DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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Center for Medicaid and State Operations/Survey & Certification Group

Ref: S&C-08-23

DATE: **May 30, 2008**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Update of State Operations Manual (SOM) Chapter 5/Release of Person-Identifiable Data Related to Restraint/Seclusion Deaths to Protection and Advocacy Organizations

Memorandum Summary

- Section 5140 of Publication 100-07, the SOM, concerning deaths in Hospitals associated with the use of restraint or seclusion, has been revised to correspond to the regulatory requirements at 42 CFR 482.13(g) and to reflect operational procedures implemented since the revised regulation took effect in January, 2007.

- The process for disclosing Hospital restraint/seclusion death report information to Protection and Advocacy (P&A) organizations has been revised to comply with the Privacy Act of 1974, Centers for Medicare and Medicaid Services (CMS) data release policies, and the Automated Survey Processing Environment (ASPEN) Complaints/Incidents Tracking System (ACTS) System of Records (SOR) Notice of May 23, 2006.

- CMS Regional Offices (ROs) are to release to P&As selected information on each restraint/seclusion death report case authorized for on-site investigation. A P&A that wants more detailed information, including the patient's identity, must subsequently submit an approved Data Use Agreement (DUA) or DUA Update to the RO. The process for a P&A to obtain an approved DUA is described in the amended SOM.

- P&A requests for investigation results are to be submitted to State Agencies (SAs). SAs will handle the requests in accordance with their data use agreement with CMS.

Hospital reporting requirements at 42 CFR 482.13(g), which was effective January 8, 2007, for deaths associated with use of restraints or seclusion, are as follows:

1. Hospitals must report the following information to CMS:

    - Each death that occurs while a patient is in restraint or seclusion.
    - Each death that occurs within 24 hours after the patient has been removed from restraint or seclusion.
    - Each death known to the hospital that occurs within one week after restraint or seclusion where it is reasonable to assume that use of restraint or placement in seclusion contributed directly or indirectly to a patient's death. "Reasonable to assume" in this context includes, but is not limited to, deaths related to restrictions of movement for prolonged periods of time, or death related to chest compression, restriction of breathing, or asphyxiation.

2. Each death must be reported to CMS by telephone no later than the close of business the next CMS business day following knowledge of the patient's death.

3. Hospital staff must document in the patient's medical record the date and time the death was reported to CMS.

This revised reporting requirement greatly expanded the number of restraint/seclusion-associated death reports CMS receives, but the number of cases that warrant an on-site investigation remains very small. As a result, utilizing the Hospital Restraint/Seclusion Death Report Worksheet to evaluate pertinent information from Hospitals submitting a required report, ROs determine for each case whether to authorize an SA survey. Section 5140 of the SOM has been revised to reflect the new reporting requirements, the respective responsibilities of ROs and SAs, and the process to be used for Hospital restraint/seclusion-associated death reports.

P&As are State-designated organizations that are authorized access to investigation reports and related materials under various federal laws: the Developmental Disabilities Assistance and Bill of Rights Act, 42 USC 15043 et seq.; the Protection and Advocacy for Individuals with Mental Illness Act, 42 USC 10801 et seq.; and the Protection and Advocacy for Individual Rights Act, 29 USC 794e(f). Because of their federally-authorized role, under the previous reporting regulation, CMS shared information on all reported cases, all of which were also investigated on-site, with the P&A organization designated for the area where the reporting hospital was located. However, the change in the volume and type of reports CMS receives also necessitates changes in CMS' policies for sharing hospital restraint/seclusion death report data with P&As.

Additional changes are also required in order to assure that data sharing is consistent with the requirements of federal statutory privacy requirements, CMS' data release policies, and the ASPEN Complaints/Incidents Tracking System (ACTS) System of Records (SOR) Notice published May 23, 2006 in the *Federal Register* (SOR-09-70-0565). Section 5140.4 has been revised to reflect the updated policy and process. Key points include the following:

1. ROs are to provide P&As, without any case-specific prior request from the P&A, a limited amount of information on each restraint/seclusion death report case where the RO authorizes a SA on-site investigation. No personally identifiable information is to be released at this point. Cases selected for investigation are more likely to involve situations that may fall within the federal authority for P&As, and thus CMS seeks to make the P&A aware of the case.

2. Consistent with the ACTS SOR, if the P&A wants more detailed information, including the patient's name, it must submit a case-specific request for this information to the RO, along with an approved DUA or DUA update. The RO will then release a copy of the Hospital Restraint/Seclusion Death Report Worksheet and/or information from the ACTS Hospital Restraint/Seclusion Death module.

3. If the P&A wants information from the SA investigation of the case, it must contact the SA, which will follow the standard procedures for release of person-identifiable data from ACTS. These are addressed in the SA's data use agreement with CMS.

An advance copy of the revised SOM section 5140 is attached. The final version will be released as a Publications Manual transmittal later this year and may differ slightly from this advance copy.

Effective Date: Immediately. Please ensure that all appropriate staff are fully informed within 30 days of the date of this memorandum.

Training: The information contained in this letter should be shared with all survey and certification staff, their managers, and the State/RO training coordinators.

If you have any questions concerning the revised procedures for Hospital restraint/seclusion-associated death reports, please contact David Eddinger at david.eddinger@cms.hhs.gov

/s/
Thomas E. Hamilton

cc: Regional Office Survey and Certification Management

Attachment: (1)

CMS Manual System

Pub. 100-07 State Operations Provider Certification

Department of Health & Human Services (DHHS)
Centers for Medicare & Medicaid Services (CMS)

Transmittal **Advance Copy** **Date:**

SUBJECT: Revisions to State Operations Manual (SOM) Chapter 5, Section 5140, Hospital Restraints/Seclusion Death Reporting and Investigation.

I. SUMMARY OF CHANGES: Chapter 5, Section 5140, Hospital Restraints/Seclusion Death Reporting and Investigation, was updated to reflect changes in policies and procedures related to new and amended regulations at 42 CFR 482.13(e), (f), and (g).

- **Chapter 5, Section 5140.1 has been revised to incorporate the current regulatory text governing Hospital reporting requirements found at 42 CFR 482.13(g).**
- **Chapter 5, Section 5140.2 was revised to delete all text and is now reserved for future use.**
- **Chapter 5, Section 5140.3 was revised to articulate the respective responsibilities of CMS Regional Offices and State Survey Agencies**
- **Chapter 5 Section 5140.4 was revised to reflect process changes necessitated by the regulatory requirements at 42 CFR 482.13(e), (f), and (g). In addition, the process for Notice to Protection and Advocacy Organizations has been updated to conform to the Privacy Act of 1974, CMS data release policies and the ASPEN Complaints/Incidents Tracking System (ACTS) System of Records Notice of May 23, 2006.**

NEW/REVISED MATERIAL - EFFECTIVE DATE*: Upon Issuance
IMPLEMENTATION DATE: Upon Issuance

Disclaimer for manual changes only: The revision date and transmittal number apply to the red italicized material only. Any other material was previously published and remains unchanged.

II. CHANGES IN MANUAL INSTRUCTIONS: (*N/A if manual not updated.*)
(R = REVISED, N = NEW, D = DELETED) – (*Only One Per Row.*)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	Section 5140.1
D	Section 5140.2 – now reserved
R	Section 5140.3
R	Section 5140.4

III. FUNDING: No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2008 operating budgets.

IV. ATTACHMENTS:

	Business Requirements
X	**Manual Instruction**
	Confidential Requirements
	One-Time Notification
	Recurring Update Notification

***Unless otherwise specified, the effective date is the date of service.**

5140 - Hospital Restraints/Seclusion Death Reporting and Investigation – *Advance Copy*

5140.1 - Background

The Centers for Medicare & Medicaid Services (CMS) hospital restraint and seclusion requirements are found in the Hospital COP, Patients' Rights; Interim Final Rule at 42 CFR 482.13, Standards (e),(f) *and (g)*.

The hospital's reporting requirement *for* death*s associated with the use of* restraint *or* seclusion is located at 42 CFR 482.13(*g*) and states*:*

"Standard: Death reporting requirements: Hospitals must report deaths associated with the use of seclusion or restraint.

(1) The hospital must report the following information to CMS:

(i) Each death that occurs while a patient is in restraint or seclusion.

(ii) Each death that occurs within 24 hours after the patient has been removed from restraint or seclusion.

(iii) Each death known to the hospital that occurs within 1 week after restraint or seclusion where it is reasonable to assume that use of restraint or placement in seclusion contributed directly or indirectly to a patient's death. "Reasonable to assume" in this context includes, but is not limited to, deaths related to restrictions of movement for prolonged periods of time, or death related to chest compression, restriction of breathing or asphyxiation.

(2) Each death referenced in this paragraph must be reported to CMS by telephone no later than the close of business the next business day following knowledge of the patient's death.

(3) Staff must document in the patient's medical record the date and time the death was reported to CMS."

Hospitals are required to report a restraint/seclusion death via telephone to their CMS RO.

The interpretive guidelines found in the Hospital Appendix A for 42 CFR 482.13(e) – (g) discuss in detail what is considered a restraint or seclusion, the requirements governing hospital use of restraint or seclusion and these reporting requirements.

5140.2 – *[Reserved]*

5140.3 - Responsibilities

Regional Offices (ROs)

The RO maintains a Hospital Restraint/Seclusion Death Report Worksheet for each case reported. The RO is also responsible for data entry into the ACTS Restraint/Seclusion Death Module (see Process discussion below).

Each RO designates one contact person and a backup person who serves as the point of contact, coordination, and communication regarding reporting, investigation and follow-up for the death-reporting requirement under Patients' Rights.

State Agencies (SAs)

Hospitals report patient deaths associated with restraint or seclusion, as previously discussed, to their CMS RO*, not to the SA*. Any hospital patient restraint or seclusion death report received by a*n* SA directly from a hospital (or other source) *must be* forwarded immediately *by the SA* to its RO.

The SA conducts a complaint investigation related to a patient death associated with a hospital's use of restraints or seclusion only when the RO authorizes the investigation.

SAs are to *assist ROs in educating* the hospitals in their State *about their obligation to report to* their RO any death that *meets the reporting requirements found in 42 CFR 482.13(g).* State Agencies are to provide hospitals with their RO contact name and telephone number, as well as the hospital reporting procedures contained in this policy.

SAs respond to requests from Protection and Advocacy (P&A) organizations, or any other parties, for information on survey findings related to specific cases identified by the requestor. SAs handle these requests in accordance with the SA's data use agreement (DUA) with CMS.

5140.4 - Process

*T*he RO evaluates the information *required to be reported* by the hospital *under 42 CFR 482.13(g)* to determine *whether* the situation *warrants an on-site investigation. The RO uses the Hospital Restraint/Seclusion Death Report Worksheet when recording the hospital's telephonic report. The RO may not require any hospital to complete and submit a hard copy of the worksheet. However, a hospital may volunteer to submit a completed worksheet in lieu of providing the requested information telephonically. The RO may provide a template worksheet to hospitals that volunteer to submit their reports via a completed worksheet.*

From the worksheet detail provided by the hospital the RO evaluates whether the case might involve a violation of 42 CFR 482.13(e) through 42 CFR 482.13(g) and authorizes an on-site investigation if there appears to be a possible violation. It is likely that the majority of hospital reports of deaths associated with the use of seclusion or restraint will ***not*** *require an on-site investigation.* If the *RO determines that the* restraint/seclusion death report *requires on-site investigation*, within 2 working days of receiving the report, the RO *enters the reported information into the ACTS restraint/seclusion module and* immediately notifies the SA to authorize a *complaint* survey to investigate the hospital's compliance with the Patient's Rights *CoP* at 42 CFR 482.13*(e), (f), or (g), including the reported case.* The SA *accesses the ACTS restraint/seclusion module to see the details of the reported case prior to conducting the on-site* investigation. The SA should complete *the* investigation within five working days of receipt of survey authorization from the RO.

In addition to completing the ACTS Restraint/Seclusion module for all cases that are authorized for on-site investigation, the RO also completes this module for all cases reported by hospitals to the RO during the months of April, October, and January, regardless of whether an on-site investigation was authorized, in order to provide a detailed and representative data base that supports analysis of deaths associated with hospital use of restraint and seclusion

Notice to Protection and Advocacy Organizations

At the same time that the RO notifies the SA and *authorizes* the *on-site* survey, *the RO also notifies* the appropriate P&A *organization within the State where the hospital is located*. *This notification is provided only in those cases for which an on-site survey is authorized.* The RO provides the following information to the P&A: hospital's name, hospital's address, *date the restraint/seclusion-associated death occurred, patient's diagnosis, and type(s) of restraint/seclusion used.* THIS IS THE **ONLY** INFORMATION TO BE SUPPLIED TO *P&A* ORGANIZATIONS *ON AN UNSOLICITED BASIS*. *No individual identifiers are to be provided.* The names and *addresses for* each State's P&A can be located at the following Web site: http://www.protectionandadvocacy.com.

After reviewing the summary provided by the RO, consistent with the ACTS Notice of a Modified or Altered System of Records (SOR) published May 23, 2006 in the Federal Register (SOR 09-70-0565), the P&A may request more detailed information, including the name of the deceased, contained in the ACTS restraint/seclusion module and on the worksheet for the case. The P&A must have an ACTS Data Use Agreement (DUA) in place before the RO may provide a copy of the worksheet and/or information from the ACTS module.

- *For the first request by a P&A for restraint/seclusion death report information concerning a specific case, the P&A must complete and sign Form CMS-R-0235, Agreement for Use of CMS Data Containing Individual Identifiers. In line 5 the P&A*

should reference the case involving [hospital name and address] and a restraint/seclusion associated death that occurred on [date]. The P&A must submit the completed Form to the Director, Division of Privacy Compliance, Centers for Medicare and Medicaid Services, Mailstop N2-04-27, 7500 Security Boulevard, Baltimore, MD 21244-1850. That Division will review the DUA, assign a unique DUA identifier to it, and return a signed copy to the P&A. The P&A must submit a copy of the signed DUA with its request for the specific restraint/seclusion death report to the RO, and the RO will provide the requested information.

- *For each subsequent request by a P&A for restraint/seclusion death report information concerning a specific case, the P&A must complete and sign Form CMS-R-0235U, Data Use Agreement, Update to Existing Data Use Agreement. In line 3 the P&A should reference the case involving [hospital name and address] and a restraint/seclusion associated death that occurred on [date]. The P&A must submit the completed Form to the Director, Division of Privacy Compliance, Centers for Medicare and Medicaid Services, Mailstop N2-04-27, 7500 Security Boulevard, Baltimore, MD 21244-1850. That division will sign the updated agreement and return a copy to the P&A. The P&A must then submit a copy of the signed DUA update with its request for the specific restraint/seclusion death report to the RO, and the RO will provide the requested information.*

P&A requests for information about the on-site survey should be submitted to the SA and handled by the SA in accordance with the SA's ACTS DUA agreement with CMS.