative Session.”<sup>331</sup>

**11. ARE ERROR REPORTS PROTECTED FROM LEGAL DISCOVERY?** Yes.<sup>332</sup>

**12. IMMUNITY FOR REPORTERS?** Yes.<sup>333</sup> Nevada also provides legal protection against retaliation for reporters of sentinel events.<sup>334</sup>

**13. ANY PAY-FOR-PERFORMANCE PROGRAMS IMPLEMENTED?** “There are no related pay-for-performance programs currently” nor are any such programs under consideration.<sup>335</sup>

**14. RELEVANT STATUTES AND REGULATIONS:** NEV. REV. STAT. §§ 439.800-890 (2005 & Supp. 2008); NEV. REV. STAT. §§ 630.293-96, 630.505-07 (LEXIS 2008); NEV. ADMIN. CODE §§ 439.900-915 (2008).

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324. *Id.*

325. NEV. ADMIN. CODE § 439.915(2) (2008).

326. NEV. REV. STAT. § 439.855 (2005 & Supp. 2008).

327. E-mail from O’Mara, *supra* note 317.

328. *Id.*

329. NEV. REV. STAT. § 439.845 (2005 & Supp. 2008).

330. E-mail from O’Mara, *supra* note 317.

331. *Id.*

332. NEV. REV. STAT. § 439.840(2) (2005 & Supp. 2008); *id.* § 439.860.

333. *Id.* § 439.880.

334. NEV. REV. STAT. ANN. §§ 630.293, 630.296, 630.505, 630.507 (LEXIS 2008).

335. E-mail from O’Mara, *supra* note 317.

**15. OTHER RESOURCES:** Nev. State Health Div., Sentinel Event Report, [http://health.nv.gov/sentinel/Forms/UpdatedForms105/SER\\_Section\\_One\\_Man\\_Oct05.pdf](http://health.nv.gov/sentinel/Forms/UpdatedForms105/SER_Section_One_Man_Oct05.pdf) (last visited Nov. 15, 2008).

**16. DATE REPORTING STARTED:** January 1, 2005.<sup>336</sup>

#### NEW HAMPSHIRE

New Hampshire has “established a commission to review and analyze quality of care issues including, but not limited to, medical errors, unexpected adverse outcomes, and near misses, and to propose changes to improve health care.”<sup>337</sup> New Hampshire regulations also provide for physician practices to develop and implement “quality assurance program[s] to monitor, evaluate and improve the quality and appropriateness of the care provided to patients, so that important problems and trends in the delivery of care are identified and steps are taken to correct problems and to take advantage of opportunities to improve care.”<sup>338</sup>

#### NEW JERSEY

**1. GENERAL DESCRIPTION:** Health care facilities must report “serious preventable adverse events” to the Department of Health and Senior Services.<sup>339</sup>

**2. IS REPORTING MANDATORY?** Yes.<sup>340</sup>

**3. REPORT RECIPIENT(S):** The Department of Health and Senior Services (or the Department of Human Services in the case of a state psychiatric hospital).<sup>341</sup>

The health care facility is also obligated to inform a patient or resident (or the patient/resident’s guardian or representative) of any “serious preventable adverse event.”<sup>342</sup>

**4. IS REPORTING CONDUCTED ELECTRONICALLY?** No. Facilities are currently expected to submit event reports via fax.<sup>343</sup> However, “[t]he Department [of Health and Senior Services] anticipates the development of an Internet web-based electronic reporting system.”<sup>344</sup>

**5. WHAT FACILITIES MUST PROVIDE REPORTS?** Licensed health care facilities and state psychiatric hospitals.<sup>345</sup>

**6. WHAT INCIDENTS MUST BE REPORTED?** All “serious preventable adverse event[s]” must be reported to the Department of Health and Senior Services.<sup>346</sup> A

336. *Id.*

337. N.H. REV. STAT. ANN. § 151-G:1 (2008).

338. N.H. CODE ADMIN. R. ANN. HE-P 401.03 (2008).

339. N.J. STAT. ANN. § 26:2H-12.25(c) (West 2007).

340. *Id.*

341. *Id.*; N.J. ADMIN. CODE § 8:43E-10.6(a) (2008).

342. N.J. ADMIN. CODE § 8:43E-10.7 (2008).

343. *Id.* § 8:43E-10.6(d).

344. *Id.* § 8:43E-10.6(n).

345. N.J. STAT. ANN. § 26:2H-12.25(a) (West 2007) (defining “health care facility”).

serious preventable adverse event is defined as “an adverse event that is a preventable event and results in death or loss of a body part, or disability or loss of bodily function lasting more than seven days or still present at the time of discharge from a health care facility.”<sup>347</sup> An “[a]dverse event” is defined as “an event that is a negative consequence of care that results in unintended injury or illness, which may or may not have been preventable.”<sup>348</sup> A “[p]reventable event” is “an event that could have been anticipated and prepared against, but occurs because of an error or other system failure.”<sup>349</sup> Health care professionals are also encouraged, but not required, to report near-misses, preventable events, and adverse events.<sup>350</sup> Regulations specifically enumerate events that qualify as “serious preventable adverse events.” This list generally matches the twenty-eight “serious reportable events” listed by the NQF.<sup>351</sup>

**7. MUST HOSPITAL-ACQUIRED INFECTIONS BE REPORTED?** Yes. The Health Care Facility-Associated Infection Reporting and Prevention Act requires general hospitals to report information related to health care-associated infections to the Department of Health and Senior Services.<sup>352</sup> In April 2008, the Department of Health and Senior Services proposed new rules to implement this authority.<sup>353</sup>

**8. DEADLINES:** Health care facilities must notify the Department of Health and Senior Services (or the Department of Human Services, if applicable) of any event subject to mandatory reporting within five business days of discovering the event.<sup>354</sup> If inadequate information exists for a complete report by the deadline, facilities may submit an initial partial report.<sup>355</sup>

**9. PENALTIES AND ENFORCEMENT MECHANISMS:** The Commissioner of Health and Senior Services may impose the following enforcement remedies against a health care facility for violations of licensure regulations or other statutory requirement: “[c]ivil monetary penalty”; “[c]urtailment of admissions”; “[a]ppointment of a receiver or temporary manager”; “[p]rovisional license”; “[s]uspension of a license”; “[r]evocation of a license”; and an “[o]rder to Cease

346. *Id.* § 26:2H-12.25(4)(c).

347. *Id.* § 26:2H-12.25(a).

348. *Id.*

349. *Id.*

350. *Id.* § 26:2H-12.25(e)(1).

351. *See* N.J. ADMIN. CODE §§ 8:43E-10.6(f)-(j) (2008); *supra* Appendix. The National Quality Forum and New Jersey lists are nearly identical, with the exception that the New Jersey regulations do not specifically include the event of artificial insemination with the wrong donor sperm or wrong egg as a reportable event and the New Jersey regulations do not cover criminal events.

352. N.J. STAT. ANN. § 26:2H-12.41 (West 2007). *See generally* Health Care Facility-Associated Infection Reporting and Prevention Act, *id.* §§ 26:2H-12.39 to .45.

353. 40 N.J. Reg. 1958(a) (Apr. 21, 2008).

354. N.J. ADMIN. CODE § 8:43E-10.6(b) (2008)

355. *Id.*

and Desist operation of an unlicensed health care facility.”<sup>356</sup> Regulations require the assessment of civil monetary penalties for failure to report serious preventable adverse events.<sup>357</sup> The Department of Health and Senior Services shall assess penalties of \$1000 per day for general hospitals for each day following the date the report was due, with a maximum penalty of \$100,000 per event.<sup>358</sup> The penalty falls to \$250 per day for all other facilities, with a maximum penalty of \$25,000 per event.<sup>359</sup> The Department must also assess penalties against facilities that fail to disclose serious preventable adverse events to patients or residents. If a facility fails to report an event to a patient or resident, and the facility also has not reported that event to the Department, the facility can be fined \$1000. If the facility fails to report an event to a patient or resident, but did report that event to the Department in a timely manner, the facility can be fined \$5000.<sup>360</sup> The Department has discretion to decrease these penalties based on the compliance history of the facility and measures taken by the facility to mitigate the effect of the violation.<sup>361</sup>

**(a) Revocation of license?** Yes.<sup>362</sup>

**(b) Audits?** The Department of Health and Senior Services has authority to “conduct periodic or special inspections of licensed health care facilities” to “ascertain whether the facility complies with all applicable State and Federal licensure regulations and statutes.”<sup>363</sup> “The Department may evaluate all aspects of patient care, and operations of a health care facility, including the inspection of medical records; observation of patient care where consented to by the patient; inspection of all areas of the physical plant under the control or ownership of the licensee; and interview of the patient or resident, his or her family or other individuals with knowledge of the patient or care rendered to him or her.”<sup>364</sup>

Moreover, employees and health care professionals may submit anonymous reports to the Department of Health and Senior Services (or the Department of Human Services) “regarding preventable adverse events that are otherwise not subject to mandatory reporting.”<sup>365</sup>

**10. ARE PUBLIC REPORTS ISSUED?** Yes. “The Commissioner of Health and Senior Services and the Commissioner of Human Services shall compile their findings and recommendations for operational changes related to patient safety in

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356. *Id.* § 8:43E-3.1.

357. *Id.* § 8:43E-3.4(a)(14).

358. *Id.* § 8:43E-3.4(a)(14)(i).

359. *Id.* § 8:43E-3.4(a)(14)(ii).

360. *Id.* § 8:43E-3.4(a)(15).

361. *Id.* § 8:43E-3.4(b).

362. *Id.* § 8:43E-3.1.

363. *Id.* § 8:43E-2.1.

364. *Id.*

365. *Id.* § 8:43E-10.8.

health care facilities, based on information reported to the commissioners pursuant to the ‘Patient Safety Act.’<sup>366</sup> The commissioners issue an annual report to the Governor and the Legislature, available to the public via the Internet.<sup>367</sup> Information regarding hospital-acquired infections is available to the public via an annual Hospital Performance Report.<sup>368</sup>

**11. ARE ERROR REPORTS PROTECTED FROM LEGAL DISCOVERY?** Yes.<sup>369</sup>

However, information related to the reporting of “serious preventable adverse events” shall be shared with the Attorney General. The Department of Human Services and the Attorney General shall use this information to “exercise oversight” with a “primary emphasis on assuring effective corrective action by the facility or health care professional, reserving punitive enforcement or disciplinary action for those cases in which the facility or the professional has displayed recklessness, gross negligence or willful misconduct . . . .”<sup>370</sup>

**12. IMMUNITY FOR REPORTERS?** Reports may be filed anonymously,<sup>371</sup> but immunity is not explicitly provided by statute or regulation.

**13. ANY PAY-FOR-PERFORMANCE PROGRAMS IMPLEMENTED?** Not yet. The Commissioner’s office within the Department of Health and Senior Services reports that pay-for-performance programs are currently under discussion.<sup>372</sup>

**14. RELEVANT STATUTES AND REGULATIONS:** Patient Safety Act, N.J. STAT. ANN. §§ 26:2H-12.23 to -12.25a (West 2007); N.J. ADMIN. CODE §§ 8:43E-10.1 to -10.11 (2008).

**15. OTHER RESOURCES:** N.J. DEP’T OF HEALTH & SENIOR SERVS., PATIENT SAFETY INITIATIVE: 2006 SUMMARY REPORT (2007), [http://www.state.nj.us/health/ps/documents/ps\\_report\\_2006.pdf](http://www.state.nj.us/health/ps/documents/ps_report_2006.pdf).

**16. DATE REPORTING STARTED:** 2004.<sup>373</sup>

**NEW MEXICO**

A medical error reporting regime does not exist for this state.<sup>374</sup>

366. N.J. STAT. ANN. § 26:2H-12.25a (West 2007).

367. *Id.*

368. *Id.* §§ 26:2H-12.41, 12.43.

369. *Id.* § 26:2H-12.25(f)-(g); N.J. ADMIN. CODE § 8:43E-10.9 (2008).

370. N.J. STAT. ANN. § 26:2H-12.25(f) (West 2007).

371. Facsimile from Ruth Charbonneau, Dir. of the Office of Legal & Regulatory Affairs, Office of the Comm’r, N.J. Dep’t of Health & Senior Servs., to Jeffrey M. Tebbs, Executive Editor, Yale Journal of Health Policy, Law, & Ethics (Sept. 24, 2008) (on file with journal).

372. *Id.*

373. N.J. STAT. ANN. § 26:2H-12.23 (West 2007).

374. Facsimile from Alfredo Vigil, Cabinet Sec’y, N.M. Dep’t of Health, to Jeffrey M. Tebbs, Executive Editor, Yale Journal of Health Policy, Law, & Ethics (Sept. 18, 2008) (on file with journal).

<b>NEW YORK</b>
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**1. GENERAL DESCRIPTION:** New York has established three separate programs related to medical error reporting: 1) a long-standing hospital-based program, 2) a more recent office-based reporting program, and 3) a hospital-acquired infection reporting program that completed its pilot year on December 31, 2007.

**2. IS REPORTING MANDATORY?** 1) Yes,<sup>375</sup> 2) Unclear from statutes and regulations; 3) Yes.<sup>376</sup>

**3. REPORT RECIPIENT(S):**

- 1) Hospital-based incidents should be reported to the Department of Health's Office of Health Systems Management.<sup>377</sup>
- 2) Department of Health.<sup>378</sup>
- 3) Department of Health.<sup>379</sup>

**4. IS REPORTING CONDUCTED ELECTRONICALLY?**

- 1) Unclear from statutes and regulations.
- 2) Unclear from statutes and regulations.
- 3) Yes.<sup>380</sup>

**5. WHAT FACILITIES MUST PROVIDE REPORTS?**

- 1) All hospitals.<sup>381</sup>
- 2) Accrediting agencies for office-based surgical practices.<sup>382</sup>
- 3) General hospitals.<sup>383</sup>

**6. WHAT INCIDENTS MUST BE REPORTED?**

- 1) Within the hospital setting, the following incidents must be reported: "patients' deaths in circumstances other than those related to the natural course of illness, disease or proper treatment in accordance with generally accepted medical standards. Injuries and impairments of bodily functions, in circumstances other than those related to the natural course of illness, disease or proper treatment in accordance with generally accepted medical standards and that necessitate additional or more complicated treatment regimens or that result in a significant change in patient status, shall also be considered reportable under this subdivision . . . ."<sup>384</sup>

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375. N.Y. PUB. HEALTH LAW § 2805-*l*(1) (McKinney 2007).

376. *Id.* § 2819(2)(a).

377. N.Y. COMP. CODES R. & REGS. tit. 10, § 405.8(a) (2008).

378. N.Y. PUB. HEALTH LAW § 2998e(1) (McKinney Supp. 2008).

379. N.Y. COMP. CODES R. & REGS. tit. 10, § 405.11(c) (2008).

380. N.Y. PUB. HEALTH LAW § 2819(5)(c) (McKinney 2007).

381. *Id.* § 2805-*l*(1).

382. *Id.* § 2998-e(1) (McKinney Supp. 2008).

383. *Id.* § 2819(2)(a) (McKinney 2007).

384. N.Y. COMP. CODES R. & REGS. tit. 10, § 405.8(b)(1) (2008); N.Y. PUB. HEALTH LAW §

2) “Adverse events for all office-based surgical practices accredited by the accrediting agencies.”<sup>385</sup>

3) Hospital-acquired infections. A “hospital acquired infection” is defined as “any localized or systemic patient condition that: (a) resulted from the presence of an infectious agent . . . and (b) was not found to be present or incubating at the time of admission unless the infection was related to a previous admission.”<sup>386</sup>

**7. MUST HOSPITAL-ACQUIRED INFECTIONS BE REPORTED? Yes.**<sup>387</sup>

**8. DEADLINES:**

1) “Hospitals shall report such incidents within 24 hours of when the incident occurred or when the hospital has reasonable cause to believe that such an incident has occurred and shall take no more than seven calendar days to determine whether an incident . . . is reportable.”<sup>388</sup>

“The hospital shall give written notification within seven calendar days of the initial notification.”<sup>389</sup> The reporting hospital shall then conduct an investigation within thirty days and “provide a copy of its investigative report to the area administrator within 24 hours of its completion”<sup>390</sup>

2) Unclear from statutes and regulations.

3) “Each hospital shall regularly report to the department the hospital infection data it has collected. The department shall establish data collection and analytical methodologies that meet accepted standards for validity and reliability. In no case shall the frequency of reporting be required to be more frequently than once every six months, and reports shall be submitted not more than sixty days after the close of the reporting period.”<sup>391</sup>

**9. PENALTIES AND ENFORCEMENT MECHANISMS:** Unclear from statutes and regulations.

**(a) Revocation of license?** Unclear from statutes and regulations.

**(b) Audits?**

1) Unclear from statutes and regulations.

2) Unclear from statutes and regulations.

3) Yes. “To assure the accuracy of the self-reported hospital-acquired infection data and to assure that public reporting fairly reflects what

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2805-l(2) (McKinney Supp. 2008).

385. N.Y. PUB. HEALTH LAW § 2998-e(1) (McKinney Supp. 2008).

386. *Id.* § 2819(1) (McKinney 2007).

387. *See generally id.* § 2819; N.Y. COMP. CODES R. & REGS. tit. 10, § 405.11 (2008).

388. N.Y. COMP. CODES R. & REGS. tit. 10, § 405.8(a) (2008).

389. *Id.*

390. N.Y. PUB. HEALTH LAW § 2805-l(3) (McKinney Supp. 2008); N.Y. COMP. CODES R. & REGS. tit. 10, § 405.8(d) (2008).

391. N.Y. PUB. HEALTH LAW § 2819(3) (McKinney 2007).

actually is occurring in each hospital, the department shall develop and implement an audit process.”<sup>392</sup>

**10. ARE PUBLIC REPORTS ISSUED?**

- 1) Unclear from statutes and regulations.
- 2) Unclear from statutes and regulations.
- 3) “The commissioner shall establish a state-wide database of all reported hospital-acquired infection information for the purpose of supporting quality improvement and infection control activities in hospitals. The database shall be organized so that consumers, hospitals, healthcare professionals, purchasers and payers may compare individual hospital experience with that of other individual hospitals as well as regional and state-wide averages and, where available, national data.”<sup>393</sup>  
On or before May 1 of each year, the Commissioner of Health shall submit a report to the governor and the legislature with infection rates for each hospital, analysis of trends, and recommendations for safety and quality improvement.<sup>394</sup> This report is available to the public.<sup>395</sup>

**11. ARE ERROR REPORTS PROTECTED FROM LEGAL DISCOVERY?**

- 1) Unclear from statutes and regulations.
- 2) Unclear from statutes and regulations.
- 3) Yes.<sup>396</sup>

**12. IMMUNITY FOR REPORTERS?** Unclear from statutes and regulations.

**13. ANY PAY-FOR-PERFORMANCE PROGRAMS IMPLEMENTED?** Recent legislation authorized the Commissioner of Health to select up to five demonstration projects pertaining to one of six categories, including the “use of . . . metrics to measure and reward physician, clinic and hospital performance . . . .”<sup>397</sup>

**14. RELEVANT STATUTES AND REGULATIONS:** N.Y. PUB. HEALTH LAW § 2819 (McKinney 2007) (hospital-acquired infection reporting); N.Y. COMP. CODES R. & REGS. tit. 10, § 405.11 (2008) (hospital-acquired infection reporting); N.Y. PUB. HEALTH LAW § 2805-l (McKinney Supp. 2008) (hospital incident reporting); N.Y. COMP. CODES R. & REGS. tit. 10, § 405.8 (2008) (hospital incident reporting); N.Y. PUB. HEALTH LAW §§ 2995-2998 (McKinney 2007) (initiative to create a statewide health information system).

**15. OTHER RESOURCES:** N/A.

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392. *Id.* § 2819(7).

393. *Id.* § 2819(4).

394. *Id.* § 2819(5).

395. *Id.*

396. *Id.* § 2998-e(2) (McKinney Supp. 2008).

397. *Id.* § 2999-e(1) (McKinney 2007).

**16. DATE REPORTING STARTED:** Hospitals have been required to report medical errors to the Department of Health since 1985.<sup>398</sup> Unknown for hospital-acquired infections.

**NORTH CAROLINA**

A medical error reporting regime does not appear to exist for this state, with the exception of a statute governing the reporting of medication-related errors in the nursing home setting.<sup>399</sup>

**NORTH DAKOTA**

A medical error reporting regime does not exist for this state.<sup>400</sup>

**OHIO**

- 1. GENERAL DESCRIPTION:** The Director of Health has authority to require health care providers to submit reports regarding quality of care and safety information. Reporting is required for a discrete list of health safety events.
- 2. IS REPORTING MANDATORY?** Yes.<sup>401</sup>
- 3. REPORT RECIPIENT(S):** Director of Health.
- 4. IS REPORTING CONDUCTED ELECTRONICALLY?** Reports may be conducted electronically.<sup>402</sup>
- 5. WHAT FACILITIES MUST PROVIDE REPORTS?** All health care facilities, including hospitals.<sup>403</sup>
- 6. WHAT INCIDENTS MUST BE REPORTED?** Any unexpected complications or adverse events, including death or serious injury, that result from an operation or procedure must be reported. In addition, eleven specific quality measures must be reported, and providers must report any incidents that might have influenced the facility's overall data.<sup>404</sup> Although eleven quality measures are reported by hospitals, "only two of them apply to medical error: Iatrogenic Pneumothorax and Postoperative Respiratory Failure."<sup>405</sup>

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398. ROSENTHAL, BOOTH & BARRY, *supra* note 46, at Appendix A.

399. N.C. GEN. STAT. § 131E-128.5 (2007).

400. Facsimile from Terry L. Dwelle, Health Officer, N.D. Dep't of Health, to Jeffrey M. Tebbs, Executive Editor, *Yale Journal of Health Policy, Law, & Ethics* (Sept. 18, 2008) (on file with journal).

401. OHIO ADMIN. CODE 3701:14-02(A) (2008).

402. *Id.* 3701:14-02(E).

403. *Id.* 3701:14-02(A) (hospitals).

404. See Ohio Dep't of Health, Appendix: Annual Hospital Disclosure Quality Measures Reporting Form, [http://www.odh.ohio.gov/ASSETS/6F3AAB79274E41998783040C96103A3F/FR14\\_02app.pdf](http://www.odh.ohio.gov/ASSETS/6F3AAB79274E41998783040C96103A3F/FR14_02app.pdf) (last visited Nov. 15, 2008).

405. E-mail from Kaliyah Shaheen, Div. of Quality Assurance, Ohio Dep't of Health, to Jeffrey M. Tebbs, Executive Editor, *Yale Journal of Health Policy, Law, & Ethics* (Oct. 10, 2008, 12:37

**7. MUST HOSPITAL-ACQUIRED INFECTIONS BE REPORTED?** The Director of Health has authority to require that this data be reported, but it is unclear from statutes and regulations whether this is required.

**8. DEADLINES:** April 1 and October 1 of each year.<sup>406</sup>

**9. PENALTIES AND ENFORCEMENT MECHANISMS:** If the patient does not suffer any harm, the Director of Health may assess a \$50,000 penalty. If more than one patient is harmed, the Director of Health may impose a penalty of \$50,000 to \$100,000. If a patient suffers permanent injury, the Director of Health may impose a penalty of \$100,000 to \$150,000. If a patient dies as a result of unexpected complications or an adverse event, the Director of Health may impose a \$150,000 to \$250,000 penalty. If a health care facility does not correct any regulatory violations, the Director of Health may fine the facility an additional \$250,000.<sup>407</sup>

(a) **Revocation of license?** The Director may revoke a license if he or she deems it necessary.

(b) **Audits?** The Director of Health may audit any information submitted regarding unexpected complications and adverse events.<sup>408</sup>

**10. ARE PUBLIC REPORTS ISSUED?** No. However, within ninety days of submission, the Director of Health must make the submitted information available for sale “to any interested person or governmental entity.”<sup>409</sup>

**11. ARE ERROR REPORTS PROTECTED FROM LEGAL DISCOVERY?** Yes.<sup>410</sup>

**12. IMMUNITY FOR REPORTERS?** Unclear from statutes and regulations.

**13. ANY PAY-FOR-PERFORMANCE PROGRAMS IMPLEMENTED?** No.

**14. RELEVANT STATUTES AND REGULATIONS:** OHIO REV. CODE ANN. § 3727.33 (LexisNexis 2008); OHIO ADMIN. CODE 3701:14-02 (2008); OHIO ADMIN. CODE 3701:83-05 (2008); OHIO ADMIN. CODE 3701:83-12 (2008).

**15. OTHER RESOURCES:** N/A.

**16. DATE REPORTING STARTED:** April 1, 2007.<sup>411</sup>

#### OKLAHOMA

A medical error reporting regime does not appear to exist for this state.

#### OREGON

**1. GENERAL DESCRIPTION:** Two programs exist. The first is operated through the Oregon Patient Safety Commission and includes serious adverse events. The

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EST) (on file with journal).

406. OHIO ADMIN. CODE 3701:14-02(A) (2008).

407. *Id.* 3701:83-05.2.

408. OHIO REV. CODE ANN. § 3727.331 (LexisNexis 2008).

409. OHIO ADMIN. CODE 3701:14-02(G) (2008).

410. OHIO REV. CODE ANN. § 2305.24 (LexisNexis 2008).

411. OHIO ADMIN. CODE 3701:14-02(A) (2008).

second is operated through the Health Care Acquired Infection Advisory Committee and includes health care-acquired infections.

**2. IS REPORTING MANDATORY?** Reporting to the Patient Safety Commission is voluntary. Reporting to the Health Care Acquired Infection Advisory Committee is mandatory.

**3. REPORT RECIPIENT(S):** Patient Safety Commission; Health Care Acquired Infection Advisory Committee.

**4. IS REPORTING CONDUCTED ELECTRONICALLY?** Unclear from statutes and regulations.

**5. WHAT FACILITIES MUST PROVIDE REPORTS?** Hospitals voluntarily report to the Patient Safety Commission.<sup>412</sup>

**6. WHAT INCIDENTS MUST BE REPORTED?** “Serious [a]dverse [e]vent[s]” must be reported to the Patient Safety Commission.<sup>413</sup> A “[r]eportable [s]erious [a]dverse [e]vent . . . means any unanticipated, usually preventable consequence of patient care that results in patient death or serious physical injury.”<sup>414</sup> An appendix to the applicable regulations, available from the Patient Safety Commission, specifies twenty-three events as “serious adverse events” that are also listed by the NQF.<sup>415</sup> Hospitals are also encouraged to report less serious adverse events to the Commission.<sup>416</sup>

**7. MUST HOSPITAL-ACQUIRED INFECTIONS BE REPORTED?** Yes. Health care-acquired infections must be reported to the Health Care Acquired Infection Advisory Committee beginning in 2009. The specific types of infections that must be reported are set forth in the main authorizing rule.<sup>417</sup>

**8. DEADLINES:** Voluntary reports made to the Patient Safety Commission must be made within forty-five days of the event. Mandatory reports of health care acquired infections must be made to the Health Care Acquired Infection Advisory Committee on a quarterly basis.<sup>418</sup>

**9. PENALTIES AND ENFORCEMENT MECHANISMS:** Reporting to the Patient Safety Commission is voluntary and not subject to penalty. Civil penalties of \$500 a day shall be levied against any health care facility that is found to be in

412. OR. ADMIN. R. 325-010-0000 to -0045 (2008).

413. *Id.* 325-010-0005(4).

414. *Id.* 325-010-0001(8).

415. *See* Or. Patient Safety Comm’n, Appendix A: Reportable Hospital Serious Adverse Events, <http://www.oregon.gov/OPSC/docs/Division10Rules-final-2-1-06.pdf> (last visited Nov. 15, 2008); *supra* Appendix. Oregon’s appendix does not include the criminal events listed by the National Quality Forum, nor does it include artificial insemination with the wrong donor sperm or wrong egg. The Oregon list also includes “[a]ny perinatal death or serious physical injury unrelated to a congenital condition in an infant having a birth weight greater than 2500 grams” as a reportable event. Or. Patient Safety Comm’n, *supra*.

416. OR. ADMIN. R. 325-010-0030 (2008).

417. *Id.* 409-023-0010.

418. *Id.* 409-023-0020.

violation of the reporting requirements imposed by the Health Care Acquired Infection Advisory Committee.<sup>419</sup>

(a) **Revocation of license?** Unclear from statutes and regulations.

(b) **Audits?** Unclear from statutes and regulations.

**10. ARE PUBLIC REPORTS ISSUED?** Public reports are issued listing all hospitals that voluntarily report information to the Patient Safety Commission. The Health Care Acquired Infection Advisory Committee will begin releasing public reports of summarized data in 2010.

**11. ARE ERROR REPORTS PROTECTED FROM LEGAL DISCOVERY?** Unclear from statutes and regulations.

**12. IMMUNITY FOR REPORTERS?** Unclear from statutes and regulations.

**13. ANY PAY-FOR-PERFORMANCE PROGRAMS IMPLEMENTED?** No.

**14. RELEVANT STATUTES AND REGULATIONS:** OR. ADMIN. R. 325-010-0000 to -0045 (2008) (setting forth the Oregon Patient Safety Commission); OR. ADMIN. RULES 409-023-0000 *et seq.* (2008) (setting forth the Health Care Acquired Infection Reporting and Public Disclosure Committee).

**15. OTHER RESOURCES:** N/A.

**16. DATE REPORTING STARTED:** Unknown for the reporting of serious adverse events to the Oregon Patient Safety Commission. Mandatory reporting of health care-acquired infections to the Health Care Acquired Infection Advisory Committee starts on January 1, 2009.

#### PENNSYLVANIA

**1. GENERAL DESCRIPTION:** Hospitals, ambulatory surgical facilities, birthing centers, and abortion centers of a certain size must report medical errors (both “serious events” and “near misses”) to the Patient Safety Authority.<sup>420</sup> Serious events and infrastructure failures must also be reported to the Department of Health. Hospitals must report hospital-acquired infections to the National Health Safety Network.

**2. IS REPORTING MANDATORY?** Yes.<sup>421</sup>

**3. REPORT RECIPIENT(S):** Health care providers must provide data to nonprofit organizations designated by the Patient Safety Authority. These organizations, which are under contract with the Patient Safety Authority, must file annual reports with the legislature summarizing this information.<sup>422</sup> Currently, the Patient Safety Authority has contracts with ECRI Institute – a Pennsylvania-based non-profit health services research agency [–] and the Institute for Safe

419. *Id.* 409-023-0035.

420. E-mail from Laurene M. Baker, Dir. of Comm’n, Pa. Patient Safety Auth., to Jeffrey M. Tebbs, Executive Editor, Yale Journal of Health Policy, Law, & Ethics (Oct. 9, 2008, 13:29 EST) [hereinafter E-mail from Baker] (on file with journal).

421. 40 PA. CONS. STAT. § 1303.308 (Supp. 2008).

422. *Id.* § 1303.304.

Medication Practices [ISMP], a Pennsylvania-based non-profit medication error research organization. Analysts from ECRI Institute and ISMP . . . analyze the data and provide guidance to the Pennsylvania healthcare facilities through the Pennsylvania Patient Safety Advisory.”<sup>423</sup>

**4. IS REPORTING CONDUCTED ELECTRONICALLY?** Yes, reports are filed electronically through a secure web-based system known as the Pennsylvania Patient Safety Reporting System.<sup>424</sup>

**5. WHAT FACILITIES MUST PROVIDE REPORTS?** All licensed hospitals, ambulatory surgical facilities, birthing centers, and abortion centers that perform one hundred or more procedures per year must report “[s]erious [e]vents” and “near misses” to the Patient Safety Authority. These facilities must also report “[s]erious [e]vents” and “[i]nfrastructure failures” to the Department of Health.<sup>425</sup>

**6. WHAT INCIDENTS MUST BE REPORTED?** As noted above, serious events and incidents must be reported to the Patient Safety Authority, and serious events and infrastructure failures must be reported to the Department of Health. A serious event is defined as “an event, occurrence or situation involving the clinical care of a patient in a medical facility that results in death or compromises patient safety and results in an unanticipated injury requiring the delivery of additional health care services to the patient.”<sup>426</sup> An incident is defined as “[a]n event, occurrence or situation involving the clinical care of a patient in a medical facility which could have injured the patient but did not either cause an unanticipated injury or require the delivery of additional health care services to the patient.”<sup>427</sup> Finally, an infrastructure failure is defined as “[a]n undesirable or unintended event, occurrence or situation involving the infrastructure of a medical facility or the discontinuation of significant disruption of a service which could seriously compromise patient safety.”<sup>428</sup>

**7. MUST HOSPITAL-ACQUIRED INFECTIONS BE REPORTED?** Yes. “[A]ll hospitals must report healthcare acquired infections as Serious Events through the National Health Safety Network (NHSN) operated by the Centers for Disease Control and Prevention (CDC) reporting system . . . . [T]he Patient Safety Authority, the . . . Department of Health . . . and the Pennsylvania Healthcare Cost Containment Council . . . have access to the data reported through NHSN.”<sup>429</sup> In April 2009, nursing homes will start to report infections.<sup>430</sup>

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423. E-mail from Baker, *supra* note 420.

424. *Id.*

425. 40 PA. CONS. STAT. § 1303.404 (Supp. 2008); E-mail from Baker, *supra* note 420.

426. 40 PA. CONS. STAT. § 1303.302 (Supp. 2008).

427. E-mail from Baker, *supra* note 420.

428. *Id.*

429. *Id.*

430. *Id.*

**8. DEADLINES:** Medical facilities must report the occurrence of a serious event to the Department and the Authority within twenty-four hours of the medical facility's confirmation of the occurrence of the serious event.<sup>431</sup>

**9. PENALTIES AND ENFORCEMENT MECHANISMS:** Failure to report a serious event or infrastructure failure, "or to develop and comply with the patient safety plan or to notify the patient . . . shall be a violation of the Health Care Facilities Act," which can result in an audit or even revocation of license.<sup>432</sup> Facilities that fail to report a serious event may also be subject to a \$1000 per day administrative penalty at the discretion of the Department.<sup>433</sup>

(a) **Revocation of license?** Yes.<sup>434</sup>

(b) **Audits?** Audits appear to occur in response to a known failure to report a serious event or infrastructure failure.<sup>435</sup>

**10. ARE PUBLIC REPORTS ISSUED?** Yes. The "Pennsylvania Patient Safety Authority must file an Annual Report to the General Assembly that includes: a schedule of the year's meetings; a list of contracts entered into pursuant to Section 303 of Act 13, including the amounts awarded to each contractor; a summary of the fund receipts and expenditures, including a financial statement and balance sheet; the number of Serious Events and Incidents reported by medical facilities on a geographical basis; the information derived from the data collected, including any recognized trends concerning patient safety; the number of anonymous reports filed and reviews conducted by the Authority; the number of referrals to licensure boards for failure to report under this chapter; recommendations for statutory or regulatory changes which may help improve patient safety in the Commonwealth."<sup>436</sup> This report is public and posted on the Patient Safety Authority's website.<sup>437</sup>

**11. ARE ERROR REPORTS PROTECTED FROM LEGAL DISCOVERY?** Yes.<sup>438</sup>

**12. IMMUNITY FOR REPORTERS?** Yes.<sup>439</sup>

**13. ANY PAY-FOR-PERFORMANCE PROGRAMS IMPLEMENTED?** Yes. Starting January 1, 2009, the Department of Public Welfare will make a quality improvement payment to health care facilities that achieve at least a ten percent reduction in health care-acquired infection.<sup>440</sup>

431. 40 PA. CONS. STAT. § 1303.313 (Supp. 2008).

432. E-mail from Baker, *supra* note 420.

433. 40 PA. CONS. STAT. § 1303.313 (Supp. 2008).

434. E-mail from Baker, *supra* note 420.

435. *See id.*

436. *Id.*

437. Commonwealth of Pennsylvania Patient Safety Authority, <http://www.psa.state.pa.us> (last visited Nov. 15, 2008).

438. 40 PA. CONS. STAT. § 1303.407 (2008); *Id.* § 1303.311 (Supp. 2008).

439. *Id.* § 1303.308(c) (Supp. 2008).

440. *Id.* § 1303.407 (2008).

**14. RELEVANT STATUTES AND REGULATIONS:** 40 PA. CONS. STAT. §§ 1303.103 to .407 (2008 & Supp. 2008).

**15. OTHER RESOURCES:** N/A.

**16. DATE REPORTING STARTED:** June 2004.<sup>441</sup>

**RHODE ISLAND**

**1. GENERAL DESCRIPTION:** All health care providers are required to inform the Department of Health of injuries to patients and certain specified events.<sup>442</sup>

**2. IS REPORTING MANDATORY?** Yes.

**3. REPORT RECIPIENT(S):** The Division of Facilities within the Department of Health.

**4. IS REPORTING CONDUCTED ELECTRONICALLY?** No. Reports are made telephonically.<sup>443</sup>

**5. WHAT FACILITIES MUST PROVIDE REPORTS?** Hospitals.<sup>444</sup>

**6. WHAT INCIDENTS MUST BE REPORTED?** Injury to patients constitutes any of the following: “(1) Brain injury; (2) Mental impairment; (3) Paraplegia; (4) Quadriplegia; (5) Any type of paralysis; (6) Loss of use of limb or organ; (7) Hospital stay extended due to serious or unforeseen complications; (8) Birth injury; (9) Impairment of sight or hearing; (10) Surgery on the wrong patient; (11) Subjecting a patient to a procedure other than that ordered or intended by the patient’s attending physician; (12) Any other incident that is reported to their malpractice insurance carrier or self-insurance program; (13) Suicide of a patient during treatment or within five (5) days of discharge from an inpatient or outpatient unit (if known); (14) Blood transfusion error; and (15) Any serious or unforeseen complication, that is not expected or probable, resulting in an extended hospital stay or death of the patient.”<sup>445</sup> The following incidents must also be reported: “(i) Fires or internal disasters in the facility which disrupt the provisions of patient care services or cause harm to patients or personnel; (ii) Poisoning involving patients of the facility; (iii) Infection outbreaks as defined by the department in regulation; (iv) Kidnapping and inpatient psychiatric elopements and elopements by minors; (v) Strikes by personnel; (vi) Disasters or other emergency situations external to the hospital environment which adversely affect facility operations; [or] (vii) Unscheduled termination of any services vital to the continued safe operation of the facility or to the health and safety of its patients and personnel.” “[A]buse, neglect and mistreatment of patients”<sup>446</sup> must also be reported.

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441. E-mail from Baker, *supra* note 420.

442. R.I. GEN. LAWS § 23-17-40 (2001).

443. *Id.* § 23-17-40(a).

444. *Id.* § 23-17-40.

445. *Id.* § 23-17-40(d).

446. *Id.* § 23-17-40(2).

**7. MUST HOSPITAL-ACQUIRED INFECTIONS BE REPORTED?** Only to the extent they are covered by one of the injury categories listed above.

**8. DEADLINES:** Injuries in the first list must be reported within twenty-four hours.<sup>447</sup> Incidents in the second list must be reported within seventy-two hours of their occurrence or as soon as the hospital has reasonable cause to believe that an incident has occurred.<sup>448</sup>

**9. PENALTIES AND ENFORCEMENT MECHANISMS:** Unclear from statutes and regulations.

(a) **Revocation of license?** Unclear from statutes and regulations.

(b) **Audits?** Unclear from statutes and regulations.

**10. ARE PUBLIC REPORTS ISSUED?** The Department of Health “shall issue an annual report by March 31 each year providing aggregate summary information on the events and incidents reported by hospitals.”<sup>449</sup>

**11. ARE ERROR REPORTS PROTECTED FROM LEGAL DISCOVERY?** Unclear from statutes and regulations.

**12. IMMUNITY FOR REPORTERS?** Unclear from statutes and regulations.

**13. ANY PAY-FOR-PERFORMANCE PROGRAMS IMPLEMENTED?** No.

**14. RELEVANT STATUTES AND REGULATIONS:** R.I. GEN. LAWS § 23-17-40 (2001).

**15. OTHER RESOURCES:** N/A.

**16. DATE REPORTING STARTED:** Unknown.

#### SOUTH CAROLINA

**1. GENERAL DESCRIPTION:** All licensing hospitals and institutional general infirmaries must report accidents or incidents that result in death or serious injury to the Division of Health Licensing within the Department of Health and Environmental Control.<sup>450</sup>

**2. IS REPORTING MANDATORY?** Yes.<sup>451</sup>

**3. REPORT RECIPIENT(S):** The Division of Health Licensing in the Department of Health and Environmental Control.<sup>452</sup>

**4. IS REPORTING CONDUCTED ELECTRONICALLY?** No. Facilities must issue reports “in writing.”<sup>453</sup>

447. *Id.* § 23-17-40.

448. *Id.* § 23-17-40(c).

449. *Id.* § 23-17-40(h).

450. S.C. CODE ANN. REGS. 61-16 § 206.2 (2008).

451. *Id.*

452. *Id.*; see also *id.* § 101(A) (defining “[t]he [d]epartment”).

453. *Id.* § 206.2.

**5. WHAT FACILITIES MUST PROVIDE REPORTS?** Licensed hospitals, general hospitals, institutional general infirmaries, chronic hospitals, publicly owned health centers, diagnostic and treatment centers, and rehabilitation facilities.<sup>454</sup>

**6. WHAT INCIDENTS MUST BE REPORTED?** A record of “each accident and/or incident occurring in the facility, including medication errors and adverse drug reactions” must be retained by the facility.<sup>455</sup> Only those incidents that result “in death or serious injury, e.g., broken limb, shall be reported, in writing, to the Division of Health Licensing . . . .”<sup>456</sup> The Department of Health and Environmental Control also requires licensed hospitals and institutional general infirmaries “to annually complete a questionnaire named ‘Joint Annual Report.’”<sup>457</sup>

**7. MUST HOSPITAL-ACQUIRED INFECTIONS BE REPORTED?** Hospital-acquired infections must only be reported to the extent that they qualify as an accident or incident resulting in death or serious injury.<sup>458</sup>

**8. DEADLINES:** Reports must be made within ten days of the occurrence of the accident or incident.<sup>459</sup>

**9. PENALTIES AND ENFORCEMENT MECHANISMS:** The Department of Health and Environmental Control has the authority to “deny, suspend, or revoke licenses or assess a monetary penalty for violations” of the incident report provisions.<sup>460</sup> In determining whether to penalize a facility, the Department “will consider the following factors: specific conditions and their impact or potential impact on health, safety or welfare; efforts by the facility to correct; overall conditions; history of compliance; [and] any other pertinent conditions.”<sup>461</sup> The size of a monetary penalty may range from \$200 to \$5000, depending on the frequency of violations by a facility within a two-year period and classification of the violation (i.e., Class I, II, or III).<sup>462</sup>

(a) **Revocation of license?** Yes.<sup>463</sup>

(b) **Audits?** Unclear from statutes and regulations.

**10. ARE PUBLIC REPORTS ISSUED?** Unclear from statutes and regulations.

**11. ARE ERROR REPORTS PROTECTED FROM LEGAL DISCOVERY?** Unclear from statutes and regulations.

**12. IMMUNITY FOR REPORTERS?** Unclear from statutes and regulations.

**13. ANY PAY-FOR-PERFORMANCE PROGRAMS IMPLEMENTED?** No.

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454. *Id.* § 101(D) (defining “[f]acilities”); *id.* § 206.2.

455. *Id.* § 206.2.

456. *Id.* § 206.2.

457. *Id.* § 206.3; S.C. CODE ANN. § 61-16-101(D) (2008) (defining “[f]acilities”).

458. *See* S.C. CODE ANN. REGS. 61-16, § 206.2 (2008).

459. *Id.*

460. *Id.* 61-16, § 105.

461. *Id.*

462. *Id.*

463. *Id.*

**14. RELEVANT STATUTES AND REGULATIONS:** S.C. CODE ANN. REGS. 61-16 (2008).

**15. OTHER RESOURCES:** N/A.

**16. DATE REPORTING STARTED:** Unknown.

#### SOUTH DAKOTA

A medical error reporting regime does not appear to exist for this state.

#### TENNESSEE

**1. GENERAL DESCRIPTION:** All licensed health care facilities must report “unusual events” to the Department of Health.

**2. IS REPORTING MANDATORY?** Yes.<sup>464</sup>

**3. REPORT RECIPIENT(S):** Department of Health.<sup>465</sup> “The affected patient and/or the patient’s family, as may be appropriate, shall also be notified of the event or incident by the facility.”<sup>466</sup>

**4. IS REPORTING CONDUCTED ELECTRONICALLY?** Yes. “Tennessee receives reports via fax, mail, and electronic means.”<sup>467</sup>

**5. WHAT FACILITIES MUST PROVIDE REPORTS?** All licensed health care facilities, including hospitals<sup>468</sup> and nursing homes.<sup>469</sup>

**6. WHAT INCIDENTS MUST BE REPORTED?** “Unusual events” must be reported to the Department of Health. Unusual events are “unexpected occurrence[s] or accident[s] resulting in death, life threatening or serious injury to a patient, not related to a natural course of the patient’s illness or underlying condition.”<sup>470</sup>

“[C]ircumstances that could result in an unusual event include, but are not limited to: 1. medication errors; 2. aspiration in a non-intubated patient related to conscious/moderate sedation; 3. intravascular catheter related events including necrosis or infection requiring repair or intravascular catheter related pneumothorax; 4. volume overload leading to pulmonary edema; 5. blood transfusion reactions, use of wrong type of blood and/or delivery of blood to the wrong patient; 6. perioperative/periprocedural related complication(s) that occur within 48 hours of the operation or the procedure, including a procedure which results in any new central neurological deficit or any new peripheral neurological

464. TENN. COMP. R. & REGS. 1200-8-1.11(8) (2007).

465. *Id.*

466. *Id.* 1200-8-1.11(8)(j).

467. E-mail from Ann Thompson, Dir. of Licensure, Bureau of Health Licensure & Regulation, Div. of Health Care Facilities, to Jeffrey M. Tebbs, Executive Editor, Yale Journal of Health Policy, Law, & Ethics (Oct. 6, 2008, 18:05 EST) [hereinafter E-mail from Thompson] (on file with journal).

468. TENN. COMP. R. & REGS. 1200-8-1.11 (2007).

469. *Id.* 1200-8-6.11.

470. *Id.* 1200-8-1.11(8)(a).

deficit with motor weakness; 7. burns of a second or third degree; 8. falls resulting in radiologically proven fractures, subdural or epidural hematoma, cerebral contusion, traumatic subarachnoid hemorrhage, and/or internal trauma, but does not include fractures resulting from pathological conditions; 9. procedure related incidents, regardless of setting and within thirty (30) days of the procedure and includes readmissions, which include: (i) procedure related injury requiring repair or removal of an organ; (ii) hemorrhage; (iii) displacement, migration or breakage of an implant, device, graft or drain; (iv) post operative wound infection following clean or clean/contaminated case; (v) any unexpected operation or reoperation related to the primary procedure; (vi) hysterectomy in a pregnant woman; (vii) ruptured uterus; (viii) circumcision; (ix) incorrect procedure or incorrect treatment that is invasive; (x) wrong patient/wrong site surgical procedure; (xi) unintentionally retained foreign body; (xii) loss of limb or organ, or impairment of limb if the impairment is present at discharge or for at least two (2) weeks after occurrence; (xiii) criminal acts; (xiv) suicide or attempted suicide; (xv) elopement from the facility; (xvi) infant abduction, or infant discharged to the wrong family; (xvii) adult abduction; (xviii) rape; (xix) patient altercation; (xx) patient abuse, patient neglect, or misappropriation of resident/patient funds; (xxi) restraint related incidents; or (xxii) poisoning occurring within the facility.”<sup>471</sup>

**7. MUST HOSPITAL-ACQUIRED INFECTIONS BE REPORTED?** Not as a separate category, but a “post operative wound infection following clean or clean/contaminated implant, device, graft or drain” is considered a “procedure related incident” that may result in an “unusual event.”<sup>472</sup>

**8. DEADLINES:** After a facility learns of an unusual event, it has seven days to report the incident to the Department of Health.<sup>473</sup> The facility must also file a corrective action report with the Department of Health within forty days of identifying an unusual event.<sup>474</sup>

**9. PENALTIES AND ENFORCEMENT MECHANISMS:** “Failure to report an unusual event, submit a corrective action report, or comply with a plan of correction . . . may be grounds for disciplinary action,”<sup>475</sup> including suspension or revocation of a facility’s license.<sup>476</sup>

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471. *Id.* Additional incidents that must be reported, but do not qualify as medical errors, include “strike by staff at the facility; external disaster impacting the facility; disruption of any service vital to the continued safe operation of the facility or to the health and safety of its patients and personnel; and fires at the facility which disrupt the provision of patient care services or cause harm to patients or staff, or which are reported by the facility to any entity, including but not limited to a fire department, charged with preventing fires.” E-mail from Thompson, *supra* note 467.

472. TENN. COMP. R. & REGS. 1200-8-1.11(8)(a)(9)(iv) (2007).

473. *Id.* 1200-8-1.11(8).

474. *Id.* 1200-8-1.11(8)(d).

475. *Id.* 1200-8-1.11(8)(i); *see also* TENN. CODE ANN. § 68-11-207 (2007).

476. TENN. CODE ANN. § 68-11-207 (2007).

**(a) Revocation of license?** Yes, “the board may suspend or revoke the license” of the facility.<sup>477</sup>

**(b) Audits?** Audits are not addressed in the applicable statutes or regulations.<sup>478</sup>

**10. ARE PUBLIC REPORTS ISSUED?** Yes. “During the second quarter of each year, the Department [of Health] shall provide the Board [for Licensing Health Care Facilities] an aggregate report summarizing by type the number of unusual events and incidents reported by facilities to the Department for the preceding calendar year.”<sup>479</sup>

**11. ARE ERROR REPORTS PROTECTED FROM LEGAL DISCOVERY?** Yes.<sup>480</sup>

**12. IMMUNITY FOR REPORTERS?** Immunity for reporters is not addressed in the applicable statutes or regulations.<sup>481</sup>

**13. ANY PAY-FOR-PERFORMANCE PROGRAMS IMPLEMENTED?** No.

**14. RELEVANT STATUTES AND REGULATIONS:** TENN. COMP. R. & REGS. 1200-8-1.11 (2007); TENN. COMP. R. & REGS. 1200-8-6.11 (2007).

**15. OTHER RESOURCES:** N/A.

**16. DATE REPORTING STARTED:** Tennessee personnel are “uncertain of the reporting start date.”<sup>482</sup>

## TEXAS

**1. GENERAL DESCRIPTION:** Each hospital must develop a “Patient Safety Program” that entails an annual report to the Department of Health regarding the aggregate number of certain specified types of medical errors.

**2. IS REPORTING MANDATORY?** Yes.

**3. REPORT RECIPIENT(S):** Department of Health.

**4. IS REPORTING CONDUCTED ELECTRONICALLY?** Unclear from statutes and regulations.

**5. WHAT FACILITIES MUST PROVIDE REPORTS?** Hospitals.<sup>483</sup>

**6. WHAT INCIDENTS MUST BE REPORTED?** Medical errors must be reported. A medical error is defined as “[t]he failure of a planned action to be completed as intended, the use of a wrong plan to achieve an aim, or the failure of an unplanned action that should have been completed, that results in an adverse event.”<sup>484</sup> In their annual reports to the Department of Health, hospitals are only

477. *Id.*; E-mail from Thompson, *supra* note 467.

478. E-mail from Thompson, *supra* note 467.

479. TENN. COMP. R. & REGS. 1200-8-1.11(8)(k) (2007).

480. *Id.* 1200-8-1.11(8)(f).

481. E-mail from Thompson, *supra* note 467.

482. *Id.*

483. *See generally* 25 TEX. ADMIN. CODE § 133.48(a) (2008). Similar regulations govern other types of health care facilities in Texas.

484. *Id.* § 133.48(a)(1)(A).

required to report the aggregate numbers of the following events: “(i) a medication error resulting in a patient’s unanticipated death or major permanent loss of bodily function in circumstances unrelated to the natural course of the illness or underlying condition of the patient; (ii) a perinatal death unrelated to a congenital condition in an infant with a birth weight greater than 2,500 grams; (iii) the suicide of a patient in a setting in which the patient received care 24 hours a day; (iv) the abduction of a newborn infant patient from the hospital or the discharge of a newborn infant patient from the hospital into the custody of an individual in circumstances in which the hospital knew, or in the exercise of ordinary care should have known, that the individual did not have legal custody of the infant; (v) the sexual assault of a patient during treatment or while the patient was on the premises of the hospital or facility; (vi) a hemolytic transfusion reaction in a patient resulting from the administration of blood or blood products with major blood group incompatibilities; (vii) a surgical procedure on the wrong patient or on the wrong body part of a patient; (viii) a foreign object accidentally left in a patient during a procedure; and (ix) a patient death or serious disability associated with the use or function of a device designed for patient care that is used or functions other than as intended.”<sup>485</sup> “The hospital is not required to include any information other than the total number of occurrences of each of [these] events.”<sup>486</sup>

**7. MUST HOSPITAL-ACQUIRED INFECTIONS BE REPORTED?** No.

**8. DEADLINES:** Within forty-five days of discovering a reportable event, hospitals must complete a root cause analysis and develop an action plan to reduce the risk of similar events in the future.<sup>487</sup> On an annual basis, each hospital must provide the Department of Health with a report detailing the number of occurrences of each of the events listed above.<sup>488</sup>

**9. PENALTIES AND ENFORCEMENT MECHANISMS:** Unclear from statutes and regulations.

(a) **Revocation of license?** Unclear from statutes and regulations.

(b) **Audits?** Unclear from statutes and regulations.

**10. ARE PUBLIC REPORTS ISSUED?** Unclear from statutes and regulations.

**11. ARE ERROR REPORTS PROTECTED FROM LEGAL DISCOVERY?** Unclear from statutes and regulations.

**12. IMMUNITY FOR REPORTERS?** Unclear from statutes and regulations.

**13. ANY PAY-FOR-PERFORMANCE PROGRAMS IMPLEMENTED?** No.

**14. RELEVANT STATUTES AND REGULATIONS:** 25 TEX. ADMIN. CODE §133.48 (2008).

**15. OTHER RESOURCES:** N/A.

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485. *Id.* § 133.48(b)(1)(A).

486. *Id.* § 133.48(6).

487. *Id.* § 133.48(5).

488. *Id.* § 133.48(6).

**16. DATE REPORTING STARTED:** Unknown.**UTAH**

**1. GENERAL DESCRIPTION:** All hospitals must file reports of any “patient safety sentinel event” within seventy-two hours to the Department of Health and must file an action plan within sixty calendar days of a determination that a patient safety sentinel error occurred.

**2. IS REPORTING MANDATORY?** Yes.<sup>489</sup>

**3. REPORT RECIPIENT(S):** Department of Health.

**4. IS REPORTING CONDUCTED ELECTRONICALLY?** Action plans may be submitted in paper or electronic format.<sup>490</sup>

**5. WHAT FACILITIES MUST PROVIDE REPORTS?** General acute hospitals, critical access hospitals, ambulatory surgical centers, psychiatric hospitals, orthopedic hospitals, rehabilitation hospitals, chemical dependency/substance abuse hospitals and long-term acute care hospitals.<sup>491</sup>

**6. WHAT INCIDENTS MUST BE REPORTED?** “Patient safety sentinel events” must be reported. This term is defined as “an event which has resulted in an unanticipated death or major permanent loss of function, not related to the natural course of the patient’s illness or underlying condition or is an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof.”<sup>492</sup> The Utah Administrative Code defines patient safety sentinel events to include twenty-seven of the twenty-eight “serious reportable events” listed by the NQF.<sup>493</sup> In addition, Utah regulations include five additional events not found in the NQF list: “(iv) “unanticipated death of a full-term newborn; . . . (ix) Prolonged fluoroscopy with cumulative dose greater than 1500 rads to a single field; (x) Radiotherapy to the wrong body region; (xi) Radiotherapy greater than 25% above the prescribed radiotherapy dose; and (xii) Death or major permanent loss of function related to a health care acquired infection.”<sup>494</sup>

**7. MUST HOSPITAL-ACQUIRED INFECTIONS BE REPORTED?** Yes, facilities must report hospital-acquired infections resulting in death or major permanent loss of function.<sup>495</sup> Hospitals must also report each case of “[c]entral line associated blood stream infection.”<sup>496</sup>

489. UTAH ADMIN. CODE. r. 380-200-1 (2008).

490. *Id.* 380-200-5(2).

491. *Id.* 380-200-2 (defining “facility”).

492. *Id.*

493. *See id.* 380-200-3(2)(a)-(f); *supra* Appendix. The National Quality Forum list includes artificial insemination with the wrong donor sperm or wrong egg as a reportable event, whereas the Utah regulations do not.

494. UTAH ADMIN. CODE. r. 380-200-3(2)(d) (2008).

495. *Id.* 380-200-3(2)(d)(xii).

496. *Id.* 386-705-2 (2008); *id.* 386-705-3.

**8. DEADLINES:** Hospitals must file a report of any patient safety sentinel event within seventy-two hours to the Department of Health<sup>497</sup> and must file an action plan within sixty calendar days of a determination that a patient safety sentinel event occurred.<sup>498</sup> The Department has discretion to grant extensions.<sup>499</sup>

**9. PENALTIES AND ENFORCEMENT MECHANISMS:** Any facility that violates the sentinel event reporting requirements may be assessed “a civil money penalty not to exceed the sum of \$5,000 or be punished for violation of a class B misdemeanor for the first violation and for any subsequent similar violation within two years for violation of a class A misdemeanor . . . .”<sup>500</sup>

(a) **Revocation of license?** Unclear from statutes and regulations.

(b) **Audits?** Unclear from statutes and regulations.

**10. ARE PUBLIC REPORTS ISSUED?** Unclear from statutes and regulations.

**11. ARE ERROR REPORTS PROTECTED FROM LEGAL DISCOVERY?** Yes.<sup>501</sup>

**12. IMMUNITY FOR REPORTERS?** Unclear from statutes and regulations.

**13. ANY PAY-FOR-PERFORMANCE PROGRAMS IMPLEMENTED?** No.

**14. RELEVANT STATUTES AND REGULATIONS:** UTAH CODE ANN. § 26-33-103 (2007); UTAH CODE ANN. § 26-33A-104 (2007); UTAH CODE ANN. § 26-33A-111 (2007); Patient Safety Sentinel Event Reporting, UTAH ADMIN. CODE. r. 380-200-1 to -7 (2008); UTAH ADMIN. CODE. r. 386-705-2 to -3. (2008).

**15. OTHER RESOURCES:** N/A.

**16. DATE REPORTING STARTED:** Unknown.

#### VERMONT

**1. GENERAL DESCRIPTION:** Hospitals must report all of the “serious reportable events” specified by the NQF to the Department of Health within seven calendar days.

**2. IS REPORTING MANDATORY?** Yes.<sup>502</sup>

**3. REPORT RECIPIENT(S):** Department of Health.<sup>503</sup> In addition, hospitals are required to “disclose to patients, or, in the case of a patient death, an adult member of the immediate family, at a minimum, adverse events that cause death or serious bodily injury.”<sup>504</sup>

**4. IS REPORTING CONDUCTED ELECTRONICALLY?** No.<sup>505</sup>

497. *Id.* 380-200-3(1).

498. *Id.* 380-200-5(1).

499. *Id.* 380-200-7(1).

500. *Id.* 380-200-9.

501. *Id.* 380-200-6(1).

502. VT. STAT. ANN. tit. 18, § 1915(2) (Supp. 2007).

503. *Id.*; 13-140-068 VT. CODE R. § 1.5(5) (LEXIS 2008) (defining “[d]epartment”).

504. VT. STAT. ANN. tit. 18, § 1915(1)(D) (Supp. 2007); *see also* 13-140-068 VT. CODE R. § 2.4 (LEXIS 2008).

505. 13-140-068 VT. CODE R. § 1.7(2) (LEXIS 2008) (“Each hospital shall submit reports

**5. WHAT FACILITIES MUST PROVIDE REPORTS?** Hospitals licensed by the Board of Health.<sup>506</sup>

**6. WHAT INCIDENTS MUST BE REPORTED?** The statute specifies that administrative rules “shall list reportable adverse events, which shall include the ‘serious reportable events’ published by the National Quality Forum.”<sup>507</sup>

Adverse events are defined broadly as “any untoward incident, therapeutic misadventure, iatrogenic injury, or other undesirable occurrence directly associated with care or services provided by a health care provider or health care facility.”<sup>508</sup> Hospitals are also required to report the occurrence of any “intentional unsafe act.”<sup>509</sup>

**7. MUST HOSPITAL-ACQUIRED INFECTIONS BE REPORTED?** Hospital-acquired infections are not explicitly listed as a separate category, but could result from other reportable adverse events (e.g., the use of contaminated drugs, devices, or biologics).

**8. DEADLINES:** “Each hospital shall submit an initial report as soon as reasonably possible and no later than seven (7) calendar days after discovery or recognition of the reportable adverse event.”<sup>510</sup> A causal analysis and corrective action plan are due “no later than sixty (60) calendar days from the submission of the initial report.”<sup>511</sup>

**9. PENALTIES AND ENFORCEMENT MECHANISMS:** “[T]he commissioner [of the Department of Health] may impose on a hospital that knowingly violates [the reporting requirements] . . . a civil administrative penalty of no more than \$10,000.00 or, in the case of a continuing violation, a civil administrative penalty of no more than \$100,000.00 or one-tenth of one percent of the gross annual revenues of the health care facility, whichever is greater.”<sup>512</sup> “The Department may use all enforcement powers granted to it . . . to ensure compliance with the requirements . . . .”<sup>513</sup>

**(a) Revocation of license?** Unclear from statutes and regulations.

**(b) Audits?** Yes. “The Patient Safety Surveillance and Improvement System will conduct routine periodic reviews to evaluate a hospital’s

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required by this rule to the Patient Safety Surveillance and Improvement System using a secure transmission method, such as to and from a secure fax number, certified mail or other documented delivery system or, if established by the Department, through the secure reporting system.”)

506. *See id.* § 1.3 (LEXIS 2008).

507. VT. STAT. ANN. tit. 18, § 1914(b) (Supp. 2007); *see also* 13-140-068 VT. CODE R. § 2.5 (LEXIS 2008).

508. VT. STAT. ANN. tit. 18, § 1912(1) (Supp. 2007).

509. *Id.* § 1916; 13-140-068 VT. CODE R. § 3.1 (LEXIS 2008).

510. 13-140-068 VT. CODE R. § 2.6(1)(A) (LEXIS 2008).

511. *Id.* § 2.6(1)(B).

512. VT. STAT. ANN. tit. 18, § 1918(b) (Supp. 2007).

513. 13-140-068 VT. CODE R. § 1.10 (LEXIS 2008).

compliance . . . .”<sup>514</sup> The system will specifically review “the implementation of hospital policies and procedures.”<sup>515</sup> Hospitals are required to “provide the Patient Safety Surveillance and Improvement System with access to all information requested relating to and for the purpose of evaluating compliance . . . including . . . [a]ll original medical records, documents and databases in any format; . . . [i]nterviews with hospital staff; . . . [o]bservation of any area of the facility.”<sup>516</sup>

- 10. ARE PUBLIC REPORTS ISSUED?** Unclear from statutes and regulations.
- 11. ARE ERROR REPORTS PROTECTED FROM LEGAL DISCOVERY?** Yes.<sup>517</sup>
- 12. IMMUNITY FOR REPORTERS?** Unclear from statutes and regulations.
- 13. ANY PAY-FOR-PERFORMANCE PROGRAMS IMPLEMENTED?** No.
- 14. RELEVANT STATUTES AND REGULATIONS:** VT. STAT. ANN. tit. 18, §§ 1912–1919 (Supp. 2007); 13-140-068 VT. CODE R. §§ 1.1–4.2 (LEXIS 2008).
- 15. OTHER RESOURCES:** N/A.
- 16. DATE REPORTING STARTED:** Unknown.

**VIRGINIA**

A medical error reporting regime does not appear to exist for this state.

**WASHINGTON**

- 1. GENERAL DESCRIPTION:** Medical facilities must report adverse events to the Department of Health. Adverse events are defined in accordance with the NQF’s 2002 guidelines.
- 2. IS REPORTING MANDATORY?** Yes.<sup>518</sup>
- 3. REPORT RECIPIENT(S):** The Department of Health.<sup>519</sup>
- 4. IS REPORTING CONDUCTED ELECTRONICALLY?** A qualified, independent entity is directed to “establish an internet-based system for medical facilities and the health care workers of a medical facility to submit notifications and reports of adverse events and incidents, which shall be accessible twenty-four hours a day, seven days a week.”<sup>520</sup> At the present time, medical facilities report NQF adverse event confirmations within forty-eight hours via fax or a toll free hotline. Hospitals participating in the Healthcare Associated Infections program report through a different system.<sup>521</sup>

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514. *Id.* § 4.1(1).

515. *Id.*

516. *Id.* § 4.1(3).

517. VT. STAT. ANN. tit. 18, § 1917(a) (Supp. 2007); 13-140-068 VT. CODE R. § 1.6(1) (LEXIS 2008).

518. WASH. REV. CODE § 70.56.020(2) (Supp. 2008).

519. *Id.* § 70.56.020(2); *id.* § 70.56.010(5) (defining “department”).

520. *Id.* § 70.56.040(2).

521. E-mail from Linda Furkay, Patient Safety-Adverse Event Officer, Cmty. Health Sys.

**5. WHAT FACILITIES MUST PROVIDE REPORTS?** All medical facilities must report adverse event notifications.<sup>522</sup> A medical facility is defined as “a childbirth center, hospital, psychiatric hospital, or correctional medical facility.” Beginning in 2009, an ambulatory surgical facility shall be considered a medical facility for purposes of this reporting program.<sup>523</sup> At this time, only hospitals are included in the Healthcare Associated Infections Reporting.<sup>524</sup>

**6. WHAT INCIDENTS MUST BE REPORTED?** Medical facilities must notify the Department of Health regarding the confirmation of any “adverse event.”<sup>525</sup> Adverse events are defined to include “the list of serious reportable events adopted by the [N]ational [Q]uality [F]orum in 2002, in its consensus report on serious reportable events in health care. The [D]epartment [of Health] shall update the list, through adoption of rules, as subsequent changes are made by the [N]ational [Q]uality [F]orum.”<sup>526</sup>

**7. MUST HOSPITAL-ACQUIRED INFECTIONS BE REPORTED?** Yes. Starting July 1, 2008, hospitals were required to collect data related to health care-associated infections for central-line associated bloodstream infections acquired in the intensive care unit. Beginning January 1, 2009, hospitals shall collect data on ventilator-associated pneumonia, and beginning January 1, 2010, hospitals shall collect data on surgical site infections, deep sternal wound infection in cardiac surgeries (including coronary artery bypass graft), total hip and knee replacement surgeries, and abdominal or vaginal hysterectomies.<sup>527</sup> Hospitals must submit these data to the Department of Health via the National Healthcare Safety Network at the Centers for Disease Control and Prevention.<sup>528</sup> Outbreaks or suspected outbreaks of disease that occur or are treated in a health care facility may also be reportable under the state’s notifiable disease law.<sup>529</sup>

**8. DEADLINES:** Medical facilities must notify the Department of Health of adverse events within forty-eight hours of confirmation of the event.<sup>530</sup> A subsequent report containing a root cause analysis and a corrective action plan

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Office, Wash. State Dep’t of Health, to Jeffrey M. Tebbs, Executive Editor, Yale Journal of Health Policy, Law, & Ethics (Sept. 24, 2008, 09:58 EST) [hereinafter E-mail from Furkay] (on file with journal).

522. WASH. REV. CODE § 70.56.020(2) (Supp. 2008).

523. *Id.* § 70.56.010(10); E-mail from Furkay, *supra* note 521.

524. E-mail from Furkay, *supra* note 521.

525. WASH. REV. CODE § 70.56.020(2) (Supp. 2008).

526. *Id.* § 70.56.010(1).

527. *Id.* § 43.70.056(2)(a).

528. *Id.* § 43.70.056(2)(b).

529. E-mail from Furkay, *supra* note 521; *see also* WASH. ADMIN. CODE § 246-101-001 to -120. (2008).

530. WASH. REV. CODE § 70.56.020(2) (Supp. 2008).

must be submitted within forty-five days of the initial confirmation of the event.<sup>531</sup>

**9. PENALTIES AND ENFORCEMENT MECHANISMS:** “The intent of the law is quality improvement and there are no sanctions or citations in the law.”<sup>532</sup> If the Department of Health discovers that an event is not reported, the “department shall direct the facility to report or to undertake an investigation of the event.”<sup>533</sup>

**(a) Revocation of license?** No.

**(b) Audits?** No.

**10. ARE PUBLIC REPORTS ISSUED?** The Department of Health is directed to contract with a “qualified, independent entity to receive notifications and reports of adverse events and incidents.” This entity must produce an annual report for the governor and legislature regarding the “number of adverse events and incidents reported by medical facilities, in the aggregate, on a geographical basis, and a summary of actions taken by facilities in response to the adverse events or incidents” as well as “recommendations to medical facilities on a facility-specific or on a statewide basis regarding changes, trends, and improvements in health care practices and procedures for the purpose of reducing the number and severity of adverse events or incidents.”<sup>534</sup> This report must be publicly available on the Department of Health’s website.<sup>535</sup> Starting December 1, 2009, and each December 1 thereafter, the Department of Health must also “prepare and publish a report on its website that compares the health care-associated infection rates at individual hospitals in the state using the data reported in the previous calendar year . . . .”<sup>536</sup>

**11. ARE ERROR REPORTS PROTECTED FROM LEGAL DISCOVERY?** No. “The notification of an adverse event . . . shall be subject to public disclosure and not exempt from disclosure . . . . Any public disclosure of an adverse event notification must include any contextual information the medical facility chose to provide” with its original report to the Department of Health.<sup>537</sup> However, health care-associated infection reports are protected from discovery.<sup>538</sup>

**12. IMMUNITY FOR REPORTERS?** Unclear from statutes and regulations.

**13. ANY PAY-FOR-PERFORMANCE PROGRAMS IMPLEMENTED?** No.

**14. RELEVANT STATUTES AND REGULATIONS:** WASH. REV. CODE § 43.70.056 (Supp. 2008); WASH. REV. CODE §§ 70.56.010 to .050 (Supp. 2008).

**15. OTHER RESOURCES:** N/A.

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531. *Id.* § 70.56.020(2)-(4).

532. E-mail from Furkay, *supra* note 521.

533. WASH. REV. CODE § 70.56.020(5) (Supp. 2008).

534. *Id.* § 70.56.040(1)-(3).

535. *Id.* § 70.56.040(3)(c).

536. *Id.* § 43.70.056(3)(d).

537. *Id.* § 70.56.050(b).

538. *Id.* § 43.70.056(2)(e)(ii).

**16. DATE REPORTING STARTED:** June 5, 2006.<sup>539</sup>**WEST VIRGINIA**

A medical error reporting regime does not appear to exist for this state.

**WISCONSIN**

A medical error reporting regime does not appear to exist for this state.

**WYOMING**

**1. GENERAL DESCRIPTION:** All health care facilities must report “safety events” to the Department of Health.

**2. IS REPORTING MANDATORY?** Yes, until June 30, 2010.<sup>540</sup>

**3. REPORT RECIPIENT(S):** Department of Health.<sup>541</sup>

**4. IS REPORTING CONDUCTED ELECTRONICALLY?** The Department of Health “may design the reporting system so that a facility may file by electronic means . . . [and] shall encourage a facility to use the electronic filing option when that option is feasible for the facility.”<sup>542</sup>

**5. WHAT FACILITIES MUST PROVIDE REPORTS?** Every licensed health care facility.<sup>543</sup>

**6. WHAT INCIDENTS MUST BE REPORTED?** “Safety events” must be reported, which are defined as “unexpected occurrence[s] involving death or serious physical or psychological injury or the risk thereof . . . .”<sup>544</sup> In 2007, safety events were defined to include twenty-seven of the twenty-eight “serious reportable events” listed by the NQF.<sup>545</sup> In 2008, the state legislature eliminated the statutory list of safety events and replaced that section of the statute with authorization for the Department of Health to issue rules or regulations identifying reportable events “using a standard taxonomy generally accepted in

539. E-mail from Furkay, *supra* note 521.

540. WYO. STAT. ANN. § 35-2-912(b) (2007). This statute has been repealed, effective June 30, 2010.

541. *Id.* (requiring report of safety events to the “department”); *id.* § 35-2-901(a)(vi) (defining “department”).

542. *Id.* § 35-2-912(c).

543. *Id.* § 35-2-912(b); *id.* § 35-2-901(a)(x) (defining “health care facility” as “any ambulatory surgical center, assisted living facility, adult day care facility, adult foster care home, alternative eldercare home, birthing center, boarding home, freestanding diagnostic testing center, home health agency, hospice, hospital, intermediate care facility for the mentally retarded, medical assistance facility, nursing care facility, rehabilitation facility and renal dialysis center”).

544. *Id.* § 35-2-912(a).

545. *See id.* § 35-2-912(a)(i)-(vi); *supra* Appendix. The National Quality Forum and Wyoming lists are nearly identical, with the exception that the Wyoming statute does not specifically include the event of artificial insemination with the wrong donor sperm or wrong egg as a reportable event.

the health care industry as indicated by endorsement of the [N]ational [Q]uality [F]orum or similar health care quality control organization.”<sup>546</sup>

**7. MUST HOSPITAL-ACQUIRED INFECTIONS BE REPORTED?** Hospital-acquired infections are not explicitly listed as a separate category, but could result from other “safety events.”

**8. DEADLINES:** Any person employed by the health care facility shall notify the patient safety officer of the facility within twenty-four hours of becoming aware of a patient safety event. The patient safety officer must then report the event to the Department of Health within fifteen days of receiving notification.<sup>547</sup>

**9. PENALTIES AND ENFORCEMENT MECHANISMS:** Any person who violates the reporting requirements or violates orders issued pursuant to those requirements “shall be deemed guilty of misdemeanor, and shall be punished except as otherwise provided therein by a fine or not more than one thousand dollars (\$1,000.00), or by imprisonment for not more than one (1) year or by both such fine and imprisonment.”<sup>548</sup>

(a) **Revocation of license?** Yes, at the Department’s discretion.<sup>549</sup>

(b) **Audits?** Unclear from statutes and regulations.

**10. ARE PUBLIC REPORTS ISSUED?** Yes. On an annual basis, the Department of Health “shall prepare and publish a report and analysis of all reported safety events for the previous year, including a trend analysis and recommendations for systemic improvements that are likely to enhance patient safety and health care.”<sup>550</sup> This report is available to the public and is forwarded to the governor, the health care commission, and Wyoming’s Joint Labor, Health, and Social Services Interim Committee.<sup>551</sup>

**11. ARE ERROR REPORTS PROTECTED FROM LEGAL DISCOVERY?** Yes.<sup>552</sup> Moreover, safety event reports shall not identify the health care professionals, facility employees, or patients involved.<sup>553</sup>

**12. IMMUNITY FOR REPORTERS?** Yes.<sup>554</sup>

**13. ANY PAY-FOR-PERFORMANCE PROGRAMS IMPLEMENTED?** No.

**14. RELEVANT STATUTES AND REGULATIONS:** WYO. STAT. ANN. § 35-2-912 (2007); 35-2-912 WYO. CODE R. §§ 1 to 14 (Supp. 2008).

546. WYO. STAT. ANN. § 35-2-912(a) (2008).

547. *Id.* § 35-2-912(b)(i).

548. *Id.* § 35-1-106.

549. *Id.* § 35-2-905(a) (stating that “the division may . . . deny, suspend or revoke a license . . . if a licensee: (i) violates any provision of this act . . .”).

550. *Id.* § 35-2-912(f).

551. *Id.*

552. *Id.* § 35-2-912(e).

553. *Id.* § 35-2-912(c).

554. *Id.* § 35-2-910(a) (stating that “any person who . . . participates in the reporting, collection, evaluation, or use of quality management information . . . shall be immune from suit in any civil action . . .”).

**15. OTHER RESOURCES:** WYO. DEP'T OF HEALTH, ADVERSE HEALTH EVENTS IN WYOMING HEALTHCARE FACILITIES: SECOND ANNUAL REPORT 2006-2007, *available at* <http://wdh.state.wy.us/Media.aspx?mediaId=3248>.

**16. DATE REPORTING STARTED:** June 30, 2005.<sup>555</sup>

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555. *Id.* § 35-2-912(b).