Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

ADVERSE EVENTS IN HOSPITALS: MEDICARE'S RESPONSES TO ALLEGED SERIOUS EVENTS

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EXECUTIVE SUMMARY

OBJECTIVES

1. To assess the responses of State survey and certification agencies and the Centers for Medicare & Medicaid Services (CMS) to complaints that allege serious adverse events.
2. To describe hospital responses to complaints that allege serious adverse events.

BACKGROUND

The term "adverse event" describes harm to a patient as a result of medical care. In response to the Tax Relief and Health Care Act of 2006, the Office of Inspector General (OIG) released a series of reports regarding adverse events. In that work, OIG estimated that over one-quarter of hospitalized Medicare beneficiaries were harmed during their hospital stays in October 2008. This report examines Medicare's responses to alleged serious adverse events. These responses represent important patient safety opportunities, yet little attention has been paid to their role in improving patient safety.

Hospitals must meet the Medicare Conditions of Participation (CoP) to participate in Medicare. On behalf of Medicare, State survey and certification agencies (State agencies) investigate complaints alleging hospital noncompliance with CoPs. Immediate jeopardy (IJ) complaints are the most serious and may allege adverse events. Also, hospitals often conduct their own investigations of adverse events independently of State agencies.

Because no national database of adverse events exists, this report uses a random sample of IJ complaints to identify alleged serious adverse events to which Medicare responded. To review the complaints, we used data from CMS, State agencies, hospital accreditors, and the hospitals associated with the sample.

FINDINGS

State agency responses to complaints alleging serious adverse events were generally timely and often found problems. For 75 of the 95 alleged events in our sample, State agencies conducted complaint surveys at hospitals within 2 days, as required. For 53 of the 95 alleged events in our sample, State agencies cited hospitals for Federal deficiencies while investigating the events. Complaints in our sample

often included limited information for State agencies to determine the priority and timing of their responses. For half of the complaint surveys, CMS set the scope of the survey to address multiple CoPs.

State agencies and CMS missed opportunities to incorporate patient safety principles in their responses. For complaint surveys at accredited hospitals, CMS directed State agencies to assess the CoP on performance improvement in only 33 of the 78 surveys and the CoP on the hospital's governing body in only 12. State agencies performed little longer term monitoring to verify that hospitals' corrective actions resulted in sustained improvements. After completing complaint surveys, State agencies required the hospitals to submit performance data for only 1 of the 19 complaints that required corrective action plans. State agencies did not always disclose the nature of complaints to hospitals, thus limiting hospitals' ability to learn from alleged events.

CMS informed the Joint Commission of few complaints, impeding the Joint Commission's oversight of its accredited hospitals. Contrary to CMS's policy of notifying accreditors of all complaints against the hospitals they accredit, CMS regional offices notified accreditors of only 28 of the 88 sampled complaints against accredited hospitals.

Hospitals investigated most complaints in our sample, finding State agency responses valuable but disruptive. Hospitals reported being aware of 87 of the complaints in our sample and investigated 75 of them, beginning two-thirds of their investigations before State agencies arrived to conduct their onsite complaint surveys. Hospitals' investigations were multidisciplinary and often involved hospital leadership. Hospitals found that State agency responses lent urgency but also disrupted their own responses.

Hospital corrective actions resulted largely in training coupled with policy and process changes. Hospitals took 1 or more corrective actions in response to each of 64 complaints. Hospitals' responses to 58 of these complaints included training staff as a corrective action, and the responses to 42 complaints included policy or process changes. Hospitals took disciplinary actions, such as firing staff, in one-third of complaints resulting in corrective actions. For just under one-third of complaints resulting in corrective actions, the corrective actions included changes to devices, software, or workspaces designed to prevent adverse events by forcing staff into a course of action, rather than relying on their memory or adherence to procedures.

RECOMMENDATIONS

Require that all Immediate Jeopardy complaint surveys evaluate compliance with the Condition of Participation on quality assurance and performance improvement. CMS identifies this CoP as central to patient safety and to a hospital's ability to identify, track, analyze, and prevent adverse events. Furthermore, CMS should consider limiting the initial scope of the IJ complaint survey to this CoP and the allegation itself.

Ensure that State agencies monitor hospitals' corrective actions for sustained improvements. Defining and monitoring outcome measures are important elements of quality improvement and, thereby, patient safety. After hospitals have implemented corrective actions, CMS should require State agencies to monitor the results—for example, by collecting and analyzing hospitals' performance data or by revisiting hospitals. State agencies should take action when hospitals' corrective actions fail to yield effective and sustained improvements.

Amend guidance on disclosure to explain the nature of complaints to hospitals. Improving disclosure to hospitals would provide them with opportunities to analyze and learn from alleged adverse events.

Improve communication with accreditors. CMS should ensure that its regional offices follow its policy on notifying accreditors of complaints against accredited hospitals. CMS could clarify its instructions and educate regional office staff on how and when to notify accreditors of complaints against accredited hospitals.

AGENCY COMMENTS

CMS concurred with our recommendations and described how it will increase the prominence of the CoP on quality assessment and performance improvement in complaint surveys, enhance monitoring of the efficacy of corrective actions, and improve communication with hospitals at the outset of complaint surveys. CMS also stated that it will work with its regional offices to improve their compliance with its policy to notify accreditation organizations of complaints against accredited hospitals.

We made minor changes to the report based on technical comments from CMS.

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BACKGROUND

Statutory Mandate and Office of Inspector General Response

The Tax Relief and Health Care Act of 2006 requires that the Office of Inspector General (OIG) report to Congress regarding the incidence of "never events" among Medicare beneficiaries, among other topics.[1] (For the relevant text of this Act, see Appendix A.) To meet the requirements of this Act, OIG released a series of reports beginning in 2008 and will publish additional reports based on ongoing work. (See Appendix B for a list of OIG reports in the series.) The published reports assessed State adverse event reporting systems, public disclosure of adverse events, and the national incidence of adverse events among the Medicare population.

This report supplements that body of work by assessing the responses of State survey and certification agencies (State agencies) and CMS to complaints that allege serious adverse events. It also describes the hospitals' responses, which helps in understanding the backdrop against which the former responds. These responses represent important patient safety opportunities, yet little attention has been paid to their role in improving patient safety.

Adverse Events in Hospitals

The health care community now uses the term "adverse event" more commonly than "never event." An adverse event is generally defined as patient harm as a result of medical care or in a hospital. Although an adverse event indicates that the care resulted in an undesirable clinical outcome and may involve errors, adverse events do not always involve errors, negligence, or poor quality of care and are not always preventable.[2] OIG estimated that in October 2008, 13.5 percent of

[1] Tax Relief and Health Care Act of 2006, P.L. 109-432 § 203.

[2] R.M. Wachter, *Understanding Patient Safety*, McGraw-Hill, 2008.

hospitalized Medicare beneficiaries experienced an adverse event during their hospital stays. Those events resulted in a prolonged hospital stay, permanent harm, life-sustaining intervention, or death. Furthermore, OIG's analysis estimated that an additional 13.5 percent of beneficiaries experienced adverse events that resulted in temporary harm, such as prolonged vomiting or hypoglycemia.[3]

The Institute of Medicine (IOM) is often credited with first drawing attention to adverse events in hospitals.[4] More recently, many organizations and payers have further defined the harm associated with adverse events or developed payment policies related to them. For example, the National Quality Forum (NQF) maintains a list of events associated primarily with patient death or serious disability that are both egregious and preventable.[5] (See Appendix C for the list of NQF-defined serious reportable events.) In addition, on October 1, 2008, CMS began denying hospitals higher Medicare payments for care associated with certain hospital-acquired conditions (HACs).[6] Examples of HACs include catheter-associated urinary tract infections and patient injuries because of falls.[7] (See Appendix D for the complete list of CMS-defined HACs.) In January 2009, CMS published three National Coverage Determinations denying payment for three surgery-related adverse events: wrong site, wrong patient, and wrong procedure.[8, 9, 10]

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[3] OIG, *Adverse Events in Hospitals: National Incidence Among Medicare Beneficiaries*, OEI-06-09-00090, November 2010.

[4] IOM, *To Err is Human: Building a Safer Health System*, 1999.

[5] NQF, *Serious Reportable Events in Healthcare 2006 Update.* Accessed at http://www.qualityforum.org on December 13, 2010.

[6] *Fiscal Year (FY) 2009 Hospital Inpatient Prospective Payment System Final Rule*, 73 Fed. Reg. 48434, 48471-48472 (August 19, 2008); CMS, CMS Manual System, Change Request 6189 (Oct. 3, 2008).

[7] The Deficit Reduction Act of 2005, P.L. 109-171 § 5001(c)(1), required HACs to meet the following criteria: conditions that are high cost, high volume, or both; conditions that, when present as a secondary diagnosis, result in a higher payment; conditions that could be reasonably prevented by using readily available evidenced-based guidelines; and conditions that are identifiable based on one or more unique diagnosis codes. Social Security Act, § 1886(d)(4)(D)(iv), 42 U.S.C. § 1395ww(d)(4)(D).

[8] CMS, "Decision Memo for Surgery on the Wrong Body Part," January 15, 2009. Accessed at http://www.cms.hhs.gov on December 8, 2010.

[9] CMS, "Decision Memo for Surgery on the Wrong Patient," January 15, 2009. Accessed at http://www.cms.hhs.gov on December 8, 2010.

[10] CMS, "Decision Memo for Wrong Surgery Performed on a Patient," January 15, 2009. Accessed at http://www.cms.hhs.gov on December 8, 2010.

Adverse events can be defined more broadly than NQF has done in its list of serious reportable events or than CMS has done with its list of HACs and nonpayment policies. For example, the event could result in harm that is psychological or that stems from abuse or neglect. CMS uses these broader definitions in its evaluation of harm to Medicare beneficiaries.[11]

Patient Safety

Since IOM's seminal work, the health care community has widely adopted the goal of improving patient safety. Experts point to the importance of evidence-based medicine and quality improvement activities to improve patient safety.[12] Such activities generally emphasize principles such as learning from adverse events through reporting, analysis, and measurement. Furthermore, experts cite the importance of the commitment by a hospital's leadership and staff to creating a culture of safety and achieving improved quality.[13]

Preventing, identifying, and responding to adverse events are typically among the goals of patient safety efforts. However, identifying adverse events is challenging. Methods to identify adverse events—such as medical record reviews, examination of hospital incident reporting systems, patient interviews, and billing data analysis—have strengths and limitations and can also be resource intensive.[14] Complaints about hospitals represent another potential way to identify adverse events.

Medicare's Quality Oversight of Hospitals

Medicare's quality oversight of hospitals is based on the Medicare Conditions of Participation (CoP).[15] CoPs are minimal health and safety requirements that hospitals must meet to be eligible for Medicare participation.[16] They cover topics ranging from the credentialing and

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[11] CMS, *State Operations Manual (SOM),* Pub. 100-07, Appendix Q. Accessed at http://www.cms.gov on September 17, 2010.

[12] Donald M. Berwick, "The Science of Improvement," *Journal of the American Medical Association (JAMA)*, Vol. 299, No. 10, March 2008, pp. 1182-1184; Lucian L. Leape, Donald M. Berwick, and David W. Bates, "What Practices Will Most Improve Safety? Evidence-Based Medicine Meets Patient Safety," *JAMA*, Vol. 288, No. 10, July 2002, pp. 501-507.

[13] James P. Bagian, "Patient Safety: What Is Really at Issue?", *Frontiers of Health Services Management*, Vol. 22, No. 1, Fall 2005, pp. 3-16.

[14] OIG, *Adverse Events in Hospitals: Methods for Identifying Events*, OEI-06-08-00221, March 2010.

[15] 42 CFR pt. 482.

[16] Social Security Act, § 1861(e), 42 U.S.C. § 1395x(e); 42 CFR § 488.3(a)(2).

privileging of physicians to the hospital's governing body and management. (See Appendix E for the current list of 23 CoPs.) Each CoP includes related standards that hospitals must meet.[17]

Patient safety is encompassed in the CoP on quality assessment and performance improvement (QAPI). The QAPI CoP requires hospitals to maintain effective quality assurance and performance improvement systems that emphasize feedback and learning.[18] It also places responsibility for QAPI on the hospitals' governing bodies. Likewise, the CoP on the hospital's governing body further states the governing body's accountability for the entire institution.[19]

The Department of Health and Human Services (HHS) and CMS consider the principles incorporated in these CoPs to be critical to promoting patient safety. HHS recently launched the Partnership for Patients, an initiative designed to make health care delivery safer, more reliable, and less costly. Among other things, this initiative emphasizes the importance of governing bodies in developing and maintaining a culture of safety at hospitals.[20] In its comments on OIG's report on the national incidence of adverse events among the Medicare population, CMS stressed the importance of these CoPs to patient safety.[21]

Hospitals may choose accreditation or demonstrate to CMS that they meet the CoPs; over 90 percent opt for accreditation.[22, 23] Pursuant to the Social Security Act, hospitals accredited by certain national accreditors are deemed to meet the CoPs; CMS refers to them as hospitals with deemed status.[24, 25] Hospitals that do not opt for accreditation can demonstrate to CMS that they meet the CoPs through

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[17] *SOM*, ch. 1, § 1016. Accessed at http://www.cms.gov on March 18, 2011.

[18] 42 CFR § 482.21.

[19] 42 CFR § 482.12.

[20] HHS, *Partnership for Patients*. Accessed at http://www.healthcare.gov on April 28, 2011.

[21] OIG, *Adverse Events in Hospitals: National Incidence Among Medicare Beneficiaries*, OEI-06-09-00090, November 2010, pp. 71-72.

[22] Social Security Act, § 1864(a), 42 U.S.C. § 1395aa(a); 42 CFR § 488.10(a)(1).

[23] Social Security Act, § 1865, 42 U.S.C. § 1395bb; 42 CFR § 488.5(a).

[24] Ibid.

[25] Three organizations accredit hospitals for participation in Medicare: the Joint Commission, the American Osteopathic Association, and Det Norske Veritas Healthcare. The Joint Commission accredits the majority of accredited hospitals.

a survey process by a State survey and certification agency (State agency).[26]

The accreditation process and the State agency process rely on periodic onsite inspections—called surveys—of hospitals. Generally, accreditors or State agencies conduct surveys to add hospitals to Medicare, reevaluate hospitals in the program, and respond to complaints and adverse events.

State Agency Responses to Complaints

The Social Security Act requires the Secretary to enter into agreements with State agencies to investigate allegations that hospitals have not complied with Federal requirements.[27] Because State agencies are responsible for ensuring that participating providers of health care services continually meet Federal requirements, CMS requires that the agencies promptly review complaints and reports of incidents, regardless of providers' accreditation status.[28]

CMS considers an allegation to be "an assertion of improper care or treatment that could result in the citation of a Federal deficiency."[29] (A Federal deficiency means that the hospital is not in full compliance with one or more of the CoPs.) Such allegations may involve adverse events. State agencies learn of allegations through their complaint processes. The complaint process, therefore, represents a key part of CMS's patient safety system because it is a potential resource for identifying and responding to adverse events.

State agencies may receive self-reported allegations from hospitals, or they may receive allegations from patients or others in the form of complaints. They may also identify allegations through media reports. For the purposes of this study, we will refer to all allegations as complaints, regardless of their source.

The quality and completeness of information provided by a complainant plays an important role in the State agency's response. State agency staff and CMS regional office staff rely on the details in the complaints to determine the priority and scope of their responses. For example, upon receiving a complaint, a State agency assigns an investigative

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[26] Social Security Act, § 1864(a), 42 U.S.C. § 1395aa(a); 42 CFR § 488.10(a)(1).

[27] Social Security Act, §§ 1864(a) and (c), 42 U.S.C. §§ 1395aa(a) and (c); 42 CFR §§ 488.10 and 488.11.

[28] *SOM*, ch. 5, § 5000.2. Accessed at http://www.cms.gov on September 17, 2010.

[29] *SOM*, ch. 5, § 5010. Accessed at http://www.cms.gov on September 17, 2010.

priority based on CMS policy.[30] The highest priority is "immediate jeopardy" (IJ), which CMS defines as "a situation in which the provider's noncompliance with one or more requirements of participation has caused, or is likely to cause, serious injury, harm, impairment, or death...."[31] IJ complaints trigger an unannounced onsite survey within 2 working days of receipt of the complaint.[32]

The accreditation status of the hospital involved in the complaint also plays an important role in determining how the State agency responds. If the hospital is accredited, the State agency must forward the complaint to the CMS regional office for approval to conduct a complaint survey.[33] The CMS regional office also identifies the CoPs to be covered in the complaint survey that the State agency will conduct.[34] By identifying the CoPs to be covered, the regional office determines the survey's scope. For nonaccredited hospitals, the State agency determines the scope of the complaint survey and does not need the regional office's approval.[35, 36]

Outcomes of State Agency Responses

During a complaint survey, the State agency may find that a hospital has one or more Federal deficiencies. The actions that the State agency takes are determined by the level of the deficiency (condition or standard) and the hospital's accreditation status.[37] Actions can include requiring the hospital to submit a plan of correction to the State agency. CMS states that, in addition to describing corrective actions, a plan of correction must describe the monitoring procedure that the hospital will

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[30] *SOM*, ch. 5, §§ 5070 and 5075. Accessed at http://www.cms.gov on September 17, 2010.

[31] 42 CFR § 489.3; *SOM*, ch. 5, § 5075.1.

[32] Lower priority complaints may trigger an unannounced onsite survey within 45 days or be investigated by the State agency during its next onsite survey. *SOM*, ch. 5, § 5075.9. Accessed at http://www.cms.gov on September 17, 2010.

[33] Ibid.

[34] *SOM*, ch. 5, § 5100.1. Accessed at http://www.cms.gov on September 17, 2010.

[35] *SOM*, ch. 5, § 5200.1. Accessed at http://www.cms.gov on September 17, 2010.

[36] The State agency also does not require the CMS regional office's approval to conduct a complaint survey of an accredited hospital if the basis of the complaint investigation is potential noncompliance with State requirements. *SOM*, ch. 5, § 5100.1. Accessed at http://www.cms.gov on September 17, 2010.

[37] A condition-level deficiency means that the manner and degree of noncompliance results in failure to substantially comply with the entire CoP. A standard-level deficiency means that noncompliance exists, but the manner and degree of noncompliance does not rise to the level of substantial noncompliance with the entire CoP.

use to ensure that corrective actions are effective and sustained.[38] State agency actions can also include recommending that CMS begin the process to terminate the hospital from participating in Medicare. The State agency may also return to the hospital to conduct a full survey covering all the CoPs.[39]

A nonaccredited hospital must submit a plan of correction for any deficiencies.[40] An accredited hospital must submit a plan of correction only for condition-level deficiencies in certain instances. When the State agency identifies a condition-level deficiency during a complaint survey of an accredited hospital, the CMS regional office removes the hospital's deemed status and the hospital comes under the State agency's jurisdiction. The State agency must then conduct a full survey of the hospital; the results of that survey determine what further steps the State agency will take.

Finally, CMS policy requires CMS's regional offices to notify accreditors of all complaints forwarded by State agencies once they are resolved.[41]

Investigation of Complaints by Accreditors

Accreditors may investigate and respond to complaints against accredited hospitals regardless of whether State agencies have responded. Like State agencies, accreditors review and assign priorities to complaints. Complaints assigned the highest priority may trigger unannounced onsite surveys.

Other Oversight Entities That May Respond to Adverse Events

Entities other than State agencies and accreditors may respond to adverse events. For example, the Centers for Disease Control and Prevention may respond to infectious disease outbreaks. State protection and advocacy agencies may respond to events involving elder abuse. State professional licensure boards may respond when events involve problems with licensed professionals, such as doctors or nurses. Local law enforcement may also respond, especially when the events involve suicides or crimes, such as assaults.

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[38] *SOM*, ch. 2, § 2728B. Accessed at http://www.cms.gov on September 17, 2010.
[39] *SOM*, ch. 5, § 5100.2. Accessed at http://www.cms.gov on September 17, 2010.
[40] *SOM*, ch. 5, § 5200.1. Accessed at http://www.cms.gov on September 17, 2010.
[41] *SOM*, ch. 5, § 5100. Accessed at http://www.cms.gov on September 17, 2010.

Hospital Responses to Adverse Events

Hospitals have a frontline responsibility to respond to adverse events and prevent harm from them. Hospitals can investigate actual or alleged adverse events themselves independently of any external response (such as from the State agency or accreditor). Their investigations can also precede, coincide with, or follow others' responses. Likewise, hospitals can institute their own corrective actions based on their investigations. Hospitals' internal systems for identifying, tracking, and responding to alleged adverse events are critical to promoting patient safety and ensuring that events are responded to appropriately.

Scope

This report assesses State agencies' and CMS's responses to a sample of IJ complaints against hospitals. We use IJ complaints to identify serious adverse events because they are likely to signify situations involving patient harm and because no national database of adverse events exists. This report includes IJ complaints against accredited and nonaccredited hospitals received by State agencies during fiscal year (FY) 2008.

We focus on State agencies because of their role in responding to complaints about accredited and nonaccredited hospitals. We focus on CMS because of its role in directing State agency responses.

Finally, this report also describes hospitals' responses to the IJ complaints. We include this information because we believe it provides important context about what is happening at hospitals when State agencies respond.

METHODOLOGY

This study relied on a review of a simple random sample of IJ complaints against hospitals, which we used as a proxy for serious adverse events. Our other data sources were CMS, State agencies, accreditors, and the hospitals associated with the complaints in our sample. In planning for our review, we conducted structured interviews with staff at CMS, accreditors, and other stakeholders.

Sample Selection

We first obtained a file from CMS's Automated Survey Processing Environment Complaints Tracking System (ACTS) of all IJ complaints

against hospitals that State agencies received, investigated, and closed during FY 2008.[42] After consulting with CMS, we excluded alleged violations of the Emergency Medical Treatment and Active Labor Act (EMTALA) because they were less likely to represent adverse events and because they are monitored differently.[43] After we excluded alleged EMTALA violations, the file of IJ complaints contained 351 complaints. From it, we selected a simple random sample of 100 complaints against 81 hospitals. We removed one complaint from the sample after data from CMS and State agencies showed that two complaints in our sample involved the same alleged event. Our final sample contained 99 complaints against 81 hospitals. (See Appendix F for more information about the complaints in our sample.)

Data Collection

For each of the complaints in our sample, we collected data from CMS, State agencies, hospital accreditors, and hospitals.

Data from CMS and State Agencies

From CMS and State agencies we requested:

- the full Complaint Investigation Report, which contains data and narrative details on the intake of the complaint, the complaint survey, deficiencies cited, and other information;
- Form(s) 2567, Statement of Deficiencies and Plan of Correction, resulting from the survey(s) related to the complaint;
- if applicable, Form 2802, Request for Validation of Accreditation Survey for Hospital, showing the CMS regional office's approval for the State agency to conduct a complaint survey and its approved scope, i.e., the CoPs to be covered;
- if available, other supporting documents, such as correspondence between the oversight entities and hospitals.

We received the Complaint Investigation Report for each of the 99 complaints in our sample. We received one or more Forms 2567 for

[42] We focused on short-term hospitals that generally have an average length of stay of fewer than 25 days and do not include long-term care, rehabilitation, psychiatric, or children's hospitals.

[43] Social Security Act §§ 1866(a)(1)(I), 1866(a)(1)(N), and 1867, 42 U.S.C. §§ 1395cc(a)(1)(I), 1395cc(a)(1)(N), and 1395dd. EMTALA sets forth requirements for medical screening examinations for medical conditions, as well as necessary stabilizing treatment or appropriate transfer of individuals seeking emergency treatment at hospitals.

96 of the complaints in our sample. We received Forms 2802 for 82 of the complaints in our sample against accredited hospitals.[44] We received other supporting documents for 90 of the complaints in our sample.

Data from Hospital Accreditors

We used data from the three hospital accreditors to determine that 92 of the 99 complaints in our sample were against hospitals accredited by the Joint Commission. None of the complaints in our sample were against hospitals accredited by the American Osteopathic Association or Det Norske Veritas Healthcare.

We provided the Joint Commission with a list of complaints along with the dates and brief descriptions of the alleged events underlying the complaints. We asked the Joint Commission for details regarding its awareness of those events and its responses. The Joint Commission provided this information for all of the complaints.

Data from Hospitals

To supplement data from CMS, State agencies, and the Joint Commission, we sent a questionnaire (the hospital questionnaire) to the hospitals associated with the complaints in our sample. If a hospital had more than one complaint in our sample, we sent one questionnaire for each complaint. The hospital questionnaire covered hospitals' responses to the events and the responses by Medicare and other oversight entities. For nonresponders and for responders with questions, we followed up by telephone and email. (We did not disclose any protected health information by email.) Hospitals did not complete questionnaires for three complaints for which they were unaware of the underlying adverse events and three complaints for which staff turnover or change in hospital ownership hampered access to the necessary people and records. We received no response from two hospitals. In total, we obtained completed questionnaires from 74 hospitals, covering 91 of the complaints in our sample.

[44] We received 86 Forms 2802. We removed 4 of these forms from our analysis because they were for complaints against nonaccredited hospitals, leaving forms that covered 82 of the 92 complaints in our sample against accredited hospitals. Of the remaining 10 complaints against accredited hospitals, no Form 2802 was required for 2 complaints because the State agency conducted the complaint survey under State authority and for 1 complaint because the State agency was already onsite at the hospital for a different survey. Seven complaints had no Form 2802 because the State agency failed to get CMS approval, as required. We notified CMS of these complaints.

Finally, to add context to our understanding, we selected a small, purposive subsample of seven complaints against four hospitals to use as case studies of the responses from hospitals and oversight entities. When we selected this subsample, we considered the nature of the events alleged in the complaints and hospital characteristics, including location, size, and mission (e.g., nonprofit, for-profit, academic, or community). Case studies consisted of:

- interviews with hospital staff about the alleged event(s) underlying the sampled complaints,
- a review of the hospital's response to the alleged event(s) and related documentation, and
- a review of the response(s) by State agencies, CMS, and accreditors.

Analysis

We removed 4 complaints from our analysis because they alleged unsafe conditions but did not allege serious adverse events, leaving 95 complaints that alleged serious adverse events. We used data from CMS and State agencies to assess their oversight responses to these complaints. We used data from CMS and the Joint Commission to assess CMS's role in the oversight responses to the complaints lodged against accredited hospitals. We used data from hospitals' completed questionnaires to describe their responses to the complaints. Finally, we supplemented our analysis with data from our seven case studies. (See Table 1 for a summary of our data sources.)

Table 1: Data Sources by Analysis Topic

Analysis Topic	Number of Complaints	Data Source	Number Analyzed
State agency responses for all hospitals	95	Complaint investigation reports	95
		Forms 2567	92
		Supporting documents from complaint files	87
		OIG hospital questionnaire	87
		Case studies	7
CMS role in responses for accredited hospitals	88	Forms 2802	78
		Supporting documents from complaint files	80
		Data from the Joint Commission	88
Hospital responses	87	OIG hospital questionnaire	87
		Case studies	7
Hospital investigations	75	OIG hospital questionnaire	75
		Case studies	7
Hospital corrective actions	64	OIG hospital questionnaire	64
		Case studies	7

Source: OIG analysis of complaint sample.

Limitations

This study used a sample of IJ complaints from ACTS as a way to identify serious adverse events to which State agencies and CMS responded. It relied in part on State agencies' initial prioritization of complaints, which is based on limited and highly variable information from complainants. This study is not intended to be a comprehensive review of State survey agencies' responses to all complaints, nor is it intended to be a review of ACTS. We did not determine whether the adverse events alleged in the complaints took place. We did not independently verify the data reported to us by CMS, State agencies, accreditors, and hospitals. The results of our review cannot be projected to all complaints in ACTS, nor can they be projected to adverse events as a whole.

Standards

This study was conducted in accordance with the *Quality Standards for Inspection and Evaluation* approved by the Council of the Inspectors General on Integrity and Efficiency.

State agency responses to complaints alleging serious adverse events were generally timely and often found problems

State agencies have no control over the quantity or quality of complaints that they receive; nevertheless, they are obligated to take them seriously and respond appropriately. CMS requires that State agencies begin their onsite surveys in response to complaints prioritized as IJ complaints within 2 working days of intake.[45]

State agencies conducted complaint surveys for most of the complaints in our sample within 2 days, as required

Although they typically received IJ complaints weeks after adverse events allegedly occurred, State agencies responded within 2 days, as required, for 75 of the 95 complaints in our sample. They began the remaining surveys from 3 days to as long as 3 months after receiving the complaints. According to CMS staff, CMS clarified its instructions to State agencies on investigative priorities and timelines in 2008, the year that this study examines. This may have led State agencies and CMS regional offices to reprioritize some complaints from a lower investigative priority to the higher IJ priority, resulting in those IJ complaints' being investigated more than 2 days after intake.

State agencies cited hospitals for deficiencies while investigating over half the complaints in our sample

State agency investigations of 53 of the 95 complaints in our sample led to the hospitals' being cited for deficiencies. Investigations into the four most common types of complaints—sexual assault, medication error, physical abuse by hospital staff, and restraint problems—along with suicide, led to the most citations for deficiencies. Together, these five types of events represented half or more of the IJ complaints in our sample that allege adverse events and those with deficiencies. (See Table 2 for deficiencies by type of alleged event.)

[45] *SOM*, ch. 5, § 5075.9. Accessed at http://www.cms.gov on December 13, 2010.

Table 2: Deficiencies by Type of Alleged Event

Type of Alleged Event	Number of Complaints	Number with Deficiencies
Sexual assault	13	8
Medication error	10	4
Physical abuse by staff	10	7
Restraint-related	10	6
Delay in treatment	5	2
Patient elopement/transport issues	5	1
Patient fall	5	3
Suicide	5	4
Neglect	4	1
Pressure ulcers	4	3
Wrong surgery (site or side)	4	2
Foreign object retained	3	2
Misdiagnosis	3	1
Verbal abuse by staff	3	2
Complications during/following childbirth	2	1
Surgical fire	2	2
Inappropriate treatment/handoff	1	1
Infant to wrong parents	1	1
Infectious outbreak	1	0
Medical device-related injury	1	0
Other fire	1	0
Perforation during catheterization	1	1
Transfusion error	1	1
Total	**95**	**53**

Source: OIG analysis of FY 2008 ACTS data.

Complaints in our sample often included limited information for State agencies to determine the priority and timing of their responses

About half of the complaints in our sample included 10 or fewer sentences describing the alleged events. The initial information included in IJ complaints often lacked details such as the pre- and post-event chronology, patient diagnosis, and the location in the hospital where the event occurred. (See Table 3 for details on information contained in complaints.)

Table 3: Initial Information Received by State Agencies for a Sample of Complaints Alleging Serious Adverse Events

Information	Number of Complaints (n = 95)
Type of event	93
Description of harm	87
Date of event	73
Gender of patient	69
Chronology pre-event	47
Initial diagnosis	46
Chronology post-event	39
Location in hospital where event occurred	36
Time of day when event occurred	36
Age of patient	32
Procedure being performed	31
Staff present when event occurred	21

Source: OIG analysis of FY 2008 ACTS data.

For half of the complaint surveys, CMS set the scope of the survey to address multiple Conditions of Participation

As part of CMS's process of approving State agencies' complaint surveys of accredited hospitals, its regional offices direct State agencies to evaluate hospitals' compliance with one or more selected Medicare CoPs. In half of the 78 surveys of accredited hospitals that CMS regional offices approved, the regional offices directed State agencies to evaluate compliance with multiple CoPs—from two to as many as seven. Overall, regional offices directed State agencies to assess compliance with 199 Medicare CoPs during their 78 complaint surveys of accredited hospitals. State agencies' complaint surveys found that hospitals were noncompliant with 45 of these CoPs.

State agencies and CMS missed opportunities to incorporate patient safety principles in their responses

Patient safety principles emphasize quality improvement and learning from adverse events to prevent them from recurring. Medicare's complaint survey process offers ways for State agencies and CMS to incorporate patient safety principles when responding to alleged adverse events in hospitals. These include the opportunity to evaluate hospitals' quality improvement systems and governance mechanisms by assessing how the hospitals addressed alleged events. They also include the opportunity to monitor and evaluate hospitals' corrective actions for sustained improvement and to share information with hospitals, thereby providing an opportunity for hospitals to learn.

CMS directed State agencies to assess the hospitals' performance improvement systems in fewer than half of their complaint surveys at accredited hospitals

In our sample, CMS regional offices directed State agencies to assess hospitals' compliance with the QAPI CoP for 33 of the 78 complaint surveys they approved. CMS established the QAPI CoP to improve patient safety in the hospital setting. [46] Central to this CoP is the idea that the hospital should take responsibility for improving its performance rather than relying on the survey process and the threat of punitive actions. Patient safety experts contend that a high-functioning quality improvement system bolstered by strong hospital leadership enables hospitals to detect adverse events, learn from them, and prevent their recurrence.[47]

CMS rarely directed State agencies to assess governance during their complaint surveys at accredited hospitals

Only 12 of the 78 complaint surveys in our sample included State surveyors' examining the CoP regarding hospitals' governing bodies. This CoP states that a hospital's governing body is legally responsible for the conduct of the hospital as an institution, including its quality improvement system.[48] Hospital leadership and medical staff are accountable to the governing body. The governing body ensures that medical staff members are properly credentialed and competent to

[46] 42 CFR § 482.21.

[47] James P. Bagian, "Patient Safety: What Is Really at Issue?", *Frontiers of Health Services Management,* Vol. 22, No. 1, Fall 2005, pp. 3-16.

[48] 42 CFR § 482.12.

deliver safe and effective care. Experts in patient safety recognize the importance of governing bodies in establishing and maintaining a culture of safety in health care organizations.[49] Executives at case study hospitals stated that their governing bodies play an important role in demanding medical staff accountability for quality care.

State agencies performed little monitoring to verify that hospitals' corrective actions resulted in sustained improvements

State agencies required hospitals to submit plans of correction in response to 19 complaints: 15 against accredited hospitals and 4 against nonaccredited hospitals. However, their oversight of these plans was limited largely to ensuring that acceptable plans were in place. State agencies visited hospitals to verify initial implementation of 17 of the 19 plans. Only one hospital was required to submit data to the State agency showing longer term compliance. In that case, the State agency requested that the hospital submit data monthly, without specifying an endpoint. CMS guidance states that hospitals should institute corrective actions that are effective and sustained.[50] Indeed, patient safety experts stress the importance of hospitals' measuring outcomes associated with process changes.[51]

Even though they were not required to do so, accredited hospitals voluntarily submitted plans of correction for standard-level deficiencies identified during an additional 31 complaint surveys in our sample. None of these plans required hospitals to submit data showing longer term compliance. To verify that hospitals had implemented the changes called for in the plans, State agencies followed up on eight of these voluntary plans with in-person revisits and one by telephone.

State agencies did not always disclose the nature of the complaints to the hospitals, thereby limiting hospitals' ability to learn from alleged events

State agencies can be an important source of information for hospitals. In fact, hospital staff reported in our hospital questionnaire that they first learned about 16 of the complaints in our sample when State agency surveyors arrived at their hospitals. However, hospital staff told us that they never learned the nature of 3 of the complaints, and staff

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[49] NQF, *Hospital Governing Bodies and Quality of Care: A Call to Responsibility*, December 2, 2004.

[50] *SOM*, ch. 2, § 2728B. Accessed at http://www.cms.gov on September 17, 2010.

[51] James P. Bagian, "Patient Safety: What Is Really at Issue?", *Frontiers of Health Services Management,* Vol. 22, No. 1, Fall 2005, pp. 3-16.

had trouble identifying the nature of 27 complaints in our sample without our assistance. Discussions with hospital personnel during our site visits corroborated these concerns; they noted that surveyors sometimes declined to share the nature of the complaints they came to investigate.

Such limited disclosure can prevent hospitals from learning about alleged events, which may be near misses. A near miss is "an event or situation that did not produce patient injury, but only because of chance."[52] Patient safety experts identify near misses as important learning opportunities to prevent recurrence of adverse events.[53]

CMS guidance on complaint procedures does not address whether State surveyors should reveal the nature of the complaints to hospital staff. Rather, CMS guidance on disclosure is limited to protecting the confidentiality of the complainant.[54] This approach to disclosure contrasts with the complaint guidance that CMS provides to nursing home surveyors; CMS advises them to disclose the general nature of the surveys to the nursing homes' administrators while maintaining complainant confidentiality.[55]

CMS informed the Joint Commission of few complaints, impeding the Joint Commission's oversight of its accredited hospitals

CMS's policy calls for its regional offices to—once complaints are resolved—notify accreditors of all complaints against hospitals they accredit.[56] However, CMS notified the Joint Commission of only 28 of the 88 complaints against hospitals it accredited.

Of these 28 complaints, the Joint Commission had records of notification from CMS for only 8 complaints. In total, the Joint Commission reported being aware of 23 complaints because, in addition to the 8 complaints it learned of from CMS, it learned of 15 other complaints from self-reporting hospitals, the media, and others.

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[52] Agency for Healthcare Research and Quality, *Patient Safety Network Glossary*. Accessed at http://www.psnet.ahrq.gov on September 21, 2010.

[53] J.P. Bagian, J. Gosbee, C.Z. Lee, et al., "The Veterans Affairs Root Cause Analysis System in Action," *Journal on Quality Improvement,* Vol. 28, Number 10, Fall 2002, pp. 531-545.

[54] *SOM*, ch. 5, § 5010. Accessed at http://www.cms.gov on September 21, 2010.

[55] *SOM*, ch. 5, § 5300.2. Accessed at http://www.cms.gov on September 17, 2010.

[56] *SOM*, ch. 5, § 5100. Accessed at http://www.cms.gov on September 17, 2010.

Officials at the Joint Commission told us that its being unaware of complaints against its accredited hospitals compromises Medicare's quality oversight system in several ways. First, it impedes the ability of accreditors to respond to complaints that may be related to adverse events or other problems at hospitals they oversee. This in turn can deprive accreditors of important information when reviewing a hospital's performance to determine whether to renew its accreditation. Finally, not sharing the results of the complaint surveys prevents accreditors from using the survey results to improve the consistency between the outcomes of accreditation surveys and those of State agencies. Such consistency is a key measure that CMS uses to assess the performance of accreditors.[57]

See Appendix G for a description of how the Joint Commission responded to the complaints in our sample of which it became aware.

Hospitals investigated most complaints in our sample, finding State agency responses valuable but disruptive

Hospitals reported being aware of 87 of the complaints in our sample, and they investigated 75 of them. We were unable to determine why hospitals did not investigate the remainder.

Two-thirds of hospital investigations started before the State agencies began their complaint surveys

Hospitals began 49 of their 75 investigations before the State agencies arrived to conduct their onsite complaint surveys. Hospitals learned of the majority of alleged events underlying complaints from their staff, such as someone on the care team treating the patient. They responded most swiftly when they learned of events in this way. In these cases, hospitals began half of their investigations within a day of the events and three-quarters within 6 days. In contrast, investigations took longer to start when hospitals learned about the events from an outside entity, such as a State agency. In those cases, hospitals began half of their investigations within 22 days of the events and three-quarters within 78 days.

[57] 42 CFR §§ 488.1 and 488.8.

Hospitals' investigations were multidisciplinary and often involved hospital leadership

Of the teams that hospitals assembled to investigate the 75 complaints, all but 1 included multiple disciplines; 45 teams drew staff from 4 or more disciplines. The disciplines most commonly represented on the investigation teams were nursing, risk management, hospital administration, and quality improvement. Multidisciplinary teams enable hospitals to bring a wide range of expertise and experience to their investigations.

Hospitals reported that medical, executive, or clinical leadership was involved in all investigations. Involvement ranged from planning and conducting investigations to disseminating the results of investigations to hospital staff. Leadership involvement gives prominence to the investigation and demonstrates the hospital's institutional commitment to patient safety.[58]

Hospitals reported that they informed their governing bodies of 59 of the 87 complaints of which they were aware. Furthermore, hospitals reported that their governing bodies participated in their responses to about half of complaints, most commonly by disseminating the investigation results within the hospital.

Hospitals reported that State agency responses lent urgency to the hospitals' responses, promoted awareness of the Medicare CoPs, and increased transparency

Hospitals reported that the presence of State agency surveyors elevated the seriousness of their investigations. They noted that the attention contributed not only to the urgency of any corrective actions stemming from the alleged events, but sometimes also validated the hospitals' responses.

Hospitals also identified the investigations as being valuable because by referencing the CoPs, they promoted awareness of them. The Joint Commission accredited nearly all of the hospitals in our sample, and thus hospitals tended to be more familiar with its standards than with the CoPs.

Furthermore, some hospitals in our sample reported that the State agency complaint surveys helped them reinforce transparency and

[58] James P. Bagian, "Patient Safety: What Is Really at Issue?", *Frontiers of Health Services Management,* Vol. 22, No. 1, Fall 2005, pp. 3-16.

public accountability in dealing with adverse events. For example, during our site visits, hospital leadership often mentioned the important role that the State agency surveys—and their publicly available reports—can have in the hospital's accountability to its patients, its staff, and the public. HHS and others promote public accountability as an important avenue to earning the public's trust.[59, 60] Notably, four hospitals in our sample alerted the media about the alleged adverse events by issuing a press release or holding a press conference.

Hospitals reported that State agency responses sometimes disrupted their investigations

Complaint investigations are inherently disruptive for hospitals. Hospitals cited the State agencies' surveys as disruptive particularly when the State agencies were onsite while hospitals' investigations or corrective actions were still underway. Twenty-four corrective actions were underway when the State agencies began their complaint surveys. For example, one hospital was already making changes aimed at preventing additional adverse events. These changes included updating its policies and retraining staff; the hospital was retraining staff when the State agency arrived. The hospital found that the State agency's actions disrupted the hospital's efforts and led to additional training within a few days of the hospital's initial retraining.

When complaints resulted in multiple responders, the disruption was magnified. With multiple responders, the hospitals sometimes found it confusing to navigate multiple investigations, standards, corrective actions, and timelines. In some cases, the hospitals observed that the magnitude of the responses appeared to be out of proportion to the likelihood of the alleged events' recurring.

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[59] D. M. Dudzinski, P. C. Hébert, M. B. Foglia, et al., "The Disclosure Dilemma—Large-Scale Adverse Events," *New England Journal of Medicine,* Vol. 363, No. 10, September 2010, pp. 978-986.

[60] HHS, Agency for Healthcare Research and Quality, Press Release, *Study Recommends Disclosure of Medical Mistakes That Affect Multiple Patients*, September 1, 2010. Accessed at http://www.ahrq.gov on October 7, 2010.

Hospital corrective actions resulted largely in training coupled with policy and process changes

Hospitals reported taking corrective actions when their complaint investigations found problems and to resolve deficiencies identified by State agencies. They reported taking such actions in 64 of the 87 complaints of which they were aware. (See Table 4 for the corrective actions taken by hospitals.)

Table 4: Hospital Corrective Actions in Response to Internal Investigations and/or State Agency Complaint Surveys

Corrective Action	Number of Complaints (n = 64)	Percent of Complaints
Training staff	58	91%
Policy changes	31	48%
Process changes	31	48%
Disciplinary action	22	34%
Improvements/upgrades to physical plant	19	30%

Source: OIG analysis of hospitals' responses to OIG questionnaire.

Hospitals' responses to 58 of the 64 complaints resulting in corrective actions included training staff as a corrective action, and the responses to 42 complaints included a policy or process change. Hospitals' responses to 39 complaints resulting in corrective actions included both training staff and changing policies or processes. For example, one hospital changed its policy on administering medication through gastronomy tubes and also educated nursing staff on the new policy. Another hospital changed its sedation protocol and educated physicians on the new process.

Hospitals took disciplinary actions less frequently, in one-third of complaints resulting in corrective actions. The most common action was a personnel action, such as firing or suspending staff. Hospitals also reported taking actions regarding privileging (restricting a practitioner's scope of practice) and referring staff to law enforcement, among other actions.

For just under one-third of the complaints resulting in with corrective actions, the corrective actions included changes to devices, software, or workspaces. Such changes are designed to prevent adverse events by forcing staff into a course of action, rather than relying on their memory or adherence to procedures. Examples of such actions taken by hospitals include changing the color of ports on intravenous tubing, changing screens on software for electronic medical records, and

changing the location of equipment and supplies. Because such changes may require the assistance of vendors and manufacturers, they can take more time and be more difficult to implement than policy and process changes, which the hospital can make independently.

Finally, we did not evaluate the appropriateness or effectiveness of hospitals' corrective actions. However, as we noted earlier in this report, CMS conducted little monitoring to verify that hospitals' corrective actions resulted in sustained improvement.

Medicare relies on State agencies and CMS to respond to IJ complaints—many of which allege adverse events—in hospitals. Therefore these responses are an important part of Medicare's patient safety system as well as the regulatory mechanism for ensuring that hospitals comply with the Medicare CoPs. Hospitals' responses are also critical components in ensuring that adverse events are addressed appropriately.

This report identified missed opportunities for State agencies and CMS to incorporate patient safety principles into Medicare's responses to adverse events. Such principles include assessing hospitals' performance improvement systems and governing bodies, monitoring hospitals for sustained improvements, and maximizing opportunities for hospitals to learn from alleged adverse events. CMS also often failed to inform the Joint Commission of complaints about hospitals it accredits, thereby impeding the Joint Commission's oversight.

Our recommendations address these shortcomings, which can undermine the effectiveness of Medicare's responses to IJ complaints. We recommend that CMS:

Require that all Immediate Jeopardy complaint surveys evaluate compliance with the Condition of Participation on quality assurance and performance improvement

The QAPI CoP requires that hospitals have systems in place to identify, track, analyze, and prevent adverse events. Ensuring that hospitals have a robust QAPI system should be a priority. To reinforce the importance of improving the quality and safety of care, CMS should elevate the prominence of the QAPI CoP in complaint surveys. CMS should require its regional offices and the State agencies to ensure that this CoP is placed on surveyors' agendas for all IJ complaint surveys of hospitals.

Furthermore, CMS should consider limiting the initial scope of its complaint surveys to the allegation itself and QAPI CoP. As we have shown, State agencies and CMS often learn of IJ complaints weeks after adverse events allegedly occurred, often after hospitals began their investigations and corrective actions. Also, when State agencies and CMS learn of events, they must determine the scope of complaint surveys with little information beyond basic details. Limiting the initial scope of complaint surveys to the allegation itself and the QAPI CoP would enable surveyors to focus their initial efforts on investigating the

complaints and determining how well the hospitals addressed them. If surveyors find that the hospitals have not adequately addressed the problems or that ongoing noncompliance might exist, they should broaden their complaint surveys to evaluate compliance with the governing-body CoP and other relevant CoPs.

Ensure that State agencies monitor hospitals' corrective actions for sustained improvements

Defining and monitoring outcome measures are important elements of quality improvement and, thereby, patient safety. Accordingly, CMS should require State agencies to monitor hospitals' performance when they require hospitals to develop plans of correction to resolve deficiencies. Such monitoring should occur after hospitals have implemented their plans of correction and might include collecting and analyzing hospital performance data or revisiting hospitals to conduct onsite reviews of performance data. State agencies should take action when hospital corrective actions fail to yield effective and sustained improvements.

Furthermore, as we have shown, State agencies sometimes followed up onsite after accredited hospitals submitted voluntary plans of correction in response to standard-level deficiencies. We recognize that in an environment of limited resources and competing priorities such followup is not easily provided. Thus, CMS could give greater weight to following up and monitoring accredited hospitals with condition-level deficiencies rather than standard-level deficiencies.

Amend guidance on disclosure to explain the nature of complaints to hospitals

CMS should explore ways to improve communication with hospitals during complaint surveys. For complaint surveys of nursing homes, CMS's SOM instructs State agencies to explain the nature of the problems they are investigating during the surveys' entrance conferences while not divulging the exact problems or the identity of the complainants.[61] However, for complaint surveys of hospitals, the SOM instructs State agencies only to conduct an exit conference during which surveyors should review survey findings and any deficiencies found.[62] A culture of learning—for example, learning from adverse events as well

[61] *SOM*, ch. 5, § 5300.2. Accessed at http://www.cms.gov on September 17, 2010.

[62] *SOM*. ch. 5, § 5080.2. Accessed at http://www.cms.gov on September 17, 2010.

as from near misses—is a basic principle of patient safety.[63] To maximize the opportunities for hospitals to learn from the complaints being investigated, the hospitals must know something about the nature of the complaints.

Improve communication with accreditors

CMS should ensure that its regional offices follow its policy on notifying accreditors. CMS should clarify its instructions in the SOM and educate regional office staff on how and when to notify accreditors of complaint surveys against accredited hospitals. This would improve Medicare's system of quality oversight by informing accreditors of potential problems at hospitals they oversee.

Furthermore, CMS should work with the Joint Commission and other accreditors to ensure that their systems for tracking information received from CMS are functioning properly.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

CMS concurred with our recommendations and described steps it will take to increase the prominence of the QAPI CoP in complaint surveys. These steps include issuing guidance on the types of allegations that warrant a review of the QAPI CoP, analyzing data to determine whether CMS can better direct survey attention to QAPI, and developing onsite survey tools to improve assessment of compliance with the QAPI CoP. CMS also described steps it will take to improve monitoring the efficacy of corrective actions. These steps include emphasizing to regional offices and State agencies CMS's revisit policy (i.e., its policy requiring State agencies to return to hospitals to ensure that they are in substantial compliance), reassessing its policy regarding followup on deficiency findings in accredited hospitals, and examining the use of data to improve followup on plans of correction. Finally, CMS stated that it will explore ways to improve communication with hospitals about complaint investigations and work with regional offices to improve compliance with its policy on notifying accreditation organizations of complaints against accredited hospitals.

For the full text of CMS's comments, see Appendix H. We made minor changes to the report based on technical comments from CMS.

[63] IOM, *To Err is Human: Building a Safer Health System*, 1999.

APPENDIX ~ A

Tax Relief and Health Care Act of 2006

P.L. 109-432 § 203

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.

APPENDIX ~ B

Office of Inspector General Series of Reports on Adverse Events

December 2008

Adverse Events in Hospitals: Overview of Key Issues, OEI-06-07-00470

Adverse Events in Hospitals: State Reporting Systems, OEI-06-07-00471

Adverse Events in Hospitals: Case Study of Incidence Among Medicare Beneficiaries in Two Counties, OEI-06-08-00220

January 2010

Adverse Events in Hospitals: Public Disclosure of Information About Events, OEI-06-09-00360

March 2010

Adverse Events in Hospitals: Methods for Identifying Events, OEI-06-08-00221

November 2010

Adverse Events in Hospitals: National Incidence Among Medicare Beneficiaries, OEI-06-09-00090

APPENDIX ~ C

National Quality Forum Serious Reportable Events

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 foreign object in a patient after surgery or procedure
E.	Intraoperative or immediately postoperative death
Product or Device Events	
A.	Patient death or serious disability associated with 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
Patient Protection Events	
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
Care Management Events	
A.	Patient death or serious disability associated with a medication error
B.	Patient death or serious disability associated with a hemolytic reaction because of administration of incompatible blood or blood products
C.	Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while cared for in a health care facility
D.	Patient death or serious disability associated with hypoglycemia, the onset of which occurs while patient is being 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 Stage IV pressure ulcers acquired after admission to a health care facility
G.	Patient death or serious disability because of spinal manipulative therapy
H.	Artificial insemination with the wrong donor sperm or wrong egg
Environmental Events	
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 a fall while being 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
Criminal Events	
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

Source: National Quality Forum, *Serious Reportable Events in Health Care 2006 Update: Consensus Report*, Washington, DC, 2007, p. 7.

APPENDIX ~ D

Centers for Medicare & Medicaid Services Hospital-Acquired Conditions

Conditions
1. Foreign object retained after surgery
2. Air embolism
3. Blood incompatibility
4. Pressure ulcers (stages III and IV)
5. Falls and Trauma
A. Fracture
B. Dislocation
C. Intracranial injury
D. Crushing injury
E. Burn
F. Electric shock
6. Manifestations of poor glycemic control
A. Hypoglycemic coma
B. Diabetic ketoacidosis
C. Nonketotic hyperosmolar coma
D. Secondary diabetes with ketoacidosis
E. Secondary diabetes with hyperosmolarity
7. Catheter-associated urinary tract infection
8. Vascular catheter-associated infection
9. Deep vein thrombosis/pulmonary embolism associated with the following
A. Total knee replacement
B. Hip replacement
10. Surgical site infection
A. Mediastinitis after coronary artery bypass graft
B. Associated with certain orthopedic procedures involving the
a. Spine
b. Neck
c. Shoulder
d. Elbow
C. Associated with certain bariatric surgical procedures for obesity
a. Laparoscopic gastric bypass
b. Gastroenterostomy
c. Laparoscopic gastric restrictive surgery

Source: *Fiscal Year 2009 Hospital Inpatient Prospective Payment System Final Rule*, 73 Fed. Reg. 48434, 48471–48472 (Aug. 19, 2008).

APPENDIX ~ E

Medicare Hospital Conditions of Participation

Condition	Code of Federal Regulations Title 42 Citation
Compliance with Federal, State, and local laws	§ 482.11
Governing body	§ 482.12
Patients' rights	§ 482.13
Quality assessment and performance improvement program	§ 482.21
Medical staff	§ 482.22
Nursing services	§ 482.23
Medical record services	§ 482.24
Pharmaceutical services	§ 482.25
Radiologic services	§ 482.26
Laboratory services	§ 482.27
Food and dietetic services	§ 482.28
Utilization review	§ 482.30
Physical environment	§ 482.41
Infection control	§ 482.42
Discharge planning	§ 482.43
Organ, tissue, and eye procurement	§ 482.45
Surgical services	§ 482.51
Anesthesia services	§ 482.52
Nuclear medicine services	§ 482.53
Outpatient services	§ 482.54
Emergency services	§ 482.55
Rehabilitation services	§ 482.56
Respiratory care services	§ 482.57

APPENDIX ~ F

Sampled Complaints by State

State	Number of Complaints
Tennessee	21
Missouri	9
California	8
North Carolina	8
Texas	8
Florida	7
Iowa	5
Kentucky	5
West Virginia	5
Louisiana	4
Arkansas	3
Kansas	3
Oklahoma	3
Connecticut	1
District of Columbia	1
Illinois	1
Maryland	1
Minnesota	1
New York	1
Ohio	1
Oregon	1
Rhode Island	1
Vermont	1
Total	**99**

Source: Office of Inspector General (OIG) analysis of Fiscal Year (FY) 2008 Automated Survey Processing Environment Complaints Tracking System (ACTS) data.

Alleged Events and Patient Deaths in Sampled Complaints

Type of Alleged Event	Number of Complaints	Complaints Including a Patient Death
Sexual assault	13	0
Medication error	10	4
Physical abuse by staff	10	0
Restraint-related	10	7
Delay in treatment	5	2
Patient elopement/transport issues	5	0
Patient fall	5	0
Suicide	5	5
Neglect	4	2
Pressure ulcers	4	0
Wrong site surgery	4	0
Foreign object retained	3	0
Misdiagnosis	3	1
Verbal abuse by staff	3	0
Complications during/following childbirth	2	2
Surgical fire	2	0
Inappropriate treatment/handoff	1	1
Infant to wrong parents	1	0
Infectious outbreak	1	0
Medical device-related injury	1	0
Other fire	1	0
Perforation during catheterization	1	0
Transfusion error	1	1
Unsafe conditions	4	0
Total	**99**	**25**

Source: OIG analysis of FY 2008 ACTS data.

Sampled Complaints by National Quality Forum Serious Reportable Events

National Quality Forum Serious Reportable Events	Number of Complaints
Sexual assault on a patient within or on the grounds of the health care facility	13
Patient death or serious disability associated with the use of restraints or bedrails	7
Patient suicide, or attempted suicide resulting in serious disability	5
Surgery performed on the wrong body part	4
Patient death or serious disability associated with a medication error	4
Stage III or IV pressure ulcers acquired after admission to a health care facility	4
Retention of a foreign object in a patient after surgery or other procedure	3
Intraoperative or immediately post-operative death in an ASA Class I patient	1
Patient death or serious disability associated with patient elopement (disappearance)	1
Patient death or serious disability associated with a hemolytic reaction	1
Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy	1
Patient death or serious disability associated with a burn	1
Not a National Quality Forum event	54
Total	**99**

Source: OIG analysis of FY 2008 ACTS data.

Sampled Complaints by Centers for Medicare & Medicaid Services Adverse Event Typologies

Hospital-Acquired Conditions	Number of Complaints
Falls and trauma	12
Pressure ulcer, stage III or IV	4
Foreign object retained after surgery	3
Blood incompatibility	1
Not a hospital-acquired condition	79
Total	**99**

Source: OIG analysis of FY 2008 ACTS data.

Surgery-Related Events	Number of Complaints
Surgery on the wrong body part	2
Wrong surgery performed on a patient	2
Not a surgery-related event	95
Total	**99**

Source: OIG analysis of FY 2008 ACTS data.

Joint Commission Response to Complaints

The Joint Commission was aware of 23 of the 95 complaints in our sample. It responded to these complaints through its traditional compliance process and its sentinel event process. In a few cases, it responded through both processes. See Table G-1 for detail on how the Joint Commission responded to the complaints.

Table G-1: Joint Commission Responses to Complaints

Type of Response	Number of Responses	Percentage of Responses
Traditional compliance process only	11	48%
Sentinel event process only	8	35%
Both processes	4	17%
Total	23	100%

Source: Office of Inspector General analysis of FY 2008 Joint Commission data.

The Joint Commission responded through its compliance process primarily by requesting written responses and conducting onsite surveys of hospitals. For seven of the alleged events in our sample, it requested written responses in the form of plans of correction or response letters. The Joint Commission requested a plan of correction from a hospital when the Centers for Medicare & Medicaid Services notified it that a hospital was out of compliance with the Conditions of Participation. When an event alleged in a complaint was less serious, the Joint Commission requested that the hospital write a response letter to explain how the hospital had corrected the problem.

The Joint Commission conducted six onsite surveys in response to six complaints in our sample. It did so when the complaints indicated that immediate threats to patient safety might exist at the hospitals. The Joint Commission conducted four onsite surveys within 31 working days of receiving the complaints and conducted the other two surveys 39 and 88 working days after receiving the complaints.

The Joint Commission responded to 12 complaints with its sentinel event process. The sentinel event process is triggered if a complaint alleges an event on the Joint Commission's list of sentinel events.[64] (See Table G-2.) The process focuses on ensuring that hospitals have

[64] The Joint Commission, *Comprehensive Accreditation Manual for Hospitals* (*CAMH*) SE-3 - SE-4 (2009).

conducted thorough and credible root cause analyses of the events and prepared action plans of risk reduction strategies and measures for evaluating their effectiveness.[65]

Table G-2: Joint Commission Sentinel Events

Description of Sentinel Event
Event resulting 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
Event is one of the following (even if the outcome was not death or major permanent loss of function unrelated to the natural course of the patient's illness or underlying condition):
Suicide of any patient receiving care, treatment, and services in a staffed-around-the-clock care setting or within 72 hours of discharge;
Unanticipated death of a full-term infant;
Abduction of any patient receiving care, treatment, and services;
Discharge of an infant to the wrong family;
Rape;
Hemolytic transfusion reaction involving administration of blood or blood products having major blood group incompatibilities (ABO, Rh, other blood groups);
Surgical and nonsurgical invasive procedure on the wrong patient, wrong site, or wrong procedure;
Unintended retention of a foreign object in a patient after surgery or other procedure;
Severe neonatal hyperbilirubinemia (bilirubin >30 milligrams/deciliter);
Prolonged fluoroscopy with cumulative dose >1,500 rads to a single field or any delivery of radiotherapy to the wrong body region or >25% above the planned radiotherapy dose;
Any other event defined by accredited hospital as a sentinel event.

Source: The Joint Commission.

The Joint Commission followed up on improvements identified by onsite surveys and root cause analysis by requiring hospitals to submit performance data. When it cites hospitals for noncompliance with standards or when hospitals submit action plans in response to sentinel events, the Joint Commission requires hospitals to submit documentation and performance data to verify sustained improvement. The performance data cover 4 months after improvements were put in place and must show that the hospitals are reaching performance targets. Failure to submit data or to show improvement might adversely affect a hospital's accreditation status.[66, 67] The Joint Commission reported that every hospital it cited for noncompliance or that submitted a root cause analysis later provided performance data.

[65] The Joint Commission, *CAMH* SE-2 (2009).

[66] The Joint Commission, *CAMH* SE-11 - SE-12 (2009).

[67] The Joint Commission, *CAMH* ACC-46 - ACC-47 (2009).

APPENDIX ~ H

Agency Comments

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: AUG 1 8 2011

TO: Daniel R. Levinson
Inspector General

FROM: /S/
Donald M. Berwidk. M.D.
Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: "Adverse Events in Hospitals: Medicare's Responses to Alleged Serious Events" (OEI-01-08-00590)

Thank you for the opportunity to review and comment on this very timely and important study. In this report, the Office of Inspector General (OIG) examines the response of the Center for Medicare & Medicaid Services (CMS) and State Survey Agencies (SAs) to allegations of serious adverse events in hospitals. An "adverse event" refers in the OIG study to harm to a patient as a result of medical care or in a health care setting.

There is no greater opportunity for far reaching improvement in the experience of individuals and families in the United States health care system than in the arena of patient safety – and no greater opportunity for savings to the taxpayer and the beneficiary without reducing access to care.

We note that since the incidents reviewed in this report, the Department of Health and Human Services (HHS) has launched a new and ambitious public-private partnership entitled the "Partnership for Patients." This national Partnership will help improve the quality, safety and affordability of health care not just for Medicare beneficiaries, but for all Americans. HHS and CMS are working with a wide variety of public and private partners to achieve the two core goals of this Partnership:

- Keeping patients from getting injured or sicker in the health care system, and
- Helping patients heal without complication by improving transitions from acute-care hospitals to other care settings, such as home or a skilled nursing facility.

In just a few months, more than 4,000 organizations – including more than 2,500 hospitals – have signed the Partnership Pledge.

One of CMS' long-standing approaches to public protection in health care involves the setting of clear quality and safety expectations for providers that participate in Medicare or Medicaid, otherwise known as the Conditions of Participation (CoPs). CMS' survey and certification (S&C) program provides for onsite review of the extent to which providers are in compliance with these public expectations, both through periodic comprehensive surveys (standard surveys) and complaint investigations.

The CMS and State SAs conduct approximately 4500 – 4800 onsite complaint investigations in hospitals each year. The OIG found that State agency responses to complaints alleging serious adverse events were generally conducted in a timely manner, and that the investigations often found problems in hospital compliance with CMS quality of care and safety requirements. For example, of the 95 alleged events in the study sample, the OIG found that 53 (55.7 percent) resulted in a CMS finding of deficiency. Both the OIG and CMS consider CMS complaint investigations to offer important opportunities for improvement in health care quality and safety.

We are very appreciative of the investment of time and resources that the OIG is making to contribute to the store of knowledge and ideas on this topic. We particularly appreciate this review of how we can use our authorities more effectively to reduce adverse events in hospitals. The recommendations of this report will help us strengthen the Partnership for Patients as we work together with hospitals and other health care providers to improve patient safety.

As indicated in greater detail below, we will immediately take action in a number of areas based on the OIG recommendations.

OIG Recommendation

Require that all Immediate Jeopardy complaint surveys evaluate compliance with the Condition of Participation on quality assurance and performance improvement.

CMS Response

We concur with the intent of this recommendation, and will take the following actions:

(a) ***Guidance***: We will issue specific guidance regarding:

- The type of allegations that must always include review of the CoP for quality assessment and performance improvement (QAPI).
- The process by which the relevance of QAPI must be assessed for all other types of allegations.

- The circumstances under which a staged survey should be conducted, in which the initial scope of the complaint investigation is limited but wider review may later be triggered depending on the findings from the initial stage of the survey.

With regard to complaints that are triaged at the level of immediate jeopardy (IJ), we will assess the evidence with regard to the potential that IJ allegations might automatically imply a high probability of non-compliance with QAPI requirements, or whether a different QAPI targeting method might be superior. We are confident that the end result will be a much greater surveyor focus on the extent to which hospitals fulfill QAPI responsibilities than in the past.

With regard to the OIG sub-recommendation that CMS limit the initial scope of complaint surveys to the allegation itself and the QAPI CoP, we will assess the extent to which a staged survey is advisable and under what circumstances.

(b) ***Risk Analysis:*** We will analyze available data to determine the extent to which:

- Data may help CMS better direct survey attention to QAPI.
- Data may assist surveyors to prepare for onsite surveys that may involve QAPI.

(c) ***Onsite QAPI Survey Tools:*** We will develop and test survey tools that will:

- Improve the ability of surveyors to identify problems in a hospital's compliance with the CMS regulatory requirement that every hospital have an effectively functioning, internal quality assessment and performance improvement system.
- Improve the ability of hospitals to assess their own compliance with CMS requirements for QAPI.

As we wholeheartedly agree with the OIG on the importance of assessing compliance with the QAPI CoP, we have taken a number of recent steps to enhance the capability of State SAs to conduct such assessments. These include:

- ***Training***: We are currently beta testing an on-line surveyor training course that reviews the fundamentals of the evolving discipline of patient safety. Once finalized, we expect that this course will be required for all surveyors who conduct QAPI surveys.

- ***Technical Expert Panel:*** We convened a Technical Expert Panel that met in January and in March of 2011 to assist us in developing interpretive guidelines for the QAPI CoP, as well as a structured tool to guide surveyors in assessing a hospital's QAPI program.

- ***Field Testing of Tools***: Beginning in late August 2011 we will start field testing the surveyor QAPI tool in a limited number (8-10) of volunteer States. If successful, we expect to implement such a tool nationwide in the future. As a result, SAs will not only be reviewing QAPI compliance on more hospital surveys, but they will have enhanced capacity to conduct effective, consistent reviews.

OIG Recommendation

Ensure that State agencies monitor hospitals' corrective actions for sustained improvements.

CMS Response:

We concur with the need for increased focus on the efficacy of corrective actions, and will undertake the following:

(a) ***Follow-up Policy:*** We will:

- Re-emphasize Revisit Policy: Current CMS policy already requires revisits by the SA to ensure the hospital is in substantial compliance with the CoP(s) following implementation of a Plan of Correction. We will reiterate this existing policy to the Regional Offices (ROs) and SAs.

- Reassess Follow-up Policy for Accredited Hospitals: We will reassess current regulatory expectations with regard to the manner in which CMS currently follows up on deficiency findings in accredited hospitals. In particular, current policy requires a full survey of an accredited hospital when a Condition-level deficiency is found, and also delays important action on the original deficiency finding from a complaint investigation while the subsequent full survey is pending. We will re-evaluate this policy to assess whether there may be a more effective process for ensuring prompt remedial action or focusing survey attention on the particular areas that most warrant onsite review.

(b) ***Performance Data:*** We will analyze available data to determine the extent to which:

- Performance data may help CMS better direct survey attention to hospitals in which there is a greater risk that plans of correction may not be implemented effectively or may not be sustained over time.
- Performance data may assist surveyors in following up with hospitals subsequent to implementation of plans of correction.

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CMS Recommendation

Amend guidance on disclosure to explain the nature of complaints to hospitals.

CMS Response

We concur and will explore ways in which communication with hospitals may be improved, particularly with regard to complaint investigations.

CMS Recommendation

Improve communication with accreditors.

CMS Response

We fully agree on the value of clear, prompt and adequate communication between CMS and CMS-approved accrediting organizations. Current CMS policy calls for CMS ROs to send to the accreditors those complaints that do not suggest serious violations that warrant a Federal survey. For complaints that do warrant a Federal survey, our policy is for the ROs to copy accreditors on their correspondence to the accredited hospital. Such correspondence includes communicating survey results and enforcement actions, if applicable. Where a Federal survey has been conducted, we believe it is more beneficial for the AOs to have the actual SA survey findings, not just the complainant's allegation. We will clarify the existing policy for the ROs and work with them to enhance compliance.

Thank you for your attention to this key area of health care and for specific ideas on methods by which our oversight of hospitals may be improved.

Attachment

ACKNOWLEDGMENTS

This report was prepared under the direction of Joyce M. Greenleaf, Regional Inspector General for Evaluation and Inspections in the Boston regional office, and Russell W. Hereford, Deputy Regional Inspector General.

Kenneth Price served as the team leader for this study. Other principal Office of Evaluation and Inspections staff from the Boston regional office who contributed to the report include Jesse Valente and Carolyn Kenline; central office staff who contributed include Rita Wurm.

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