



JAN - 5 2010

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

This memorandum report provides information about policies, practices, and plans for public disclosure of information about adverse events occurring in hospitals and patient privacy protections for adverse event data. Publicly disclosing adverse event information can educate healthcare providers about the causes of events, potentially leading to improvements in patient safety and assisting patients when making decisions about their care. However, there is concern that disclosure could undermine patient privacy.

Among the entities that we reviewed, including 17 selected State adverse event reporting systems, 8 selected Patient Safety Organizations (PSO) overseen by the Agency for Healthcare Research and Quality (AHRQ) and the Centers for Medicare & Medicaid Services (CMS), we found only limited public disclosure of information about adverse events. Among these entities, seven State systems disclose more extensive information about the causes of adverse events and prevention strategies than other State systems. Such disclosure may provide the medical community with valuable information for improving patient safety. All reviewed entities protect patient privacy through policies, practices, and legal provisions.

BACKGROUND

Statutory Mandate and Office of Inspector General Response

The Tax Relief and Health Care Act of 2006 (the Act) requires that the Office of Inspector General (OIG) report to Congress regarding the incidence of “never events” among Medicare beneficiaries; the extent to which the Medicare program paid, denied payment, or recouped payment for services furnished in connection with such events; and the processes that CMS uses to identify such events and deny or recoup payment.^{1, 2} The Act also mandates that OIG recommend, as appropriate, potential processes for public disclosure of information about events, which will ensure patient privacy and permit the use of the information for a root-cause analysis to inform the public and the medical community about safety issues. (For relevant text of the Act, see Appendix A.) To meet the requirements of the Act, OIG published a series of reports in 2008 and will publish additional reports based on ongoing work.³

Adverse Events in Hospitals

Since the Act went into effect, patient safety issues have continued to receive attention from policymakers, the health care industry, and patient safety advocates. The health care community now uses the term “adverse event” more commonly than “never event” to refer to harm experienced by a patient as a result of medical care. After consulting with congressional committee staff in 2007, we modified our approach and terminology to be consistent with evolving patient safety research and industry trends.

As used in this study, an adverse event is defined as harm to a patient as a result of medical care or harm that occurs in a healthcare setting. Although an adverse event often indicates that the care resulted in an undesirable clinical outcome and may involve medical errors, adverse events do not always involve errors, negligence, or poor quality of care and may not always be preventable.⁴

Following a review of Medicare policies and expenditures, as well as consultation with officials from CMS and AHRQ, we chose to focus our work on inpatient admissions to acute care hospitals. In 2007, 12.3 million Medicare beneficiaries were hospitalized⁵ and inpatient hospital costs constituted the largest portion of Medicare expenditures (30 percent in 2007).⁶

¹ Tax Relief and Health Care Act of 2006 (TRHCA), P.L.No. 109-432 § 203.

² For purposes of the Act, the term “never event” means “an event that is listed and endorsed as a serious reportable event by the National Quality Forum (NQF) as of November 16, 2006.” TRHCA, § 203(d). NQF uses the term “serious reportable events” to describe a specific list of events associated primarily with patient death or serious disability that “should never occur in a health care setting.” These became known as “never events.” The list is available online at <http://www.qualityforum.org/Topics/Safety.aspx>. Accessed on August 12, 2009.

³ The studies released in 2008 include: Department of Health and Human Services (HHS), OIG, *Adverse Events in Hospitals: Overview of Key Issues*, OEI-06-07-00470, December 2008; OIG, *Adverse Events in Hospitals: State Reporting Systems*, OEI-06-07-00471, December 2008; and OIG, *Adverse Events in Hospitals: Case Study of Incidence Among Medicare Beneficiaries in Two Counties*, OEI-06-08-00220, December 2008.

⁴ R.M. Wachter, *Understanding Patient Safety*, McGraw-Hill, 2008.

⁵ CMS, *Statistics Book*, Table IV.1: Medicare/short-stay hospital utilization, 2008, p. 43.

⁶ Based on data contained in the Congressional Budget Office (CBO), *Fact Sheet for CBO's March 2008 Baseline: Medicare*, March 12, 2008. Available online at <http://www.cbo.gov/budget/factsheets/2008b/medicare.pdf>. Accessed on October 21, 2009.

Reporting Information About Adverse Events

In *To Err is Human: Building a Safer Health System*, the Institute of Medicine (IOM) recommended a nationwide system for collecting standardized data about serious medical errors and other adverse events.⁷ IOM maintained that adverse event reporting would ensure provider accountability, and that standardized data definitions would allow stakeholders to compile data, analyze reports, and target areas to improve patient safety. At present, there is no centralized adverse event reporting system to which all hospitals submit adverse event data and which, in turn, disseminates adverse event information to a national audience. Rather, there are separate Federal, State, and nongovernmental entities that receive and disclose adverse event information. Depending on the entity, reporting by hospitals is either voluntary or mandatory, and the entities have different data collection procedures, privacy protections, and dissemination practices. For this memorandum report, we reviewed the following entities, which receive information about adverse events from hospitals:

- State adverse event reporting systems;
- PSOs; and
- CMS, in its role as recipient of Medicare claims that include information about hospital-acquired conditions.

We selected these entities because (1) many State systems have a history of collecting and analyzing adverse event data; (2) PSOs represent a significant, recent Federal effort to collect national adverse event data; and (3) CMS claims data include information about adverse events affecting Medicare beneficiaries, a specific population of interest identified in the Act.

State Adverse Event Reporting Systems

In the 2008 report, *Adverse Events in Hospitals: State Reporting Systems*, OIG found that 25 States and the District of Columbia operated systems to collect adverse event data submitted by hospitals.⁸ All of these State systems received information about the event itself and the name of the hospital. However, they differed in a variety of ways, including whether reporting was voluntary or mandatory, how information about events was reported, and the types of events reported. State systems also differed on the criteria used to define adverse events, the amount and type of information submitted about patients, and whether hospitals' submissions included information about the causes of events.

Patient Safety Organizations

AHRQ is implementing a recently established program to collect national adverse event information. Hospitals may voluntarily submit information about adverse events to

⁷ L. T. Kohn, J. M. Corrigan, and M. S. Donaldson, editors, *To Err is Human: Building a Safer Health System, A Report of the Committee on Quality of Health Care in America*, Institute of Medicine, 1999.

⁸ OIG, *Adverse Events in Hospitals: State Reporting Systems*, OEI-06-07-00471, December 2008.

PSOs, which will allow PSOs to perform analysis of aggregated data. PSOs may, in turn, provide hospitals with analysis and recommendations for improving patient safety and quality of care. A variety of organizations are eligible to become PSOs; AHRQ determines whether they meet certain criteria to perform “patient safety activities.”⁹ Examples of organizations that have sponsored a PSO include hospital associations, hospital chains, existing patient safety consultant groups, and newly created organizations.¹⁰ As of December 1, 2009, AHRQ had certified 72 PSOs.¹¹

AHRQ is creating and will maintain the Network of Patient Safety Databases (NPSD) to provide an “evidence-based management resource for providers, patient safety organizations, and other entities.”¹² PSOs will submit adverse event information received from hospitals to the NPSD through “common formats,” which are standardized data

collection forms that AHRQ is developing. Additionally, AHRQ has issued two contracts to facilitate transmission of adverse event data from PSOs to the NPSD. The Iowa Foundation for Medical Care will be responsible for removing patient identifiers from PSO data prior to submission to the NPSD. Westat will operate the NPSD itself. The NPSD will allow AHRQ to receive and publicly disclose non-identifiable adverse event data at a national level. Once the NPSD is operational, the Patient Safety Act requires that the data be used to analyze national and regional statistics, including trends and patterns of reported adverse events, and for publicly disclosing findings from such analyses.¹³

CMS Receipt of Medicare Claims

In processing Medicare claims, CMS uses hospital claims data to identify certain adverse events, called hospital-acquired conditions. Since October 1, 2007, CMS has required that hospitals assign a present on admission (POA) indicator to each diagnosis for acute inpatient Medicare claims.¹⁴ The POA indicator differentiates diagnoses that were hospital-acquired from those that were present on admission. This was an initial step in complying with the Deficit Reduction Act of 2005 (DRA), which required CMS to select hospital-acquired conditions for which hospitals would not be paid higher Medicare reimbursement.¹⁵ CMS selected 10 categories of conditions for the Medicare hospital-acquired condition policy, which became effective October 1, 2008, and denies hospitals

⁹ The Secretary delegated authority to AHRQ to make these determinations, as well as to fulfill other requirements of the Patient Safety Act. Patient Safety and Quality Improvement Act of 2005, P.L.No. 109-41 § 2, Public Health Service Act, §§ 923 and 924, 42 U.S.C. §§ 299b-23 and -24; 73 Fed. Reg. 70732 (Nov. 21, 2008).

¹⁰ AHRQ, *PSO Update: Final Rule & Common Formats*, December 8, 2008. Available online at https://www.psopp.org/c/document_library/get_file?uuid=c03fb6c5-0de4-49e2-9a1f-fc6ee47c2e28&groupId=10218. Accessed on December 22, 2009.

¹¹ AHRQ, *Patient Safety Organizations*. Available online at <http://www.pso.ahrq.gov/listing/alphalist.htm>. Accessed on December 1, 2009.

¹² 42 U.S.C. § 922b-23(a).

¹³ 42 U.S.C. § 299b-23(c).

¹⁴ CMS, *CMS Manual System*, Change Request 5679 (July 20, 2007).

¹⁵ DRA, P.L.No. 109-171 § 5001(c)(1), Social Security Act § 1886(d)(4)(D), 42 U.S.C. § 1395ww(d)(4)(D).

higher payment for Medicare admissions complicated by the 10 conditions.¹⁶ Appendix B contains a list of these conditions.

¹⁶ Fiscal Year 2009 Inpatient Prospective Payment System Final Rule, 73 Fed. Reg. 48434, 48471-48491 (Aug. 19, 2008); CMS, *CMS Manual System*, Change Request 6189 (Oct. 3, 2008).

Public Disclosure of Information About Adverse Events

Public disclosure of adverse event information offers potential benefits, yet may also lead to unintended negative consequences. For example, publicly disclosing adverse event information can educate healthcare providers about the causes of events potentially leading to improvements in patient safety, and assist patients making decisions about their care. However, there is concern that disclosure of event information could undermine patient privacy and that naming the hospital where an event occurred, or the individual providers involved, could discourage reporting of events.

METHODOLOGY

Scope

For this memorandum report, we reviewed policies, practices, and plans for publicly disclosing information about adverse event causes and prevention strategies, while protecting patient privacy. We did not examine hospital or provider confidentiality issues, such as naming the hospital where an event occurred in disclosures, except for possible patient privacy implications. We reviewed 17 selected State adverse event reporting systems, 8 selected PSOs that will forward data to AHRQ's NPSD, and CMS. Data collection for this study was performed from July through September 2009. Findings represent policies, practices, and plans in place during that time.

Selection of State Adverse Event Reporting Systems and PSOs

Using data from the OIG report *Adverse Events in Hospitals: State Reporting Systems* (OEI-06-07-00471) and initial contacts with State system staff, we identified 17 State adverse event reporting systems that, as of July 2009, collected information from acute care hospitals about patients affected by adverse events and the causes of those events.¹⁷ States using these systems are: Colorado, Florida, Maine, Maryland, Massachusetts (two systems), Minnesota, Nevada, New Jersey, New York, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Utah, and Vermont.

Using AHRQ's Directory of PSOs and contacts with PSO staff, we identified the first eight PSOs that either received or intended to receive adverse event information from acute care hospitals.¹⁸ These PSOs are: California Hospital Patient Safety Organization; Clinical Practice Advancement Center; ECRI Institute PSO; HealthWatch; Human Performance Technology Group, Inc.; Institute for Safe Medication Practices; Missouri Center for Patient Safety; and, Peminic, Inc.

Data Collection and Analysis

We conducted structured interviews with staff from the 17 State adverse event reporting systems to determine the extent to which State systems disclose information about events,

¹⁷ We did not review State systems that, based on information from the 2008 OIG report, did not collect information from acute care hospitals both about patients affected by adverse events and the causes of those events.

¹⁸ HHS, AHRQ, *Alphabetical Directory of Listed Patient Safety Organizations*. Available online at <http://www.pso.ahrq.gov/listing/alphalist.htm#P0002>. Accessed on October 22, 2009.

their causes, corrective actions, risk reduction strategies, and patients affected by events. We also reviewed relevant documents recently published by State systems, such as reports, periodic bulletins, safety alerts, and information on State system Web sites. Regarding patient privacy, we determined the extent to which State systems collect information about patients and the extent to which they disclose this information. We also identified State legal prohibitions against compelled release of information about patients, and confirmed our interpretations with State system staff.

We conducted structured interviews with staff from AHRQ and the eight PSOs regarding the extent to which they disclose information about adverse events, their future plans for disclosure, the status of efforts necessary for the NPSD to become operational, and patient privacy issues. We reviewed relevant documents, such as AHRQ's interim guidance for PSOs, proposed and final rules for PSOs, contracts related to PSOs and the NPSD, and the Patient Safety Act. We examined the Patient Safety Act for requirements regarding protections of patient privacy that apply to information submitted to PSOs and forwarded to the NPSD.

We interviewed CMS staff regarding current and planned public disclosure of information from Medicare claims data that include POA indicators. We reviewed claims data and relevant documents to identify the extent to which these data could inform the public about hospital-acquired conditions, their causes, and patient safety issues. We also examined mechanisms that CMS uses to protect patient privacy when it allows access to Medicare claims data.

Limitations

Although numerous entities collect information about adverse events, we could not examine all such entities for this memorandum report. Examples of other entities that receive adverse event information not examined in this memorandum report include the Centers for Disease Control and Prevention's National Health Safety Network, which receives reports of hospital-acquired infections; and a variety of data systems at the Food and Drug Administration (FDA) that receive reports of adverse events associated with approved drugs, devices, and biologics, among others.¹⁹

Standards

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

¹⁹ A recent OIG report examined adverse event reporting to FDA for medical devices. OIG, *Adverse Event Reporting for Medical Devices*, OEI-01-08-00110, October 2009.

RESULTS

Public Disclosure of Information About Adverse Events is Limited Among the Entities in Our Review

Seven State adverse event reporting systems disclosed more extensive information about the causes of adverse events and prevention strategies than other State systems. Such disclosure may provide the medical community with valuable information for improving patient safety. Another three State systems disclosed less extensive information about adverse events. AHRQ plans to disclose adverse event information but has not because data are not yet available in the NPSD. CMS is considering plans for disclosing information about hospital-acquired conditions in the future.

Seven State Systems Publicly Disclosed More Extensive Information About Causes of Adverse Events and Prevention Strategies Than Other State Systems. These seven systems provided information to educate the medical community on how to prevent or reduce the occurrence of adverse events. Disclosure by these systems was based on multiple reports of similar adverse events and included analysis of their causes. Disclosures also contained information about actions taken by hospitals to correct identified vulnerabilities, strategies to reduce the risk of events occurring, and demonstrated improvements by hospitals. Table 1 provides details about the types of adverse event information disclosed by the 17 State systems that we reviewed.

For example, one State system published an article addressing adverse events related to anticoagulants (blood-thinning medications). The article combined information from hundreds of adverse event reports received by the State system and data from evidence-based research. In brief case summaries, the article provided details about the events, including the level of patient harm and identified causes. To address the causes, the article recommended that hospitals establish anticoagulation management service programs that would document these services, educate patients and families, and gauge progress in improving performance. State system staff followed up 6 months after the article was distributed to hospitals and found that over half of hospitals in the State reported making changes as a result of the article.

In contrast, three systems that we reviewed disclosed less extensive information about causes and prevention strategies for events. These systems disclosed either information about individual events or lists of events compiled from submitted hospital reports. For example, two systems posted information about individual events, including event type and date, hospital name and department, and possible contributing factors, but did not disclose root-cause analysis information drawn from data about multiple occurrences. The remaining system listed all reported corrective actions that hospitals anticipated making, such as planned training, but did not indicate which events led to the planned actions.

Table 1: Adverse Event Information Disclosed by Selected State Systems

	Disclosure About Individual Events		Disclosure Based on Information From Multiple Events			
Seven State systems with more extensive disclosure						
Maryland	•		•		•	•
Massachusetts, BRM*	•	•	•	•	•	•
Massachusetts, DPH*	•	•	•	•	•	
Minnesota			•	•	•	•
New Jersey	•	•	•		•	•
Oregon	•	•			•	•
Pennsylvania		•	•	•	•	•
Three State systems with less extensive disclosure						
Colorado	•	•				
Maine				•		
Rhode Island	•	•				
Seven State systems with no disclosure						
Utah						
Florida						
Nevada						
New York						
South Carolina						
South Dakota						
Vermont						
* BRM abbreviates the Board of Registration in Medicine and DPH abbreviates the Department of Public Health.						

Source: OIG review of 17 selected State adverse event reporting systems, 2009.

AHRQ Plans To Disclose Adverse Event Information, but the NPSD Is Not Operational and Possible Barriers to Data Submission Exist. AHRQ plans to use aggregated PSO data from the NPSD to identify national and regional trends of adverse events, and to make this information available to the public. AHRQ’s plans include generating two public reports, as required by the Patient Safety Act: a report about effective strategies for reducing medical errors and increasing patient safety, and a report containing trend analysis results.

AHRQ officials estimated that initial NPSD data will be available for analysis and disclosure in early 2011. These initial data will include identification of adverse events and their contributing factors for hospitals. AHRQ officials reported additional plans to collect data about the causes of adverse events (e.g., root-cause analysis) and to expand data collection beyond hospitals to other healthcare settings, such as nursing homes. However, AHRQ has not announced a timeline for these additional plans.

Staff from several PSOs that we reviewed reported barriers that could limit hospital participation with PSOs and data submission to the NPSD. For example, staff from one PSO reported that some hospitals had questioned the costs and benefits of PSO participation. Additionally, staff from two PSOs indicated that they were unsure about the value of submitting data to the NPSD.

Beyond AHRQ's disclosure of PSO data, individual PSOs can also generate learning materials for hospitals. Staff from only one PSO that we reviewed indicated plans to share such information directly with the public. These staff reported plans to include information about medication-related adverse events in a medication safety newsletter available to all healthcare professionals and consumers.

CMS Is Considering Plans for Public Disclosure of Information About Medicare Hospital-Acquired Conditions, a Subset of Adverse Events. CMS officials indicated that CMS is considering posting the incidence of hospital-acquired conditions on its Hospital Compare Web site, which currently includes other quality measures about hospitals. Additionally, CMS may publicly disclose results from an ongoing evaluation focused on the Medicare hospital-acquired conditions policy, its effects on Medicare reimbursement, utilization, quality, patient safety, and any unintended consequences. CMS contracted for the evaluation in September 2009, and will determine the extent of disclosure after findings are known.

Although valuable for ascertaining the incidence of hospital-acquired conditions, Medicare claims data lack information about the causes of these conditions or prevention strategies, limiting their usefulness for improving patient safety. CMS officials acknowledged that supplemental information about the circumstances under which a beneficiary experienced a hospital-acquired condition could allow better understanding of causes and development of prevention strategies. To collect such information, CMS is considering combining hospital-acquired condition data with data from other systems.

All Reviewed Entities Protect Patient Privacy Through Policies, Practices, and Legal Provisions

Each entity that we reviewed has patient privacy protections. These protections vary across entities and include policies regarding what patient identifiers are collected, practices regarding disclosing patient identifiers, and legal protections that apply to patient identifiers.

State Systems Either Do Not Collect or Disclose Patient Identifiers and Most Prohibit the Compelled Release of Patient Identifiers. Five State systems that we reviewed do not collect any patient identifiers, such as the patient's name or address. Because these State systems do not collect patient identifiers, they cannot disclose such information. See Appendix C for the types of patient identifiers that each of the 17 selected State systems collect.

Our review found no instances in which the remaining 12 State systems disclosed patient identifiers publicly. Rather, most publications referred to patients in ways that would prevent identification of individuals. For example, one approach to protecting patient privacy involved developing profiles of typical patients who experience a type of event, such as female, Caucasian, 60–64 years of age, and admitted to the hospital an average of 13 days prior to the event. However, we noticed that some publications contained a level of detail that could be used to identify the patient. The possibility of compromised patient privacy could be heightened under certain circumstances, such as when an adverse event involves a patient who lives in a smaller community and when media reports about an event contain additional information that can be matched to disclosed information about the event.

Beyond disclosure of patient information in publications intended for learning, State systems may be asked to disclose patient identifiers under four circumstances: public records requests, civil judicial proceedings, criminal judicial proceedings, and administrative proceedings. State laws vary regarding prohibitions against State systems being compelled to release patient identifiers in these instances. Eight of the seventeen systems that we reviewed have State laws that expressly prohibit the compelled release of patient identifiers under all four circumstances. State laws for another eight systems prohibit compelled release under at least one, but not all, of the circumstances. Table 2 lists the four circumstances and whether State laws prohibit systems from being compelled to release patient identifiers under each circumstance. Appendix D expands Table 2 by providing citations to relevant State laws and regulations.

For three systems, we found it difficult to ascertain whether State laws prohibited the system from being legally compelled to release patient identifiers under one or more of these circumstances. For example, one State law specifies that adverse event information “shall be confidential, except for official purposes,” but does not define official purposes. These ambiguous laws could require further administrative or judicial interpretation regarding protection of patient privacy.

Table 2: Legal Prohibitions Against Compelled Release of Patient Identifiers by Selected State Adverse Event Reporting Systems

Colorado	Prohibited	Prohibited	Prohibited	Prohibited
Florida	Prohibited	Prohibited	Not prohibited	Prohibited
Maine*	Prohibited	Prohibited	Prohibited	Prohibited
Maryland	Prohibited	Prohibited	Not prohibited	Not prohibited
Massachusetts, BRM#	Prohibited	Prohibited	Prohibited	Prohibited
Massachusetts, DPH#	Prohibited	Not prohibited	Not prohibited	Not prohibited
Minnesota*	Prohibited	Not prohibited	Not prohibited	Not prohibited
Nevada	Prohibited	Prohibited	Prohibited	Prohibited
New Jersey	Prohibited	Prohibited	Prohibited	Prohibited
New York	Prohibited	Unclear	Unclear	Unclear
Oregon*	Prohibited	Prohibited	Not prohibited	Prohibited
Pennsylvania*	Prohibited	Prohibited	Prohibited	Prohibited
Rhode Island	Prohibited	Prohibited	Prohibited	Prohibited
South Carolina*	Prohibited	Unclear	Unclear	Unclear
South Dakota	Unclear	Unclear	Unclear	Unclear
Utah	Prohibited	Prohibited	Prohibited	Prohibited
Vermont	Prohibited	Prohibited	Not prohibited	Prohibited
<p>*This State system does not collect patient identifiers. # BRM abbreviates the Board of Registration in Medicine and DPH abbreviates the Department of Public Health.</p>				

Source: OIG review of 17 selected State adverse event reporting systems, 2009.

Patient Identifiers Collected by PSOs Will Be Removed Before Submission to the NPSD, and Patient Privacy Is Protected Under the Patient Safety Act. The initial common formats for PSO data include patient identifiers, such as patient name, date of birth, and medical record number. To ensure that no patient identifiers are disclosed to the public, an AHRQ contractor will remove patient identifiers before submission to the NPSD.²⁰ The contractor is also tasked with developing a protocol for suppressing descriptive information that could compromise patient identity. For example, if only one hospital performed liver transplants in a State, an adverse event report involving a liver transplant in the State would require suppressing either the State name or the procedure name to protect patient privacy.

To encourage hospitals to report information about adverse events, Federal privilege and confidentiality protections apply to adverse event information collected by PSOs.²¹ Privilege protections outlined in the Patient Safety Act limit or forbid the use of PSO data in criminal, civil, administrative, or other proceedings. Additionally, confidentiality

²⁰ Congress mandated that the NPSD use nonidentifiable information. 42 U.S.C. § 299b-23.

²¹ 42 U.S.C. § 299b-22.

protections prohibit PSOs from disclosing any identifiable information about a provider or patient.

Patient Identifiers Collected by CMS Are Released Only Through Data Use Agreements Based on Federal Laws That Protect Patient Privacy. Medicare claims contain information about Medicare beneficiaries including names, Medicare numbers, addresses, dates of birth, gender, and race; and details about their hospital stays, such as provider names, billing numbers, diagnosis codes, and charges for services.²² Although CMS has not disclosed information to the public about hospital-acquired conditions identified through Medicare claims data, it does allow access to claims data in two forms: full Medicare claims data and limited datasets. Full Medicare claims data include beneficiary and provider identifiers, whereas limited datasets exclude or aggregate all identifiers of patients and providers. For example, instead of the beneficiary's date of birth, limited datasets contain an age range, such as "[age] 65 through 69."²³

To access either full or limited datasets, users must demonstrate a need for the data, state the intended use of the research, and sign a data use agreement that includes specific provisions regarding the protection of patient privacy.²⁴ Pursuant to the Privacy Act of 1974, CMS will only release claims data to a user who "agrees to implement appropriate management, operational and technical safeguards sufficient to protect the confidentiality, integrity and availability of the information and information systems and to prevent unauthorized access."²⁵ Additionally, CMS's Privacy Board must review and approve each request for access to full datasets with identifiers and any publications resulting from use of identifiable data.²⁶

²² CMS, *Medicare Claims Processing Manual* ch. 25. Available online at <http://www.cms.hhs.gov/manuals/downloads/clm104c25.pdf>. Accessed on October 22, 2009.

²³ CMS, *LDS Inpatient SNF Claim Record Data Dictionary*, 2009. Available online at <http://www.cms.hhs.gov/LimitedDataSets/Downloads/SAFidsINPMar2009.pdf>. Accessed on October 22, 2009.

²⁴ CMS has two distinct data use agreements. Form CMS-R-0235 is used when the recipient is receiving data containing individual identifiers. Form CMS-R-0235L is used when the recipient is receiving limited data sets. Available online at <http://www.cms.hhs.gov/PrivProtectedData/>. Accessed on December 2, 2009.

²⁵ 71 Fed. Reg. 67137, 67142 (Nov. 20, 2006).

²⁶ The CMS Privacy Board safeguards personally identifiable information, assures that there is minimal privacy risk to an individual when information is released to a researcher, and ensures compliance with the Privacy Act of 1974 and the HIPAA Privacy Rule. Available online at <http://www.cms.hhs.gov/SystemLifecycleFramework/downloads/privacypolicy.pdf>. Accessed on November 25, 2009.

CONCLUSION

This memorandum report contains no recommendations and is being issued directly in final form. We did not make recommendations for two reasons. First, we concluded that it is not appropriate to make a broad recommendation for a public disclosure process. Entities collect adverse event data for different purposes, such as for generating information for patient safety improvements, conducting oversight of hospitals, or processing payments for healthcare services. Given these differences, we believe that it is less useful to propose a standard process for public disclosure than it is to describe the current and planned practices of the entities that we reviewed. Second, all these entities have patient privacy protections. Therefore we did not identify particular privacy concerns that warrant recommendations.

The disclosure practices of the seven State systems with more extensive disclosure can serve as models for other entities. These systems disclose analysis of the causes of events, evidence-based guidance for reducing occurrences, and information about demonstrated improvements by hospitals. This type of information, if disseminated by other State systems and entities that receive adverse event information, could help to improve patient safety.

PSOs are expected to provide AHRQ with national data about adverse events and contributing factors. Once common formats are fully implemented, AHRQ will be positioned to publicly disclose more extensive information about the causes of events, prevention strategies, and the effectiveness of those strategies. It is encouraging that some PSOs are currently receiving adverse event information from hospitals and are preparing to submit data to the NPSD. However, successful implementation will require AHRQ to address the barriers that staff from one PSO described, including that some hospitals question the cost and benefit of PSO participation.

Using only Medicare claims data, CMS is limited in what it can disclose about hospital-acquired conditions, because claims data do not contain information about causes. However, CMS's plan to supplement claims data with other data sources appears to have the potential to generate new and useful information about hospital-acquired conditions, their causes, and prevention.

If you have comments or questions about this memorandum report, please provide them within 60 days. Please refer to report number OEI-06-09-00360 in all correspondence.

APPENDIX A: TAX RELIEF AND HEALTH CARE ACT OF 2006

P.L.No. 109-432

DIVISION B – MEDICARE AND OTHER HEALTH PROVISIONS

TITLE II—MEDICARE BENEFICIARY PROTECTIONS

SEC 203 OIG STUDY OF NEVER EVENTS

(a) Study.—

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

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

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

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

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

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

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

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

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

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

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

(A) will ensure protection of patient privacy; and

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

APPENDIX A (continued)

(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: MEDICARE LIST OF HOSPITAL-ACQUIRED CONDITIONS

The Centers for Medicare & Medicaid Services (CMS) list of hospital-acquired conditions is divided into 10 categories. Effective October 1, 2008, CMS no longer pays a higher reimbursement for hospitalizations complicated by these categories of conditions if they were not present on admission.

1. Foreign object retained after surgery
2. Air embolism
3. Blood incompatibility
4. Pressure ulcers (stages III and IV)
5. Falls
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
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 Final Inpatient Prospective Payment System Rule, 73 Fed. Reg. 48434, 48471 (August 19, 2008).

APPENDIX C: PATIENT IDENTIFIERS COLLECTED BY SELECTED STATE ADVERSE EVENT REPORTING SYSTEMS

System	Name	Address	Date of Birth	Identifiable Number
Colorado				•
Florida	•	•		•
Maine				
Maryland	•		•	
Massachusetts, BRM [#]	•		•	
Massachusetts, DPH [#]	•		•	
Minnesota				
Nevada			•	
New Jersey	•	•	•	•
New York			•	•
Oregon				
Pennsylvania				
Rhode Island				•
South Carolina				
South Dakota	•			
Utah			•	
Vermont		•		
* Includes medical record number, hospital billing number, unique identifier, or patient identification number. # BRM abbreviates the Board of Registration in Medicine and DPH abbreviates the Department of Public Health.				

Source: Office of Inspector General review of 17 selected State adverse event reporting systems, 2009.

APPENDIX D: LEGAL PROHIBITIONS AGAINST COMPELLED RELEASE OF PATIENT IDENTIFIERS BY SELECTED STATE ADVERSE EVENT REPORTING SYSTEMS

Colorado ¹	Prohibited	Prohibited	Prohibited	Prohibited
Florida ²	Prohibited	Prohibited	Not prohibited	Prohibited
Maine ^{3*}	Prohibited	Prohibited	Prohibited	Prohibited
Maryland ⁴	Prohibited	Prohibited	Not prohibited	Not prohibited
Massachusetts, BRM ^{5#}	Prohibited	Prohibited	Prohibited	Prohibited
Massachusetts, DPH ^{6#}	Prohibited	Not prohibited	Not prohibited	Not prohibited
Minnesota ^{7*}	Prohibited	Not prohibited	Not prohibited	Not prohibited
Nevada ⁸	Prohibited	Prohibited	Prohibited	Prohibited
New Jersey ⁹	Prohibited	Prohibited	Prohibited	Prohibited
New York ¹⁰	Prohibited	Unclear	Unclear	Unclear
Oregon ^{11*}	Prohibited	Prohibited	Not prohibited	Prohibited
Pennsylvania ^{12*}	Prohibited	Prohibited	Prohibited	Prohibited
Rhode Island ¹³	Prohibited	Prohibited	Prohibited	Prohibited
South Carolina ^{14*}	Prohibited	Unclear	Unclear	Unclear
South Dakota ¹⁵	Unclear	Unclear	Unclear	Unclear
Utah ¹⁶	Prohibited	Prohibited	Prohibited	Prohibited
Vermont ¹⁷	Prohibited	Prohibited	Not prohibited	Prohibited

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| <ol style="list-style-type: none"> 1. Colorado Revised Statutes (CRS) 25-1-124(4); CRS 24-72-204. 2. Florida Statutes § 395.0197(7). 3. 22 Maine Revised Statutes § 8754(3). 4. Code of Maryland Regulations 10.07.06.09. 5. Massachusetts General Law (MGL) ch. 4, § 7; MGL. ch. 111, §§ 204 and 205; 243 Code of Massachusetts Regulations 3.04. 6. MGL ch. 4, § 7. 7. Minnesota Statutes § 144.7065, sub. 0. 8. Nevada Revised Statutes Annotated (NRS) § 439.840 (as amended by 2009 Nevada Statutes 153 § 8); NRS § 439.860. 9. New Jersey Statutes § 26:2H-12.25(f). 10. New York Consolidated Law Service Public Health § 2805- m. Note: Section 2805-m of the New York Public Health Law states that adverse events reports submitted to the State shall be kept confidential and shall not be subject to discovery in civil actions. | <ol style="list-style-type: none"> 10. (continued) While Section 2805-m does not expressly state that it affords adverse event reports an evidentiary privilege, judicial decisions suggest that it does. Moreover, although at least one intermediate appellate court has held that this statute applies to grand jury subpoenas, the State's highest court has not addressed this issue. 11. Oregon Laws 2003, ch. 686, § 12. 12. 40 Pennsylvania Statutes (PS) § 1303.311(h); 40 PS §§ 1303.311(d). 13. Rhode Island General Laws §§ 23-17-40(g), 23-17-15, and 23-17-25(a). 14. South Carolina Code Annotated §§ 44-7-315(A) and § 44-7-315(B); S.C. Code Ann. § 44-7-310. 15. South Dakota Codified Laws § 34-12-17. 16. Utah Administrative Code (UAC) R380-200-6 and R380-210-5; Title 26, Chapter 3 of the Utah Code; Utah Code Annotated (UCA) §§ 26-3-7 and 26-3-9; UCA § 63G-2-201. 17. 18 Vermont Statutes Annotated § 1917. |
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*This State system does not collect patient identifiers.
 # BRM abbreviates the Board of Registration in Medicine and DPH abbreviates the Department of Public Health.

Source: Office of Inspector General review of 17 selected State adverse event reporting systems, 2009.