DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201

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/S/

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SUBJECT: Memorandum Report: *Few Adverse Events in Hospitals Were Reported to State Adverse Event Reporting Systems*, OEI-06-09-00092

This memorandum report provides information requested by officials of the Centers for Medicare & Medicaid Services (CMS) about hospital reporting of adverse events to State reporting systems. The Office of Inspector General (OIG) collected this information while conducting a 2001–2012 series of studies about adverse events in hospitals.

SUMMARY

Previous OIG work found that an estimated 27 percent of Medicare beneficiaries hospitalized in October 2008 experienced harm from medical care, either serious adverse events (defined as events resulting in prolonged hospitalization, permanent disability, life-sustaining intervention, or death) or temporary harm events (defined as events requiring intervention but not resulting in lasting harm). To determine this rate of adverse and temporary harm events (referred to collectively as events), we examined medical records for a nationally representative sample of 780 hospitalized Medicare beneficiaries in October 2008. Prior OIG work also found that in 2008, about half of States operated adverse event reporting systems to monitor the occurrence of events in hospitals. Typically, these States required hospitals to report only specific types of events and analyzed the events in aggregate. This memorandum extends our prior work by providing national estimates for the extent to which events experienced by Medicare beneficiaries occurred in States that operated adverse event reporting systems, whether States required reporting of the identified events, and whether the hospitals reported the events to the State systems.

We found that an estimated 60 percent of adverse and temporary harm events nationally occurred at hospitals in States with reporting systems, yet only an estimated 12 percent of events nationally met State requirements for reporting. We also found that hospitals reported only 1 percent of events. Most of the events that States required to be reported, but that hospitals did not report, were not identified by internal hospital incident reporting systems. This suggests that low reporting to State systems is more likely the result of hospital failure to identify events than from hospitals neglecting to report known events.

BACKGROUND

Adverse Events in Hospitals

Beginning in 2008, OIG released a series of reports regarding adverse events in hospitals. For the report *Adverse Events in Hospitals: National Incidence Among Medicare Beneficiaries*, we conducted a physician review of medical records for a nationally representative sample of 780 Medicare beneficiaries hospitalized in October 2008. We found that an estimated 13.5 percent of hospitalized Medicare beneficiaries experienced adverse events. An additional 13.5 percent of beneficiaries experienced temporary harm events.[1]

For the report *Hospital Incident Reporting Systems Do Not Capture Most Patient Harm*, we determined whether the 189 hospitals where these events occurred had identified the events through their internal incident reporting systems. We found that all the hospitals had incident reporting systems designed to capture staff reports regarding adverse events, yet hospital staff reported only 14 percent of events experienced by Medicare beneficiaries.[2] Hospital administrators indicated that staff often did not report events because they identified them not as patient harm, but rather as expected side effects.

State Adverse Event Reporting Systems

In the 2008 report *Adverse Events in Hospitals: State Reporting Systems*, we found that 25 States and the District of Columbia (hereinafter referred to as 26 States) operated systems to collect adverse event data submitted by hospitals.[3] All these State systems received event descriptions and hospital names, but varied as to whether they made reporting voluntary or mandatory, what types of events they specified should be reported, and what additional information they asked hospitals to report. Most State systems required hospitals to report a subset of adverse events, usually serious events resulting in permanent disability or death, and events likely to affect the broader hospital population, such as infections. To date, no Federal standards require States to operate adverse event reporting systems.

States with adverse event reporting systems used the reported information both to hold hospitals accountable and to promote learning about adverse events. Twenty-three of the twenty-six States with reporting systems routinely investigated reported events. Additionally, 18 of the 26 States used event reports to provide patient safety information and educational tools to hospitals, including the State incidence of adverse events, early warnings of new or widespread threats to patient safety, and analysis of contributing factors.[4]

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

[2] OIG, *Hospital Incident Reporting Systems Do Not Capture Most Patient Harm*, OEI-06-09-00091, January 2012.

[3] OIG, *Adverse Events in Hospitals: State Reporting Systems*, OEI-06-07-00471, December 2008.

[4] Ibid.

METHODOLOGY

We reviewed State policies to determine which events identified in our previous study were ones that States required hospitals to report. We then collected any reports about these events that hospitals sent to States. Based on the national random sample of hospitalized Medicare beneficiaries, we projected rates for the following: events experienced by Medicare beneficiaries that occurred in States that operated adverse event reporting systems in 2008 and events that these States required hospitals to report to the State systems. Appendix A contains estimates and confidence intervals for these statistics. We also determined which events hospitals reported to these State systems.

STANDARDS

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

RESULTS

Although half of States operated adverse event reporting systems in 2008, only 12 percent of events met State requirements for reporting

An estimated 60 percent of adverse and temporary harm events nationally occurred at hospitals in States with reporting systems, yet only an estimated 12 percent of events nationally met State requirements for reporting. Of the events that States required to be reported, over half occurred in Pennsylvania, which required reporting of all events regardless of severity.[5] Table 1 breaks down the events by whether they were required to be reported to State systems.

Table 1: Percentage of Hospital Events, by State and Whether State Required Event to be Reported

Whether State Required Event to be Reported	Percentage of All Events
Event Occurred in State With Adverse Event Reporting System	**60%**
Event did not meet State reporting requirements	49%*
Event met State reporting requirements	12%*
Event Occurred in State Without Adverse Event Reporting System	**40%**
Total Events	**100%**

Source: OIG analysis of the 293 information requests completed by hospitals where events occurred.
* Percentages do not sum to 60 percent because of rounding.

Hospitals reported very few sampled events that States required to be reported

Within our sample, hospitals reported only 3 of the 35 events required to be reported to a State reporting system. All 3 of these reported events occurred in Pennsylvania, which had a total of 22 events among sampled beneficiaries Statewide. All three of the reported events caused temporary harm to beneficiaries and were of types commonly targeted by hospital patient safety efforts (allergic reaction, fall, and pressure ulcer).

[5] Pennsylvania: 40 P.S. § 1303.313.

Nearly all unreported events also went undetected by internal hospital incident reporting systems. Of the 32 events that hospitals did not report to State systems as required, hospitals identified only 1 event within an internal incident reporting system. For the remaining 31 events, hospitals had no record indicating that staff recognized the event had occurred. This suggests that the low rate of reporting to State adverse event reporting systems is due largely to hospital staff not identifying incidents of harm as reportable events.

Many of the events not reported to State systems as required involved serious harm to hospitalized Medicare beneficiaries. Six of the thirty-two events contributed to patient death, including cases involving lack of patient monitoring and missed diagnoses. For example, one patient death was the result of acute renal failure caused by the hospital not recognizing and treating a serious systemic inflammatory response syndrome (bacteremia). Another patient death was the result of poor insulin management escalating to a hypoglycemic coma. Other unreported events required the use of life-sustaining interventions, indicating that hospital staff were clearly alerted to a problem but still did not report the events.

Further, the less serious, temporary harm events that hospitals did not report included many events that can become serious if not ameliorated, such as excessive bleeding and intravenous volume overload. The treatment required to stop the progression of these events also implies that in each case, hospital staff were likely aware of the patient's condition but did not perceive the condition as an event.

Table 2 lists the events in our sample that States required to be reported to adverse event reporting systems, whether hospital staff reported these events to incident reporting systems within the hospitals, and whether the events were reported to the State systems.

Table 2: Adverse Events That Required Hospital Reporting to State Adverse Event Reporting Systems (n=35)

State	Type of Event	Level of Harm	Reported within Hospital	Reported to State System
CA	Excessive bleeding	Contributed to death		
CO	Blood stream infection	Contributed to death		
IN	Fall	Prolonged hospital stay		
IN	Pulmonary embolism	Prolonged hospital stay		
KS	Excessive bleeding	Contributed to death		
MD	Excessive bleeding	Prolonged hospital stay	•	
MD	Excessive bleeding	Prolonged hospital stay		
MD	Hypoglycemic coma	Life-sustaining intervention		
MD	Hypotension	Prolonged hospital stay		
MD	Catheter infection	Prolonged hospital stay		
NJ	Excessive bleeding	Contributed to death		
NJ	Hypoglycemic coma	Contributed to death		
NY	Blood stream infection	Contributed to death		
PA	Acute renal failure	Temporary harm		
PA	Acute renal failure	Permanent harm		
PA	Allergic reaction	Temporary harm	•	•
PA	Allergic reaction	Temporary harm		
PA	Congestive heart failure	Prolonged hospital stay		
PA	Dysrhythmia	Temporary harm		
PA	Excessive bleeding	Temporary harm		
PA	Excessive bleeding	Temporary harm		
PA	Fall	Temporary harm	•	•
PA	Nausea and vomiting	Temporary harm		
PA	Pressure ulcer	Temporary harm	•	•
PA	Pulmonary embolism	Prolonged hospital stay		
PA	Sepsis	Life-sustaining intervention		
PA	Skin tear	Temporary harm		
PA	Surgical tear	Temporary harm		
PA	Urinary retention	Temporary harm		
PA	Urinary tract infection	Permanent harm		
PA	Intravenous volume overload	Prolonged hospital stay		
PA	Intravenous volume overload	Temporary harm		
PA	Intravenous volume overload	Temporary harm		
PA	Intravenous volume overload	Temporary harm		
TN	Acute renal failure	Prolonged hospital stay		

Source: OIG analysis of information provided by hospitals regarding 293 identified events, 2011. Level of harm from the National Coordinating Council for Medication Errors Reporting and Prevention Index for Categorizing Errors, Press Release, *Medication Errors Council Revises and Expands Index for Categorizing Errors: Definitions of Medication Errors Broadened*, June 12, 2001.

CONCLUSION

Although half of States operated adverse event reporting systems in 2008, hospitals reported few events to State systems. For all but one event that was not reported to State systems as required, the hospitals did not identify the events within internal incident reporting systems. This indicates that low reporting to State systems is more likely to result from hospital failure to identify events than from hospitals' neglecting to report known events. CMS, States, and other stakeholders should be aware of this low rate of reporting to State systems as they consider strategies to reduce adverse events in hospitals.

This report is being issued directly in final form because it contains no recommendations. If you have comments or questions about this memorandum report, please provide them within 60 days. Please refer to report number OEI-06-09-00092 in all correspondence.

APPENDIX A

Estimates and Confidence Intervals

We computed estimates and corresponding 95-percent confidence intervals using appropriate statistical methods based on the sample.

Table A: Hospital Adverse Events and State Reporting (n=293)

Adverse Event	Point Estimate	95-Percent Confidence Interval	
		Lower Bound	Upper Bound
Event Occurred in State With Event Reporting System	**60.4%**	**52.5%**	**67.8%**
Event did not meet State reporting requirements	48.5%	40.9%	56.1%
Event met State reporting requirements	12.0%	8.2%	17.2%
Event Occurred in State Without Event Reporting System	**39.6%**	**32.2%**	**47.5%**
Total Events			

Source: OIG analysis of the 293 information requests completed by hospitals where events occurred.