CMS Manual System

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

Transmittal 50 **Date: JULY 10, 2009**

SUBJECT: Revisions to Chapter 5, "Complaint Procedures"

I. SUMMARY OF CHANGES: Chapter 5, Section 5140, "Hospital Restraints/Seclusion Death Reporting and Investigation," is updated to reflect changes in policies and procedures related to new and amended regulations at 42 CFR 482.13(e), (f), and (g). We have deleted just the information contained in §5140.2, "Hospital Reporting Methods," because the information is no longer valid. However, we will reserve that section for a future revision. In addition, we have added new Exhibits 292 through 295 to facilitate implementation of the Data Use Agreement Process described in §5140.4.

NEW/REVISED MATERIAL - EFFECTIVE DATE*: July 10, 2009
IMPLEMENTATION DATE: July 10, 2009

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. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

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	5/Table of Contents
R	5/5140.1/Background
R	5/5140.2/Hospital Reporting Methods
R	5/5140.3/Responsibilities
R	5/5140.4/Process
N	Exhibit 292/Instructions for Completing the Data Use Agreement (DUA) Form CMS-R-0235
N	Exhibit 293/CMS DUA: ACTS SOR Attachment – P&A
N	Exhibit 294/DUA Multi-Signature Addendum/Release of Hospital Restraint/Seclusion Death Reports to Protection and Advocacy Organizations
N	Exhibit 295/DUA Disclosure Tracking Addendum/Release of Hospital Restraint/Seclusion Death Reports to Protection and Advocacy Organizations

III. FUNDING: No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2009 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.**

State Operations Manual
Chapter 5 - Complaint Procedures

Table of Contents

(Rev. 50, 07-10-09)

5140.1 - Background

(Rev. 50; Issued: 07-10-09; Effective/Implementation Date: 07-10-09)

The Centers for Medicare & Medicaid Services (CMS) hospital restraint and seclusion requirements are found in the Hospital COP, Patients' Rights at 42 CFR 482.13, Standards (e),(f) *and (g)*. *(See also 71 FR 71378, December 6, 2006)*

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 at 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]*

(Rev. 50; Issued: 07-10-09; Effective/Implementation Date: 07-10-09)

5140.3 - Responsibilities

(Rev. 50; Issued: 07-10-09; Effective/Implementation Date: 07-10-09)

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 Automated Survey Processing Environment (ASPEN) Complaint Tracking System (ACTS) Restraint/Seclusion Death Module and for maintenance of Data Use Agreement files related to disclosures to Protection and Advocacy Agencies. (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 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.

The 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 at 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.

The 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. The SAs handle these requests in accordance with the SA's Data Use Agreement (DUA) with CMS.

5140.4 - Process

(Rev. 50; Issued: 07-10-09; Effective/Implementation Date: 07-10-09)

*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.*

Using 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 5 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 provides written notification, by mail or email, to* the appropriate *Protection and Advocacy (*P&A*) Organization within the State where the hospital is located*. *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 website, and at the drop down menu entitled "Get Help in Your State:" www.ndrn.org .*

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 relating to that case, including the name of the deceased contained in the ACTS restraint/seclusion module and the worksheet for the case. The P&A must have an approved CMS Data Use Agreement (DUA), Form CMS-R-0235, (Exhibit 292) in place before the RO may release a copy of the worksheet and/or information from the ACTS restraint/seclusion module.

Form CMS-R-0235 may be submitted by a P&A to CMS in advance of any specific request for person-identifiable data. Once the P&A has an approved DUA and has submitted a copy of it to the RO, that DUA applies to all subsequent disclosures to the P&A of person-identifiable data in response to requests for hospital restraint/seclusion death information to the RO. It is not necessary for the P&A to submit a DUA update for each individual request.

In order to get an approved DUA, the P&A must complete and submit a signed CMS DUA, Form CMS-R-0235, including an initialed DUA ACTS SOR- P&A Attachment (Exhibit 293) 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. When completing the Form, P&As must note the following in particular:

- *Line 5 of the DUA must state "Restraint/Seclusion Hospital Death Reports." The "Years" and "System of Record" columns should be left blank;*

- *Line 12 must state "CMS DUA: ACTS SOR Attachment – P&A;"*

- *The DUA must be signed by the P&A official whom the P&A designates as "Custodian," i.e., the individual who will have actual possession of and responsibility for the data released under the DUA; and*

- *A P&A may designate more than one Custodian, but if it does so, each individual must complete and sign a Multi-Signature Addendum Form (Exhibit 294).*

For each disclosure of personally identifiable data to a P&A that has an approved DUA, the RO must complete the DUA Tracking Addendum (Exhibit 295), sequentially listing each case file disclosed. Disclosure of person-identifiable data is permitted only for those cases where the:

- *RO has previously notified the P&A, without providing person-identifiable data, of a hospital restraint/seclusion death report for which a SA survey has been authorized; or*

- *P&A identifies in its request an individual and hospital by name and requests restraint/seclusion death report information that may have been submitted by that hospital with respect to that individual.*

The DUA Tracking Addendum must show the DUA number of the primary P&A DUA. The RO must enter the ACTS Intake Number, Requestor's Name and Title, Name of the P&A, Address, Telephone Number and E-Mail Address, (if applicable). Because the RO is responsible for tracking all disclosures made, the RO must sign the Addendum for each disclosure. ROs must ensure that the responsibilities related to processing hospital restraint/seclusion death reports are clearly articulated and implemented within the RO.

Custodians may be added or deleted over the life of the primary DUA. To add a new Custodian under an existing DUA, the P&A must submit the following to the RO: a letter from the P&A describing the activities planned for the new Custodian and the length of time over which the Custodian will serve, and a Multi-Signature Addendum signed by the appropriate official from the P&A. The Multi-Signature Addendum must show the DUA number of the existing primary P&A DUA. The P&A must assign a case number to all Multi-Signature Addendums beginning with "1" and adding consecutively thereafter. CMS will use this number to track the number of Custodians in each P&A. When a P&A seeks to delete an existing Custodian, it must send the RO a letter to this effect. The RO will strike out the name of the deleted Custodian from the DUA or Multi-Signature Addendum that added that Custodian, dating and initialing the deletion. The letter from the P&A removing the Custodian must be kept on file.

Any 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.

Exhibit 292

(Rev. 50; Issued: 07-10-09; Effective/Implementation Date: 07-10-09)

INSTRUCTIONS FOR COMPLETING THE DATA USE AGREEMENT (DUA) FORM CMS-R-0235

(AGREEMENT FOR USE OF CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS) DATA CONTAINING INDIVIDUAL IDENTIFIERS)

http://www.cms.hhs.gov/cmsforms/downloads/cms-r-0235.pdf

`Exhibit 293

(Rev. 50; Issued: 07-10-09; Effective/Implementation Date: 07-10-09)

DUA #

CMS DUA: ACTS SOR Attachment - P&A

[Attachment to CMS Data Use Agreement (Form CMS-R-0235) for Disclosures to Protection and Advocacy Organizations (P&A) Consistent With the ACTS System of Record (SOR)]

This Attachment describes how the CMS Data Use Agreement (DUA) applies to the Automated Survey Processing Environment (ASPEN) Complaint Tracking System (ACTS) System of Record (SOR) with respect to disclosure to a State-mandated Protection and Advocacy (P&A) organization of data related to a hospital report of a death associated with use of restraint or seclusion.

Clarifications to DUA Sections:

The section references found below refer to the CMS DUA (Form CMS-R-0235) that must be signed by each P&A organization accessing hospital restraint and seclusion-related death report information.

- *The reference to the Health Insurance Portability and Accountability Act in the introductory paragraph is not applicable.*
- *Section 4: CMS Contract # is not applicable. This DUA applies to an entity designated by a State to serve as a State-mandated P&A organization.*
- *Section 4: In its entirety, the second paragraph concerning the use of data for a study or research, etc. is not applicable for purposes of this Agreement. The permissible data uses can be found below in this Attachment.*
- *Section 5: All Hospital Restraint/Seclusion Death Report Worksheets for which on-site investigations are authorized are covered by the DUA and will continue to be covered as long as the ACTS SOR exists.*
- *Section 6: This completion date is not applicable to the use of data under the ACTS SOR.*
- *Section 9: This section does not apply to the use of ACTS SOR data for investigative purposes and/or reports by a state-designated P&A organization.*

Permissible Data Uses:

The ACTS SOR permits certain disclosures to assist a State-mandated P&A organization that provides legal representation and other advocacy services to beneficiaries. Under the DUA, the Requestor, as a State-mandated P&A organization, may use hospital restraint/seclusion death report data released to it

to investigate such incidents. This and any other disclosure or use of personally identifiable information under the ACTS SOR is governed by the terms of the DUA and, thereby, terms of the Privacy Act of 1974, Centers for Medicare & Medicaid Services (CMS) data release policies, and the ACTS SOR Notice of May 23, 2006.

Requestor's Initials and Date

The language contained in this Attachment cannot be altered in any form.

Exhibit 294

(Rev. 50; Issued: 07-10-09; Effective/Implementation Date: 07-10-09)

DUA Multi-Signature Addendum

Release of Hospital Restraint/Seclusion Death Reports to Protection and Advocacy Organizations

This Addendum #_____ to DUA #_____ must be executed prior to the disclosure of any person-identifiable restraint/seclusion death report data to an alternate or additional Custodian designated by the Protection and Advocacy organization (P&A).

Prior to the Regional Office (RO) releasing person-identifiable restraint/seclusion hospital death report data to a State-mandated P&A authorized to investigate such incidents/complaints, the P&A must have a valid Data Use Agreement (DUA), signed by the P&A-designated Custodian and approved by CMS, on file with the RO. The "Custodian" is the individual within the P&A who will have actual possession of and responsibility for the data files, and who will be an official of the P&A. If an alternate or additional Custodian is designated by the P&A, that individual must submit a signed Multi-Signature Addendum Form to the RO.

On behalf of the below-named P&A, the undersigned individual hereby attests that he or she is authorized to enter into this Agreement and agrees to the terms and provisions of the aforementioned existing DUA.

_____

Name of Custodian (typed or printed)

_____

Agency/Organization

_____

Street Address

_____

City/State/ZIP Code

_____

Telephone (Include Area Code) *E-Mail Address (if applicable)*

_____

Signature *Date*

_____

Exhibit 295

(Rev. 50; Issued: 07-10-09; Effective/Implementation Date: 07-10-09)

DUA Disclosure Tracking Addendum

Release of Hospital Restraint/Seclusion Death Reports to Protection and Advocacy Organizations

This Addendum to DUA #_____ must be executed prior to the disclosure of any person-identifiable restraint/seclusion hospital death report data to ensure the disclosure will comply with the requirements of the Privacy Act, the Privacy Rule, and CMS data release policies. It must be completed prior to the release of, and access to, specified data files containing personal information and individual identifiers.

When Regional Offices (ROs) release person-identifiable hospital death report data to a state-mandated Protection and Advocacy (P&A) Agency/Organization authorized to investigate such incidents/complaints, the P&A must have a signed Data Use Agreement (DUA) on file with CO and the RO. The RO is responsible for tracking all disclosures made and the RO representative making the disclosure of person-identifiable data must sign this Addendum.

The following individual(s) have requested and been granted access to the CMS restraint/seclusion hospital death report data for investigations and associated activities.

_____ *(Intake Number)*	_____ *(Intake Number)*
_____ *(Name of Requesting Custodian)*	_____ *(Name of Requesting Custodian)*
_____ *(Title)*	_____ *(Title)*
_____ *(Agency/Organization)*	_____ *(Agency/Organization)*
_____ *(Street Address)*	_____ *(Street Address)*
_____ *(City/State/ZIP Code)*	_____ *(City/State/ZIP Code)*
_____ *(Phone No. and E-Mail Address, if applicable)*	_____ *(Phone No. and E-Mail Address, if applicable)*
_____ *(RO Signature)* *(Release Date)*	_____ *(RO Signature)* *(Release Date)*