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State of California—Health and Human Services Agency
California Department of Public Health



EDMUND G. BROWN JR.
Governor

AFL REVISION NOTICE

Subject: Centers for Medicare and Medicaid (CMS) Restraint/Seclusion Death Reporting Requirements

Revision To: AFL 12-34

Revision Date: December 7, 2012

Attachment: AFL 12-49

This notice is to inform you that the California Department of Public Health has revised All Facilities Letter (AFL) 12-34. The attached AFL 12-49 supersedes AFL 12-34 and is issued to reflect its applicability to Acute Psychiatric Hospitals as well as General Acute Care Hospitals and Critical Access Hospitals with Acute Psychiatric or Rehabilitative Distinct Parts. It also includes new contact information for questions.

There have been no additional changes to the requirements related to CMS's hospital reporting procedures for patient deaths associated with the use of restraints or seclusion, since those that took effect July 16, 2012, which were described in AFL 12-34 and are repeated in the attached AFL 12-49.

Please review the AFL and contact CMS Region IX at (415) 744-3735, if you have further questions.



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December 7, 2012

AFL 12-49
(Supersedes AFL 12-34)

TO: General Acute Care Hospitals
Acute Psychiatric Hospitals
Critical Access Hospitals with Psychiatric or Rehabilitative Distinct Part Units

SUBJECT: Reissue of AFL 12-34 Addressing Changes to Centers for Medicare and Medicaid (CMS) Restraint/Seclusion Death Reporting Requirements

AUTHORITY: 42 Code of Federal Regulations (CFR) 482.13(e)-(g)

This letter is to alert facilities to changes that took effect July 16, 2012 to hospital reporting procedures for patient deaths associated with the use of restraints or seclusion.

All hospitals must continue to report to CMS no later than by close of the next business day the discovery of:

- 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 1 week after restraint or seclusion where it is reasonable to assume that use of the 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.

The requirement has changed, however, for deaths that occur when:

- No seclusion has been used, and
- The only restraints used on the patient were applied to the patient's wrist(s) and composed solely of soft, non-rigid, cloth-like materials.

In such a case, hospital staff must record the death in an internal log or other system only, and do not need to report the death to CMS.

For all restraint related deaths, regardless of whether only soft wrist cuffs were involved, hospital staff must document in the patient's medical record not only the date and time of death, but also when the death was reported to CMS and/or recorded in the hospital's internal log or system.

If only soft wrist cuff restraints were involved, the hospital must document the death not later than seven days after the death. The internal log or other system the hospital uses for this purpose must be available in either written or electronic form to CMS immediately upon request. Each entry must include the patient's:

- Name
- Date of birth
- Date of death
- Attending physician's name, or other licensed independent practitioner who was responsible for the care of the patient
- Medical record number
- Primary diagnosis(es)

All other reportable restraint or seclusion related deaths should be faxed or mailed to CMS in writing using the *Hospital Restraint/Seclusion Death Report Worksheet* (attached). Please enter in all required fields of the worksheet. These fields are marked with an "*". If there are missing fields, you will be asked to re-submit the worksheet.

The CMS Regional Office also accepts reports by phone. There is no need to alert CMS by phone if the worksheet has already been faxed to the CMS Regional Office. Once a facility has faxed the report, the reporting process is complete. If a facility does not have fax access or prefers to deliver the report solely by phone, it must provide all of the information requested on the reporting worksheet in a voicemail. Please refer to CMS' *Hospital Restraint/Seclusion Death Reporting, Effective Date: June 16, 2012* (attached) for more information.

Facilities are responsible for following all applicable laws. Facilities should refer to the full text of 42 CFR 482.13 to ensure compliance. The most recent changes were published May 16, 2012. CDPH's failure to expressly notify facilities of legislative or regulatory changes does not relieve them of responsibility to be in compliance.

For additional questions related to these requirements, please contact the CMS Regional Office at 415-744-3735.

Sincerely,

Original signed by Debby Rogers

Debby Rogers, RN, MS, FAEN
Deputy Director
Center for Health Care Quality

Attachments

HOSPITAL RESTRAINT/SECLUSION DEATH REPORT WORKSHEET
(Revised 7/12)

A. Regional Office (RO) Contact Information:

RO Contact's Name: Rosanna Dominguez Fax Number: 443-380-8909

*Date of Report to RO: _____ Time: _____

B. Provider Information:

*Hospital Name: _____ *CCN: _____

Address: _____ City: _____ State: _____ Zip Code: _____

*Person Filing the Report: _____ *Filer's Phone Number: _____

C. Patient Information:

*Name: _____ *Date of Birth: _____

*Admitting Diagnoses: _____ *Date of Admission: _____

*Date of Death: _____ *Time of Death: _____

*Cause of Death: _____

*Did the Patient Die: (*check one only*)

_____ While in Restraint, Seclusion, or Both

_____ Within 24 Hours of Removal of Restraint, Seclusion, or Both

_____ Within 1 Week, Where Restraint, Seclusion or Both Contributed to the Patient's Death

*Type: Physical Restraint _____ Seclusion _____ Drug Used as a Restraint _____

***Was a Two Point Soft Wrist Restraint used alone, without seclusion or chemical restraint or any other type of physical restraint? Yes _____ No _____**

If YES, check "02" below and stop. No further information is required.

If NO, complete the rest of the worksheet.

*If Physical Restraint(s), Type:

_____ 01 Side Rails

_____ 02 Two Point, Soft Wrist

_____ 03 Two Point, Hard Wrist

_____ 04 Four Point, Soft Restraints

_____ 05 Four Point, Hard Restraints

_____ 06 Forced Medication Holds

_____ 07 Therapeutic Holds

_____ 08 Take-downs

_____ 09 Other Physical Holds

_____ 10 Enclosed Beds

_____ 11 Vest Restraints

_____ 12 Elbow Immobilizers

_____ 13 Law Enforcement Restraints

_____ 14 Other Physical Holds

If Drug Used as Restraint: *Drug Name _____ Dosage _____

D. Hospital-Reported Restraint/Seclusion Information:

*1. Reason(s) for Restraint/Seclusion use: (mandatory only if answer to D.4. is "Yes") _____

2. Circumstances Surrounding the Death: _____

3. Restraint/Seclusion Order Details:

a. Date & Time Restraint/Seclusion Applied: _____

b. Date & Time Last Monitored: _____

*c. Total Length of Time in Restraint/Seclusion: _____

*4. Was restraint/seclusion used to manage violent or self-destructive behavior? Yes___ No___

*a. If YES, was 1 hour face-to-face evaluation documented? Yes___ No___

If NO, skip to Section E.

*b. Date/Time of Last Face-to-face Evaluation: _____

*c. Was the order renewed at appropriate intervals based on patient's age? Yes___ No___

Note: Orders may be renewed at the following intervals for up to 24 hours:

<i>> 18 years of age</i>	<i>every 4 hours</i>
<i>9 – 17 years of age</i>	<i>every 2 hours</i>
<i>< 9 years of age</i>	<i>every hour</i>

*5. If simultaneous restraint and seclusion ordered, describe continuous monitoring method(s):

E. RO Action (CMS Only):

1. *Was a survey authorized? Yes___ No___

If YES, date SA received authorization for investigation: _____

If NO, provide brief rationale: _____

2. *If answer to E1 is yes, date RO contacted P & A: _____

(Do not contact the P&A unless a survey was authorized)

3. In the past two years, has a survey related to a restraint/seclusion death at this hospital resulted in finding condition-level patients' rights deficiencies? Yes___ No___

****Mandatory field***

Hospital Restraint/Seclusion Death Reporting

Effective date: July 16, 2012

These changes to the current reporting process are an integral part of CMS' efforts to reduce procedural burdens on providers.

What Deaths need to be Reported:

1. A death involving ONLY a soft two-point soft wrist restraint and NO seclusion

- Hospitals are required to record the information of the death into an internal log or other system
- Each entry must be made no later than seven days after the date of death of the patient
- The record must include the patient's name, date of birth, attending physician, primary diagnosis(es), and medical record number



Hospitals must make this information available to CMS in either written or electronic form immediately upon request.

2. A death involving ALL other types of restraints and ALL forms of seclusion

- Hospitals are required to continue regular reporting procedures
- Hospitals must contact CMS by telephone no later than the close of business on the next business day following knowledge of the patient's death
- The hospital staff MUST document in the patient's medical record the date and time the death was reported to CMS
- It is recommended that these reports be included in the hospital's log

Points of contact for CMS Region 9

Rosanna Dominguez / data tracking and reporting
Alex Garza / content and completeness
Linda Brim / content and completeness

NOTE: Failure to comply with the regulation could prompt a survey covering Conditions of Participation for Patient Rights

Procedure for Reporting:

A hospital designee will need to either fax the worksheet, mail the report to the CMS Regional Office or call and report the information to Rosanna Dominguez at (415-744-3735).

Regional Office fax number: 443-380-8909

If mailed, our address is:

Division of Survey and Certification
Centers for Medicare and Medicaid Services
90 7th Street, Suite 5-300 (5W)
San Francisco, CA 94103



E-mail is NOT acceptable

Frequently Asked Questions

Does CMS need to be alerted by phone if the worksheet has already been faxed to the RO?

No. The Regional Office can accept reports two ways, by fax or solely over the phone. If a facility faxes the report, this will complete the reporting process.

Can a facility create their own worksheet instead of using the CMS worksheet?

Yes. It is recommended to use the CMS worksheet however, as long as a facility has captured all of the same information that is required within the CMS worksheet, it will be accepted.



What are the most common reasons for CMS having to place a follow up call to the facility?

Missing Information

Poor Handwriting (CMS recommends electronic entry)

Unacceptable Explanations (i.e. TBA, unknown, blank responses)

Missing Pages of Report