

Supporting Statement
Report of a Hospital Death Associated with Restraint and/or Seclusion
(Form CMS-10455)

A. Background

We are submitting this PRA package seeking extension of the OMB approval for an electronically submitted version of the CMS-10455 form.

When a death occurs in a hospital (including Critical Access Hospital (CAH) with a rehabilitation or psychiatric Distinct Part Unit (DPU)) that is associated with the use of restraints and/or seclusion, the hospital staff must complete the online Form CMS-10455 (42 CFR §482.13(g)(1). The hospital staff must also document the date and time that CMS was notified of the death in the patient’s medical record (42 CFR §482.13(g)(3)(i).

When a death occurs during the use of 2-point soft cloth wrist restraints with no seclusion, or within 24 hours after the patient was removed from such restraints, the hospital must document the information required by 42 CFR §482.13(g)(4)(ii) into a hospital log or internal system within 7 days from the date of death (42 CFR §482.13(g)(4)(i). The hospital is not required to submit this log or internal records to the CMS Location, however, they must be made available in either written or electronic form to CMS immediately upon request (42 CFR §482.13(g)(4)(iii). In addition, the hospital staff must also document the date and time that the required information was entered into the hospital’s log or internal system in the patient’s medical record (42 CFR §482.13(g)(3)(ii).

B. Justification

1. Need and Legal Basis

Provisions implementing this statutory reporting requirement for hospitals participating in Medicare are found at 42 CFR §482.13(g), as revised in the final rule that published on May 16, 2012 (77 FR 29034). This regulation also applies to Critical Access Hospitals (CAHs) with distinct part units (DPUs); since CAH DPUs are subject to the Hospital Conditions of Participation.

42 CFR §482.13(g) requires that hospitals and CAHs with DPUs report deaths associated with the use of restraint and/or seclusion directly to the CMS locations. This regulation requires that information about patient deaths associated with the use of restraint and/or seclusion must be reported to the CMS Locations using the online CMS-10455 form titled “*Report Of A Hospital Death Associated With The Use Of Restraint Or Seclusion.*”

42 CFR §482.13(g) categorizes deaths associated with restraint and/or seclusion into the following three scenarios:

- (1) Death that occurs while a patient is in restraint or seclusion (excluding those in which only 2-point soft wrist restraints were used and the patient was not in seclusion at the time of death);

- (2) Death that occurs within 24 hours after the patient has been removed from restraint or

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seclusion (excluding those in which only 2-point soft wrist restraints were used and the patient was not in seclusion within 24 hours of their death); and

- (3) Death known to the hospital or CAH with DPU that occurs within one week after restraint or seclusion where it is **reasonable to assume** that use of restraint or placement in seclusion contributed directly or indirectly to a patient's death, regardless of type(s) of restraint used on the patient during this time.

Section 482.13(g)(2)(iii) defines the term "**reasonable to assume**" in this context as including, but is not limited to, death related to restrictions of movement for prolonged periods of time, or death related to chest compression, restriction of breathing, or asphyxiation.

§482.13(g)(2) requires that when no seclusion has been used and when only 2-point soft wrist restraints used on the patient were applied exclusively to the patient's wrist(s), which are composed solely of soft, non-rigid, cloth-like materials, the staff of hospitals or CAHs with DPU are not required to submit this information directly to the CMS RO. The following circumstances listed below are required to be recorded in an internal log or other system:

- i. Any death that occurs while a patient is in a restraint but not seclusion and the only restraints used on the patient were applied exclusively to the patient's wrist(s) and were composed solely of soft, non-rigid, cloth-like materials; and
- ii. Any death that occurs within 24 hours after a patient has been removed from restraint, when no seclusion has been used and the only restraints used on the patient were applied exclusively to the patient's wrist(s) and were composed solely of soft, non-rigid, cloth-like materials.

Section 482.13(g)(3) further requires that the hospital or CAH with DPU document any death that occurs while a patient is in 2-point soft wrist restraints without seclusion in an internal hospital log or other internal system for reporting deaths. §482.13(g)(4) requires that the entry in the hospital record or internal log must be made by no later than seven days after the date of death of the patient. The record kept by the hospital must include the patient's name, date of birth, date of death, attending physician, primary diagnosis, and medical record number. The hospitals must make this information available to CMS in either written or electronic form immediately upon request.

In addition, §482.13(g)(3) requires that the hospital or CAH with DPU staff document the date and time the death was reported to CMS in the patient's medical record for any patient whose death is associated with the use of restraint and/or seclusion.

Sections 1861(e) (1) through (8) of the Social Security Act define the term "hospital" and its requirements to be eligible for Medicare Participation. Additionally, §1861(e)(9) of the Act specifies that a hospital must also meet such requirements that the Secretary finds necessary in the interest of the health and safety of the hospital's patients. Under this authority, the Secretary has established in regulations at 42 CFR Part 482 the requirements that a hospital must meet to participate in the Medicare program.

Section 1905(a) of the Act provides that Medicaid payments may be applied to hospital services. Under regulations at 42 CFR §440.10(a)(3)(iii), 42 CFR §440.20(a)(3)(ii), and 42 CFR

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§440.140, hospitals are required to meet the Medicare Conditions of Participation in order to participate in Medicaid.

The Child Health Act (CHA) of 2000 established in Title V, Part H, Section 591 of the Public Health Service Act (PHSA) minimum requirements concerning the use of restraint and seclusion in facilities that receive support with funds appropriated to any Federal department or agency. In addition, the CHA enacted Section 592 of the PHSA, which establishes minimum mandatory reporting requirements for deaths in such facilities associated with use of restraint or seclusion.

2. Information Users

The intent of this information collection regarding patient deaths associated with the use of restraint/seclusion is to allow CMS to identify those deaths that warrant on-site investigation to determine the hospital's compliance with the Medicare Condition of Participation for patient's rights. The data also supports analysis of trends in restraint/seclusion-associated deaths, which might identify possible areas for improvement by hospitals and CAHs with DPUs in general.

CMS performs an on-site investigation if we find that a hospital's or a CAH's with DPUs rate of deaths associated with use of seclusion and/or restraints is excessive. We define the term "excessive" as more than one death associated with the use of restraints or seclusion per year.

We believe that if a hospital or CAH with DPUs are properly meeting the Conditions of Participation for patient's rights, they would be constantly monitoring patients when they are put in restraints and/or seclusion. Constant monitoring of patients in restraints and/or seclusion allows hospital staff to intervene if problems arises, especially ones that are potentially life threatening to the patient. If a hospital or CAH with DPUs have more than one restraint/seclusion related death per year it would indicate that the hospital may not be meeting the Conditions of Participation for patient's rights and therefore an investigation is warranted.

3. Improved Information Technology

Since December 2, 2019, the CMS-10455 form has been electronically submitted by hospitals and CAHs with DPUs to the applicable CMS Location electronically. To submit a CMS-10455 form, a hospitals or CAH with DPU inserts the following URL into any web browser and clicks to access the electronic Form CMS-10455:

https://restraintdeathreport.gov1.qualtrics.com/jfe/form/SV_5pXmjIw2WAzto8J. The hospital or CAH DPU must complete sections A-D of the electronic form CMS-10455 to report a death associated with the use of restraints and/or seclusion.¹

¹ See QSO Memo 20-04-Hospital-CAU DPU, revised January 17, 2020 at <https://www.cms.gov/files/document/qso-20-04-hospital-cah-dpu-revised.pdf>.

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Electronic reporting of this data assures that all of the information required by 42 CFR §482.13(g) is being collected. It also reduces burden for the CMS Locations staff because the electronically reported data goes directly into the CMS system. Prior to the implementation of the electronic form CMS-10455, the CMS Locations staff had to manually enter the data from each CMS-10455 form received.

4. Duplication of Similar Information

The information proposed for collection via the online CMS-10455 form is the minimum necessary to assist CMS in determining whether the case warrants on-site investigation, i.e., hospital name, address, CMS Certification Number; name and business number of the person filing the report; patient's name, date of birth, date of death, primary diagnosis, cause of death, medical record number; and information about the restraint or seclusion used.

When there has been a death associated with all other uses of restraints or seclusion, the hospital or CAH with DPUs staff must complete the online CMS-10455 form and submit it electronically to the applicable CMS Location. However, when there has been a death but only 2 point soft cloth wrist restraints were used with no seclusion, the hospital or CAH with DPUs are only required to document the information required by §482.13(g)(4) in an internal hospital log or record. Hospitals or CAHs with DPUs only have to submit this information to CMS upon request. These external and internal reporting requirements are mutually exclusive and therefore not duplicative. The data collected using the CMS-10455 form as required by 42 CFR §482.13(g)(3) and (g)(4) does not duplicate any external information collection.

5. Small Business

These requirements do affect small businesses; however, the information collected is a requirement for all hospital or CAH with DPUs to participate in the Medicare program. This reporting requirement was reduced with the introduction of the online electronic CMS-10455 submission process.

6. Less Frequent Collection

This information is required to be reported within 24 hours of the hospital's or CAH's with DPUs knowledge of a reportable patient death. The estimated number of reports will vary based on the size of the hospital or CAH with DPUs, the types of services it offers, and the characteristics of its patient population.

7. Special Circumstances for Information Collection

There are no special circumstances associated with this collection.

8. Federal Register and Outside Consultation

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The 60-day Federal Register notice published on June 13, 2022 (87 FR 35784). No public comments were received.

The 30-day Federal Register notice published on August 24, 2022 (87 FR 51985).

9. Payments or Gifts

There are no payments or gifts associated with this collection.

10. Confidentiality

There is no sensitive or confidential information collected on the CMS-10455 form. Personally, identifiable information may be collected about the deceased person and recorded in an internal hospital log or system as required by §482.13(g)(2). However, this information will be maintained by the hospital who will be responsible for maintaining confidentiality for this information. CMS would not have access to this information unless they request it, however, it is anticipated that CMS if CMS requests access to this information, it would be to view the information only to ensure that the hospital is actually collecting and documenting correctly and that CMS would not take possession of any sensitive or personally identifiable information.

The Privacy Act System of Records used will be the Automated Survey Processing Environment (ASPEN) Complaints/Incidents Tracking System (ACTS), System No. 09-70-1519 as described in Federal Register, Volume 71, Page Number 29644 (published 5/23/2006).

11. Sensitive Questions

There are no questions of a sensitive nature associated with this form. See section #10 above.

12. Estimate of Burden

There are currently 6,579 hospitals and CAHs with DPUs in the U.S. that are enrolled in Medicare program. These hospitals and CAHs are required to report deaths associated with restraints and seclusion.

As the table below shows, in 2020, the CMS Locations (formerly known as “CMS Regional Offices”) received 3,137 electronic CMS-10455 forms. Statistically, this equates to approximately **48%** of the 6,579 hospitals and CAHs having submitted a CMS-10455 form in 2020.

- 3,137 divided by 6,579 = 0.4768

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CMS Location	Number of CMS-10455 forms received in 2020
1	194
2	89
3	332
4	797
5	877
6	206
7	26
8	168
9	383
10	65
TOTAL	3,137

A. Burden for Completion of the CMS-10455 form

We estimate that it would take a hospital or CAH staff person approximately 15 minutes to complete *each* electronic CMS-10455 form. We further estimate that the total annual time burden for the completion and submission of *all* CMS-10455 forms across the 48% of hospitals of CAHs that submit them annually would be **784 hours**.

- 15 minutes x 3,137 CMS-10455 forms per year = 47,055 minutes
- 47,055 minutes divided by 60 minutes per hour = 784.25 hours

We believe that the person at the hospital or CAH who would complete the CMS-10455 form would have a job that falls under the U.S. Bureau of Labor Statistics job category of Medical and Health Services Manager. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a Medical and Health Services Manager is \$57.61.² This wage, adjusted for the employer’s overhead and fringe benefits, would **\$115.22 per hour**.

We estimate that the cost burden for the completion of *each* CMS-10455 form by a hospital or CAH would be **\$28.80**.

- \$115.22 per hour divided by 60 min. per hr.= \$1.92 per minute
- \$1.92 per minute x 15 = \$28.80

² <https://www.bls.gov/oes/current/oes119111.htm>

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We further estimate that the total annual cost burden for completion of *all* CMS-10455 forms *across* the 40% of hospitals and CAHs that would be submitting them annually would be **\$90,332.48**

- 784 hours x \$115.22 per hour = \$90,332.48

B. Burden Related to Documenting Deaths Associated with the Use of Soft Cloth Wrist Restraints in the Hospital's Internal Log or Other System for Recording Deaths.

Section 482.13(g)(2) requires that when no seclusion has been used and when the only restraints used on the patient are those applied exclusively to the patient's wrist(s), and which are composed solely of soft, non-rigid, cloth-like materials, the hospital staff must record the following information in an internal log or other system:

- (i) Any death that occurs while a patient is in such restraints.
- (ii) Any death that occurs within 24 hours after a patient has been removed from such restraints.

There are currently 6,579 hospitals and CAHs in the U.S. We estimate that approximately 10% of these hospitals would have patient deaths associated with the use of soft cloth wrist restraints annually. We say this because we believe that the risk of death from use of soft cloth wrist restraints is much lower than the risk from use of hard leather restraints on all 4 limbs, lap and shoulder restraints or other types of restraints. This would equate to **658 deaths** associated with the use of soft wrist restraints annually.

- 6,579 hospitals % 100 = 65.79 = 1%
- 65.79 x 10 = 658 = 10%

We estimate that it would take **10 minutes** for the hospital staff to document the required information in the hospital's internal log or other system for *each* death associated with the use of soft cloth wrist restraints. We further estimate that the total annual time burden across all hospitals and CAHs that have deaths associated with the use of soft cloth wrist restraints would be **110 hours**:

- 10 minutes x 658 patient deaths per year = 6,580 minutes
- 6,580 minutes divided by 60 minutes per hour = 109.66 hours

We believe that the person at the hospital or CAH who would document deaths associated with the use of soft cloth wrist restraints in the internal hospital log or other internal hospital system would have a job that falls under the U.S. Bureau of Labor Statistics job category of Medical and Health Services Manager. As stated above, the adjusted hourly wage for this job is \$115.22 per hour.

We estimate that the cost burden for documentation of *each* patient death associated with the use of soft cloth wrist restraints would be **\$19.20**.

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- \$115.22 per hour divided by 60 minutes - \$1.92 per minute
- \$1.92 per minute x 10 min. = \$19.20

We further estimate that the total annual cost burden for documentation of *all* patient deaths associated with the use of soft cloth wrist restraints per year would be **\$12,674.20**.

- 110 hours x \$115.22 per hour = \$12,674.20

C. Burden Related to Entering Information Related to Deaths Associated with Use of Restraints and/or Seclusion or Deaths Related to the Use of Soft Cloth Wrist Restraints in the Patient's Medical Record.

42 CFR §482.13(g)(3) requires the hospital to document in the patient's medical record the following: (1) the date and time the death was reported to CMS if restraints and/or seclusion were used (§482.13(g)(1)), or (2) the date and time the documentation was made in the internal log or other hospital system for deaths associated with the use of soft cloth wrist restraints (§482.13(g)(2)).

In section 12(A) above, we estimate that there are approximately 3,137 deaths associated with the use of restraints and or seclusion per year. In section 12(B) above, we estimated that there are approximately 658 deaths associated with the use of soft cloth wrist restraints per year. This would equate to a total of **3,795** patient deaths annually in which an entry in the medical record would be required.

3,137 patient deaths associated with the use of restraints and/or seclusion
658 patient deaths associated with the use of soft cloth wrist restraints
**3,795 Total patient deaths requiring documentation be placed in the
patient's medical record**

We estimate that it would take approximately **5 minutes** for the hospital staff to document the required information about the patient's death in a patient's medical record or in the internal log or other system for deaths.

We further estimate that the total annual time burden across all hospital and CAHs for adding the required information into *all* 3,795 deceased patient's medical records would be **316 hours**.

- 3,795 deceased patients x 5 minutes = 18,975 minutes
- 18,975 minutes divided by 60 minutes per hour = 316.25 hours

We believe that the person at the hospital who would enter this information into the patient's medical record would be a Registered Nurse. According to the U.S. Bureau of Labor

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Statistics, the mean hourly wage for a Registered Nurse is \$39.78.³ This wage, adjusted to account for the employer’s overhead and fringe benefits, would be **\$79.56**.

We estimate that the cost burden to the hospital or CAH for documenting the required information in *each* deceased patient’s medical record would be **\$6.63**.

- \$79.56 divided by 60 minutes = \$1.326 per minute
- \$1.326 per minute x 5 min. = \$6.63

We further estimate that the total annual cost burden across all hospitals and CAHs for documenting the required information in all deceased patient’s medical records would be **\$25,140.96**.

- 316 hours x \$79.56 = \$25,140.96

D. Summary of Time and Cost Burdens

Time Burden for Completion of *Each* Task Required for Deaths Related to Use of Restraints and or Seclusion or Soft Cloth Wrist Restraints – *per each hospital or CAH*

Completion of CMS-10455 form	15 minutes
Documenting in Hospital Internal of Other System	10 minutes
<u>Documenting in the deceased patients’ medical records</u>	<u>5 minutes</u>
TOTAL	30 minutes

Time Burden for Completion of *All* Tasks Related to Deaths Related to Use Restraints and or Seclusion or Soft Cloth Wrist Restraints *Across All Hospitals and CAHs*

Completion of CMS-10455 form	784 hours
Documenting in Hospital Internal of Other System	110 hours
<u>Documenting in the Deceased Patients Medical Records</u>	<u>316 hours</u>
TOTAL	1,210 hours

³ <https://www.bls.gov/oes/current/oes291141.htm>.

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Cost Burden for Completion of *Each* Task Related to Deaths Related to Use Restraints and or Seclusion or Soft Cloth Wrist Restraints – *per each hospital or CAH*

Completion of CMS-10455 form	\$28.80
Documenting in Hospital Internal of Other System	\$19.20
Documenting in the deceased patients' medical records	\$ 6.63
TOTAL	\$54.63

Cost Burden for Completion of *All* Tasks Related to Deaths Related to Use Restraints and or Seclusion or Soft Cloth Wrist Restraints *Across All Hospitals and CAHs*

Completion of CMS-10455 form	\$ 90,332.48
Documenting in Hospital Internal of Other System	\$ 12,674.20
Documenting in the deceased patients' medical records	\$ 25,140.96
TOTAL	\$128,147.64

13. Capital Costs

There are no anticipated capital costs associated with this collection.

14. Federal Cost Estimates

The Report of a Hospital Associated Death from Restraint/Seclusion is to be completed by the hospital for each death described in 42 CFR § 482.13(g)(1).

The Federal government would incur cost for the time required for the CMS Location staff to review the CMS-10455 forms that are submitted. As stated above, we estimate that 3,137 CMS-10455 forms are submitted per year.

We estimate that it would take the CMS Location staff approximately 20 minutes to review **each** CMS-10455 form. We further estimate that the total annual time burden for review of the CMS-10455 forms submitted **across all** hospitals and CAHs annually would be **1,046 hours**.

- 3,137 CMS-10455 forms per year x 20 minutes per form = 62,740 minutes
- 62,740 minutes divided by 60 minutes per hour = 1,045.66 hours

We believe that the person that the CMS Locations that would review the CMS-10455 forms would be a at least a GS-13. Step 6. The mean hourly wage for this grade level is \$57.96.⁴ This wage, adjusted for the employer's overhead and fringe benefits, would be **\$115.92**. We estimate that the cost burden for review of **each** CMS-10455 form would be **\$38.64**.

- 20 minutes x \$115.92 = \$38.64

⁴ <https://www.federalpay.org/gs/calculator>

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We further estimate that the total annual cost burden for review of *all* CMS-10455 forms submitted *by all* hospitals and CAHs annually would be **\$121,252.32**.

- \$115.92 x 1,046 hours = \$121,252.32

15. Burden Changes/Program changes

The table below shows the changes in burden from the previous PRA package submission.

Task	Total Requested	Program Change Due to Change in Burden Calculations	Currently Approved
a. Annual number of responses for the CMS-10455	3,137 responses	-7,789	10,926 responses
b. Annual time burden to complete CMS-10455 forms across all hospitals/CAHs	784 hours	+293 hours	491 hours
c. Annual time burden to document deaths associated with the use of soft cloth wrist restraints in the hospital's internal log or other system – across all hospitals/CAHs	110 hours	-316 hours	426 hours
d. Annual time burden for entering information about deaths associated with use of restraints and/or seclusion or deaths related to the use of soft cloth wrist - restraints in the patient's medical record - across all hospital/CAH	316 hours	+316 hours	0 hours
e. One-time time burden related to training <i>each</i> hospital or CAH to use of the { electronic CMS-10455 form.	0 hours	-1 hour	1 hour
f. One-time time burden across all hospitals and CAHs related to training all hospitals and CAHs to use of the electronic CMNS-10455 form	0 hours	-6,389 hours	6,389 hours
g. Annual cost burden to complete CMS-10455 forms across all hospitals/CAHs	\$90,332	+\$57,314	\$33,018
h. Annual cost burden to document deaths associated with the use of soft cloth wrist restraints in the hospital's internal log or other system – across all hospitals/CAHs	\$12,674	-\$15,996	\$28,670
i. Annual cost burden for entering information about deaths associated with use of restraints and/or seclusion or deaths related to the use of soft cloth wrist - restraints in the patient's medical record - across all hospital/CAH	\$25,141	+\$25,141	\$0
j. One-time cost burden across all hospitals and CAHs related to training all hospitals and CAHs to use of the electronic CMNS-10455 form.	\$0	-\$4,299,797	\$4,299,797

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Total Annual Responses	3,137 responses	-7,789 responses	10,926 responses
Total Hour Burden	1,210 hours	-6,096 hours	7,306 hours
Total Cost Burden	\$128,148	+\$62,160	\$65,988

As the above table shows, the number of responses has decreased by 7,789. The total number of annual burden hours has decreased by 6,096 hours and the total annual cost burden has increased by \$62,160. These changes can be explained by several factors.

The decrease in the number of responses and burden hours can be attributed to the fact that the number of responses and cost burden in the previous PRA package was higher than usual due to the addition of a one-time burden that was added for training hospital and CAH staff in the use of the electronic format CMS-10455 that was released with the previous PRA package. As this was a one-time burden, we have not included this burden in this PRA package. Thus, the number of responses and time burden have decreased in the current PRA package.

Also, the number of responses has decreased, as expected, due to the addition of instructions to the CMS-10455 form which assist a hospital in determining when it was necessary to submit the form and reducing unnecessarily submitted CMS-10455 forms reporting deaths related to the use of 2-point soft cloth wrist restraints and no seclusion. It had been noted by the CMS ROs that hospitals and CAHs with DPUs were frequently submitting Form CMS-10455 when it was not required to directly report (i.e. 2-point soft wrist restraint with no seclusion reporting). The unnecessary direct reporting accounted for nearly half of the form CMS-10455 forms received by the ROs since the reporting requirement changed. In addition, due to the burden of submitting a paper version of form CMS-10455 by fax or email, the submission process remains cumbersome.

The increase in the cost burden is due to the use of the higher U.S. Bureau of Labor Statistic wage rates for May 2021. In the previous PRA package, a single wage rate of only \$33.65 was used. However, in the current PRA package we have used an adjusted wage rates⁵ of \$115.22 for a Health and Medical Services Manager and \$79.56 for a Registered Nurse. These increased wage rates account for the increased cost burden. We have used these updated, higher wage rates as required by OMB.

16. Publication and Tabulation Dates

The results of this collection will not be published.

⁵ The base hourly wage rate is doubled to allow for the employer's overhead and fringe benefit.

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17. OMB Expiration Date

CMS will display the OMB expiration date on the collection instrument.