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CENTERS for MEDICARE & MEDICAID SERVICES

Center for Medicaid and State Operations / Survey and Certification Group

Ref: S&C-06-31

DATE: **September 29, 2006**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Hospital Death Reporting Requirements Related to Behavior Management Restraint and Seclusion

Letter Summary

- This memo summarizes and emphasizes the responsibilities of hospitals, State Agencies, Regional Offices and Central Office as they relate to behavior management restraint and seclusion deaths.
- Hospitals, States, and the Centers for Medicare & Medicaid Services have clear responsibilities and timeframes for reporting and investigating deaths related to behavior management restraint and seclusion.

The purpose of this letter is to reiterate the Centers for Medicare & Medicaid Services' (CMS) policy regarding the responsibility and the process by which hospitals report patient deaths associated with restraint or seclusion to CMS as required under 42 CFR 482.13(f), *Seclusion and restraint for behavior management*. A recent report by the Department of Health and Human Services Office of Inspector General, "*Hospital Reporting of Restraint and Seclusion Related Death,"* highlighted shortcomings in compliance with this policy.

Background

The Patients' Rights, Interim Final Rule, published July 2, 1999, requires at 42 CFR 482.13(f)(7) that a hospital must report to CMS any patient death that occurs while the patient is restrained or in seclusion for behavior management, e.g., for violent behavior toward self or others. It also requires reporting where it is reasonable to assume that a patient's death is the result of restraint or seclusion used for behavior management.[1]

[1] **NOTE:** There is no death reporting requirement under standard (e), *"Restraint for acute medical and surgical care."* When the restraint/seclusion is used in an emergency to address violent behavior presenting a risk to the patient or others, it falls under the behavior management standard at (f), including the death reporting requirement, rather than the acute medical/surgical standard at (e).

Restraint/Seclusion Death Reporting Responsibilities

CMS and State Agencies (SAs) must consistently implement their death reporting responsibilities, as provided for in Section 5140, Chapter 5 of the State Operations Manual:

Hospitals - Hospitals must report directly to their CMS regional office (RO) any deaths that result from restraint or seclusion used for behavior management. The deaths must be reported to the RO **prior to the close of business on the business day following the day of the patient's death.**

State Agencies - SAs must notify hospitals in their State that a hospital must report directly to its RO any death that occurs while a patient is restrained or in seclusion for management of behavior, or where it is reasonable to assume that a patient's death is a result of restraint or seclusion used to manage violent behavior. SAs must provide hospitals the CMS RO contact name and telephone number for death reporting, as well as a description of the process outlined below that CMS and the SA will follow after receipt of a report.

If a hospital reports a restraint/seclusion death to the SA, the SA should advise the hospital to contact the RO directly. In addition, the SA is required to forward a report from any source of a behavior management restraint/seclusion death to the RO, on the same day that the SA receives the report.

Regional Offices – Each RO will designate an RO staff person(s) who will serve as the point of contact, coordination, and communication regarding reporting, investigation, and follow-up for the death-reporting requirement under Patients' Rights. Upon receipt of a report of a death, the RO will begin collecting information on the case on the Restraint/Seclusion Death Report Worksheet. This worksheet, a copy of which is attached, is for use by both the SA and CMS to gather information and to track the investigation.

In addition, the RO must periodically contact SAs to request information regarding restraint and seclusion-related deaths they may have. This will help the RO to verify that it is learning of restraint/seclusion deaths that should have been reported by hospitals to the RO.

Central Office (CO) - CMS CO will maintain a central listing of restraint/seclusion death reports and a copy of all Restraint/Seclusion Death Report Worksheets collected, and will contact ROs as needed for updates during each investigation.

CO will also periodically contact the Food and Drug Administration (FDA) for any deaths reported to the FDA through its MedWatch Reporting process for deaths related to medical devices[2]. CO will forward information on reports received from the FDA to the appropriate ROs, for investigation.

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[2] The FDA requires that suspected medical device-related deaths be reported by manufacturers and user facilities, i.e., hospitals, by mail, using the "MedWatch FDA Form 3500A." The form must be properly and fully completed and forwarded within 10 working days of the patient's death. Further details can be found at http://www.fda.gov/medwatch/report/instruc.htm. The FDA forwards these reports to CMS.

Restraint/Seclusion Death Investigation Process

The RO evaluates the information provided in a hospital's report of a restraint/seclusion death to verify that the case involves seclusion or restraint use for behavior management subject to 42 CFR 482.13(f)(7), and not usage related to acute medical or surgical care subject to 42 CFR 482.13(e). If the restraint/seclusion death falls under the behavior management standard:

Within 2 working days of receipt of the report, the RO notifies**—**

- **the SA,** authorizing a survey to investigate the hospital's compliance with the Patient's Rights Condition of Participation;

    - ✓ The RO provides the SA prior to the SA going on-site with the Restraint/Seclusion Death Report Worksheet containing all the data the RO has collected to date from the hospital.

- **CO**; and
- **the hospital's accrediting organization**, if deemed, and the **appropriate State Protection and Advocacy Group (P&A)** providing them with the hospital's name and address, the patient's name, and the date of death.

The SA—

- Handles each restraint/seclusion death report as a complaint investigation and enters into the ASPEN Complaints/Incidents Tracking System (ACTS). Intake procedures for hospitals for related restraints/seclusion deaths are described in the ACTS manual located at https://www.qtso.com/download/ASPEN/ACO_8.6_PG.pdf.

- Completes the investigation within **5 working days** of receiving the survey authorization from the RO.

    - ✓ In addition to its regular complaint investigation paperwork the **SA obtains and fills in missing Restraint/Seclusion Death Report Worksheet information** during the survey. The worksheet should not be given to the hospital for completion.

- Sends via electronic mail or faxes a copy of the fully completed Restraint/Seclusion Death Report Worksheet **to the RO** w**ithin two working days** of completing the survey,

Within two working days following receipt of the completed Restraint/Seclusion Death Report Worksheet from the SA, the RO sends a the worksheet via electronic mail or faxes a copy of it to the CMS CO contact, Anna Gibson, CMSO/SCG/DACS. The CO regularly reviews the status of all outstanding restraint/seclusion death reports with each region.

Future Death Reporting Requirements

CO is working towards developing death reporting protocols that are consistent across provider types, as regulations require. Towards that end, we are working to ensure consistent data entry into ACTS and use of a common worksheet to collect needed data.

Effective Date: The information contained in this memorandum is current policy and is in effect for all behavior management restraint or seclusion deaths reported under 42 CFR 482.13(f)(7).

Training: To improve compliance with the existing restraint/seclusion death reporting requirements, this information should be shared by SAs with hospitals. CO will share with hospital associations and accreditation organizations that provide training to hospitals on compliance issues.

/s/
Thomas E. Hamilton

cc: Survey and Certification Regional Office Management

Attachment

Restraint/Seclusion Death Report Worksheet

Contact Information
RO contact's name:_____
Date of RO contact:_____RO Contact's phone number:_____
Facility contact: _____
Facility contact's phone number:_____

Provider Information
Hospital Name:_____Provider Number_____
Address:_____Zip Code:_____

Patient Information
Name:_____
Date of Birth/Age:_____Medicare/Medicaid Number:_____
Admitting Diagnoses_____
Date of Admission:_____Date/time of Death:_____
Cause of Death:_____
Did the facility conduct a root cause analysis? yes_____ no_____
NOTE: Hospitals may provide the following information over the telephone, or to the SA during its investigation.
Length of Time in Restraints/seclusion:_____
Circumstances surrounding the death:_____
_____
_____
_____
_____
_____
Results of any facility investigation:
_____
_____
_____
_____
_____
_____
Restraint/Seclusion Information
Type: Physical Restraint _____ Seclusion _____ Drug Used as a Restraint_____
Restraint Standard: Acute Medical/Surgical Care _____ Behavioral Management _____
Restraint Method:_____
Reason(s) for seclusion/restraint use:_____
Less restrictive methods of behavior management considered:_____
_____
Restraint/seclusion order date/time:_____
_____
Quote actual restraint/seclusion order(s)_____
_____

Monitoring method(s), frequency, last date/time monitored:_____
_____
Last date/time of assessment_____
Were there previous instances of restraint/seclusion deaths since 8/2/99? yes_____ no____
_____
_____
If there were prior deaths, were steps taken with previous deaths to prevent reoccurrence?
_____
_____
Additional
Information/Comments:_____
_____
_____
_____
_____
_____
_____
_____

Action Information

Facility notifications
Other agencies the provider notified: (SA, FDA, etc.)
Agency/date/time:_____
Agency/date/time:_____
Agency/date/time:_____
Agency/date/time:_____

SA action(s)
Date of receipt of restraint/seclusion death report from RO:_____
Date of Survey:_____
Date the completed Restraint/Seclusion Death Report forwarded to RO:_____

RO action(s)
Date sent as complaint to SA:_____
Date authorized SA complaint survey:_____
Date/Method/Person notifying CO:_____

CO action(s)
Date of receipt of initial restraint/seclusion death report:_____
Date of receipt of initial restraint/seclusion death report worksheet:_____
Date of receipt of complete restraint/seclusion death report worksheet_____
Person recording the information:_____