DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201

DATE: July 24, 2025

TO: Mehmet Oz, M.D.
Administrator
Centers for Medicare & Medicaid Services

FROM: Ann Maxwell
Deputy Inspector General
for Evaluation and Inspections

SUBJECT: Memorandum Report: *Hospitals Reported Few Captured Patient Harm Events to CMS and States* (OEI-06-18-00402)

This memorandum report provides information to the Centers for Medicare & Medicaid Services (CMS) about hospital reporting of captured patient harm events pursuant to CMS program and State requirements. The Office of Inspector General (OIG) collected this information while conducting a study of hospitals' identification and response to patient harm events. The full results of the study are described in the report *Hospitals Did Not Capture Half of Patient Harm Events, Limiting Information to Make Care Safer* (OEI-06-18-00401).

Summary

Our study raises concerns that hospitals are not consistently following CMS and State reporting requirements intended to monitor patient safety. Nationwide, we determined that 16 percent (15 of 94) of harm events that hospitals identified and captured in their incident reporting or other surveillance systems were required to be reported externally per CMS and State requirements. Yet, in our sample, hospitals reported only 5 of 15 captured events per these requirements.

External reporting is a crucial component in addressing patient safety. It holds hospitals accountable for patient harm events and is intended to promote awareness and encourage learning from such events. Our results show a significant discrepancy between the events that CMS and States expected hospitals to report and the events that hospitals actually reported. The low rate of reporting raises questions about hospital transparency and accountability for patient harm that occurs in their facilities. We urge CMS, States, hospitals, and others (e.g., accreditation organizations) to consider these results as they develop new strategies to improve patient safety.

Background

OIG established the first national rate of harm among hospitalized Medicare patients in a report released in 2010 which found that 27 percent of patients were harmed by the care they received.[1] Since that time, national attention to identifying and preventing patient harm has increased. Yet, in a 2022 report, OIG found that patient harm continued to be widespread.[2] We noted in that report similar results to those in the prior study, that 25 percent of hospitalized Medicare patients experienced harm events during their stays, and 43 percent of these could have been prevented if patients had received better care.

Reducing the rate of patient harm is a goal shared by hospitals across the country. To reduce patient harm, hospitals seek to identify and capture harm events within their incident reporting and other surveillance systems. They use this information to understand the harm that occurs in their facilities and to guide their patient safety improvement activities. In 2012, OIG found that despite these efforts, hospitals were unaware of the majority of harm events that occurred in their facilities—they failed to capture 86 percent of such events.[3] We updated this rate in our 2025 report and found that hospitals failed to capture half of harm events (49 percent) in their incident reporting or other surveillance systems, which suggests improvement in the years since our first report.[4] However, hospitals continue to have limited information about harm events; such information is needed to make safety improvements to prevent future harm from occurring in their facilities.

CMS Reporting Requirements

Medicare-participating hospitals are subject to a 1-percent payment penalty under the Hospital-Acquired Conditions Reduction Program if they do not routinely report the incidence of certain patient harm events.[5, 6] These hospitals are further subject to a one-quarter annual payment reduction under the Hospital Inpatient Quality Reporting Program if hospitals fail to report certain measures (including events) and meet other requirements.[7] As part of these programs, CMS requires hospitals to report harm events that involve healthcare-associated

[1] OIG, *Adverse Events in Hospitals: National Incidence Among Medicare Beneficiaries* (OEI-06-09-00090), Nov. 15, 2010.

[2] OIG, *Adverse Events in Hospitals: A Quarter of Medicare Patients Experienced Harm in October 2018* (OEI-06-18-00400), May 5, 2022.

[3] OIG, *Hospital Incident Reporting Systems Do Not Capture Most Patient Harm* (OEI-06-09-00091), Jan. 5, 2012.

[4] OIG, *Hospitals Did Not Capture Half of Patient Harm Events, Limiting Information Needed to Make Care Safer* (OEI-06-18-00401), July 29, 2025.

[5] Social Security Act (SSA) § 1886(p)(1) and 42 CFR § 412.172.

[6] Other Federal reporting requirements exist but did not apply to the harm events in this study. For examples of these other requirements, see 42 CFR § 482.13(g) and 21 U.S.C. 360i(b); 21 CFR § 803.30.

[7] SSA § 1886(b)(3)(B)(viii) and 42 CFR § 412.140(c).

infections tracked by the National Healthcare Safety Network (NHSN), a system managed by the Centers for Disease Control and Prevention (CDC).[8, 9] To maintain consistency in reporting, CDC sets criteria for reporting these healthcare-associated infections.[10] In 2015, CMS and CDC issued a joint reminder to providers to address concerns about health care facilities not reporting these events.[11]

State Reporting Requirements

Many States mandate reporting of specific types of harm events, often focusing efforts on the most serious types of harm such as those that result in permanent harm or death.[12] In October 2018, the period during which the harm events in our study occurred, a total of 26 States and the District of Columbia had mandatory reporting systems.[13] Most of these apply only to a narrow set of events, such as "serious reportable events" which are defined by the National Quality Forum.[14] See Exhibit 1 on the next page for a list of States with mandatory patient harm event reporting systems.

[8] SSA, §§ 1886(d) and (p); 42 CFR §§ 412.170 and 172.

[9] Note that in October 2018 (when the events occurred), hospitals were also required to report the healthcare-associated infections under the Hospital Inpatient Quality Reporting Program. These measures were removed beginning for calendar year 2020. See CMS, *Hospital IQR Program: Summary of Changes for FY 2022 Payment Determination/CY 2020 Reporting Period*. Accessed on Mar. 20, 2025.

[10] Information about CMS's Hospital-Acquired Condition Reduction Program and the events required to be reported to NHSN can be found here: https://qualitynet.cms.gov/inpatient/hac and https://www.cdc.gov/nhsn/index.html.

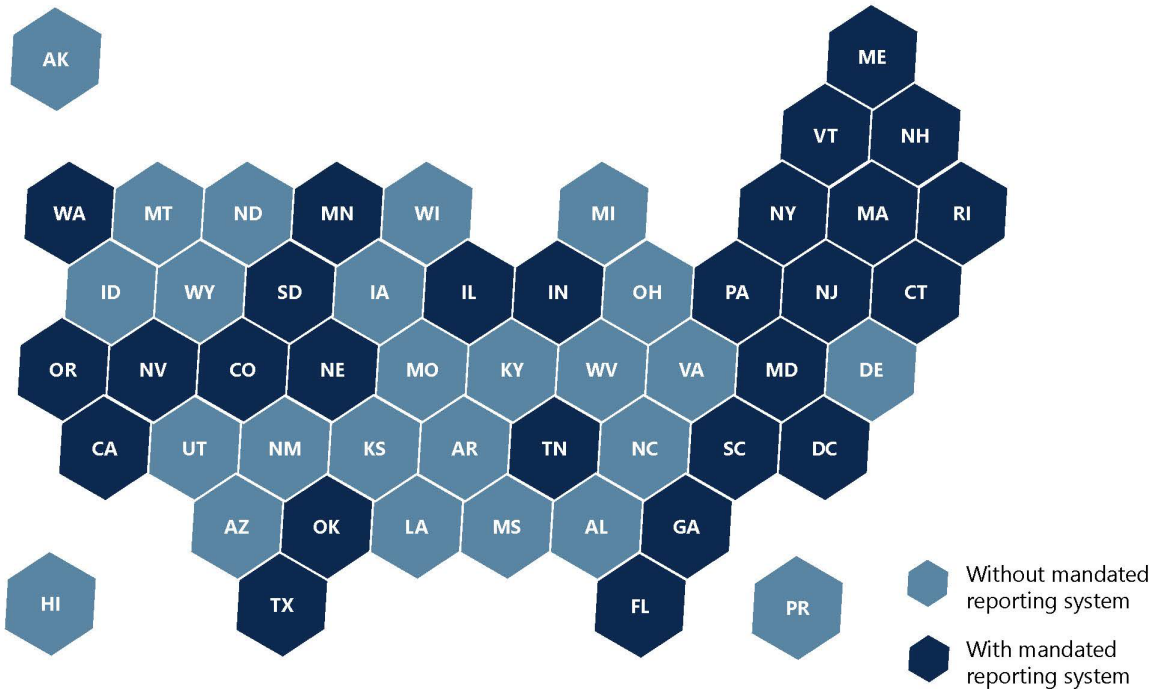
[11] CMS and CDC, *Adherence to the CDC's Infection Definitions and Criteria is Needed to Ensure Accuracy, Completeness, and Comparability of Infection Information*, Oct. 2015. Accessed on Jan. 23, 2023.

[12] Some States also require reporting of healthcare-associated infections to NHSN. We did not examine these requirements; instead, we assessed CMS program requirements for reporting to NHSN. In 2013, 35 States, the District of Columbia, and Puerto Rico required reporting of such infections to either NHSN or State reporting systems. See Herzig, et al., "State-Mandated Reporting of Health Care-Associated Infections in the United States: Trends Over Time," *American Journal of Medical Quality*, Sept. 2015.

[13] Our review of these State policies did not include a legal review. In most cases, these requirements were straight-forward (e.g., hospitals were required to report serious reportable events defined by the National Quality Forum).

[14] National Quality Forum, *Serious Reportable Events in Healthcare—2011 Update: A Consensus Report*, 2011.

Exhibit 1: Twenty-six States and the District of Columbia had a mandated harm event reporting system in October 2018



Source: OIG review of State reporting systems.
Note: Some States without a reporting system may still require hospitals to report to NHSN.

Prior OIG Work

Prior OIG work has found low rates of hospital reporting to State reporting systems for patient harm events. A previous study on State reporting systems found that 25 States and the District of Columbia had reporting systems for hospital patient harm events in 2008, but hospitals reported few events to these systems.[15] In a followup study to our 2010 national harm rate report, we found that most of the events mandated for reporting were not identified by hospitals—an estimated 12 percent of events nationally met State requirements for reporting, yet hospitals reported only 1 percent of all harm events.[16]

[15] OIG, *Adverse Events in Hospitals: State Reporting Systems* (OEI-06-07-00471), Dec. 15, 2008.

[16] In that report, we found that hospitals reported only 3 of 293 harm events, yet 35 events were mandated to be reported. See OIG, *Few Adverse Events in Hospitals Were Reported to State Adverse Event Reporting Systems* (OEI-06-09-00092), July 19, 2012.

Methodology

For this memorandum report, we traced 299 harm events experienced by a nationally representative sample of 770 Medicare patients discharged in October 2018. OIG identified these events through a comprehensive medical record review.[17]

We administered a survey to the hospitals at which the harm events occurred to determine the extent to which they captured and responded to those events.[18] We received responses for 266 of the 299 harm events. If hospitals captured the harm event, we asked whether they reported it to any external entities, including NHSN and State reporting systems. For harm events where hospitals did not affirmatively indicate that they reported the event to an external entity (i.e., answered "No" or "Don't know"), we considered those events not reported.

Our review focused on harm events that hospitals captured. Of the 266 harm events for which we received responses to our survey, hospitals captured only 94 events. These events occurred at 56 hospitals across 25 States and the District of Columbia. This review allowed us to estimate a national rate for hospital reporting of harm events to external entities including NHSN and States. (See Appendix for point estimates and 95-percent confidence intervals.)

We compared hospital survey responses for each captured harm event against reporting requirements set by CMS and the States in which the hospitals were located. For State requirements, we reviewed the State policies that were in place at the time of the harm events to determine which types of events the States required hospitals to report. A physician also confirmed that the clinical details associated with the events met State criteria for reporting. For CMS requirements, a physician and nurse infection-prevention specialist reviewed the events to determine whether they met NHSN's reporting criteria.

Standards

We conducted this work in accordance with the *Quality Standards for Inspection and Evaluation* issued by the Council of the Inspectors General on Integrity and Efficiency.

Results

Hospitals did not report all of the captured harm events per requirements established by CMS and States. We determined that 16 percent (15 of 94) of captured harm events were required

[17] For more information about these harm events, see our 2022 national incidence report, *Adverse Events in Hospitals: A Quarter of Medicare Patients Experienced Harm in October 2018* (OEI-06-18-00400).

[18] See our 2025 report, *Hospitals Did Not Capture Half of Patient Harm Events, Limiting Information Needed to Make Care Safer* (OEI-06-18-00401), for a detailed methodology and comprehensive survey results.

to be reported to CMS and/or States.[19] Yet, in our sample, hospitals reported only 5 of 15 captured events required for reporting per these requirements.

Confusion over requirements on whether captured harm events met mandatory reporting criteria likely contributed to underreporting of events. For example, staff in one hospital indicated that they did not report a *Clostridioides difficile* (*C. diff*) infection to NHSN, as required by CMS, because they considered the infection to be present on admission. However, our physician-reviewers determined that the infection developed more than 3 days after the patient was admitted to the hospital and therefore was not present on admission. Prior OIG work raised similar concerns regarding ways in which hospitals may be deviating from Federal definitions for reportable healthcare-associated infections, which potentially results in underreporting of harm events to NHSN.[20]

For the remaining 79 events not required to be reported externally, hospitals voluntarily reported 7 of those events. Hospitals reported these events to accreditation organizations, States, professional health care groups, and other entities for learning purposes.[21]

Below, we provide a breakdown of the extent to which hospitals failed to meet CMS and State reporting requirements among the captured harm events in our sample.

CMS reporting. Nine captured events in our sample met the requirements to be reported to NHSN, yet hospitals reported only four of these events.[22] The reported events included two surgical site infections involving an abdominal hysterectomy and colon surgery; a *C. diff* infection; and a catheter-associated urinary tract infection.

Only four of nine events were reported per CMS program requirements

The events that hospitals did not report included two *C. diff* infections, a central-line associated bloodstream infection, a surgical site infection involving methicillin-resistant *Staphylococcus aureus* (MRSA), and a surgical site infection following colon surgery that culminated in postoperative sepsis. When we followed up with hospitals on why these events were not reported externally, we found that they either incorrectly believed that the events did not meet reporting criteria set by NHSN or were unable to determine whether the event had been reported.

[19] Note that of the 94 captured events in our sample, 2 events were required to be reported to both NHSN and States.

[20] OIG, *CMS Validated Hospital Inpatient Quality Reporting Program Data, But Should Use Additional Tools to Identify Gaming* (OEI-01-15-00320), May 1, 2017.

[21] Note that this rate does not include harm events reported to patient safety organizations because that information is protected under the Patient Safety and Quality Improvement Act of 2005. See 42 U.S.C. §§ 299b-21 to 299b-26.

[22] In addition to the 5 healthcare-associated infections that were not reported as required, hospitals stated that 4 of 13 hospital-acquired conditions in our sample—tracked by CMS programs and payment policies—were not captured by their hospital incident reporting or other surveillance systems. For the definition of a hospital-acquired condition, see SSA §§ 1886(d)(4)(D)(iv) and 1886(p).

State reporting. Eight of the captured harm events in our sample were required to be reported to States, but hospitals reported only one of these events. The reported event involved a patient who experienced excessive bleeding caused by medication for treatment of blood clots that led to permanent brain injury.

Only one of eight events was reported per State requirements

Some of the captured harm events that hospitals did not report to States included the most severe types of harm—two events resulted in permanent harm and another two events contributed to the patients' deaths. For one of the fatal events, our physician-reviewers attributed the death to a 5-day delay for surgery needed to treat necrotic (i.e., dying) intestinal tissue after the patient had been admitted with sepsis and complaints of abdominal pain. Our physician-reviewer determined that this event should have been reported to the State authorities, but when we followed up with the hospital, staff could not confirm whether they reported the event. The remaining three events that hospitals did not report involved infections that prolonged the patients' hospital stays, including a respiratory infection, a central line-associated bloodstream infection, and the *C. diff* infection that States required to be reported to their systems.

Conclusion

Hospitals reported few patient harm events to CMS and States, thereby limiting hospital transparency and accountability for harm that occurred in their facilities. When hospitals fail to identify and report harm events to the appropriate oversight entities, they stymie independent feedback needed to take corrective actions. The lack of such actions hampers system-level improvements that can prevent future harm from occurring. We urge CMS, States, and other groups (e.g., accreditation organizations and other Federal agencies) to weigh these results as they develop new strategies to improve patient safety.

These results also support the recommendations made in our companion report, *Hospitals Did Not Capture Half of Patient Harm Events, Limiting Information Needed to Make Care Safer* (OEI-06-18-00401). In that report, we recommended that CMS and the Agency for Healthcare Research and Quality align patient harm event definitions to drive a more comprehensive capture rate of harm events. We also recommended that CMS ensure that surveyors prioritize the Medicare Quality Assessment and Performance Improvement requirement to hold hospitals accountable for patient harm and instruct Quality Improvement Organizations to use information about harm events to assist hospitals in identifying weaknesses in their incident reporting or other surveillance systems.

This memorandum report is being issued directly in final form because it contains no recommendations. If you have questions about this memorandum or would like to request a briefing by the OIG team, please contact me or one of your staff may contact the program specialist assigned to this study. Please refer to product number OEI-06-18-00402 in all correspondence.

Appendix: Estimates, Confidence Intervals, and Key Statistics

We obtained our sample of harm events from the data in our national incidence report *Adverse Events in Hospitals: A Quarter of Medicare Patients Experienced Harm in October 2018* (OEI-06-18-00400). In that study, we sampled 770 Medicare patients discharged from short-term acute-care hospitals in October 2018. These patients experienced 299 harm events during their stays across 179 hospitals. The estimates included in this memorandum are based on responses from 56 hospitals that captured harm events. These responses represent 61 Medicare patients who experienced a total of 94 harm events during their hospital stays. Below, we present the corresponding 95-percent confidence intervals.

Exhibit 2: Event-level estimates and confidence intervals for captured harm events mandated for CMS and State reporting (n=94)

Estimate Description	Number of Events in Sample	Estimated Percentage of Events	95-Percent Confidence Interval	
			Lower Bound	Upper Bound
Events mandated for CMS and State reporting				
Events mandated for reporting to NHSN (per CMS program requirement) and/or States*	15	16.0%	9.8%	24.9%
Events not mandated for reporting to NHSN and States	79	84.0%	75.1%	90.2%

Source: OIG analysis of survey data, 2024. This data includes 94 harm events experienced by 61 hospitalized Medicare patients in October 2018.

*Two events were required for reporting to both NHSN and State reporting systems.