

Department of Health and Human Services

**OFFICE OF  
INSPECTOR GENERAL**

**ADVERSE EVENTS IN HOSPITALS:  
STATE REPORTING SYSTEMS**



Daniel R. Levinson  
Inspector General

December 2008  
OEI-06-07-00471

# *Office of Inspector General*

<http://oig.hhs.gov>

---

The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452, as amended, is to protect the integrity of the Department of Health and Human Services (HHS) programs, as well as the health and welfare of beneficiaries served by those programs. This statutory mission is carried out through a nationwide network of audits, investigations, and inspections conducted by the following operating components:

## *Office of Audit Services*

The Office of Audit Services (OAS) provides auditing services for HHS, either by conducting audits with its own audit resources or by overseeing audit work done by others. Audits examine the performance of HHS programs and/or its grantees and contractors in carrying out their respective responsibilities and are intended to provide independent assessments of HHS programs and operations. These assessments help reduce waste, abuse, and mismanagement and promote economy and efficiency throughout HHS.

## *Office of Evaluation and Inspections*

The Office of Evaluation and Inspections (OEI) conducts national evaluations to provide HHS, Congress, and the public with timely, useful, and reliable information on significant issues. These evaluations focus on preventing fraud, waste, or abuse and promoting economy, efficiency, and effectiveness of departmental programs. To promote impact, OEI reports also present practical recommendations for improving program operations.

## *Office of Investigations*

The Office of Investigations (OI) conducts criminal, civil, and administrative investigations of fraud and misconduct related to HHS programs, operations, and beneficiaries. With investigators working in all 50 States and the District of Columbia, OI utilizes its resources by actively coordinating with the Department of Justice and other Federal, State, and local law enforcement authorities. The investigative efforts of OI often lead to criminal convictions, administrative sanctions, and/or civil monetary penalties.

## *Office of Counsel to the Inspector General*

The Office of Counsel to the Inspector General (OCIG) provides general legal services to OIG, rendering advice and opinions on HHS programs and operations and providing all legal support for OIG's internal operations. OCIG represents OIG in all civil and administrative fraud and abuse cases involving HHS programs, including False Claims Act, program exclusion, and civil monetary penalty cases. In connection with these cases, OCIG also negotiates and monitors corporate integrity agreements. OCIG renders advisory opinions, issues compliance program guidance, publishes fraud alerts, and provides other guidance to the health care industry concerning the anti-kickback statute and other OIG enforcement authorities.



## E X E C U T I V E   S U M M A R Y

---

### OBJECTIVE

To identify and describe State adverse event reporting systems and how States use the reported information.

---

### BACKGROUND

The Tax Relief and Health Care Act of 2006 (the Act) mandates that the Office of Inspector General (OIG) report to Congress regarding the incidence of “never events” among Medicare beneficiaries. Never events are a specific list of serious events, such as surgery on the wrong patient, that the National Quality Forum (NQF) deemed “should never occur in a health care setting.” Expanding beyond this specific list, this and other OIG reports use the broader term “adverse event” which describes harm to a patient as a result of medical care, such as infection because of contaminated equipment.

This report describes State adverse event reporting systems as of January 2008 in all 50 States and the District of Columbia (hereinafter referred to as States). Our review is based on State documents, such as regulations, policies and procedures, other materials that reference adverse events, and aggregate reports of adverse events provided by States with systems. We conducted structured interviews by telephone with staff from each State who were responsible for either the State adverse event reporting system or State oversight of patient safety in hospitals.

---

### FINDINGS

**As of January 2008, 26 States had hospital adverse event reporting systems and another State had taken action to develop one.** Each of the 26 States’ systems met the criteria that we used. They were authorized through State law, had formal policies and procedures for reporting, and were actively collecting data from hospitals. The remaining 25 States did not have adverse event reporting systems, although 1 State had passed legislation to authorize a system and was developing policies and procedures. Many of the States’ systems were relatively new, with 10 systems being operational for less than 3 years.

**Reporting systems varied in terms of what events were reported, criteria used for selection, and type of information reported.**

Twenty-three States established their own lists of reportable adverse events, and three States used NQF’s list of Serious Reportable Events.

## EXECUTIVE SUMMARY

State criteria for determining whether an event is reportable focus primarily on the level of harm caused to the patient, although additional criteria affect whether the same event would be reportable in other States. Each of the 26 States' systems had different requirements regarding the information that must be included about the following: the event itself, the patient involved in the event, the result of any root cause analyses, and any corrective action plans and/or risk reduction strategies.

**Most States with systems reported having mechanisms to identify underreporting and strategies to improve reporting.** Staff from 15 of the 26 States acknowledged that hospitals do not always submit reports when adverse events occur. To identify specific instances of underreporting, staff reported that their State: analyzes reported data (11 States); compares hospital reports against complaints, referrals, and administrative databases (16 States); and conducts onsite audits (3 States). To motivate hospitals to report, States have several strategies, including protection of reported data from improper disclosure, monetary penalties for hospitals that fail to report, and provision of feedback to hospitals about reported events.

**Twenty-three States reported using data to hold individual hospitals accountable; 18 reported using data to promote learning and prevent adverse events.** To hold hospitals accountable for their patient care performance, staff from 23 of the 26 States with systems explained that adverse event reports resulted in desk or onsite audits, and/or State-led investigations of the hospitals' handling of reported events. Four of these States also reported using adverse event reports in licensing decisions for hospitals. Eighteen of the twenty-six States use reports to communicate with hospitals about best practices and Statewide incidence of adverse events, to provide early warnings about specific patient safety issues, and to provide details about specific events on State Web sites. Of the remaining eight States, three had systems that had been in operation for about 1 year at the time of data collection in early 2008 and were still developing hospital communication mechanisms and five States did not report using adverse event reports to provide information to hospitals.

---

## CONCLUSION

In the absence of both a national system and Federal guidelines regarding State reporting systems, about half of the States have taken

the initiative to implement hospital adverse event reporting systems. These systems appear to be disparate, with each tracking different events, employing different reporting criteria, and requiring differing accompanying information. The differences we found make State adverse event reporting systems data unsuitable for use in the aggregate to identify national incidence and trends. Despite these distinctions among reporting systems, we noted that most States use reported data in similar ways. To improve patient safety, States use reports to assess individual hospitals' responses to adverse events, and also draw from reports to promote learning and prevent adverse events. States may find that opportunities exist to expand their use of reported data by employing methods used by other States. Finally, although the 26 States require hospitals to report adverse events when they occur, staff from most of these States described mechanisms used to identify underreporting. Beyond strategies currently being used, States may find it prudent to consider other means to ensure reporting by hospitals.

---

## AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

We received comments on a draft of this report from the Agency for Healthcare Research and Quality (AHRQ) and CMS. AHRQ and CMS provided positive comments on the draft report.

AHRQ called for greater precision when discussing the differences between NQF's list of Serious Reportable Events (formerly referred to as "never events") and CMS's payment policies for hospital-acquired conditions. Although this report does not examine CMS's payment policies, we will ensure that other OIG reports on this topic make these distinctions clear.

CMS expressed its belief that the report should more clearly describe the impediments facing the Federal Government and CMS in managing data identifying adverse events given the existing fragmented systems. According to CMS, data from State systems are not useful in understanding national issues and trends because of the variability in States' identification of adverse events. We modified the report's conclusion to underscore that data from State adverse event reporting systems are unsuitable for national-level analyses.

Because of the variability among State-based systems, CMS indicated that it would be helpful to identify potential solutions, such as amending the Patient Safety Act to make reporting of well-defined

## E X E C U T I V E   S U M M A R Y

adverse events mandatory. CMS also indicated that it would be helpful to identify other partners in reporting system efforts, such as AHRQ. In planning future work in this area, we will consider the issues addressed in CMS's comments.

Finally, CMS stated that it had recently issued a letter to State Medicaid Directors about Medicaid payment implications for selected adverse events. CMS explained that the intent of this letter was to offer States an opportunity to tie Medicaid payment to performance through denial of payment for selected adverse events. According to CMS, there are seven pending State Plan Amendments to restrict payment for selected adverse events, and State systems used to prevent or recoup Medicaid payments could serve as a model for a national system.



## T A B L E O F C O N T E N T S

EXECUTIVE SUMMARY .....	i
INTRODUCTION .....	1
FINDINGS .....	7
Twenty-six States had adverse event reporting systems. ....	7
Reporting systems varied across States. ....	8
States reported having mechanisms to identify underreporting and strategies to improve reporting .....	12
States reported using data for accountability and learning .....	14
CONCLUSION .....	19
Agency Comments and Office of Inspector General Response ...	19
APPENDIXES .....	21
A: Glossary of Selected Terms .....	21
B: National Quality Forum List of Serious Reportable Events ..	22
C: Tax Relief and Health Care Act of 2006 .....	23
D: States With Adverse Event Reporting Systems .....	25
E: State-by-State Reporting Requirements for Hospital Adverse Events .....	26
F: Agency Comments .....	27
ACKNOWLEDGMENTS .....	30

---

## OBJECTIVE

To identify and describe State adverse event reporting systems and how States use the reported information.

---

## BACKGROUND

The term “adverse event” describes harm to a patient as a result of medical care. An adverse event indicates that the care resulted in an undesirable clinical outcome and that the clinical outcome was not caused by an underlying disease. Adverse events include medical errors, such as use of incompatible blood products. They may also include more general substandard care that can result in harm, such as infection because of contaminated equipment, incorrect diagnoses, and lack of patient monitoring during treatment. Research, policies, and action taken to reduce adverse events often focus on mistakes and systemic problems with care. However, adverse events do not always involve errors, negligence, or poor quality of care and may not always be preventable.

A variety of terms, lists, and definitions are used to identify and address harmful health care events. For a glossary of selected terms, see Appendix A. The term “never event” is used to describe a specific list of serious events that the National Quality Forum (NQF) determined “should never occur in a health care setting” and are associated primarily with patient death or serious disability.<sup>1</sup> NQF currently uses the term “serious reportable events” to describe this list. For the list of NQF “Serious Reportable Events,” see Appendix B. Expanding beyond the specific events defined by NQF, this and subsequent Office Inspector General (OIG) reports use the broader and more common term “adverse event” to provide for a more comprehensive examination of key issues.

### **Statutory Mandate and Office of Inspector General Response**

The Tax Relief and Health Care Act of 2006 (the Act) requires that OIG study events that cause harm to Medicare beneficiaries. The Act specifically mandates that OIG study the incidence of “never events” among Medicare beneficiaries, payment by Medicare or beneficiaries for services furnished in connection with such events, and administrative

---

<sup>1</sup> NQF is a public-private organization created to develop and implement a national strategy for health care quality measurement and reporting. This list is available online at <http://www.qualityforum.org/about>. Accessed on October 10, 2008.



processes of the Centers for Medicare & Medicaid Services (CMS) to identify events and deny or recoup payment. OIG is also to report to Congress on the studies conducted, including recommendations for such legislation and administrative action as OIG determines appropriate. For relevant text of the Act, see Appendix C.

Following a review of Medicare policies and expenditures, as well as consultation with CMS and the Agency for Healthcare Research and Quality (AHRQ), we chose to focus much of our work on the hospital setting. In 2006, 12.5 million Medicare beneficiaries were hospitalized,<sup>2</sup> with inpatient hospital costs constituting the largest portion of Medicare expenditures (32 percent in 2006).<sup>3</sup> Also, many current efforts by Federal Government agencies and private entities to research and address adverse events target care provided in hospitals.

OIG is conducting a series of studies through 2009 to fulfill the requirements in the Act and to inform decisionmakers regarding adverse events. To facilitate OIG efforts to comply with the Act, we first sought to identify key issues regarding adverse events in hospitals to provide direction and context for our future work.<sup>4</sup> A key issue identified was hospital reporting of adverse events. This study focuses on State efforts to operate adverse event reporting systems. Other OIG studies focus on estimating the incidence of adverse events among Medicare beneficiaries, Medicare beneficiaries receiving potentially inappropriate drug pairs that may reflect medication errors, and responses to adverse events in hospitals.

### **Adverse Event Reporting Systems**

A State-level adverse event reporting system (hereinafter referred to as a system) collects data regarding adverse events that have taken place in hospitals and other health care settings. The Institute of Medicine (IOM) report, “To Err is Human: Building a Safer Health Care System,” outlines key issues associated with reporting and collecting data and a

---

<sup>2</sup> CMS, “Statistics Book,” Table IV.1: Medicare/short-stay hospital utilization, 2008, p. 43. Available online at <http://www.cms.hhs.gov/CapMarketUpdates/Downloads/2008CMSStats.xls.pdf>. Accessed on November 12, 2008.

<sup>3</sup> Based on data contained in Congressional Budget Office (CBO) “Fact Sheet for CBO’s March 2007 Baseline: Medicare,” March 7, 2007. Available online at <http://www.cbo.gov/budget/factsheets/2007b/medicare.pdf>. Accessed on September 8, 2008.

<sup>4</sup> “Adverse Events in Hospitals: Overview of Key Issues,” 2008, OEI-06-07-00470.

national plan to address adverse events.<sup>5</sup> As part of this plan, IOM recommended the creation of a nationwide system that provides for the collection of standardized data by State governments when adverse events occur. IOM maintained that reporting has the potential to serve two purposes: to hold individual hospitals accountable for performance and to provide information that could lead to improved patient safety.

To date, no national adverse event system exists and there are no Federal standards regarding State systems. Instead, States may opt to require hospitals to report adverse events, identify and define which events are reportable, and establish parameters surrounding the specific information for hospitals to report.

As mentioned previously, NQF has identified a list of serious reportable events. This list has six categories of events, five of which relate to the provision of care: surgical, product or device, patient protection, care management, and environmental. The sixth category involves criminal events and is included by NQF because such events could indicate an unsafe environment for patients. The criteria for inclusion on this list require that events be:<sup>6</sup>

- of concern to the public, health care professionals, and providers;
- clearly identifiable, measurable, and so feasible to include on a list;
- such that the risk of occurrence is significantly influenced by the policies and procedures of a health care facility; and
- unambiguous, usually preventable, and serious; and
  - adverse; and/or
  - indicative of a problem in a health care facility's safety systems; and/or
  - important for public credibility or accountability.

A number of Federal and nongovernmental entities receive adverse event reports from hospitals and other health care entities. For example, the Food and Drug Administration (FDA) receives information

---

<sup>5</sup> L. T. Kohn, J. M. Corrigan, and M. S. Donaldson, eds., "To Err is Human: Building a Safer Health System, A Report of the Committee on Quality of Health Care in America," Institute of Medicine, p. 102. Washington, DC, National Academy Press, 2000.

<sup>6</sup> NQF, "Serious Reportable Events in Healthcare, 2006 Update," 2007, pp. 4, D-4.

about adverse events involving drugs, biologics, and medical devices.<sup>7</sup> Additionally, hospitals participating in Medicare must report to CMS all deaths associated with the use of seclusion or restraints as well as develop and maintain systems for tracking adverse events.<sup>8</sup> The Joint Commission, which establishes standards and accredits hospitals, encourages but does not require accredited hospitals to report certain adverse events deemed sentinel events to the Joint Commission.<sup>9</sup>

Additionally, to address concerns about patient safety, the Patient Safety and Quality Improvement Act of 2005 (the Patient Safety Act) was enacted.<sup>10</sup> The Patient Safety Act requires the Department of Health and Human Services to establish a national network of Patient Safety Organizations (PSO) to, among other tasks, accept voluntary reports of adverse events from hospitals.<sup>11</sup> In November 2008, AHRQ designated the first 15 PSOs and is continuing to solicit applications for additional PSOs.<sup>12</sup> AHRQ has also developed common formats for use by Patient Safety Organizations, which delineate definitions and data elements that allow hospitals to collect and submit standardized information regarding adverse events.<sup>13</sup>

---

## METHODOLOGY

### Scope

This report identifies and describes adverse event reporting systems in all 50 States and the District of Columbia (hereinafter referred to as States) as of January 2008.

---

<sup>7</sup> 21 CFR § 314.80(c), 21 CFR § 600.80(c), 21 CFR § 606.170, 21 CFR Part 803, 21 CFR § 1271.350. FDA Safety Information and Adverse Event Reporting Program. Available online at <http://www.fda.gov/medwatch/index.html>. Accessed on October 15, 2008.

<sup>8</sup> 42 CFR §§ 482.13(g) and 482.21(a)(2).

<sup>9</sup> Sentinel events are defined by the Joint Commission as “unexpected occurrences involving death or serious physical or psychological injury, or risk thereof.” The Joint Commission, “Sentinel Event Policy and Procedures.” Available online at <http://www.jointcommission.org/SentinelEvents/PolicyandProcedures/>. Accessed on August 7, 2008.

<sup>10</sup> The Patient Safety Act, P.L. No. 109-41.

<sup>11</sup> Ibid, at § 923.

<sup>12</sup> AHRQ, “Alphabetical Directory of Listed Patient Safety Organization.” Available online at <http://www.pso.ahrq.gov/listing/psolist.htm>. Accessed on November 20, 2008.

<sup>13</sup> 73 Fed. Reg. 50974 (August 29, 2008).

### Identification of States With Reporting Systems

For purposes of this report, we considered a State to have an adverse event reporting system if its system:

- was authorized through State statute, rules, or Executive order;
- had policies and procedures for reporting; and
- was actively receiving reports from hospitals as of January 1, 2008.

To identify States with systems, we created a list from the following sources: (1) AHRQ's Patient Safety Incident Reporting Systems metadatabase,<sup>14</sup> (2) the National Academy of State Health Policy's Patient Safety Toolbox,<sup>15</sup> and (3) information from State adverse event reporting systems' Web sites. We also called States to confirm the information.

For States without known systems, we gathered information from State Web sites as an entry point for locating departments and divisions responsible for oversight of patient safety in hospitals. We then called States to confirm that the State did not have a system.

### Data Collection

We conducted three data collection activities: (1) a review of State statutes and regulations, policy and procedural documents, and other documents provided by States, such as annual reports that draw from reported events; (2) structured telephone interviews with State staff who were responsible for either the State adverse event reporting system or State oversight of patient safety in hospitals; and (3) collection of the number of adverse events from State annual reports, spreadsheets submitted by State staff, and State Web sites.

**Document Review.** We requested and reviewed documentation provided by States regarding their systems. We also collected and reviewed documents from States' Web sites. This information included State statutes, regulations, policies and procedures, adverse event report forms, annual reports, and patient safety alerts/bulletins.

**Structured Interviews With Selected Staff.** We conducted structured interviews by telephone with staff from each State who were responsible

---

<sup>14</sup> AHRQ Patient Safety Research Coordinating Center Portal. Available online at <https://mdis.s-3.com>. Accessed on October 1, 2007.

<sup>15</sup> National Academy of State Health Policy, "Patient Safety Toolbox." Available online at <http://www.pstoolbox.org/>. Accessed on February 8, 2007.

## I N T R O D U C T I O N

for either the system or State oversight of patient safety in hospitals. We developed and administered separate interview protocols for States with systems and States without systems.

For each State with a system, we asked State staff questions about:

- system administration, including entities responsible for operating the system, State laws and regulations related to reporting, how adverse events are defined and reported, and mechanisms to ensure reporting;
- information recorded in the system as an adverse event report, such as information about causal analysis (hereinafter referred to as root cause analysis), interventions, actions, strategies designed to reduce the risk of occurrence (hereinafter referred to as risk reduction strategies), and corrective action plans; and
- how the State uses reported information.

We asked staff from each State without a system questions about any State-sponsored actions to develop one.

**Adverse Event Reports.** We requested that States provide the aggregate number of adverse events received from hospitals in 2006 by the type of adverse event.<sup>16</sup> States provided these data through spreadsheets, published annual reports, and/or their Web sites.

### **Limitations**

The information in this report reflects State efforts as reported by State staff. We verified this information by reviewing supporting documents that staff provided or we accessed through State Web sites. However, we did not independently verify the extent to which States with systems are using reported information in the manner described by State staff.

Data regarding the number of adverse events received by State systems in 2006 are not standardized across States. Therefore, we could not aggregate adverse event reports or identify trends or patterns based on the number of reported adverse events across States.

### **Quality Standards**

This study was conducted in accordance with the “Quality Standards for Inspections” issued by the President’s Council on Integrity and Efficiency and the Executive Council on Integrity and Efficiency.

---

<sup>16</sup> For some States with reporting systems, 2006 was the most recent full year for which data were available at the time of our data request in February 2008.

**As of January 2008, 26 States had hospital adverse event reporting systems and another State had taken action to develop one**

Each of the 26 States' systems met the criteria that we used: they were authorized through State law, had formal policies and procedures

for reporting, and were actively collecting data from hospitals. The remaining 25 States did not have systems, although 1 State had passed legislation authorizing a system and was developing policies and procedures.<sup>17</sup> Four of the twenty-six States with systems supplement reports received from hospitals with reports from hospital staff and the public.<sup>18</sup> In most of these States, governmental agencies (usually the Department of Health or another State department) received reports; however, two States contracted with nongovernmental entities to collect these data.

Many of the 26 States' systems were relatively new and implemented within the last 10 years. As of January 2008, 10 systems had been in operation less than 3 years, 8 had been in operation 4–9 years, and 8 had been operating for 10 years or more. Eighteen States submitted the number of adverse events reported by hospitals during 2006.<sup>19</sup> For this timeframe, the number of adverse events reported by hospitals in these States ranged from 6 to 16,442 events.<sup>20</sup> However, as we describe on the next page, given States' differences in the types of events and criteria used for selection, it is not surprising that such a wide range of reported events exists. See Appendix D for more information about each State's system and the number of events reported in 2006 by State.

<sup>17</sup> Illinois Adverse Health Care Events Reporting Law of 2005, 410 Ill. Comp. Stat 522, Article 10. Although the statute directed that the State's system be "fully operational" by January 1, 2008, the system was not actively collecting data from hospitals at the time of our data collection and therefore did not meet our criteria for inclusion.

<sup>18</sup> Hospital staff may submit adverse event reports directly to the State in Indiana, Kansas, Pennsylvania, and South Dakota. Members of the public may submit adverse event reports directly to the State in Kansas and South Dakota.

<sup>19</sup> Twenty-two States reported collecting data in 2006. We received aggregate data for the entire year from 18 of these 22 States. Of the remaining four States, one provided data that combined totals from hospitals and ambulatory surgical centers; staff from one State reported that they could not aggregate reported events; and the other two States began collecting data in mid-2006 and, therefore, could not report complete data for the year.

<sup>20</sup> This range does not include the number of near misses reported to Pennsylvania in 2006.

**Reporting systems varied in terms of what events were reported, criteria used for selection, and type of information reported**

We examined information reported by State staff in the 26 States with systems and identified differences in three

major areas: the list of reportable events; criteria for determining whether events are reportable; and the extent to which adverse event details, such as the specific location in which the event occurred or key factors that contributed to the event, must also be submitted to the State.

**Twenty-three States established their own lists of reportable adverse events, and three States used the National Quality Forum's list of Serious Reportable Events**

Eight of the twenty-three States that established their own lists of reportable events used the NQF list of Serious Reportable Events as a starting point and modified it by adding events and/or by not using some events on the NQF list.<sup>21</sup> In general, States that established their own lists of events have wide variation in the events that are included. Some States identify very specific events. For example, Ohio requires hospitals to report all incidents of postoperative respiratory failure. Other States have broad specifications that could capture a range of events. For example, Pennsylvania requires hospitals to report any serious event, occurrence, or situation involving the clinical care of a patient in a medical facility that results in an unanticipated injury and requires additional medical care.<sup>22</sup>

**State criteria for determining whether an event is reportable focus primarily on the level of harm caused to the patient, although additional criteria affect whether the same event would be reportable in other States**

All States with systems ask hospitals to gauge whether harm was caused to the patient and to assess the severity of this harm when determining whether an event should be reported. We developed five categories to describe how systems use severity of harm to determine

<sup>21</sup> State staff expressed one of two general opinions about the use of the NQF list. Most of those that used the list believed that it would be useful for sharing information about events across States. Most of those that did not use the list reported that they considered the list "vague" and open to interpretation. Two States (Maine and Massachusetts) reported comparing their State-determined list with the NQF list and found that their reporting criteria led to the identification of a much larger number of events.

<sup>22</sup> Medical Care Availability and Reduction of Error Act, P.L. No. 154, No. 13, chapter 3, §§ 302 and 313 (a).

whether events are reportable. These categories include:

- *Events resulting in death.* These events may include death unrelated to the patient's underlying condition, unanticipated death, or death as an outcome of any reportable adverse event. All States use this criterion for at least one reportable event. For example, South Dakota requires hospitals to report any death resulting from circumstances other than natural causes, such as accidents, abuse, negligence, or suicide.<sup>23</sup>
- *Events resulting in long term harm or permanent disability.* These events may include serious disability or loss of bodily function. Twenty-three States use this criterion for at least one reportable adverse event. For example, Maine requires hospitals to report any major permanent loss of function that is not present on admission.<sup>24</sup>
- *Events resulting in harm and likely to require additional medical care.* These events may include unanticipated injury or life-threatening, serious, or unforeseen complications. Twenty-four States use this criterion for at least one reportable adverse event. For example, Connecticut requires hospitals to report any incident in which a gas line designated for oxygen to be delivered to a patient contains the wrong gas.<sup>25</sup>
- *Events not resulting in identifiable physical harm.* These events may not result in death or physical disability and may not require additional medical care. They are reportable because they happened and may reflect vulnerabilities in the hospital environment. Twenty-three States use this criterion for at least one reportable adverse event. For example, Tennessee requires hospitals to report instances in which there is misappropriation of patient funds.<sup>26</sup>
- *Near misses.* These events are occurrences that could have resulted in an adverse event but the event was averted and the patient was not harmed. Only one State, Pennsylvania, uses this criterion for

---

<sup>23</sup> Administrative Rules of South Dakota, § 44:04:01:07.

<sup>24</sup> Maine: Title 22, chapter 1684, §§ 8752.4(A)(2); 8753.

<sup>25</sup> State of Connecticut Department of Public Health, "Legislative Report to the General Assembly: Adverse Event Reporting," October, 2007, p. 9. Available online at <http://www.ct.gov/dph/lib/dph/hisr/hcqsar/healthcare/pdf/adverseeventreportoct2007.pdf>. Accessed on March 20, 2008.

<sup>26</sup> Tennessee Health Data Reporting Act of 2002 Code, § 68-11-211(d)(2)(xx).



reportable adverse events, e.g., when medical staff narrowly avert conducting wrong-site surgery.<sup>27 28</sup> Staff from this State explained that by requiring hospitals to identify and report near misses, the State has the opportunity to bring about changes to prevent an event from reaching a patient. For example, Pennsylvania received a near miss report about a patient who nearly died because of confusion over the meaning of the patient's color-coded wristband. Some hospital staff believed that the patient's wristband color meant "do not resuscitate," when it actually meant something else. The incident prompted the State to issue an advisory on the risks associated with using specific colors to convey clinical information.

Although harm forms the foundation for reporting criteria, 13 States also ask hospitals to evaluate additional criteria, such as the length of time the patient experienced a certain outcome (8 States), whether the condition persisted at the date of discharge from the hospital (8 States), and whether persons other than the patient were also affected by the event (4 States). Hence, the severity of harm coupled with additional criteria affects whether the same adverse event is reportable in different States. To illustrate, if a medical device is used or functions other than as intended, it is a reportable event in:

- Georgia if the outcome is death of the patient;<sup>29</sup>
- New York if the outcome is death or serious injury to the patient or hospital personnel;<sup>30</sup> and
- New Jersey if the outcome is patient death, loss of a body part, disability, or loss of bodily function lasting more than 7 days or present at discharge.<sup>31</sup>

---

<sup>27</sup> Pennsylvania Patient Safety Authority, "PA-PSRS Automated Data Interface XML Specifications, Part 3," Version 6.4, September 19, 2007, p. 12.

<sup>28</sup> Staff from two other States indicated that although mandated by legislation to collect data on near misses, they had not implemented this provision as of January 2008.

<sup>29</sup> Georgia Hospital Rules, § 290-9-.07(2)(a)1(i).

<sup>30</sup> State of New York Department of Health, "NYPORTS, Section 3: Includes and Excludes List, Version 4," 2005, p. 5.

<sup>31</sup> New Jersey Department of Health and Senior Services, "Mandatory Patient Safety Reporting Requirements for Licensed Health Care Facilities (Revised): Patient Safety Initiative," 2008, pp. 3–5. Available online at: [http://www.nj.gov/health/ps/documents/final\\_directions\\_march08.pdf](http://www.nj.gov/health/ps/documents/final_directions_march08.pdf). Accessed on April 3, 2008.

### **State requirements differ regarding what information hospitals must provide in adverse event reports**

Each of the 26 States' systems had different requirements regarding the information that must be included about the following: the event itself, the patient involved in the event, the result of any root cause analyses, and any corrective action plans and/or risk reduction strategies. See Appendix E for a listing of information that should be submitted to each State.

*Information that describes the event.* At a minimum, adverse event reports in all 26 States with systems must identify the type of adverse event and the hospital in which the event occurred. Twenty-four States also require the hospital to submit additional information about the adverse event itself, including the date the event occurred and a summary description of the event. Twenty States also require the hospital to report the location or service area in which the adverse event occurred, such as an emergency department, operating room, laboratory, or intensive care unit.

*Information about the patient.* Nineteen of the twenty-six States require hospitals to submit information about the patient involved in the event. These States all require the hospital to submit the patient's date of birth. Other information required includes the patient's diagnosis (16 States); the impact of the event on the patient (12 States); and identifying information such as the patient medical record number (5 States) and/or the patient billing number (2 States).

*Results of a root cause analysis.* Seventeen of the twenty-six States require the hospital to submit documentation of the results of its root cause analysis of the event.<sup>32</sup> This documentation must include information regarding factors that contributed to the event (16 States), any identified cause for the event (12 States), and the names or titles of the persons who conducted the root cause analysis (7 States).

*Corrective action plans and/or risk reduction strategies.* Twenty of the twenty-six States require the hospital to submit a corrective action plan or a risk reduction strategy that the hospital has determined will reduce the risk of future occurrences of the event. Some of these States require additional information, such as a timeline for implementation of the

---

<sup>32</sup> Some of these States do not use the term "root cause analysis" to describe their causal analyses, but the elements typically considered as part of root cause analysis were present in State reporting forms for each of these States.

strategies (11 States), measures of effectiveness (10 States), entities responsible for implementation (10 States), and entities responsible for monitoring the effectiveness of the risk reduction strategies (9 States).

**Most States with systems reported having mechanisms to identify underreporting and strategies to improve reporting**

Staff from 15 of the 26 States acknowledged that hospitals do not always submit reports when adverse events occur. However,

staff from nearly all of these States were reluctant to estimate the extent to which adverse events go unreported, typically expressing that they could not know how many events actually occur. Nonetheless, staff described methods to identify specific instances of underreporting and explained strategies that their States use to encourage hospitals to submit reports.

**States identify instances of underreporting by comparing hospitals and by matching reports against other data sources**

Staff from 11 of the 26 States with systems explained that their State analyzes reported data to identify specific instances of underreporting. For example, Pennsylvania identified reporting disparities among hospitals by analyzing the number of reports per hospital for every 1,000 patient-days.<sup>33</sup> It found a wide range of reports across hospitals, with the top 25 percent of reporting hospitals submitting 36 to 302 adverse event reports per 1,000 patient-days, and the bottom 25 percent of hospitals reporting 0 to 8 events per 1,000 patient-days. State staff theorized that this range could be explained by hospitals' differing interpretations of events; systems for identifying events; cultures regarding patient safety; and/or patient case mix, which can affect the rates of serious events.

Staff from 16 of the 26 States reported identifying specific instances of hospital underreporting by comparing hospital reports against complaints, referrals, and administrative databases. For example, staff from one State explained that underreported events are discovered through referrals received from its Medicaid contractors. In one such case, the contractor discovered potential adverse events during a routine review of the utilization of Medicaid services. Similarly, staff

---

<sup>33</sup> Pennsylvania Patient Safety Authority, "2007 Annual Report," April 29, 2008, p. 32. Available online at [http://www.psa.state.pa.us/psa/lib/psa/annual\\_reports/annual\\_report\\_2007.pdf](http://www.psa.state.pa.us/psa/lib/psa/annual_reports/annual_report_2007.pdf). Accessed on May 7, 2008.

from another State reported receiving referrals from State certification surveyors who discover events during onsite reviews. Other States reported actively identifying underreported events by reviewing patient death records (two States), administrative databases that contain inpatient or emergency room data (two States), and Medicaid claims data (one State).

Finally, staff from three States also reported uncovering events by conducting onsite audits of hospitals that rarely file reports. State staff reported that, during these visits, they review committee meeting notes, e.g., notes of the operating room committee or the coding committee; examine accident report data; and assess the hospital's processes related to patient safety and adverse events, all of which may reveal unreported events.

**Strategies to improve reporting include legal protections to prevent improper disclosure, monetary penalties for failing to report, and provision of useful information to hospitals about reported events**

Twenty-five of the twenty-six States with systems reported that information submitted to the system is kept confidential. State staff highlighted the importance of maintaining confidentiality by explaining that hospitals would be hesitant to send in a report or provide specific details about the adverse event if that information were made public. One unintended consequence of publicizing hospital-specific information is that high numbers of reports by a hospital can be misinterpreted as an indicator of poor quality. As staff explained, hospitals that frequently submit reports may be more vigilant about identifying and reporting adverse events and that the number of reported events should not be viewed as an indicator of quality.

The extent to which information is kept confidential varies among States. For example, one State posts public reports on its Web site; reports include the name of the hospital, the date of the adverse event, general information about the event, and the hospital's subsequent actions. The State does not, however, reveal identifying information about patients or clinicians. In contrast, staff from another State explained that reporting is completely confidential and that it destroys all reports after it takes appropriate action.

Staff from four States reported that the State may impose monetary penalties on hospitals that fail to report adverse events. For example, a hospital's failure to report adverse events within the timeframes specified in California regulations could result in an administrative

penalty of \$100 day for each day that the adverse event goes unreported.<sup>34</sup> However, staff from these four States indicated limited use of these penalties for hospitals' failure to report adverse events.

Finally, staff from 20 of the 26 States conveyed that using information from adverse event reports to assist hospitals can provide incentives for hospitals to submit reports. For example, State staff explained that generating early warning alerts about problems discovered from adverse event reports and making adverse event data available for use in hospital training can benefit hospitals and cause them to be more frequent and thorough reporters.

**Twenty-three States reported using data to hold individual hospitals accountable; 18 reported using data to promote learning and prevent adverse events**

State staff whom we interviewed identified two major purposes for their adverse event reporting systems: to hold individual hospitals accountable for their

patient care performance and to disseminate information more broadly with the goals of allowing hospitals to learn from others' experiences and preventing adverse events.

**To hold individual hospitals accountable, States reported conducting administrative reviews of data contained in reports**

Staff from 23 of the 26 States with systems explained that all adverse event reports resulted in desk audits (21 States), onsite audits (2 States), and/or State-led investigations of hospitals' handling of reported events. In the remaining three States, officials we spoke with did not report using adverse event reports to deal with hospitals individually.

According to staff, these States conduct desk audits of reports to ensure that the hospital provided complete information for all required fields. The desk audit typically involves reviewing supplemental information, such as the hospital's root cause analysis and corrective action plan. Based on the quality of the report and supplemental information, the State may contact the hospital directly by telephone to gather more information or provide instructions on completing the reporting form, conducting a root cause analysis, or designing risk reduction strategies. If the desk audit or follow-up calls reveal that the hospital did not

<sup>34</sup> California Health and Safety Code, § 1280.4.

handle the event appropriately, staff from 12 of the 21 States reported following up with onsite audits, although staff explained that resources limited this activity. According to staff from these States, onsite visits typically include a review of relevant records, which may uncover additional adverse events that the hospital failed to report.

Staff from four States also reported using adverse event reports in licensing decisions for hospitals. They explained that known adverse events are one of many factors used to decide whether to revoke a hospital's license, and that loss of licensure based on a single event has not happened. For example, staff from one of these States explained that revocation could occur only after the hospital conducted an inadequate investigation of an event that was deemed "serious," did not develop an appropriate corrective action plan, failed to correct State-cited deficiencies, and was in the process of losing or had already lost its accreditation status. As of January 2008, staff reported that a single adverse event report had never led to the loss of licensure for a hospital operating in this State.

**With the goal of preventing adverse events and promoting learning, States generate reports, conduct training, produce patient safety bulletins and alerts, and post details about specific events on State Web sites**

Staff from 18 of the 26 States with systems explained that they also use reports to communicate with hospitals about best practices and Statewide incidence of adverse events, to provide early warnings about specific patient safety issues, and to provide details about specific events. Three of the remaining eight States had systems that had been in operation for about 1 year at the time of data collection in early 2008, and staff said they were still developing hospital communication mechanisms. The other five States did not report using adverse event reports to provide information to hospitals for the purpose of promoting learning and preventing adverse events. Generally, States used four methods to communicate with hospitals: annual or semiannual reports, State-led patient safety training or other initiatives, patient safety bulletins/alerts, and State Web sites.

*Annual or semiannual reports.* Eleven of the twenty-six States draw from adverse event reports to issue documents that include information on the number of adverse events reported, the number of adverse events by category, and information to help readers interpret the data. These States typically release such reports to hospitals on an annual or semiannual basis. They also make the reports public by posting them on the State Web site.

Annual reports in 10 of these 11 States communicate additional information regarding trends in reporting over time, findings of root cause analyses, or prevention strategies undertaken by the State or hospitals. For example, Minnesota's "Adverse Health Events in Minnesota" report published in January 2008 included the number of events reported within a year by category, e.g., "wrong site surgery," a listing of root cause analysis results by event category, and prevention strategies for both hospitals and patients.<sup>35</sup>

*State-led patient safety trainings or other initiatives.* Twelve of the twenty-six States draw from adverse event reports to conduct patient safety training or initiatives. State-led training is typically focused on one specific patient-safety issue. For example, citing high numbers of adverse event reports on patient falls, New Jersey conducted a workshop in 2006 that led to the development of fall reduction programs specific to each participating hospital's needs.<sup>36</sup> Such training can also serve as a forum to allow hospitals to share best practices to improve patient safety. State-led patient safety initiatives also focus on particular patient safety issues to generate broader policy guidance. For example, in response to high numbers of surgical errors, New York convened a panel to develop preoperative surgery protocols to prevent wrong site surgery, wrong procedures, and procedures on the wrong patient. The panel of clinical experts reviewed policies and procedures from a variety of sources and released final protocols in 2001 (which were cited by the Joint Commission as a helpful reference for other States).<sup>37 38</sup>

---

<sup>35</sup> Minnesota Department of Health, "Adverse Events in Minnesota," January 2008. Available online at <http://www.health.state.mn.us/patientsafety/ae/aereport0108.pdf>. Accessed on June 20, 2008.

<sup>36</sup> New Jersey Department of Health and Senior Services, "Falls Collaborative," Patient Safety Reporting Initiative, February 2006: Issue 2, p. 1. Available online at [http://www.state.nj.us/health/ps/documents/feb2006\\_newsletter.pdf](http://www.state.nj.us/health/ps/documents/feb2006_newsletter.pdf). Accessed on June 20, 2008.

<sup>37</sup> Joint Commission, "Sentinel Event Alert: A Follow-up Review of Wrong Site Surgery," Issue 24, December 5, 2001. Available online at [http://www.jointcommission.org/JointCommission/Templates/GeneralInformation.aspx?NRMODE=Published&NRNODEGUID=%7bA4210FD1-1836-4D34-A068-76F7FBCBA014%7d&NRORIGINALURL=%2fSentinelEvents%2fSentinelEventAlert%2fse\\_a\\_24%2ehtm&NRCACHEHINT=Guest#2](http://www.jointcommission.org/JointCommission/Templates/GeneralInformation.aspx?NRMODE=Published&NRNODEGUID=%7bA4210FD1-1836-4D34-A068-76F7FBCBA014%7d&NRORIGINALURL=%2fSentinelEvents%2fSentinelEventAlert%2fse_a_24%2ehtm&NRCACHEHINT=Guest#2). Accessed on June 20, 2008.

<sup>38</sup> New York State Department of Health, "New York State Health Department Releases Pre-Operative Protocols to Enhance Safe Surgical Care," February 8, 2001. Available online at <http://www.health.state.ny.us/press/releases/2001/preop.htm>. Accessed on June 20, 2008.

*Patient safety bulletins and alerts.* Nine of the twenty-six States draw from reports to produce advisory bulletins or patient safety alerts, which often focus on one patient safety issue and provide clinical direction or describe prevention strategies used by other hospitals. For example, a 2007 issue of Maryland's "Clinical Alert" examines adverse events caused primarily by equipment vendors being present during surgery, a scenario that had been reported by hospitals.<sup>39</sup> Pennsylvania also uses adverse event reports to produce quarterly bulletins that examine a range of patient safety issues and typically include clinical reminders, best practice anecdotes, policy alerts, and reporting guidance.<sup>40</sup>

*Web site postings.* After following up on reported events through desk or onsite audits or investigations, three States post findings on their State Web site that contain details about both the reported event and the affected patient. One State posts summary information for every reported event, including the name of the hospital where the event took place, the date and description of the event, and several details about the affected patient. These details include the patient's gender, age range, medical background information, and the reason for admission. For example, one posting reported that a female in her 30s with a history of traumatic brain injury, who had been admitted for abdominal pain, had eloped from the hospital. Similarly, two other States post the results of some investigations spurred by reported events that contain patient specific details. However, these States do not post findings for every reported event, only those that are likely to cause serious injury or death to the patient. Each of the three States' Web site postings also provide information about the results of investigations, including the results of root cause analyses, corrective actions taken by the hospital, and indications of whether these actions were found to be appropriate by the State.

The public disclosure of adverse event reports and resulting investigations on State Web sites could be used to prevent adverse events and promote learning. However, in some of these postings, we

---

<sup>39</sup> Maryland Department of Health and Mental Hygiene, "Clinical Alert: An Unnecessary Distraction, Vendors in Operating Room," Vol. 4, No. 3, Winter 2007. Available online at <http://dhmh.maryland.gov/ohcg/download/alerts/alert-v4-n3-winter2007.pdf>. Accessed on May 23, 2008.

<sup>40</sup> Pennsylvania Patient Safety Advisory. Available online at <http://www.psa.state.pa.us/psa/cwp/view.asp?a=1293&q=445966&psaNav=1>. Accessed on June 9, 2008.



## F I N D I N G S

noticed a level of detail that could be used to identify the patient. The possibility of compromised patient privacy could be heightened under certain circumstances, such as when an adverse event involves a patient who lives in a smaller community and when media reports about an event contain additional information that can be matched with information contained in a Web site posting.

## C O N C L U S I O N

In the absence of both a national comprehensive mandatory system and Federal guidelines regarding State reporting systems, about half of the States have implemented hospital adverse event reporting systems. These systems appear to be disparate, with each tracking different events; employing different reporting criteria; and requiring differing accompanying information, such as the cause of the event and corrective actions to prevent recurrence. Not surprisingly, a wide range of reported events exist across States. The differences we found make State adverse event reporting systems data unsuitable for use in the aggregate to identify national incidence and trends. To the extent that States adopt common reporting formats, such as those developed by AHRQ for use by Patient Safety Organizations, such differences could diminish over time.

Despite the distinct attributes of each State system, we noted that most States reported using data in similar ways to improve patient safety. For instance, staff from all but three States reported using data to assess individual hospitals' response to adverse events, and to work with hospitals when their responses are found to be inadequate. We also found similarities in States' use of reported information to promote learning, with 18 States using information to communicate with hospitals about Statewide incidence, best practices, and/or to provide early warnings about specific patient safety issues. States may find that opportunities exist to expand their use of reported data by employing the communication methods used by other States.

Finally, although the 26 States require hospitals to report adverse events when they occur, staff from most of these States agreed that events are underreported. Although States have identified several strategies for improvement, they continue to find instances of hospitals' failures to submit reports by comparing hospital reports against administrative data, through the results of onsite audits, or through complaints and referrals. Beyond measures currently being used, States may find it prudent to consider other means to more effectively ensure reporting by hospitals.

---

### AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

We received comments on a draft of this report from AHRQ and CMS. AHRQ and CMS provided positive comments on the draft report.

## C O N C L U S I O N

AHRQ called for greater precision when discussing the differences between NQF's list of Serious Reportable Events (formerly referred to as "never events") and CMS's payment policies for hospital-acquired conditions. Although this report does not examine CMS's payment policies, we will ensure that other OIG reports on this topic make these distinctions clear.

CMS expressed its belief that the report should more clearly describe the impediments facing the Federal Government and CMS in managing data identifying adverse events given the existing fragmented systems. According to CMS, data from State systems are not useful in understanding national issues and trends because of the variability in States' identification of adverse events. We modified the report's conclusion to underscore that data from State adverse event reporting systems are unsuitable for national level analyses.

Because of the variability among State-based systems, CMS indicated that it would be helpful to identify potential solutions, such as amending the Patient Safety Act to make reporting of well-defined adverse events mandatory. CMS also indicated that it would be helpful to identify other partners in reporting system efforts, such as AHRQ and IOM. In planning future work in this area, we will consider the issues addressed in CMS's comments.

Finally, CMS stated that it had recently issued a letter to State Medicaid Directors, which addressed Medicaid payment implications for selected adverse events. CMS explained that the intent of this letter was to offer States an opportunity to tie Medicaid payment to performance through denial of payment for selected adverse events. According to CMS, there are seven pending State Plan Amendments to restrict payment for selected adverse events, and that State systems used to prevent or recoup Medicaid payments could serve as a model for a national system. CMS noted that hospitals already collect data about adverse events and that requiring them to send notice of such reports to State and/or Federal Governments could give regulatory authorities valuable information at minimal additional expense to hospitals.

For the full text of AHRQ and CMS comments, see Appendix F.



## GLOSSARY OF SELECTED TERMS<sup>41</sup>

**Adverse event**—Harm (injury or illness) caused by medical care. Identifying adverse events indicates that the care resulted in an undesirable clinical outcome and that the clinical outcome was not caused by an underlying disease, but does not imply an error, negligence, or poor quality care.

**Corrective action plan**—Policy and procedural actions that hospitals prepare to respond to an adverse event and to prevent recurrence.

**Medical error**—The failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim.

**Near miss**—An event or a situation that did not produce patient harm, but only because of intervening factors, such as patient health or timely intervention. Also known as a “close call.”

**Never event**—An event or a situation that should never occur in a health care setting. The National Quality Forum initially used the term “never events” to describe its list of serious events but began in 2005 to refer to the list as “serious reportable events.”

**Patient safety**—Freedom from accidental or preventable injuries caused by medical care.

**Risk reduction strategies**—Interventions, actions, and strategies designed to reduce the risk of recurrence of the event. Typically part of a corrective action plan.

**Root cause analysis**—A focused review of systems and processes to identify the basic or contributing factors that cause adverse events.

---

<sup>41</sup> Definitions derived from a variety of sources including E. Flink, C. L. Chevalier, A. Ruperto, P. Dameron, F. J. Heigel, R. Leslie, J. Mannion, and R. J. Panzer, “Lessons Learned from the Evolution of Mandatory Adverse Event Reporting Systems,” *Advances in Patient Safety*, 2005; L. T. Kohn, J. M. Corrigan, and M. S. Donaldson, eds., “To Err is Human: Building a Safer Health System,” A Report of the Committee on Quality of Health Care in America, Institute of Medicine, Washington, DC, National Academy Press, 1999; R. M. Wachter, “Understanding Patient Safety,” McGraw-Hill, 2008; and the glossary of the Agency for Healthcare Research and Quality Patient Safety Network available online at <http://www.psnet.ahrq.gov/glossary.aspx>. Accessed on October 10, 2008.

## NATIONAL QUALITY FORUM LIST OF SERIOUS REPORTABLE EVENTS

The National Quality Forum (NQF) List of Serious Reportable Events is grouped into six categories: surgical, product or device, patient protection, care management, environmental, and criminal events. “Serious” describes an event resulting in death, loss of a body part, disability, or loss of bodily function lasting more than seven days or still present at time of discharge.<sup>42</sup>

**Table 1: The National Quality Forum List of Serious Reportable Events**

<b>Surgical Events</b>	
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 foreign object in a patient after surgery or procedure
E.	Intraoperative or immediately postoperative death
<b>Product or Device Events</b>	
A.	Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the health care facility
B.	Patient death or serious disability associated with 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 health care facility
<b>Patient Protection Events</b>	
A.	Infant discharged to the wrong person
B.	Patient death or serious disability associated with patient elopement
C.	Patient suicide, or attempted suicide, resulting in serious disability while being cared for in a health care facility
<b>Care Management Events</b>	
A.	Patient death or serious disability associated with a medication error
B.	Patient death or serious disability associated with a hemolytic reaction due to 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 health care facility
D.	Patient death or serious disability associated with hypoglycemia, the onset of which occurs while patient is cared for in a health care facility
E.	Death or serious disability associated with failure to identify and treat hyperbilirubinemia in neonates
F.	Stage III or IV pressure ulcers acquired after admission to a health care facility
G.	Patient death or serious disability due to spinal manipulative therapy
H.	Artificial insemination with the wrong donor sperm or wrong egg
<b>Environmental Events</b>	
A.	Patient death or serious disability associated with an electric shock while being cared for in a health care 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 health care facility
D.	Patient death or serious disability associated with fall while cared for in a health care facility
E.	Patient death or serious disability associated with the use of restraints or bedrails while being cared for in a health care facility
<b>Criminal Events</b>	
A.	Care provided by someone impersonating a health care provider
B.	Abduction of a patient of any age
C.	Sexual assault on a patient within or on the grounds of a health care facility
D.	Death or significant injury resulting from a physical assault that occurs within or on the grounds of the facility

<sup>42</sup> NQF, “Serious Reportable Events in Healthcare, 2006 Update,” 2007, pp. vi and 6.

## TAX RELIEF AND HEALTH CARE ACT OF 2006

P. L. No. 109-432

### **DIVISION B – MEDICARE AND OTHER HEALTH PROVISIONS**

#### **TITLE II—MEDICARE BENEFICIARY PROTECTIONS**

##### **SEC 203 OIG STUDY OF NEVER EVENTS**

(a) Study.—

(1) In general.—The Inspector General in the Department of Health and Human Services shall conduct a study on—

(A) incidences of never events for Medicare beneficiaries, including types of such events and payments by any party for such events;

(B) the extent to which the Medicare program paid, denied payment, or recouped payment for services furnished in connection with such events and the extent to which beneficiaries paid for such services; and

(C) the administrative processes of the Centers for Medicare & Medicaid Services to detect such events and to deny or recoup payments for services furnished in connection with such an event.

(2) Conduct of study.—In conducting the study under paragraph (1), the Inspector General—

(A) shall audit a representative sample of claims and medical records of Medicare beneficiaries to identify never events and any payment (or recouping of payment) for services furnished in connection with such events;

(B) may request access to such claims and records from any Medicare contractor; and

(C) shall not release individually identifiable information or facility-specific information.

(b) Report.—Not later than 2 years after the date of the enactment of this Act, the Inspector General shall submit a report to Congress on the study conducted under this section. Such report shall include recommendations for such legislation and administrative action, such as a noncoverage policy or denial of payments, as the Inspector General determines appropriate, including—

(1) recommendations on processes to identify never events and to deny or recoup payments for services furnished in connection with such events; and

(2) a recommendation on a potential process (or processes) for public disclosure of never events which—

(A) will ensure protection of patient privacy; and

(B) will permit the use of the disclosed information for a root cause analysis to inform the public and the medical community about safety issues involved.

(c) Funding.— Out of any funds in the Treasury not otherwise appropriated, there are appropriated to the Inspector General of the Department of Health and Human Services \$3,000,000 to carry out this section, to be available until January 1, 2010.

(d) Never Events Defined.—For purposes of this section, the term “never event” means an event that is listed and endorsed as a serious reportable event by the National Quality Forum as of November 16, 2006.

## STATES WITH ADVERSE EVENT REPORTING SYSTEMS

**Table 2: Twenty-Six Reporting Systems and Number of Adverse Events Reported in 2006 by State**

State	Year System Began	Reportable Event List	Agency Receiving Reports	Number of Adverse Events Reported in 2006
California	2007	Modified NQF*	Department of Public Health, Office of Licensing and Certification	N/A
Colorado	1988	State determined	Department of Public Health and Environment, Health Facilities and Emergency Medical Services Division	391
Connecticut	2002	Modified NQF	Department of Public Health	240
District of Columbia	2007	Modified NQF	Health Regulation and Licensing Administration	N/A
Florida	1998	State determined	Agency for Healthcare Administration, Florida Center for Policy Analysis	716
Georgia	2003	State determined	Department of Human Resources, Office of Regulatory Services	136
Indiana	2006	NQF	Department of Health	79
Kansas	1988	State determined	Department of Health and Environment	22
Maine	2004	State determined	Department of Health and Human Services, Division of Licensing and Regulatory Services	24
Maryland	2004	State determined	Department of Health and Mental Hygiene, Office of Health Care Quality	174
Massachusetts	1980	State determined	Department of Public Health, Division of Health Care Quality	782
Minnesota	2003	NQF	Department of Health	140
Nevada	2005	State determined	State Health Division, Bureau of Health Planning and Statistics	188
New Jersey	2005	Modified NQF	Department of Health and Senior Services	450
New York	1985	State determined	Department of Health, Office of Health Systems Management	16,442
Ohio	2007	State determined	Department of Health, Office of Health Systems Management	N/A
Oregon	2006	Modified NQF	Patient Safety Commission	N/A <sup>a</sup>
Pennsylvania	2004	State determined	Patient Safety Authority	6,232 <sup>b</sup>
Rhode Island	1994	State determined	Department of Health, Division of Environmental and Health Services Regulation, Office of Facilities Regulation	271
South Carolina	1976	State determined	Department of Health and Environmental Control	N/A
South Dakota	1987	State determined	Department of Health	6
Tennessee	2000	State determined	Department of Health, Division of Healthcare Facilities	3,585
Utah	2001	Modified NQF	Department of Health	N/A
Vermont	2007	NQF	Department of Health	N/A
Washington	2006	Modified NQF	Department of Health	N/A <sup>a</sup>
Wyoming	2005	Modified NQF	Department of Health, Preventive Health and Safety Division	13

Source: Office of Inspector General analysis of States' legislation, statutes and regulations, forms, and 26 interviews, 2008.

\* NQF is the National Quality Forum List of Serious Reportable Events.

<sup>a</sup> = States began collecting data in mid-2006 and, therefore, could not report complete data for the year.

<sup>b</sup> = This range does not include the number of near misses reported to Pennsylvania in 2006.

N/A = Not available; States did not provide the number of adverse event reports for 2006.


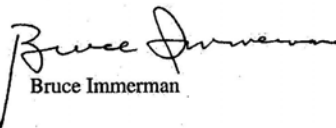


## STATE-BY-STATE REPORTING REQUIREMENTS FOR HOSPITAL ADVERSE EVENTS

Table 3: Selected Information Submitted by Hospitals to 26 States' Adverse Event Reporting Systems																					
State	Adverse Event Report Information							Patient Information					Root Cause Analysis			Corrective Action Plan and Risk Reduction Strategies					
	Hospital	Type of Event	Location or Service Area Within the Hospital	Date of Event	Date of Discovery	Detailed Description	Summary Description	Impact of the Event on the Patient	Patient Age or Date of Birth	Patient Diagnosis	Patient Medical Record Number	Patient Billing Number	Root Cause Analysis Team (Name or Title)	Identified Cause	Contributing Factors	Risk Reduction Strategies	Entities Responsible for Implementation	Timeline for Implementation	Effectiveness Measures	Monitoring Schedule	Entities Responsible To Monitor Effectiveness
California	•	•	•	•		•			•												
Colorado	•	•	•	•			•									•					
Connecticut	•	•	•	•	•	•			•	•		•				•	•	•	•		•
District of Columbia	•	•	•	•	•	•	•	•	•	•						•	•	•			•
Florida	•	•	•	•		•		•	•	•	•			•	•	•			•		
Georgia	•	•		•	•		•		•	•	•					•					
Indiana	•	•																			
Kansas	•	•	•	•			•									•					
Maine	•	•	•	•	•	•			•	•					•	•	•	•	•	•	•
Maryland	•	•	•	•			•		•	•			•	•	•	•	•	•	•	•	•
Massachusetts	•	•	•	•		•	•	•	•	•			•	•	•	•					
Minnesota	•	•	•	•	•	•		•	•	•				•	•	•	•	•	•		
New Jersey	•	•	•	•	•		•	•	•	•	•	•		•	•	•	•	•	•	•	•
Nevada	•	•	•	•			•	•	•						•	•					
New York	•	•	•	•		•	•		•	•	•		•	•	•	•	•	•	•		•
Ohio	•	•																			
Oregon	•	•	•	•	•	•	•	•	•	•					•	•		•			
Pennsylvania	•	•	•	•		•		•	•						•	•					
Rhode Island	•	•		•			•	•		•	•			•	•	•					
South Carolina	•	•	•	•			•		•					•							
South Dakota	•	•	•	•		•	•	•	•	•			•	•	•						
Tennessee	•	•		•			•		•	•			•	•	•	•	•	•	•		•
Utah	•	•	•	•	•		•	•	•	•					•	•					
Vermont	•	•	•	•	•		•		•	•			•	•	•	•	•	•	•		•
Washington	•	•	•	•	•		•						•	•	•	•	•	•	•	•	•
Wyoming	•	•		•			•	•													
<b>Total States</b>	<b>26</b>	<b>26</b>	<b>20</b>	<b>24</b>	<b>10</b>	<b>11</b>	<b>18</b>	<b>12</b>	<b>19</b>	<b>16</b>	<b>5</b>	<b>2</b>	<b>7</b>	<b>12</b>	<b>16</b>	<b>20</b>	<b>10</b>	<b>11</b>	<b>10</b>	<b>4</b>	<b>9</b>

Source: Office of Inspector General analysis of States' legislation, forms, guidance documents, and 26 interviews, 2008.

## AGENCY COMMENTS

	<p>DEPARTMENT OF HEALTH &amp; HUMAN SERVICES</p>	<p>Agency for Healthcare Research and Quality</p>
		<p>540 Gaither Road Rockville MD 20850 www.ahrq.gov</p>
<p><b>NOV 26 2008</b></p>		
<p>TO:</p>	<p>Director, Division of Office of Evaluation and Program Support Office of Evaluation and Inspections, OIG</p>	
<p>FROM:</p>	<p>Deputy Ethics Counselor</p>	
<p>SUBJECT:</p>	<p>OEI-06-08-00471 Adverse Events in Hospitals: State Reporting Systems</p>	
<p>On behalf of the Agency's Deputy Director, I want to thank your office for the opportunity to review and comment on the Office of Inspector General's (OIG) draft report entitled, Adverse Events in Hospitals: State Reporting Systems (OEI-06-08-00471). Our comments are as follows:</p>		
<ul style="list-style-type: none"> <li>• AHRQ believes that this document is an excellent report.</li> <li>• The OIG should accurately reflect PL 109-42 in its confusion of NQF never events and the Center of Medicare and Medicaid Services (CMS) no pay policy. Specifically, the CMS no pay policy overlaps with but does not track the never events. Consideration should be given to clarifying this point in the report, albeit tactfully.</li> <li>• The expanded information is fine and we like the change to the Conclusions section.</li> </ul>		
<p>Please feel free to contact me should you have any questions concerning this matter.</p>		
 <p>Bruce Immerman</p>		

## Agency comments (continued)



DEPARTMENT OF HEALTH &amp; HUMAN SERVICES

Centers for Medicare &amp; Medicaid Services

*Administrator*

Washington, DC 20201

DATE:

DEC 4 2008

TO:

Daniel R. Levinson  
Inspector General

FROM:

Kerry Weems  
Acting Administrator

SUBJECT:

Office of Inspector General (OIG) Draft Report: "Adverse Events In  
Hospitals: State Reporting Systems" (OEI-06-07-00471)

Thank you for the opportunity to review your draft report, "Adverse Events in Hospitals: State Reporting Systems." The OIG has requested extensive technical assistance from the Centers for Medicare & Medicaid Services (CMS) on this and the series of related reports on adverse events. We welcome this opportunity and believe that it will enhance the usefulness of the reports in informing policy makers.

This OIG Report is the first in a series that are required of the OIG under the Tax Relief and Health Care Act of 2006 (TRHCA). TRHCA requires the OIG to report to Congress regarding harm caused to Medicare beneficiaries and TRHCA specifically mandates the OIG to determine the incidence of never events among Medicare beneficiaries. TRHCA also requires that OIG make recommendations regarding processes to identify and recoup payments made for such events by beneficiaries and CMS. This particular report focuses on systems created by individual States for the reporting of adverse events within hospitals.

While Federal law requires some mandatory reporting for drugs, devices, vaccines, restraints, and communicable diseases and voluntary reporting of adverse events under the Patient Safety and Quality Improvement Act of 2005 (PSQIA), most of the required reporting of adverse events occurs under State reporting laws in the 26 States that have them. The report identifies that the systems reviewed varied in terms of what events were reported, criteria used for selection, and the type of information reported.

The report also notes the concern regarding under-reporting of adverse events and details some efforts to address under-reporting. It is also noted that States utilize the information gleaned from these systems in different ways. Of the 26 systems reviewed, 23 States reported using data to hold individual hospitals accountable and 18 States indicated using the data to promote learning and to prevent future adverse events.

## Agency comments (continued)

Page 2- Daniel R. Levinson

This report provides a detailed description of the basic infrastructure that exists within States to track and monitor adverse events in hospitals. However, we believe that the report should more clearly describe the serious impediments facing the Federal Government and CMS regarding the management of data identifying "Never Events" given the existing fragmented systems. As your report indicates, the present State-based system produces information which differs in each State and is not useful in understanding national issues and trends because of the variability in State identification of adverse events. It would be helpful to identify potential solutions such as amending the PSQIA to make reporting of well-defined adverse events to Patient Safety Organizations mandatory, as well as identifying potential partners, such as the Agency for Healthcare Research and Quality and the Institute of Medicine, to assist CMS in constructing a national reporting system.

The CMS, on July 31, 2008, issued a State Medicaid Director Letter (#08-004) which addressed the Medicaid payment implications to the States of "Never Events" and Medicare Hospital-Acquired conditions, which are defined subsets of the category of adverse events. That letter was intended to offer States an opportunity to use this data to tie Medicaid payment to performance through denial of payment for these selected subsets of adverse events. There are currently seven pending State Plan Amendments restricting Medicaid payment for such events. The State systems used to prevent or recoup Medicaid payments could serve as models for a national system. It should be noted that all hospitals already collect such data and do trending and root cause analysis of it for their own legal, accreditation, and quality purposes. Requiring notice of such reports to State and/or national government creates only minimal additional expense to provider hospitals and does much to give regulatory authorities solid information from which sound policy decisions can be made.

The CMS finds the OIG report to be informative and useful. The comments provided above simply underscore the need to fully describe not only the existing systems, but barriers within and between those systems that may hamper the development of processes necessary to fully implement CMS quality and fiscal systems to document never events in the Medicare program. We look forward to working with the OIG on the remaining reports in this series.



## A C K N O W L E D G M E N T S

This report was prepared under the direction of Kevin K. Golladay, Regional Inspector General for Evaluation and Inspections in the Dallas regional office, and A. Blaine Collins, Deputy Regional Inspector General for Evaluation and Inspections.

Ruth Ann Dorrill and Christi Macrina served as team leaders for this study. Deborah Cosimo served as the lead analyst. Other principal Office of Evaluation and Inspections staff from the Dallas regional office who contributed to this report include Anthony Guerrero-Soto; central office staff who contributed to this report include Rita Wurm.