CMS Manual System

Pub. 100-07 State Operations Provider Certification

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

Transmittal 88 **Date: August 27, 2013**

Transmittal 86, dated July 19, 2013, is being rescinded and replaced by Transmittal 88, dated August 27, 2013 to reflect the deletion of sections 5140.1through 5140.4 on the transmittal page as this information has been moved to new sections 5170.1 through 5170.3. Additionally, in the table of contents, sections 5171.1 through 5171.3 have been corrected to 5170.1 through 5170.3. All other information remains the same.

SUBJECT: Revisions to State Operations Manual (SOM) Chapter 5

I. SUMMARY OF CHANGES: Chapter 5, Sections 5100 through 5170 are being reorganized and updated. Corresponding to these revisions, Exhibit 294 is being updated and Exhibit 295 is being deleted.

NEW/REVISED MATERIAL - EFFECTIVE DATE*: July 19, 2013
IMPLEMENTATION DATE: July 19, 2013

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	Chapter 5/Table of Contents
D	Section 5100.2/Post-Survey Procedures
N	Section 5110/Post-Survey Procedures
N	Section 5110.1/ Substantial Compliance
N	Section 5110.2/ Condition-Level, IJ
N	Section 5110.3/ Condition-Level, Non-IJ
N	Section 5110.4/ Full Survey after Complaint Survey with Condition-level Deficiencies, When Authorized by the RO
R	Section 5130/Deemed Provider/ Supplier Refusal of Complaint Investigation Surveys
R	Section 5140/ Complaints Involving HIV-Infected Individuals (previously Section 5150)
D	Section 5140.1/Background
D	Section 5140.2/Reserved
D	Section 5140.3/Responsibilities
D	Section 5140.4/Process
R	Section 5150/Investigating Complaints Involving ESRD Services Provided by Deemed Hospitals or CAHs (previously Section 5160)

R	**Section 5160/Investigating Complaints Against ESRD Suppliers (previously Section 5170)**
R	**Section 5170/Hospital Restraints/Seclusion Death Reporting and Investigation (previously Section 5140)**
N	**Section 5170.1/Background**
N	**Section 5170.2/Responsibilities**
N	**Section 5170.3/Process**
R	**Exhibit 294/DUA Multi-Signature Addendum Release of Hospital Restraint/Seclusion Death Reports to Protection and Advocacy Organizations**
D	**Exhibit 295/DUA Disclosure Tracking Addendum**

III. FUNDING: No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2013 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

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(Rev.88, Issued: 08-27, 13)

Section 5170 Relates to Hospital Restraint/Seclusion Death Reporting and Investigation

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5210- Processing of Complaints Originating with or Investigated by the RO

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5110 - Post-Survey Procedures

(Rev.88, Issued: 08-27, 13, Effective: 07-19-13, Implementation: 7-19-13)

5110.1 - Substantial Compliance

(Rev.88, Issued: 08-27, 13, Effective: 07-19-13, Implementation: 7-19-13)

If a condition-level deficiency is not cited at a survey, the provider/supplier is in substantial compliance with the Federal requirements. The SA certifies its survey findings in ACTS within 30 calendar days after the completion of the survey. A Form CMS 2567 is prepared in all cases. Even if no deficiencies were cited, the Form CMS 2567 is issued with a statement that a survey was conducted to evaluate compliance with the listed requirements identified on the CMS-2802 and that no deficiencies were identified in these areas.

The RO randomly selects several Form CMS 2567s with standard-level deficiencies for review to determine if the RO concurs with the SA's finding of substantial compliance.

- *For all cases not selected for review of the Form CMS 2567, the RO completes the processing in ACTS of the complaint investigation Form CMS 562 and other applicable items in ACTS, and then, depending on RO practice, either the SA or RO uploads the complaint survey package into CASPER, the CMS National Reporting System.*

- *For cases selected for review of the Form CMS 2567:*

    - *If the RO concurs with the finding, the RO completes the processing in ACTS of the complaint investigation Form CMS 562 and other applicable items in ACTS, and then, depending on RO practice, either the SA or RO uploads the complaint survey package into CASPER, the CMS National Reporting System.*

    - *If the RO does not concur with the SA's findings of substantial compliance, the RO discusses with the SA any revisions needed on the Form CMS 2567 and, after the revisions are made, follows the procedures for a survey finding substantial noncompliance. (See Section 5110.2 or 5110.3, as applicable.)*

The RO either issues a notice, or authorizes the SA in ACTS to issue the provider/supplier a notice of its compliance status. The RO or SA, as applicable, issues this notice to the provider/supplier, along with a copy of the Form CMS 2567containing the survey findings. The notice indicates that the provider/supplier was found to be in substantial compliance even though there may, or may not, also be standard-level deficiencies cited. In such circumstances, the provider/supplier is not required to submit a plan of correction for any cited standard-level deficiencies, but may choose to do so because the Form CMS 2567 is available to the public. The SA and RO do not review any plan of correction the provider/supplier submits; no revisit survey is conducted. ***The RO promptly sends a copy of the notice letter and Form CMS 2567 to the applicable AO(s).*** *At the RO's or SA's discretion, the materials may be sent to the AO via e-mail.*

5110.2 - Condition-Level, IJ

(Rev.88, Issued: 08-27, 13, Effective: 07-19-13, Implementation: 7-19-13)

1. IJ Removed while the SA is On-site

If deficiencies pose an IJ and the IJ is removed while the SA is on-site, deficiency citations are made at the condition-level. Follow the procedure for condition-level noncompliance, non-IJ, in Section 5110.3 below.

***Note**: The Form CMS 2567 must state at the beginning that an IJ was cited, regardless of the fact that it was removed while the SA was on-site. An entry in ASPEN/ACTS must also be made by the RO indicating that there was an IJ citation before the survey can be uploaded to the national database, the CMS National Reporting System (CASPER). The ASPEN/ACTS systems will prompt the RO whenever a survey includes condition-level deficiencies to indicate whether there was also an IJ.*

Details of the IJ situation and the actions taken by the provider/supplier to remove the IJ must also be documented on the Form CMS 2567. Even though the IJ was removed while the SA was on-site, the provider or supplier must still be cited for condition-level noncompliance for the applicable Condition of Participation, Condition for Coverage, or Condition for Certification that is cited for non-compliance related to the IJ. The documentation must also include the date the surveyors verified that the IJ was removed prior to completion of the survey.

2. IJ not Removed while the SA is On-site

If condition-level deficiencies pose an IJ and the IJ is not removed while the SA is on-site, the SA certifies its findings in ACTS within 2 working days after the completion of the survey.

If the RO concurs with the SA's findings, the deemed provider/supplier is placed on a 23 calendar-day termination track. The RO sends the provider/supplier the Form CMS 2567, notifies the provider/supplier of the proposed termination action and effective date, which is 23 calendar days after the date of the RO's notice, and requests submission of an acceptable plan of correction to the RO within 5 calendar days of the notice. The provider/supplier is advised it will be surveyed after receipt of an acceptable plan of correction and prior to the termination date. The notice also contains a statement that "removes" the "deemed status" of the provider/supplier and places it under SA jurisdiction.

The RO sends a copy of the notice to the SA and a copy of the notice and Form CMS 2567 to the applicable AO(s). At the RO's discretion, the materials may be sent to the AO via e-mail.

***Note:** Although deemed status technically has been removed and the provider/supplier is placed under SA jurisdiction, because it is expected that deemed status will be restored once corrections are made and verified, no change is made in ASPEN to the provider's/supplier's deemed status. However, periods during which the provider/supplier is under SA jurisdiction are entered and tracked in ASPEN. Further, the AO may also conduct a survey of the facility, so long as it continues to accredit the provider/supplier under its approved Medicare accreditation program.*

When the RO receives a timely and acceptable plan of correction from the provider/supplier, it directs the SA to conduct either a full survey or an IJ follow-up survey, which is a focused, revisit-type survey, before the scheduled termination date in order to confirm that the IJ has been removed and that the provider/supplier is in substantial compliance. See Section 5110.3 for a discussion of factors the RO should consider when deciding whether a full survey is needed. If the RO authorizes a full survey, see Section 5110.4 for procedures to follow, except that the full survey must be conducted prior to the 23-day termination date.

i. No Acceptable Plan of Correction Submitted

No revisit is necessary if the provider/supplier fails to submit a timely and acceptable plan of correction. CMS will proceed to terminate a provider/supplier if it does not submit a timely and acceptable POC. See SOM Section 3254F. The public notice must be published 15 calendar days prior to the termination date. The RO notifies the applicable Medicare Administrative Contractor (MAC) via the Form CMS 2007 of the termination of the provider/supplier's Medicare agreement, including the effective date of the termination.

The RO completes the processing in ACTS of the complaint investigation Form CMS 562 and other applicable items in ACTS and then, depending on RO practice, either the SA or RO uploads the complaint survey package into CASPER, the CMS National Reporting System.

The RO sends a copy of the termination letter to the applicable AO(s). At the RO's discretion, the copy may be sent to the AO via e-mail.

ii. Post-IJ First Revisit: IJ Not Removed

At least 5 calendar days in advance of the scheduled termination date, the SA certifies to the RO in ACTs its findings, based on on-site verification, that the IJ has not been removed, and recommends that the termination action proceed.

The RO reviews the SA's findings, and if it concurs with the SA's recommendation, the RO completes the processing in ACTS of the complaint investigation Form CMS 562 and other applicable items in ACTS and then, depending on RO practice, either the SA or RO uploads the complaint survey package into the CMS National Reporting System (CASPER). The termination of the provider's/supplier's Medicare agreement is processed in ASPEN.

The RO sends the provider/supplier a final termination letter and publishes a public notice, in accordance with the termination process in Section 3010B. The provider/supplier is terminated from the Medicare program. The RO notifies the applicable Medicare Administrative Contractor (MAC) via the Form CMS 2007 of the termination of the provider/supplier's Medicare agreement, including the effective date of the termination.

The RO sends a copy of the termination notice and the Form CMS 2567 to the applicable AO(s). At the RO's discretion, the materials may be sent to the AO via e-mail.

iii. Post-IJ First Revisit: IJ Removed, Substantial Compliance

The termination action is rescinded if the IJ has been removed and substantial compliance has been achieved prior to the effective date of the termination, i.e., there are no condition-level deficiencies identified during the follow-up survey by the SA. The SA certifies its findings to the RO via ACTS at least 5 calendar days in advance of the scheduled termination date, and recommends that the termination action be rescinded.

The RO randomly selects several Form CMS 2567s with standard-level deficiencies for review, to determine if the RO concurs with the SA's finding of substantial compliance. If the RO concurs, and in all other cases where the Form CMS 2567 is not reviewed by the RO, the RO completes the processing in ACTS of the complaint investigation Form CMS 562 and other applicable items in ACTS, and then, depending on RO practice, either the SA or RO uploads the complaint survey package into CASPER, the CMS National Reporting System. If the RO does not concur with the SA's finding, the RO discusses with the SA any revisions needed on the Form CMS 2567 and, after the revisions are made, follows the procedures for substantial noncompliance.

When substantial compliance is achieved, the RO either issues a notice, or authorizes the SA in ACTS to issue the provider/supplier a notice of its compliance status, restoring its deemed status. The RO or SA, as applicable, issues this notice to the provider/supplier, along with a copy of the Form CMS 2567 containing the survey findings.

In addition, the RO sends a copy of the notice letter to the applicable AO(s). At the RO's discretion, the copy may be sent to the AO via e-mail.

Although the follow-up survey found the provider/supplier to be in substantial compliance, it may have resulted in citation(s) of standard-level deficiencies of the Form CMS 2567. Because deemed status has been restored, the provider/supplier is not obligated to submit a plan of correction to the SA, nor are any further revisits conducted. The provider/supplier may voluntarily choose to submit a plan of correction because the Form CMS 2567 will be made available to the public. The SA and RO do not review any plan of correction the provider/supplier submits; no further revisit survey is conducted.

iv. Post-IJ First Revisit: IJ Removed, Substantial Noncompliance Remains

If the IJ has been removed but substantial noncompliance (i.e., condition-level deficiencies), remain, the SA certifies its findings to the RO in ACTS within 10 working days after the survey completion date. The SA certifies that the IJ has been removed and recommends rescission of the 23 calendar-day IJ termination action, but continuation of the termination action on a 90 calendar-day termination track.

The RO reviews the SA's findings, and if it concurs with the SA's recommendation, the RO gives the provider/supplier up to 67 additional calendar days, or a total of 90 calendar days (23 plus 67) to achieve substantial compliance. The resulting revised termination date is 90 calendar days after the date of the RO's original 23-day notice. The RO sends the CMS Form 2567 from the follow-up survey to the provider/supplier with notice of the new termination date, and requests that an acceptable POC be provided to the SA within 10 calendar days of the notice.

Post-IJ Second Revisit: *The SA conducts the second revisit survey by the 60th calendar day after the date of the RO's original 23-day termination notice. Unlike the post-IJ first revisit survey, advance authorization from the RO is not required.*

(i) Post-IJ Second Revisit Survey Findings: Substantial Compliance

The termination action is rescinded if substantial compliance (i.e., no condition-level deficiencies) is achieved and documented through the onsite verification at the revisit survey. There may or may not be standard-level deficiencies cited. Within 10 working days after the completion of the revisit survey, the SA certifies to the RO its findings via ACTS and recommends that the termination action be rescinded.

The RO randomly selects some Form CMS 2567s with only standard-level deficiencies for review, to determine if the RO concurs with the SA's finding of substantial compliance. If the RO concurs, and in all other cases where the Form CMS 2567 is not reviewed by the RO, the RO completes the processing in ACTS of the complaint investigation Form CMS 562 and other applicable items in ACTS and then, depending on RO practice, either the SA or the RO uploads the complaint survey package into CASPER, the CMS National Reporting System. If the RO does not concur, the RO discusses with the SA revisions needed on the Form CMS 2567 and, after the revisions are made, follows the procedures for substantial noncompliance.

The RO either issues a notice, or authorizes the SA in ACTS to issue a notice to the provider/supplier of its compliance status and that its deemed status is restored. The RO or SA, as applicable, issues this notice to the provider/supplier, along with a copy of the Form CMS 2567 with the survey findings.

The RO sends a copy of the notice and Form CMS 2567 to the applicable AO(s). At the RO's discretion, the materials may be sent to the AO via e-mail.

i. Post-IJ Second Revisit Survey Findings: Substantial Noncompliance

If the second revisit shows that the provider/supplier fails to demonstrate substantial compliance (i.e., condition-level deficiencies are identified through on-site verification by the SA), the SA certifies to the RO its findings within 10 calendar days after the survey completion date, and recommends that the termination action proceed.

The RO reviews the SA's findings, and if it concurs with the SA's recommendation, the RO sends the provider/supplier a final termination letter and publishes a public notice 15 calendar days prior to the termination date. The provider/supplier is terminated from the Medicare program. The RO notifies the applicable Medicare Administrative Contractor (MAC) via the Form CMS 2007 of the termination of the provider/supplier's Medicare agreement, including the effective date of the termination.

The RO completes the processing in ACTS of the complaint investigation Form CMS 562 and other applicable items in ACTS and then, depending on RO practice, either the SA or RO uploads the complaint survey package into CASPER. The provider's or supplier's Medicare agreement is terminated in ASPEN.

The RO sends a copy of the final termination notice and Form CMS 2567 to the applicable AO(s). At the RO's discretion, the materials may be sent to the AO via e-mail.

5110.3 - Condition-Level, Non-IJ

(Rev.88, Issued: 08-27, 13, Effective: 07-19-13, Implementation: 7-19-13)

If the provider/supplier fails to demonstrate substantial compliance, i.e., condition-level deficiencies are identified by the SA, but they do not pose an IJ, the SA certifies its findings to the RO via ACTS within 10 working days after the survey completion date.

*The RO reviews the SA's findings, and if it concurs with the SA's recommendation, the RO **either** places the deemed provider/supplier on a 90 calendar-day termination track **or** it requires a full survey after a complaint survey.*

In determining whether to exercise its discretion to require a full survey for deemed providers and suppliers, the RO may consider factors including, but not limited to, the following:

- *The manner and degree of noncompliance identified as a result of the complaint investigation;*
- *The provider's/supplier's compliance history;*
- *Recent changes in the provider's/supplier's ownership or management;*
- *The length of time since the provider's/supplier's last accreditation survey;*
- *The availability of SA resources at the time required to conduct a full survey; and/or*
- *The advantages associated with conducting a more extensive survey compared to the advantages associated with the faster enforcement (and thus a faster potential corrective action) that result when proceeding directly to enforcement action after the complaint survey.*

Paragraph a) below discusses the procedures when the RO does not require a full survey after the complaint survey; paragraph b) discusses the procedures to follow when the RO directs the SA to conduct a full survey.

a) No full survey – proceed directly to termination track based on the complaint survey

If the RO places the deemed provider/supplier on a 90 calendar-day termination track as a result of the complaint investigation, it sends the provider/supplier the Form CMS 2567, notifies the provider/supplier of the proposed termination action and effective date, which will be 90 calendar days after the date of the RO's notice. The RO requests submission of an acceptable plan of correction to the SA within 10 calendar days. The notice also contains a statement that "removes" the "deemed status" of the provider/supplier and places it under SA jurisdiction.

The RO sends a copy of the notice to the SA and a copy of the notice and Form CMS 2567 to the applicable AO(s). At the RO's discretion, the materials may be sent to the AO via e-mail.

NOTE: *Although deemed status has technically been "removed" and the provider/supplier is placed under SA jurisdiction, because it is expected that deemed status will be restored once corrections are made and verified, no change is made in ASPEN to the provider's/supplier's deemed status. However, periods during which the provider/supplier is under SA jurisdiction are entered and tracked in ASPEN. Further, the AO may also conduct a survey of the facility so long as it continues to accredit the provider/supplier.*

The SA conducts a complaint survey revisit after the SA has received a timely and acceptable plan of correction, but no later than the 45th calendar day after the notice to the provider/supplier.

1) No Timely, Acceptable Plan of Correction Submitted

If the provider/supplier fails to submit a timely and acceptable plan of correction to the SA and as a result the SA is unable to conduct a timely revisit before the termination date, the SA notifies the RO and the RO may proceed with termination. See SOM Section 3254F. The RO publishes a public notice 15 days prior to the termination date. The RO notifies the applicable Medicare Administrative Contractor (MAC) via the Form CMS 2007 of the termination of the provider/supplier's Medicare agreement, including the effective date of the termination.

The RO approves the complaint investigation Form CMS 562 and other applicable items in ACTS and then, depending on RO practice, either the SA or RO uploads the complaint survey package into the CMS National Reporting System (CASPER). The provider's or supplier's Medicare agreement is terminated in ASPEN.

Additionally, the RO sends a copy of the notice of termination letter to the applicable AO(s).

2) First Revisit Survey Findings: Substantial Compliance

The termination action is rescinded if substantial compliance (i.e., no condition-level deficiencies) is achieved and documented through the onsite verification at the first revisit survey. There may or may not be standard-level deficiencies cited. Within 10 working days after the completion of the revisit survey, the SA certifies to the RO in ACTS its findings and recommends that the termination action be rescinded.

The RO randomly selects several Form CMS 2567s with standard-level deficiencies for review to determine if the RO concurs with the SA's finding of substantial compliance.

- *For all cases not selected for review of the Form CMS 2567, the RO completes the processing in ACTS of the complaint investigation Form CMS 562 and other applicable items in ACTS, and then, depending on RO practice, either the SA or RO uploads the complaint survey package into CASPER, the CMS National Reporting System.*

- *For cases selected for review of the Form CMS 2567:*

- *If the RO concurs with the finding, the RO completes the processing in ACTS of the complaint investigation Form CMS 562 and other applicable items in ACTS, and then, depending on RO practice, either the SA or RO uploads the complaint survey package into CASPER, the CMS National Reporting System.*

- *If the RO does not concur with the SA's findings of substantial compliance, the RO discusses with the SA any revisions needed on the Form CMS 2567 and, after the revisions are made, follows the procedures for a survey finding substantial noncompliance. (See Section 5110.2 or 5110.3, as applicable.)*

The RO either issues a notice, or authorizes the SA in ACTS to issue a notice to the provider/supplier of its compliance status and that its deemed status is restored. The RO or SA, as applicable, issues this notice to the provider/supplier, along with a copy of the Form CMS 2567 with the survey findings.

The RO sends a copy of the notice and Form CMS 2567 to the applicable AO(s). At the RO's discretion, the materials may be sent to the AO via e-mail.

3) First Revisit Survey Findings: Substantial Noncompliance

If the SA finds during the first revisit survey that the provider/supplier is not in substantial compliance with one or more Medicare conditions, the SA consults with the RO on its findings and whether to conduct a second revisit. If the RO agrees that condition-level deficiencies remain, the RO considers whether the survey findings warrant a second revisit or proceeding immediately to termination. Generally the RO authorizes a second revisit, but the RO has discretion to make an exception, based on the facts of the situation. For example, if the SA and RO determine that an immediate jeopardy was present during the first revisit, the RO might find it prudent to proceed to termination without a second revisit.

If the RO agrees that condition-level deficiencies remain and does not authorize a second revisit, the RO and SA follow the procedures outlined in paragraph 3ii. below.

If a second revisit is authorized by the RO, the SA sends the provider/supplier the Form CMS 2567 for the first revisit with notice that substantial noncompliance remains, the 90-day termination date remains in effect, a new acceptable plan of correction is required, and that an additional revisit will be conducted prior to the termination date. The SA conducts the second revisit no later than 60 calendar days after the date of the termination notice.

i. Second Revisit Survey Findings: Substantial Compliance

If substantial compliance is achieved by the provider/supplier (i.e., no condition-level deficiencies are identified through the on-site verification by the SA), the SA certifies its findings to the RO via ACTS within 10 working days after the survey completion date, and recommends that the termination action be rescinded.

The RO randomly selects some Form CMS 2567s with only standard-level deficiencies for review, to determine if the RO concurs with the SA's finding of substantial compliance. If the RO concurs, and in all other cases where the Form CMS 2567 is not reviewed by the

RO, RO completes the processing in ACTS of the complaint investigation Form CMS 562 and other applicable items in ACTS and then, depending on RO practice, either the SA or RO uploads the complaint survey package into CASPER, the CMS National Reporting System. If the RO does not concur, the RO discusses with the SA revisions needed on the Form CMS 2567 and, after the revisions are made, follows the procedures for substantial noncompliance.

The RO either issues a notice, or authorizes the SA in ACTS to issue the provider/supplier a notice letter of its compliance status and that its deemed status is restored. The RO or SA, as applicable, forwards this notice to the provider/supplier, along with a copy of the Form CMS 2567 with the survey findings.

Additionally, the RO sends a copy of the notice and the Form CMS 2567 to the applicable AO(s). At the RO's discretion, the materials may be sent to the AO via e-mail.

ii. Second Revisit Survey Findings – Substantial Noncompliance

If the second revisit survey shows that the provider/supplier fails to demonstrate substantial compliance (i.e., condition-level deficiencies are identified through on-site verification by the SA), the SA certifies its findings to the RO via ACTS within 10 calendar days after the survey completion date, and recommends that the termination action proceed.

The RO reviews the SA's findings, and if it concurs with the SA's recommendation, the RO sends the provider/supplier a final termination letter and publishes a public notice at least 15 calendar days prior to the termination date, consistent with the requirements of Section 3012. The provider/supplier is terminated from the Medicare program. The RO notifies the applicable Medicare Administrative Contractor (MAC) via the Form CMS 2007 of the termination of the provider/supplier's Medicare agreement, including the effective date of the termination.

The RO completes the processing in ACTS of the complaint investigation Form CMS 562 and other applicable items in ACTS and then, depending on RO practice, either the SA or RO uploads the complaint survey package into CASPER, the CMS National Reporting System. The provider's or supplier's Medicare agreement is terminated in ASPEN.

Additionally, the RO sends a copy of the termination notice and the Form CMS 2567 to the applicable AO(s). At the RO's discretion, the materials may be sent to the AO via e-mail.

b) Full Survey After the Complaint Survey

If the RO directs the SA to conduct a full survey following the complaint survey, it sends the Form CMS 2567 for the complaint survey to the provider/supplier in addition to a notice letter indicating that it is "removing" the provider's/supplier's deemed status and that a full survey will be conducted on an unannounced basis. The provider/supplier is not required to submit a plan of correction in response to the complaint survey findings, but may choose to do so.

The RO completes the processing in ACTS of the complaint investigation Form CMS 562 and other applicable items in ACTS and then, depending on RO practice, either the SA or RO uploads the complaint survey package into CASPER, the CMS National Reporting System.

Additionally, the RO sends a copy of the notice letter and Form CMS 2567 for the complaint survey to the applicable AO(s). At the RO's discretion, the materials may be sent to the AO via e-mail.

***NOTE:** Although deemed status technically has been removed and the provider/supplier is placed under SA jurisdiction, because it is expected that deemed status will be restored once corrections are made and verified, no change is made in ASPEN to the provider's/supplier's deemed status. However, periods during which the provider/supplier is under SA jurisdiction are entered and tracked in ASPEN. Further, the AO may also conduct a survey of the facility so long as, since it continues to accredit the provider/supplier.*

The full survey must be conducted within 60 calendar days after the RO's notice to the provider/supplier of the complaint survey results and removal of deemed status. The RO and SA follow the procedures in Section 5110.4.

5110.4 - Full Survey after Complaint Survey with Condition-level Deficiencies, When Authorized by the RO

(Rev.88, Issued: 08-27, 13, Effective: 07-19-13, Implementation: 7-19-13)

If the RO authorizes the SA to conduct a full survey after the complaint survey, the timeframes and procedures described in this section apply.

Timeframe

The full survey must be conducted within:

- *23 days after the RO's notice to the provider/supplier, if the complaint survey involved an IJ that was not removed while the survey team was on-site; or*
- *60 calendar days after the RO's notice to the provider/supplier in all other cases.*

Procedures following the full survey with findings of:

a) Full Survey Findings: Substantial Compliance

If the SA full survey finds the deemed provider or supplier to be in substantial compliance, the SA and RO follow the same procedures and timeline as at Section 5110.1. In addition, since the RO had removed deemed status, the RO either issues a notice, or authorizes the SA to issue a notice to the provider or supplier of its compliance status and that its deemed status is restored, along with a copy of the Form CMS 2567 with the survey findings.

The RO sends a copy of the notice and Form CMS 2567 to the applicable AO(s). At the RO's discretion, the materials may be sent to the AO via e-mail.

b) Full Survey Findings: Condition-Level, IJ

1. IJ Removed while the SA is On-site

If deficiencies pose an IJ and the IJ is removed while the SA is on-site, deficiency citations are made at the condition-level. Follow the procedure for condition-level noncompliance, non-IJ, in Section 5110.4c below.

***Note**: The Form CMS 2567 must state at the beginning that an IJ was cited, regardless of the fact that it was removed while the SA was on-site. An entry in ASPEN must also be made by the RO indicating that there was an IJ citation before the survey can be uploaded to the national database, the CMS National Reporting System (CASPER). The ASPEN systems will prompt the RO whenever a survey includes condition-level deficiencies to indicate whether there was also an IJ.*

Details of the IJ situation and the actions taken by the provider/supplier to remove the IJ must also be documented on the Form CMS 2567. Even though the IJ was removed while the SA was on-site, the provider or supplier must still be cited for condition-level noncompliance for the applicable Condition of Participation or Condition for Coverage that is cited for non-compliance related to the IJ. The documentation must also include the date the surveyors verified that the IJ was removed prior to completion of the survey.

2. IJ not Removed while the SA is On-site

If condition-level deficiencies pose an IJ and the IJ is not removed while the SA is on-site, the SA certifies its findings to the RO within 2 working days after the completion of the survey.

If the RO concurs with the SA's findings, the deemed provider/supplier is placed on a 23 calendar-day termination track. The RO sends the provider/supplier the Form CMS 2567, notifies the provider/supplier of the proposed termination action and effective date, which is 23 calendar days after the date of the RO's notice, and requests submission of an acceptable plan of correction to the RO within 5 calendar days of the notice.

The RO sends a copy of the notice to the SA and a copy of the notice and Form CMS 2567 to the applicable AO(s). At the RO's discretion, the materials may be sent to the AO via e-mail.

When the RO receives a timely and acceptable plan of correction from the provider/supplier, it directs the SA to conduct an IJ follow-up survey before the rescheduled termination date in order to confirm that the IJ has been removed and that the provider/supplier complies with the conditions previously cited for noncompliance.

2.1 First Revisit after Full Survey with IJ

i. No Acceptable Plan of Correction Submitted

No revisit is necessary if the provider/supplier fails to submit a timely and acceptable plan of correction. CMS will proceed to terminate a provider/supplier if it does not submit a timely and acceptable POC. See SOM Section 3254F. The public notice must be published 15 calendar days prior to the termination date. The RO notifies the applicable Medicare Administrative Contractor (MAC) via the Form CMS 2007 of the termination of the provider/supplier's Medicare agreement, including the effective date of the termination.

The SA and RO complete the processing in ASPEN of the survey kit and then, depending on RO practice, either the SA or RO uploads the complaint survey package into CASPER, the CMS National Reporting System.

The RO sends a copy of the termination letter to the applicable AO(s). At the RO's discretion, the copy may be sent to the AO via e-mail.

ii. First Revisit Survey Findings: IJ Not Removed

At least 5 calendar days in advance of the scheduled termination date, the SA certifies to the RO its findings, based on on-site verification, that the IJ has not been removed, and recommends that the termination action proceed.

The RO reviews the SA's findings, and if it concurs with the SA's recommendation, the SA and RO complete the processing of the survey kit in ASPEN and then, depending on RO practice, either the SA or RO uploads the survey package into the CMS National Reporting System (CASPER). The termination of the provider's/supplier's Medicare agreement is processed in ASPEN.

The RO sends the provider/supplier a final termination letter and publishes a public notice, in accordance with the termination process in Section 3010B. The provider or supplier is terminated from the Medicare program. The RO notifies the applicable Medicare Administrative Contractor (MAC) via the Form CMS 2007 of the termination of the provider/supplier's Medicare agreement, including the effective date of the termination.

The RO sends a copy of the termination notice and the Form CMS 2567 to the applicable AO(s). At the RO's discretion, the materials may be sent to the AO via e-mail.

iii. First Revisit Survey Findings: IJ Removed, Substantial Compliance

The termination action is rescinded if the IJ has been removed and substantial compliance has been achieved prior to the effective date of the termination, i.e., there are no condition-level deficiencies identified during the first revisit survey by the SA. The SA certifies its findings to the RO at least 5 calendar days in advance of the scheduled termination date, and recommends that the termination action be rescinded.

The RO randomly selects several Form CMS 2567s with standard-level deficiencies for review, to determine if the RO concurs with the SA's finding of substantial compliance. If the RO concurs, and in all other cases where the Form CMS 2567 is not reviewed by the RO, depending on RO practice, either the SA or RO uploads the survey package into CASPER, the CMS National Reporting System. If the RO does not concur with the SA's finding, the RO

discusses with the SA any revisions needed on the Form CMS 2567 and, after the revisions are made, follows the procedures for substantial noncompliance.

When substantial compliance is achieved, the RO either issues a notice, or authorizes the SA to issue the provider/supplier a notice of its compliance status, restoring its deemed status, along with a copy of the Form CMS 2567containing the survey findings.

In addition, the RO sends a copy of the notice letter to the applicable AO(s). At the RO's discretion, the copy may be sent to the AO via e-mail.

Although the revisit survey found the provider/supplier to be in substantial compliance, it may have resulted in citation(s) of standard-level deficiencies of the Form CMS 2567. Because deemed status has been restored, the provider or supplier is not obligated to submit a plan of correction to the SA, nor are any further revisits conducted. The provider or supplier may voluntarily choose to submit a plan of correction because the Form CMS 2567 will be made available to the public. The SA and RO do not review any plan of correction the provider/supplier submits; no further revisit survey is conducted.

iv. First Revisit Survey Findings: IJ Removed, Substantial Noncompliance Remains

If the IJ has been removed but substantial noncompliance (i.e., condition-level deficiencies), remains, the SA certifies its findings to the RO within 10 working days after the survey completion date. If the RO concurs that the IJ has been removed but that condition-level deficiencies remain, the RO considers whether the survey findings warrant a second revisit or proceeding immediately to termination. At this point the provider/supplier will have been surveyed three times, including the preceding complaint survey, with continued substantial noncompliance found in each survey and at least one IJ. Generally the RO authorizes a second revisit, but the RO has discretion to make an exception, based on the facts of the case, including the risks to patients associated with the remaining deficiencies versus providing the provider/supplier further opportunity to correct its problems in a timely manner.

If the RO does not authorize a second revisit, it follows the procedures in paragraph ii above.

If the authorizes a second revisit, the RO gives the provider/supplier up to 67 additional calendar days, or a total of 90 calendar days (23 plus 67) from the date of the notice of the IJ, to achieve substantial compliance. The resulting revised termination date is 90 calendar days after the date of the RO's original 23-day termination notice. The RO provides the provider/supplier the Form CMS 2567 for the revisit with notice of the new termination date, and requests that an acceptable POC be provided to the SA within 10 calendar days of the notice.

2.2 Second Revisit after Full Survey with IJ

The SA conducts the second revisit survey no later than 60 calendar days after the date of the RO's 23-day termination notice to the provider or supplier.

i. Second Revisit Survey Findings: Substantial Compliance

If substantial compliance is achieved by the provider/supplier (i.e., no condition-level deficiencies are identified through the on-site verification by the SA) during the second revisit survey, the SA certifies its findings to the RO within 10 working days after the survey completion date, and recommends that the termination action be rescinded.

The RO randomly selects some Form CMS 2567s with standard-level deficiencies for review, to determine if the RO concurs with the SA's finding of substantial compliance. If the RO concurs, and in all other cases where the Form CMS 2567 is not reviewed by the RO, depending on RO practice, either the SA or RO uploads the survey kit into CASPER, the CMS National Reporting System. If the RO does not concur, the RO discusses with the SA revisions needed on the Form CMS 2567 and, after the revisions are made, follows the procedures for substantial noncompliance.

The RO also either issues a notice, or authorizes the SA to issue the provider/supplier a notice, of its compliance status and that its deemed status is restored, along with a copy of the Form CMS 2567 with the survey findings.

Additionally, the RO sends a copy of the notice and the Form CMS 2567 to the applicable AO(s). At the RO's discretion, the materials may be sent to the AO via e-mail.

ii. Second Revisit Survey Findings: Substantial Noncompliance

If the second revisit shows that substantial noncompliance (i.e., condition-level deficiencies) remain, the SA certifies to the RO its findings within 10 calendar days after the survey completion date, and recommends that the termination action proceed.

The RO reviews the SA's findings, and if it concurs with the SA's recommendation, the RO sends the provider or supplier a final termination letter and publishes a public notice 15 calendar days prior to the termination date. The provider or supplier is terminated from the Medicare program. The RO notifies the applicable Medicare Administrative Contractor (MAC) via the Form CMS 2007 of the termination of the provider/supplier's Medicare agreement, including the effective date of the termination.

The SA and RO complete the processing in ASPEN of the survey kit and, depending on RO practice, either the SA or RO uploads the survey package into CASPER. The provider's or supplier's Medicare agreement is terminated in ASPEN.

The RO sends a copy of the final termination notice and Form CMS 2567 to the applicable AO(s). At the RO's discretion, the materials may be sent to the AO via e-mail.

c) Full Survey Findings: Condition-Level, Non-IJ

If the results of the full survey indicate there is substantial noncompliance (i.e., condition-level deficiencies), but the deficiencies do not constitute an IJ, the SA certifies its findings to the RO within 10 working days after the survey completion date.

The RO reviews the SA's findings, and if it concurs with the SA's recommendation, the RO places the provider or supplier on a 90 calendar-day termination track as a result of the full survey. The RO

sends the provider or supplier the Form CMS 2567 and notifies it of the proposed termination action and effective date, which will be 90 calendar days after the date of the RO's notice. The RO requests submission of an acceptable plan of correction to the SA within 10 calendar days of the notice.

Additionally, the RO sends a copy of the notice of termination letter to the applicable AO(s).

1. ***First Revisit:*** *The SA conducts the first revisit survey no later than the 45th calendar day after the date of the RO's termination notice to the provider or supplier.*

   i. First Revisit Survey Findings: Substantial Compliance

   The termination action is rescinded if substantial compliance (i.e., no condition-level deficiencies) is achieved and documented through the onsite verification at the revisit survey. There may or may not be standard-level deficiencies cited. Within 10 working days after the completion of the revisit survey, the SA certifies to the RO its findings and recommends that the termination action be rescinded.

   The RO randomly selects some Form CMS 2567s with only standard-level deficiencies for review, to determine if the RO concurs with the SA's finding of substantial compliance. If the RO concurs, and in all other cases where the Form CMS 2567 is not reviewed by the RO, the RO completes the processing of the survey kit in ASPEN and then, depending on RO practice, either the SA or the RO uploads the survey package into CASPER, the CMS National Reporting System. If the RO does not concur, the RO discusses with the SA revisions needed on the Form CMS 2567 and, after the revisions are made, follows the procedures for substantial noncompliance.

   The RO either issues a notice, or authorizes the SA to issue a notice to the provider or supplier of its compliance status and that its deemed status is restored, along with a copy of the Form CMS 2567 with the survey findings.

   The RO sends a copy of the notice and Form CMS 2567 to the applicable AO(s). At the RO's discretion, the materials may be sent to the AO via e-mail.

   ii. First Revisit Survey Findings: Substantial Noncompliance

   If the SA confirms during the first revisit survey that the provider/supplier is not in substantial compliance with one or more Medicare conditions, the SA consults with the RO on its findings and whether to conduct a second revisit. If the RO concurs that condition-level deficiencies remain, the RO considers whether the survey findings warrant a second revisit or proceeding immediately to termination. At this point the provider/supplier will have been surveyed three times, including the complaint survey, the full survey and the first revisit, with substantial noncompliance found on each survey. Generally the RO authorizes a second revisit, but the RO has discretion to make an exception, based on the facts of the case, including the risks to patients associated with the remaining deficiencies versus providing the provider/supplier further opportunity to correct its problems in a timely manner.

   If the RO does not authorize a second revisit, the RO and SA will follow the procedures outlined in paragraph 2(ii). below.

If the RO authorizes a second revisit, the SA sends the provider/supplier the Form CMS 2567 for the first revisit with notice that substantial noncompliance remains, the 90-day termination date remains in effect, a new acceptable plan of correction is required, and that an additional revisit will be conducted prior to the termination date.

2. ***Second Revisit:*** *The SA conducts the second revisit survey no later than 60 calendar days after the date of the termination notice to the provider or supplier.*

(i) Second Revisit Survey Findings: Substantial Compliance

If substantial compliance is achieved by the provider/supplier (i.e., no condition-level deficiencies are identified through the on-site verification by the SA) during the second revisit survey, the SA certifies its findings to the RO within 10 working days after the survey completion date, and recommends that the termination action be rescinded.

The RO randomly selects some Form CMS 2567s with standard-level deficiencies for review, to determine if the RO concurs with the SA's finding of substantial compliance. If the RO concurs, and in all other cases where the Form CMS 2567 is not reviewed by the RO, the RO completes the processing in ASPEN of the survey kit and then, depending on RO practice, either the SA or RO uploads the complaint and revisit surveys into CASPER, the CMS National Reporting System. If the RO does not concur, the RO discusses with the SA revisions needed on the Form CMS 2567 and, after the revisions are made, follows the procedures for substantial noncompliance.

The RO also either issues a notice, or authorizes the SA in ACTS to issue the provider or supplier a notice, of its compliance status and that its deemed status is restored, along with a copy of the Form CMS 2567 with the survey findings.

Additionally, the RO sends a copy of the notice and the Form CMS 2567 to the applicable AO(s). At the RO's discretion, the materials may be sent to the AO via e-mail.

(ii) Second Revisit Survey Findings: Substantial Noncompliance

If the second revisit shows that the provider or supplier has substantial noncompliance (i.e., condition-level deficiencies are identified through on-site verification by the SA), the SA certifies to the RO its findings within 10 calendar days after the survey completion date, and recommends that the termination action proceed.

The RO reviews the SA's findings, and if it concurs with the SA's recommendation, the RO sends the provider/supplier a final termination letter and publishes a public notice 15 calendar days prior to the termination date. The provider or supplier is terminated from the Medicare program. The RO notifies the applicable Medicare Administrative Contractor (MAC) via the Form CMS 2007 of the termination of the provider/supplier's Medicare agreement, including the effective date of the termination.

The RO completes the processing in ASPEN of the survey kit and then, depending on RO practice, either the SA or RO uploads the survey package into CASPER. The provider's or supplier's Medicare agreement is terminated in ASPEN.

The RO sends a copy of the final termination notice and Form CMS 2567 to the applicable AO(s). At the RO's discretion, the materials may be sent to the AO via e-mail.

5130 – *Deemed* Provider/ Supplier Refusal of Complaint Investigation Surveys

(Rev.88, Issued: 08-27, 13, Effective: 07-19-13, Implementation: 7-19-13)

The SA informs the provider/supplier that refusal to allow a complaint investigation survey is a basis for *termination and exclusion* from the Medicare program, in accordance with Section 1128(b)(12) of the Social Security Act. The SA notifies the RO immediately *of a refusal to allow a complaint investigation survey*.

5140 - Complaints Involving HIV-Infected Individuals

(Rev.88, Issued: 08-27, 13, Effective: 07-19-13, Implementation: 7-19-13)

As direct recipients of Federal funds, providers and suppliers are subject to provisions of Section 504 of the Federal Rehabilitation Act of 1973. Symptomatic and asymptomatic individuals who are infected with the human immunodeficiency virus (HIV), or "AIDS virus," are protected by the Rehabilitation Act as "individuals with handicaps." Therefore, HIV-infected individuals who are provided services, are employed, or are to be employed by providers and suppliers in Federally-conducted or financed programs or activities would be treated like anyone else in the workforce, so long as these individuals do not, on a case-by-case basis, pose a substantial health and safety risk to others, or pose a performance problem, and are "otherwise qualified."

A provider participating in the Medicare or Medicaid programs cannot discriminate against individuals who are HIV-infected so long as these individuals do not, on a case-by-case basis, pose a substantial health and safety risk to others and so long as the provider provides comparable services and care to non HIV-infected individuals.

The SA or the RO refers discrimination complaints to the Office of Civil Rights (OCR), which is the authority to determine whether Medicare or Medicaid providers and suppliers comply with this non-discrimination statute.

5150 - Investigating Complaints Involving ESRD Services Provided by Deemed Hospitals *or CAHs*

(Rev.88, Issued: 08-27, 13, Effective: 07-19-13, Implementation: 7-19-13)

Many of the hospitals *or CAHs* participating in the ESRD program are deemed *to meet the Medicare Conditions of Participation on the basis of their accreditation* by *a CMS-approved Medicare accreditation program*. "Deemed status" applies only to the hospital's *or CAH's* approval as a provider, not to its status as a supplier of ESRD transplantation or dialysis services. The SA investigates all complaints and allegations related solely to ESRD services since ESRD services fall outside the purview of accreditation.

5160 – Investigating Complaints Against ESRD Suppliers

(Rev.88, Issued: 08-27, 13, Effective: 07-19-13, Implementation: 7-19-13)

1. General

Refer to the guidance for investigation of complaints against non-deemed providers and suppliers. See SOM §5200.

The ESRD Networks are required to have a complaint /grievance resolution system. Networks (NW) and the SA are frequently contacted by the same complainant with the same or similar allegations. If the allegations require an onsite investigation or allege potential risk to patient health or safety, the SA is responsible for the investigation. If the allegations are primarily focused on relationship or communication issues, the NW may assume primary responsibility for the investigation. If the focus of the allegations is a medical practice issue, the SA and NW may need to collaborate on the investigation. The NWs and SA are encouraged to communicate and collaborate to reduce or prevent redundant investigations.

2. Conducting the *ESRD* Investigation

The SA surveyors must use the ESRD survey protocol in Appendix H to investigate complaints. The allegations of the complaint will determine the tasks needed. For example, an allegation of inadequate patient care staffing would require use of the following tasks, at a minimum:

- Pre survey activities;
- Entrance Conference: Provide an overview of the complaint allegations and the planned agenda for your survey time;
- Tour and observations;
- Patient interviews;
- Staff interviews;
- Record reviews;
- Review of quality management materials; and
- Exit conference.

Conduct each of the identified survey tasks in Appendix H, "Guidance to Surveyors: End-Stage Renal Disease Facilities."

3. Pre-survey Task for *ESRD* Complaint Investigations

Review the allegations of the complaint to identify needed survey tasks. Review the State Outcomes List and the Dialysis Facility Report to determine if there are data outliers related to the allegations. For example, if the complaint alleges staff members do not wash their hands, the surveyor should review the facility's rate of hospitalization and hospitalizations related to septicemia, and consider this information in the survey process.

To facilitate meeting the requirement of surveying each ESRD facility every 3 years, the SA evaluates all available information (outcome list rank, Dialysis Facility Report, time since last survey,

complaint history, NW information, etc.) to determine whether a recertification survey should be conducted at the time of the complaint investigation.

5170 - Hospital Restraints/Seclusion Death Reporting and Investigation

(Rev.88, Issued: 08-27, 13, Effective: 07-19-13, Implementation: 7-19-13)

This section applies to both deemed and non-deemed hospitals, as well as to deemed and non-deemed CAH distinct part psychiatric and rehabilitation units.

5170.1 - Background

(Rev.88, Issued: 08-27, 13, Effective: 07-19-13, Implementation: 7-19-13)

The Medicare hospital restraint and seclusion requirements are found under the Patients' Rights provisions at 42 CFR 482.13(e),(f) and (g).

Hospitals are required to report a death associated with the use of restraint/seclusion to their CMS RO in accordance with 42 CFR 482.13(g)(1).

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.

5170.2 - Responsibilities

(Rev.88, Issued: 08-27, 13, Effective: 07-19-13, Implementation: 7-19-13)

Regional Offices (ROs)

The RO receives Hospital Restraint/Seclusion Death Reports which hospitals are required to submit in accordance with 42 CFR 482.13(g)(1). The RO is responsible for communicating with hospitals in its region whether the required reports are to be submitted electronically by facsimile and/or e-mail, providing appropriate addresses or fax numbers, or whether it will also accept mail submissions.

The RO is also responsible for data entry of reports received into the Automated Survey Processing Environment (ASPEN) Complaint Tracking System (ACTS) Hospital Restraint/Seclusion Death Module and for maintenance in ACTS of information 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 hospital point of contact regarding reporting, and who is responsible for coordinating the review of reports received, and authorization of complaint surveys when appropriate.

State Agencies (SAs)

Hospitals report patient deaths associated with restraint or seclusion 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 investigation must be completed no later than five working days after RO authorization.

SAs 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)(1). Upon request, SAs are to provide hospitals with the applicable RO contact information, 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 standard CMS policy on disclosure of Federal survey information.

5170.3 - Process

(Rev.88, Issued: 08-27, 13, Effective: 07-19-13, Implementation: 7-19-13)

The RO evaluates the information required to be reported by the hospital under 42 CFR 482.13(g)(1) to determine whether the situation 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.

Using the information provided by the hospital in the worksheet, the RO evaluates whether the case warrants 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 requirement at 42 CFR 482.13(e), (f), and (g), including the reported case. The SA accesses the ACTS restraint/seclusion module to see the information reported by the hospital prior to conducting the on-site investigation. The SA is expected to complete the investigation within 5 working days of receipt of survey authorization from the RO.

Notice to Protection and Advocacy Organizations

At the same time that the RO notifies the SA that it authorizes the on-site survey, consistent with the ACTS Notice of a Modified or Altered System of Records (SOR) (71 FR 29643, May 23, 2006, SOR 09-70-0565), the RO also provides written notification, by mail or email, to the appropriate Protection and Advocacy Organization (P&A) within the State where the hospital is located, if the P&A has a Data Use Agreement(DUA) with CMS. The RO may contact CMS Central Office for a list of P&A's with current DUAs. The names and addresses for each State's P&A can be located at the following website, at the drop down menu entitled "Get Help in Your State:" www.ndrn.org . ***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, name of the deceased, and a copy of the restraint/seclusion death report submitted by the hospital. ***An entry must be made on the intake in ACTS indicating the name of the P&A to which the restraint/seclusion death report data was sent and the date it was sent.***

The P&A must have an approved CMS Data Use Agreement (DUA), Form CMS-R-0235, (Exhibit 292) in place before restraint/seclusion death report data may be disclosed to it. 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 Information Security and Privacy Management (DISPM), Centers for Medicare and Medicaid Services, Mailstop N2-04-27, 7500 Security Boulevard, Baltimore, MD 21244-1850. DISPM will review the DUA, assign a unique DUA identifier and expiration date to it, and return a signed copy to the P&A, including an expiration date. CMS Central Office Survey and Certification will maintain and make available to ROs a list of P&As with DUAs.

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).*

When approved, the DUA will have an expiration date. DISPM will alert an organization with a DUA of its upcoming expiration date and will give the organization the option of requesting a one-year DUA extension via e-mail, or to close the DUA with a DUA destruction certificate. DISPM has set up a DUA resource email box which accepts all expired DUA resolution requests at DataUseAgreement@cms.hhs.gov.

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 CMS/DISPM: 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/DISMP 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 CMS/DISPM a letter to this effect. CMS/DISPM 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 DUA process described in this section applies to disclosure of hospital restraint/seclusion death reports by CMS to P&As in those cases where the P&A did not first make a request specific to an identified patient; a DUA is not required for other disclosures of information in ACTS to a P&A when permitted in accordance with the ACTS System of Records Notice.

- *A P&A may request information about an on-site survey by submitting its request to the SA. The SA will process this request and release information to the P&A in accordance with standard CMS policy for disclosure of Form CMS 2567, Statement of Deficiencies and Plan of Correction.*

- *If the P&A identifies a particular patient, hospital, and approximate date or dates when the patient was in that hospital, and if the P&A makes a request for additional information, beyond the Form CMS 2567, related to use of restraint or seclusion on that patient, the request is forwarded to the RO. The RO may, in accordance with the ACTS System of Records Notice, release additional information to the P&A.*

Exhibit 294

(Rev.88, Issued: 08-27, 13, Effective: 07-19-13, Implementation: 7-19-13)

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 CMS 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. 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 *Director, Division of Privacy Compliance, Centers for Medicare and Medicaid Services, Mailstop N2-04-27, 7500 Security Boulevard, Baltimore, MD 21244-1850.*

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

_____