Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

HOSPITAL REPORTING OF DEATHS RELATED TO RESTRAINT AND SECLUSION

Daniel R. Levinson
Inspector General

September 2006
OEI-09-04-00350

Office of Inspector General

http://oig.hhs.gov

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

Office of Audit Services

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

Office of Evaluation and Inspections

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

Office of Investigations

The Office of Investigations (OI) conducts criminal, civil, and administrative investigations of allegations of wrongdoing in HHS programs or to HHS beneficiaries and of unjust enrichment by providers. The investigative efforts of OI lead to criminal convictions, administrative sanctions, or civil monetary penalties.

Office of Counsel to the Inspector General

The Office of Counsel to the Inspector General (OCIG) provides general legal services to OIG, rendering advice and opinions on HHS programs and operations and providing all legal support in OIG's internal operations. OCIG imposes program exclusions and civil monetary penalties on health care providers and litigates those actions within HHS. OCIG also represents OIG in the global settlement of cases arising under the Civil False Claims Act, develops and monitors corporate integrity agreements, develops compliance program guidances, renders advisory opinions on OIG sanctions to the health care community, and issues fraud alerts and other industry guidance.

EXECUTIVE SUMMARY

OBJECTIVE

To (1) determine whether hospitals fail to report restraint and seclusion-related deaths, as required, to the Centers for Medicare & Medicaid Services (CMS); and (2) evaluate CMS and State survey agency responsiveness, guidance, and monitoring concerning the reporting requirement.

BACKGROUND

Pursuant to section 1861(e)(9) of the Social Security Act, the Secretary of the Department of Health and Human Services establishes Conditions of Participation (CoP) that hospitals must meet to participate in the Medicare and Medicaid programs. In December 1997, CMS published a proposed rule to revise all existing hospital CoPs and to include a new Patients' Rights CoP. The new CoP was, in part, a response to reports of violations of patients' rights in hospitals. The new rule became final on July 2, 1999. CMS contracts with State survey agencies to assess hospital compliance with these CoPs.

The Patients' Rights CoP establishes, among other things, a reporting requirement for all hospital deaths associated with the use of restraint or seclusion for behavior management (42 CFR § 482.13(f)(7)). The term restraint includes either a physical restraint or a drug used as a restraint. A physical restraint is any manual method or device used to restrict freedom of movement or access to one's body. A drug used as a restraint is a medication that is used to control behavior or restrict movement, which is not standard treatment for a patient's medical or psychiatric condition. Seclusion is defined as involuntary confinement of a patient to a room or area from which the person is physically prevented from leaving. Hospitals must report deaths associated with restraint or seclusion for behavior management to their CMS regional office prior to close of business on the day following the event.[1] This provision became effective on August 2, 1999.

CMS requirements establish timeframes for CMS regional offices and State survey agencies to ensure that (1) investigations concerning hospital compliance with the Patients' Rights CoP are timely and (2) information about deaths related to restraint and seclusion is

[1] The reporting requirement does not apply to deaths associated with the use of restraint for acute medical and surgical care.

communicated both to Protection and Advocacy agencies and to the CMS central office in a timely manner.[2] The CMS central office compiles a roster of deaths related to restraint and seclusion based on reports that hospitals forward to regional offices.

To determine whether hospitals report to CMS all deaths related to restraint and seclusion, we compared reports received by CMS to those received by State survey agencies, Protection and Advocacy agencies, and the Food and Drug Administration for deaths that occurred between August 2, 1999 (when the reporting requirement became effective), and December 31, 2004. We also gathered information from CMS central and regional offices about CMS policies and death reporting procedures, interactions with State survey agencies, record keeping, and collection of information by the CMS central office.

FINDINGS

Hospitals failed to report to CMS 44 of 104 documented deaths related to restraint and seclusion between August 2, 1999, and December 31, 2004. We received information from CMS, State survey agencies, Protection and Advocacy agencies, and the Food and Drug Administration concerning 104 behavior management-related deaths associated with restraint and seclusion that occurred during this time period. Hospitals did not report 44 of these deaths directly to CMS. Of those deaths that hospitals reported directly to CMS, fewer than one-third were reported timely.

CMS and State survey agencies do not consistently take action in response to reported deaths in a timely manner, limiting their ability to address potentially harmful conditions. State survey agencies and CMS regional offices regularly fail to meet CMS's timelines for taking action in response to deaths related to restraint and seclusion that are reported by hospitals.

State survey agencies do not provide regular guidance on the reporting requirement. Only 52 percent of the State survey agencies indicated that, at some point, they had disseminated information to hospitals about the reporting requirement. Furthermore, fewer than

[2] Protection and Advocacy agencies, established pursuant to the Developmental Disabilities Act of 1975, provide advocacy and legal representation for people with physical or mental disabilities within the 50 States, the District of Columbia, Puerto Rico, and the U.S. Virgin Islands.

20 percent of State survey agencies provide information on an ongoing basis. Therefore, we conclude that hospitals may not understand fully the mandatory reporting requirement.

CMS does not maintain comprehensive and reliable information about reported deaths related to restraint and seclusion. CMS does not track deaths accurately because its roster excludes relevant deaths and includes others for which there is no reporting requirement. CMS regional offices do not request information from other agencies about hospital deaths related to restraint or seclusion, which would enable CMS to identify some unreported deaths.

RECOMMENDATIONS

To improve hospital reporting, the accuracy of data, and CMS's timely identification of deaths related to restraint and seclusion, CMS should:

Seek legislation to establish intermediate sanctions for hospitals that fail to report directly to CMS deaths related to restraint and seclusion. Currently, termination is the only remedy available to CMS if a hospital fails to comply with the CoP. Intermediate sanctions, such as civil monetary penalties, would provide CMS with a more appropriate remedy for hospitals that do not report timely and directly to CMS restraint-related deaths.

Consider regulatory changes that would require reporting all deaths related to the use of restraint and seclusion. If hospitals have difficulty distinguishing between medical and behavioral restraint, it may prevent them from reporting deaths as required under the current reporting requirement. Requiring hospitals to report deaths related both to use of restraint and seclusion for behavior management and to use of restraint for acute medical and surgical care could improve hospital compliance with the reporting requirement. In addition, clarifying the language in the regulation that states that a hospital must report deaths "where it is reasonable to assume that a patient's death is a result of restraint or seclusion" would eliminate further confusion. Hospitals then would have more definitive guidance to assist them in determining if a death is subject to the reporting requirement.

Instruct its regional offices and State survey agencies to adhere to timelines. CMS will be able to respond more quickly to patient safety issues if it ensures that regional offices and State survey agencies adhere to required timelines. Regional offices should hold State survey

agencies accountable for forwarding death reports and conducting complaint investigations in a timely manner.

Encourage State survey agencies to provide to hospitals ongoing training about the mandatory reporting requirement. Survey agencies could disseminate information to hospital officials regarding their reporting responsibilities during onsite reviews or annually.

Instruct regional offices to request periodic updates about deaths related to restraint and seclusion from other Federal and State agencies. We found that State survey agencies, Protection and Advocacy agencies, and the Food and Drug Administration have information regarding deaths related to restraint and seclusion for which CMS had no documentation. Improving communication with other agencies that receive and document deaths related to restraint and seclusion would help CMS identify some deaths that hospitals did not report directly to them and to maintain more comprehensive data.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

CMS generally concurred with our recommendations. CMS is considering proposing future changes that would simplify requirements for hospital reporting of restraint and seclusion-related deaths. CMS also indicated it will issue a Survey & Certification Memorandum to ensure that regional offices and survey agencies receive written instructions that reinforce the hospital death reporting timelines. Furthermore, CMS will instruct its regional offices to contact periodically survey agencies and other Federal agencies to request information regarding restraint and seclusion-related deaths.

In response to our recommendation that CMS work with Congress to establish intermediate sanctions for hospitals that fail to report deaths related to restraint or seclusion, CMS indicated that this change would be addressed most appropriately through legislative changes by Congress. We modified the recommendation to clarify that CMS should seek legislation that would allow CMS to impose intermediate sanctions against hospitals that do not comply with the reporting requirement.

TABLE OF CONTENTS

INTRODUCTION

OBJECTIVE

To (1) determine whether hospitals fail to report restraint and seclusion-related deaths, as required, to the Centers for Medicare & Medicaid Services (CMS); and (2) evaluate CMS and State survey agency responsiveness, guidance, and monitoring concerning the reporting requirement.

BACKGROUND

Medicare's Hospital Conditions of Participation

Title XVIII of the Social Security Act (the Act) establishes coverage and benefits under Part A of the Medicare program for inpatient hospital services. Section 1861(e)(9) of the Act specifies that a hospital also must meet other requirements that the Secretary of the Department of Health and Human Services (Secretary) finds necessary in the interest of the health and safety of the hospital's patients. Pursuant to this authority, the Secretary established the Conditions of Participation (CoP), which hospitals must meet to participate in the Medicare and Medicaid programs (42 CFR Part 482).

CMS contracts with State survey agencies to assess hospital compliance with CoPs. Pursuant to section 1865 of the Act, hospitals accredited by the Joint Commission on Accreditation of Healthcare Organizations (the Joint Commission) or other accrediting organizations approved by CMS, such as the American Osteopathic Association, are deemed to be in compliance with the CoPs.[3] Hospitals that are not accredited, but want to participate in the Medicare and/or Medicaid programs, receive certification through State survey agencies. State survey agencies conduct routine hospital reviews of most nonaccredited short-term acute hospitals every 3 years.[4] In addition, State survey agencies are required to conduct complaint surveys in response to allegations that hospitals are out of compliance with CoPs.

In December 1997, CMS published a proposed rule to revise all existing hospital CoPs and include a new Patients' Rights CoP (62 FR 66726). The new CoP was shaped, in part, by reports of patients' rights

[3] The Joint Commission and the American Osteopathic Association conduct onsite surveys at least every 3 years.

[4] Office of Inspector General, "CMS Oversight of Short-Term Acute Care Nonaccredited Hospitals" (OEI-01-04-00020), August 2005.

violations involving illegal and harmful uses of restraint and seclusion. On July 2, 1999, CMS published an interim final rule for the new Patients' Rights CoP for hospitals.[5] This provision became effective on August 2, 1999. Among other issues, the CoP addresses hospitals' use of restraint and seclusion. Pursuant to section 902 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, CMS must publish the final rule for the Patients' Rights CoP by December 2006.[6]

The Patients' Rights CoP defines both restraint and seclusion. A restraint is either a physical restraint or a drug used as a restraint. A physical restraint is any manual method or device used to restrict freedom of movement or access to one's body, whereas a drug used as a restraint is a medication that is not standard treatment for the patient's medical or psychiatric condition used to control behavior or restrict freedom of movement. Under the Patients' Rights CoP, seclusion occurs when a patient is confined involuntarily to a room or area and physically prevented from leaving.

Hospital Reporting Requirement for Deaths Related to Restraint and Seclusion

The Patients' Rights CoP contains two standards related to the use of restraint and seclusion: (1) restraint for acute medical and surgical care (42 CFR § 482.13(e)) and (2) restraint and seclusion for behavior management (42 CFR § 482.13(f)). The behavior management standard contains a reporting requirement that states, ". . . a hospital must report to CMS any death that occurs while a patient is restrained or in seclusion, or where it is reasonable to assume that a patient's death is a result of restraint or seclusion."[7] Under the reporting requirement, hospitals must report the death to their CMS regional office prior to close of business on the day following the event.[8] The reporting

[5] 64 FR 36070, Medicare and Medicaid Programs; Hospital Conditions of Participation: Patients' Rights.

[6] The Patients' Rights CoP interim final rule will expire after December 2006 unless the Secretary publishes a continuation of the regulation that indicates why CMS did not comply with the standard 3-year timetable for publication of final regulations.

[7] For the purpose of this report, we will refer to 42 CFR § 482.13(f)(7) as the "reporting requirement."

[8] Hospitals that must report include acute care, psychiatric, rehabilitation, long term care, children's, and alcohol-drug facilities. State hospitals must report if the restraint or seclusion-related death occurred in a part of the hospital that is certified for Medicare participation.

requirement only applies to deaths associated with the use of restraint or seclusion for behavior management, not those associated with the use of restraint for acute medical and surgical care. Hospitals that fail to report deaths related to restraint and seclusion are subject to termination from the Medicare program under section 1866 of the Act. In 1999, both the Senate and the House of Representatives introduced legislation to authorize intermediate sanctions, including civil monetary penalties, for hospitals' failure to comply with CMS's death reporting requirements.[9] However, neither bill was enacted.

Appendix A of the CMS "State Operations Manual" describes the conditions under which the death reporting requirement applies. Pursuant to the requirements, the behavior management standard applies in "emergency or crisis situations if a patient's behavior becomes aggressive or violent, presenting an immediate, serious danger to his/her safety or that of others."[10] The requirement further clarifies that the behavior management standard does not apply to situations in which a hospital restrains a "confused" patient who is removing his or her intravenous lines or ventilator intubation tube, or a patient who is "attempting to get out of bed with an unstable fractured leg." These situations, and others in which a patient is nonviolent, nonaggressive, or otherwise cooperative, "may be governed" by the acute medical and surgical care standard, which does not have a death reporting requirement.

Hospitals must report any death that occurs while a patient is in restraint or seclusion for purposes of behavior management and any death that occurs after behavior management restraint or seclusion has been discontinued and when the patient's death could be "reasonably related to that patient having been in restraint or seclusion."[11] However, the "State Operations Manual" does not provide specific guidance for hospitals to use in determining when a patient's death should be considered "reasonably related" to restraint or seclusion use.

CMS Process and Death Reporting Responsibilities

The CMS "State Operations Manual" includes requirements, first issued in a memorandum on March 23, 2000, for CMS regional offices, the

[9] Freedom From Restraint Act of 1999 (S. 736) and Patient Freedom From Restraint Act of 1999 (H.R. 1313).

[10] CMS, "State Operations Manual," Appendix A, section A-0075.

[11] CMS, "State Operations Manual," Appendix A, section A-0075.

CMS central office, and State survey agencies concerning restraint and seclusion-related death reporting.[12] When a hospital reports a death related to restraint or seclusion, the regional office determines whether the situation involved the use of restraint or seclusion for purposes of behavioral management, based on the information provided. If the regional office determines that restraint or seclusion was used for behavior management, the regional office authorizes the State survey agency to conduct an investigation into the "hospital's compliance with the Patient's Rights CoP at 42 CFR § 482.13 (including investigating the reported death)."[13]

The CMS central office is responsible for maintaining a central roster of all restraint and seclusion-related death reports and for communicating with regional offices as needed until the investigations are completed. The CMS central office also is required to maintain a copy of all report worksheets collected from the regional offices.

CMS requirements establish a timeline for regional offices and State survey agencies. For behavior management-related deaths associated with restraint or seclusion:

- Regional offices must authorize the State survey agency to conduct a complaint investigation into the hospital's compliance with the Patient's Rights CoP within 2 working days of receiving a restraint or seclusion-related death report;
- State survey agencies must forward information about hospital deaths related to restraint or seclusion to their regional office the same day they receive information directly from a hospital or other source;
- State survey agencies must complete their investigations within 5 working days of receiving the survey authorization from the regional office; and
- Regional offices must notify the central office, the relevant State Protection and Advocacy agency, and the hospital's accrediting organization, if accredited, within 2 working days of receiving a restraint or seclusion-related death report.

[12]CMS, "State Operations Manual," Chapter 5, section 5240.

[13] In accordance with the CMS "State Operations Manual," the State survey agency handles each restraint/seclusion death report as a complaint investigation.

Additional Sources of Restraint and Seclusion-Related Death Information

Protection and Advocacy agencies. In addition to CMS, Protection and Advocacy agencies (P&As) receive and collect reports of restraint and seclusion-related deaths from other sources, such as caregivers and patient advocates. These agencies, established pursuant to the Developmental Disabilities Act of 1975, provide advocacy and legal representation for people with physical or mental disabilities within the 50 States, the District of Columbia, Puerto Rico, and the U.S. Virgin Islands. The Developmental Disabilities Act of 1975 created the Protection and Advocacy for Persons with Developmental Disabilities Program (42 U.S.C. 15001). The Developmental Disabilities Act mandated that each State establish its own P&A program to legally protect the rights of persons with developmental disabilities. In 1986, Congress passed the Protection and Advocacy for Individuals with Mental Illness Act, which extended the P&A system to protect individuals with mental illness (42 U.S.C. 10801). Pursuant to 42 CFR § 51.42, P&As have the authority to investigate deaths and incidents of abuse and neglect of individuals with mental illness if the incidents are reported to their systems or if there is probable cause to believe that the incidents occurred.

Food and Drug Administration. Through the Medical Device Reporting Program, manufacturers, importers, and user facilities such as hospitals send reports to the Food and Drug Administration (FDA) about adverse events associated with medical devices. The program requires hospitals to report any death associated with a medical device, including restraints, to FDA and the manufacturer within 10 working days of the event. As part of its Hospital Bed Safety Work Group initiatives, FDA agreed to forward restraint and seclusion-related adverse event reports to CMS beginning in April 2001.[14] FDA faxes the relevant reports to CMS. This process is described in the CMS "State Operations Manual."[15]

[14] The MEDSTAT Group, Inc., "Implementation Planning Study for the Integration of Medical Event Reporting Input and Data Structure for Reporting to AHRQ, CDC, CMS, and FDA, Final Report," for the Agency for Healthcare Research and Quality, June 2002. Available online at http://interprofessional.washington.edu/ptsafety/files/room_for_improve.pdf. Accessed March 2006.

[15] CMS, "State Operations Manual," Chapter 5, section 5240.

Previous Studies on Restraint and Seclusion Reporting

In August 2000, the Office of Inspector General (OIG) issued an evaluation entitled "Restraints and Seclusion: State Policies for Psychiatric Hospitals" (OEI-04-99-00150). The report found that many State policies met the CoP, but others fell short for both public and private psychiatric hospitals with respect to the requirements for initiating restraint and seclusion use, time limits, and patient monitoring. OIG recommended that CMS work with States and accreditation organizations to improve psychiatric hospitals' compliance with the Patients' Rights CoP, with particular attention to private psychiatric hospitals. CMS's comments on the report indicated that CMS already had initiated efforts to provide education and training on the CoP to State survey agencies, P&As, accrediting organizations, and agency staff.

In October 1999, the Government Accountability Office (GAO) testified before the Senate Finance Committee on the topic of "Mental Health: Extent of Risk From Improper Restraint or Seclusion is Unknown" (GAO-T-HEHS-00-026). The testimony indicated that (1) the lack of comprehensive reporting requirements makes it impossible to identify all deaths related to restraint and seclusion; and (2) policies governing restraint and seclusion vary among Federal programs, States, and types of facilities. GAO recommended that facilities should report any injury or death associated with restraint or seclusion to the State licensing body and the P&A.

METHODOLOGY

Determining Hospital, CMS, and State Survey Agency Adherence to the Reporting Requirements

To determine whether hospitals failed to report deaths related to restraint and seclusion to CMS as required, we compared death reports and related documentation received by CMS to those received by State survey agencies, P&As, and FDA for deaths that occurred between August 2, 1999 (when the reporting requirement became effective), and December 31, 2004. We used CMS documentation (primarily the report worksheets completed by CMS regional offices) to examine CMS and State survey agencies' adherence to timelines for receiving, processing, and investigating death reports. We also conducted interviews with CMS staff from its central office and the 10 regional offices that are responsible for receiving and assessing hospital restraint and seclusion-related death reports. The purpose of these interviews was to gather

information about CMS policies and death reporting procedures, the reporting process used by hospitals, interactions with State survey agencies, record keeping, and collection of information by the CMS central office. We analyzed the responses to these interviews to supplement information contained on the report worksheets.

Collecting CMS death reporting documentation. We collected information about hospital deaths related to restraint and seclusion from CMS central and regional offices. First, we obtained copies of report worksheets for deaths that occurred between August 2, 1999, and December 31, 2004, from CMS central office staff. We also obtained copies of CMS central and regional office correspondence regarding restraint and seclusion-related death investigations. After entering information received from the CMS central office about deaths related to restraint and seclusion into an electronic database, we asked regional offices to indicate whether they had received information about any additional deaths. We then entered any additional information into a consolidated restraint and seclusion death database. We used this consolidated database to conduct our analysis of hospital reporting and to determine regional offices' and State survey agencies' responsiveness to reported hospital deaths.

Collecting P&A and State survey agency documentation. We mailed a survey and data request to all 50 State P&As and State survey agencies, as well as those in the District of Columbia, Puerto Rico, and the U.S. Virgin Islands.[16] The survey requested information about P&As and State survey agency communications with CMS central and regional offices and the process of receiving and forwarding reports. We received 53 completed surveys from P&As and 44 completed surveys from State survey agencies for a response rate of 100 percent and 83 percent, respectively. In addition to the survey, we requested that P&As and State survey agencies provide a list of all the reports they received for behavior management restraint and seclusion-related hospital deaths that occurred between August 2, 1999, and December 31, 2004. For each death report, we requested that P&As and State survey agencies provide data such as patient name, facility name, and date of death. We matched this information with CMS reports. Additionally, we requested that P&As and State survey agencies

[16] The CMS regional office in New York acts as the State survey agency for the U.S. Virgin Islands.

provide information about the source of the initial report and any documentation that P&As and State survey agencies collected during any investigation of a restraint or seclusion-related death. We received 29 completed data requests from P&As and 24 completed data requests from State survey agencies. The remaining 24 P&As and 20 State survey agencies indicated that they did not receive any reports of hospital deaths related to restraint or seclusion during this period.

Collecting FDA documentation. We identified 18 behavior management-related restraint and seclusion deaths that were included in the Manufacturer and User Facility Device Experience (MAUDE) database. The MAUDE database contains information about device-related adverse events, including restraint deaths, reported after July 31, 1996. We requested that FDA conduct a search of all medical device-related events in hospitals that resulted in death between August 2, 1999, and December 31, 2004. FDA searched for any hospital death report associated with medical devices that (1) are categorized officially as restraints, (2) are otherwise categorized but were used to restrain a patient's mobility or access to his/her body, and (3) were used while a patient was in seclusion. We also identified hospital deaths related to restraint and seclusion by searching the MAUDE online public database. We used keywords and specific restraint-related product codes for hospital deaths that were reported between August 2, 1999, and December 31, 2004.

Comparing documentation among agencies. We received information about 104 behavior management-related deaths associated with restraint and seclusion that occurred between August 2, 1999, and December 31, 2004, from CMS, State survey agencies, P&As, and FDA. The 104 deaths were comprised of 36 reports maintained by State survey agencies, P&As, and FDA, and 68 reports contained in CMS's records.

Data limitations. This evaluation does not identify the proportion of deaths related to restraint and seclusion that hospitals failed to report directly to CMS as required. This would have required reviewing thousands of records for patients who died during or following a hospital stay to determine the proportion of hospital deaths that were associated with the use of restraint or seclusion, and the proportion of hospital deaths related to restraint and seclusion that were reported to CMS. Due to time and resource constraints, we developed the alternative strategy of comparing death reports received by CMS to those collected

by other agencies to determine hospital compliance with the reporting requirement.

We did not gather directly from hospitals information about why they did not report behavior management deaths related to restraint and seclusion to CMS as required. Because many of the deaths occurred years before our data collection, we determined that a number of relevant records would have been archived and that hospital staff with first-hand knowledge of the circumstances surrounding the restraint or seclusion-related death would have been difficult to contact for interviews.

We did not receive responses from 9 of the 53 State survey agencies. It is possible that those nine State survey agencies had information about hospital deaths related to restraint and seclusion that were not reported directly to CMS. Because of this missing information, our analysis may undercount the number of deaths that hospitals did not report as required. Furthermore, the number of deaths related to restraint and seclusion may be understated because our data collection was limited to deaths that were documented by State survey agencies, P&As, and FDA.

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

Hospitals failed to report to CMS 44 of 104 documented deaths related to restraint and seclusion between August 2, 1999, and December 31, 2004

Using CMS, State survey agency, P&A, and FDA documentation, we identified 104 behavior management deaths related to restraint and seclusion that occurred between August 2, 1999, and December 31, 2004. Hospitals did not report 44 of these deaths directly to CMS as required. Hospitals must report to CMS any death that occurs while a patient is restrained or in seclusion for behavior management, or when it is reasonable to assume that a patient's death is the result of restraint or seclusion.[17] As illustrated in Table 1, we identified unreported behavior-management deaths related to restraint and seclusion based on our analysis of information from State survey agencies, P&As, and FDA, as well as in documentation maintained by CMS.

Table 1: Behavior Management Restraint and Seclusion Deaths Documented by CMS and Other Agencies

State survey agency-, P&A-, and FDA-documented deaths **not** reported by hospitals to CMS regional offices	36
CMS-documented deaths **not** reported directly by hospitals to CMS regional offices, but received second hand from other agencies	8
Total documented deaths **not** reported directly to CMS	44
CMS-documented deaths reported directly by hospitals to regional offices	60
Total deaths documented by CMS and other agencies	**104**

Source: Office of Inspector General analysis of CMS, State survey agency, P&A, and FDA death reports, 2005.

We identified 36 of the 44 unreported deaths by comparing CMS documentation to that of State survey agencies, P&As, and FDA. We forwarded all of the death reports we received from other agencies to the respective CMS regional office to determine whether the deaths were associated with restraint or seclusion for purposes of behavior management and, therefore, reportable under the requirement. According to CMS, 36 of these deaths were reportable. Based on our review of CMS documentation, hospitals failed to report an additional eight deaths directly to CMS, although CMS received the information second hand from State survey agencies or P&As. Hospitals reported

[17] 42 CFR § 482.13(f)(7).

six of the eight deaths to other entities (such as the State survey agency or P&A) rather than directly to CMS. Hospitals did not report two of the eight deaths to any agency. State survey agencies discovered these deaths during a complaint investigation or routine survey and forwarded the information to CMS.

Most deaths that hospitals reported directly to CMS were reported late

Of the 60 behavior management restraint and seclusion-related death reports provided directly to CMS by hospitals, fewer than one-third were reported to CMS before the close of business on the day after the patient's death, as required. The median number of days between a patient's death and hospitals' notification to CMS was 7.[18]

CMS and State survey agencies do not consistently take action in response to reported deaths in a timely manner, limiting their ability to address potentially harmful conditions

CMS regional offices and State survey agencies regularly fail to meet CMS's timelines for taking action in response to deaths related to restraint and seclusion that are reported by hospitals. CMS established timelines for regional office and State survey agency responsibilities to ensure that investigations proceed in a timely manner. As illustrated in Table 2, neither regional offices nor State survey agencies consistently met these timelines. This analysis is based on a total of 51 deaths that were identified as behavioral management-related in CMS documentation and were reported directly to CMS. We included only deaths that occurred after March 23, 2000 (when CMS first issued these requirements to regional offices and State survey agencies), in these calculations.

State survey agencies did not provide regional offices with timely information about relevant deaths in approximately 50 percent of cases. Regional offices and State survey agencies authorized and started complaint investigations later than required for approximately one-third of the deaths for which documentation is available. In addition, regional offices often failed to forward information about deaths related to restraint and seclusion to P&As and CMS central office within 2 days after the receipt of the death report, as required.

[18] Regional offices received death reports, on average, 37 days after a patient's death.

CMS's and State survey agencies' delayed actions may limit their effectiveness in addressing unsafe conditions in hospitals. State agency surveyors must address underlying problems quickly because other patients may be at risk for harm. Despite this, complaint investigations were not started until after the required time period for more than one-third of the reported deaths.

Table 2: Comparison of CMS-Established Timelines to Actual Death Report Timelines for Behavioral Management-Related Deaths

Action	Policy Guideline (Days)	Actual Median Time (Days)	Percentage of Deaths That Did Not Meet the Guideline[19]
State survey agency to regional office notification (N=31)	0 (same day)	1.0	49%
Regional office contact to authorization of investigation (N= 29)	2	2.0	28%
Regional office authorization to State survey agency starting investigation (N=30)	5	4.5	33%
Regional office contact to P&A notification (N=47)	2	3	38%
Regional office contact to central office (N=45)	2	6	51%

Source: Office of Inspector General analysis of CMS restraint and seclusion-related death documentation, 2005.

CMS's policy requires that regional offices notify P&As of relevant restraint and seclusion deaths in hospitals within 2 working days. This notification provides P&As with information that could allow them to undertake their own investigations into the circumstances surrounding a patient's death. Regional offices' untimely notification may make it more difficult for P&As to initiate investigations while hospital staff members are still available and familiar with the circumstances surrounding the death.

State survey agencies do not provide regular guidance on the reporting requirement

CMS requirements state that State survey agencies are responsible for educating hospitals about the reporting requirement. Despite this, only 23 of the

[19] Deaths were excluded from the analysis if the documentation was missing information about the date on which one of the actions occurred. We used a 360-day calendar to calculate the number of days between these actions (30 days for each month).

44 (52 percent) State survey agencies that provided data on this issue indicated that, at some point, they had disseminated information about the CoP to hospitals. In addition, only 8 of the 44 (18 percent) State survey agencies provide reporting requirement information to hospitals on an ongoing basis. According to P&A survey responses, hospitals' lack of information about the reporting requirement may contribute to their failure to comply.

Hospitals may not understand fully the mandatory reporting requirement for deaths related to restraint and seclusion. Despite the availability of written standards for the reporting requirement, CMS regional offices noted that hospitals may have difficulty determining whether the reporting requirement applies to a particular death. Six of 10 regional offices indicated that it is not always clear whether a patient is being restrained for behavior management or for acute medical or surgical care. The reporting requirement applies to situations in which a patient is restrained or secluded for violent, aggressive, or assaultive behavior. In cases in which patients are described as "confused," "disorientated," or "uncooperative," hospital staff may be unsure whether the reporting requirement applies. In addition, hospital staff may have difficulty determining when it is "reasonable to assume" that a death that follows restraint or seclusion use was the "result of restraint or seclusion."

CMS does not maintain comprehensive and reliable information about reported restraint and seclusion-related deaths

The CMS roster is of limited value because it excludes information about relevant death reports and, in some cases, includes deaths for which there is no reporting requirement. We determined that deaths reported by hospitals to CMS regional offices or discovered by other Federal or State agencies are not always included in the central roster.

CMS's requirement states: "The CMS Central Office contact will maintain the central death report roster and a copy of all death report worksheets collected."[20] We identified several problems with CMS's central roster and other documentation that central and regional offices maintain about deaths related to restraint and seclusion:

[20] CMS, "State Operations Manual," Chapter 5, section 5240.

- CMS's central roster does not include information about all deaths for which regional offices maintain documentation. These deaths may not have been included in the central roster because (1) the regional office did not forward the information to the central office; (2) the regional office forwarded the information, but it was not received by the appropriate central office contact; or (3) the central office contact received the information, but did not include it in the roster.
- Although the reporting requirement only applies to deaths related to restraint or seclusion for behavior management, CMS's central roster includes information about both behavioral and acute medical deaths without clearly distinguishing between the two. This may occur because the requirement does not state specifically that only behavioral deaths should be included in the central roster. As a result, CMS is not able to identify how many death reports in their central roster apply to the reporting requirement.
- Almost one-third of the death reports maintained by CMS central and regional offices include no information about whether the death was associated with behavioral or medical restraint use. Regional offices may not have been able to make this determination at the time the initial death reports were received from the hospital. Regional offices did not update their records after staff determined whether the deaths were associated with behavioral or medical restraint use.

- CMS's documentation does not include information about reportable deaths that have been identified by other agencies. CMS regional offices do not communicate regularly with other Federal or State agencies to compare information about hospital deaths related to restraint and seclusion. Therefore, they remained unaware of a number of deaths to which the reporting requirement applies.

RECOMMENDATIONS

To improve hospital reporting, the accuracy of data, and CMS's timely identification of deaths related to restraint and seclusion, CMS should:

Seek Legislation To Establish Intermediate Sanctions for Hospitals That Fail To Report Deaths Related to Restraint and Seclusion Directly to CMS

CMS's current sanction options are limited. When CMS discovers previously unreported deaths, hospitals must submit a plan of correction. If the deficiencies are not resolved satisfactorily, CMS's only recourse is to initiate termination proceedings. Instituting civil monetary penalties for hospitals' failure to report deaths related to restraint and seclusion, as required, may give hospitals more incentive to report these deaths directly to CMS in a timely manner.

Consider Regulatory Changes That Would Require Reporting of All Deaths Related to Restraint and Seclusion

If hospitals have difficulty distinguishing between medical and behavioral restraint, it may prevent them from reporting deaths as required under the current reporting requirement. Requiring hospitals to report deaths related to restraint and seclusion for both behavior management and acute medical and surgical care may remove this uncertainty and improve hospital compliance. In addition, clarifying the language in the regulation that states that a hospital must report deaths "where it is reasonable to assume that a patient's death is a result of restraint or seclusion" would eliminate further confusion.

Instruct its Regional Offices and the State Survey Agencies To Adhere to Timelines

CMS will be able to respond more quickly to patient safety issues if it can ensure that regional offices and State survey agencies adhere to its guidelines. Regional offices should hold State survey agencies accountable for reporting deaths and conducting complaint investigations in a timely manner. Because hospitals rarely undergo routine reviews to address restraint and seclusion death reporting, timely complaint investigations are an important opportunity for surveyors to ensure that hospital policies and procedures are appropriate.

Encourage State Survey Agencies To Provide Ongoing Training to Hospitals About the Mandatory Reporting Requirement

State surveyors could educate hospital staff on their reporting obligations during routine onsite reviews or on an annual basis. P&A survey responses suggest that hospitals' lack of awareness of the reporting requirement may contribute to their failure to report. P&As' most common suggestion for improving hospital reporting of deaths related to restraint and seclusion was for CMS to improve education and communication about the requirement. CMS also could work with the Joint Commission and the American Osteopathic Association to make restraint and seclusion-related death reporting a more prominent part of their hospital review process.

Instruct Regional Offices To Request Periodic Updates About Deaths Related to Restraint and Seclusion From Other Federal and State Agencies

We found that State survey agencies, P&As, and FDA maintained records of a number of deaths related to restraint and seclusion for which CMS had no documentation. Improving communication with other agencies that receive and document deaths related to restraint and seclusion would help CMS identify some deaths that hospitals did not report directly to them and maintain more comprehensive data.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

CMS generally concurred with our recommendations. CMS is considering proposing future changes that would simplify requirements for hospital reporting of restraint and seclusion-related deaths. CMS also indicated it will issue a Survey & Certification Memorandum to ensure that regional offices and survey agencies receive written instructions that reinforce the hospital death reporting timelines. Furthermore, CMS will instruct its regional offices to contact periodically survey agencies and other Federal agencies to request information regarding restraint and seclusion-related deaths.

In response to our recommendation that CMS work with Congress to establish intermediate sanctions for hospitals that fail to report deaths related to restraint or seclusion, CMS indicated that this change would be addressed most appropriately through legislative changes by Congress. We modified the recommendation to clarify that CMS should seek legislation that would allow CMS to impose intermediate sanctions

against hospitals that do not comply with the reporting requirement. CMS's comments are included in their entirety in the Appendix.

APPENDIX

AGENCY COMMENTS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

JUL 18 2006

Administrator
Washington, DC 20201

TO: Daniel R. Levinson
Inspector General

FROM: Mark B. McClellan, M.D. Ph.D.
Administrator

SUBJECT: OIG Draft Report: "Hospital Reporting of Restraint and Seclusion Related Deaths" (OEI-09-04-00350)

Thank you for the opportunity to review and comment on the above-referenced report from the Office of Inspector General (OIG). The Centers for Medicare & Medicaid Services (CMS) appreciates the contributions and valuable input by the OIG in protecting hospital patients from abuse and neglect. The purpose of this report was to (1) determine if hospitals fail to report restraint and seclusion-related deaths to CMS and (2) evaluate CMS and State Survey Agency (SA) monitoring, guidance, and responsiveness to the reporting requirement.

While the OIG stated that many of the deaths were reported, we are concerned that not all hospitals reported all deaths. We are also taking steps to assure that the SAs and the CMS Regional Offices achieve more rapid and complete compliance. We outline these actions below, in conjunction with the OIG's recommendations.

OIG Recommendation

Consider working with Congress to establish intermediate sanctions for hospitals that fail to report deaths related to restraint and seclusion directly to CMS.

CMS Response

We believe that this is primarily a statutory issue and most appropriately addressed through legislative change by Congress.

OIG Recommendation

Instruct the CMS Regional Offices and State Survey Agencies to adhere to timelines.

CMS Response

We concur. CMS will ensure that the ROs and SAs receive written instructions that reinforce the hospital death reporting requirements related to restraint and seclusion by issuing a Survey & Certification Memorandum and posting it on the CMS Survey and Certification Website. The timeframes for reporting deaths related to restraint and seclusion will also be addressed during monthly calls with the hospital industry.

Page 2 - Daniel R. Levinson

OIG Recommendation

Instruct the CMS Regional Offices and State Survey Agencies to adhere to timelines.

CMS Response

We concur. CMS will ensure that the ROs and SAs receive written instructions that reinforce the hospital death reporting requirements related to restraint and seclusion by issuing a Survey & Certification Memorandum and posting it on the CMS Survey and Certification Website. The timeframes for reporting deaths related to restraint and seclusion will also be addressed during monthly calls with the hospital industry.

OIG Recommendation

Consider a regulatory change that would require reporting of all restraint and seclusion-related deaths.

CMS Response

We concur. Current regulations require reporting of deaths related to restraint and seclusion for behavior management only. CMS recognizes the confusion this may cause with provider reporting requirements and is considering proposing future changes that would simplify when a hospital is expected to report restraint and seclusion-related deaths.

OIG Recommendation

Instruct Regional Offices to request periodic updates about restraint and seclusion-related deaths from Federal and State agencies.

CMS Response:

We concur. We will instruct ROs to periodically contact SAs and other Federal agencies, i.e., FDA, to request information regarding restraint and seclusion-related death information they may have obtained.

OIG Recommendation

Encourage State Survey Agencies to provide ongoing training to hospitals about the mandatory reporting requirement.

CMS Response

CMS will seek the support of hospital provider groups and accreditation organizations to provide ongoing death reporting training sessions in order to increase the level of understanding and improve hospital compliance.

ACKNOWLEDGMENTS

This report was prepared under the direction of Paul A. Gottlober, Regional Inspector General for Evaluation and Inspections in the San Francisco regional office, and Deborah W. Harvey, Assistant Regional Inspector General. Other principal Office of Evaluation and Inspections staff who contributed include:

Camille Harper, *Project Leader*

China Eng, *Program Analyst*

Michael Henry, *Program Analyst*

Doris Jackson, *Program Specialist*

Tricia Davis, *Director, Medicare Branch*