

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

A. Background

1. Introduction

Currently, when a death occurs in a hospital or a 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 Form CMS-10455 and submit it directly to the CMS Regional Office (RO) via fax and/or email. However, when a death associated with the use of restraint and/or seclusion has occurred, but only 2-point soft cloth wrist restraints were used and the patient was not in seclusion at the time or within 24 hours of the death, the hospital is only required to document the information required by 42 CFR §482.13(g)(4)(ii) in an internal log or record. The hospital does not directly submit these logs or records to the CMS RO, but must be made available in either written or electronic form to CMS immediately upon request. The date and time of death reported to CMS and required reporting must also be documented in the patient's medical record.

We are submitting this PRA package seeking OMB approval for an electronically submitted version of the currently approved paper version Form CMS-10455.

2. Regulatory Background Form CMS-10455

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 RO. This regulation requires that information about patient deaths associated with the use of restraint and/or seclusion must be reported to the CMS RO by fax or email. This information must be reported by using the form CMS-10455, entitled "*Report Of A Hospital Death Associated With The Use Of Restraint Or Seclusion.*"

42 CFR §482.13(g) deaths associated with restraint and/or seclusion is categorized 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 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

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

(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, hospital or CAHs with DPU staff 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 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.

Form CMS-10455 was amended in 2016 adding instructions to assist in determining when it was necessary to submit the form and reducing the burden to providers in directly reporting

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

deaths related to the use of 2 point soft cloth wrist restraints and no seclusion. The form CMS-10455 was amended because the restraint-related reporting requirements were amended in 2016 making it unnecessary for hospitals and CAHs with DPUs to submit the Form CMS-10455 for deaths associated with 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.

At this time, we are seeking OMB approval of an electronically submitted version of the current OMB-approved paper version of the Form CMS-10455.

B. Justification

1. Need and Legal Basis

Sections 1861(e) (1) through (8) of the Social Security Act define the term “hospital” and its requirements to eligible for Medicare Participation. Additionally, Section 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 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.

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 would also apply to Critical Access Hospitals (CAHs)

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

with distinct part units (DPUs); since CAH DPUs are subject to the Hospital Conditions of Participation.

Consistent with the provisions of §482.13(g)(1), CMS has determined it will accept required reports of hospital deaths associated with use of restraint or seclusion via facsimile or electronically, on a standard form for which we are seeking OMB approval, the Report of a Hospital Death Associated with Restraint/Seclusion. The information proposed for collection via the proposed 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.

2. Information Users

The intent of this information collection regarding patient deaths associated with the use of restraint/seclusion is for CMS to identify those cases 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 would perform an on-site investigation if we find that a hospital's or 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, so that intervention can occur if problems arises, especially one that is 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

Currently, the paper Form CMS-10455 must be completed by the hospital or CAHs with DPUs staff and either faxed or emailed to the Regional Office (RO) based on each RO's preference.

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

The information from the Form CMS-10455 is entered into the CMS tracking system (currently ASPEN Complaint Tracking System (ACTS)) and related survey and certification databases by the RO staff. It has been noted that information from the Form CMS-10455 has only been entered in ACTS when a survey was warranted.

The electronic Form CMS-10455 that will be directly submitted by the hospital or CAHs with DPU staff automatically to the CMS ROs will allow CMS to collect all information whether a survey was conducted or not. By electronically capturing the required reporting, we will be assured that all data is being collected and will reduce CMS RO burden from having to separately enter death reporting information.

4. Duplication of Similar Information

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 Form CMS-10455 and directly submit to the CMS RO via fax or email. 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 log or record. The hospital or CAHs with DPUs only have to submit this log to CMS immediately 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 the business (hospital or CAH with DPUs) to participate in the Medicare program. These paperwork requirements would be reduced with the electronic submission process, but the reporting requirements remain necessary to meeting the Medicare participation requirements of the law.

The requirements for electronic submission of Form CMS-10455 will require minimal training; however, there will be no cost to the provider for single web-based sign-on required to transmit Form CMS 10455 to the CMS RO.

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

6. Less Frequent Collection

This information is required to be reported within 24 hours of the hospital's or CAH's with DPU's knowledge of a reportable patient death. The estimated number of information collections 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

The 60-day Federal Register notice published on February 14, 2019 (84 FR 4075).

One public comment was received in response to the February 14, 2019 Federal Register notice. The commenter stated the sentence in the Federal Register notice "**Currently, the hospital, CAH, or psychiatric DPU must submit the form CMS-10455 to the CMS RO via fax or email, based on RO's preference**" is incorrect. Our response to this comment is provided in a separate document.

The reporting requirements and the data review process related to Form CMS-10455 was discussed with a RO workgroup and it was identified that the current form in use does not provide detailed information that allows the RO staff to make survey determinations based solely on the review of provider documentation.

The 30-day Federal Register notice published on May 20, 2019 (84 FR 22850).

9. Payments or Gifts

There are no payments or gifts associated with this collection.

10. Confidentiality

Personally identifiable information will be collected concerning the person who reports the

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

information on the hospital’s behalf, as well as the patient who died, and will be released only in accordance with Agency policy and applicable law.

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.

12. Estimate of Burden

All 6,389 hospitals (this number includes the estimated number of CAHs with DPUs) currently enrolled in Medicare are required to report deaths associated with restraints and seclusion. The current average number of reports per hospital is 1 per year. The total hospital annual responses for 2015 was 2,708 as RO 9 had not submitted their information as of the date of this report. The total number of CMS-10455 forms received by each CMS RO in 2016 and 2017 is listed in the table below:

CMS Regional Office Number	Number of CMS-10455 forms received in 2016	Number of CMS-10455 forms received in 2017
1	92	146
2	70	41
3	340	281
4	979	688
5	594	700
6	115	149
7	27	36
8	119	103
9	471	415
10	60	58
TOTAL	2,867	2,617

A. Burden Related to Training Webinar for Use of the Electronic CMS-10455 Form

CMS will provide a 1 hour training webinar to the hospitals and CAHs with DPUs which will teach how to complete and submit the electronic CMS-10455 form. We would require

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

that all 6,389 hospitals and CAHs with DPUs review this training webinar. We estimate that approximately 10 employees at each hospital would review the training webinar at that these employees would be registered nurses. According to the U.S. Bureau of Labor Statistics, the mean hourly wages for a registered nurse is \$33.65 (<https://www.bls.gov/ooh/healthcare/registered-nurses.htm>).

1. Time Burden for Review of Training Webinar By Each Hospital or CAH With DPU

- 1 hour webinar x each hospital = 1 hour

2. Time Burden for Review of Training Webinar By All Hospital or CAH With DPU

- 1 hour webinar x 6,389 hospitals = 6,389 hours

3. Cost Burden for Review of Training Webinar By Each Hospital or CAH With DPU

- 1 hour webinar x \$33.65 per hour = \$33.65
- \$33.65 x 10 employees = **\$336.50**

4. Cost Burden for Review of Training Webinar By ALL Hospital or CAH With DPU

- 1 hour webinar x \$33.65 per hour = \$33.65
- \$33.65 x 10 employees = \$336.50
- \$336.50 x 6,389 hospitals & CAHs w/ DPUs = **\$2,150**

B. Burden Related to Completion of the Form CMS-10455

We estimate that it will take hospital/CAH nursing administration staff approximately 15 minutes to complete the electronic Form CMS-10455. We believe that this work would be performed by a registered nurse. According to the U.S. Bureau of Labor Statistics, the mean hourly wages for a registered nurse is \$33.65 (<https://www.bls.gov/ooh/healthcare/registered-nurses.htm>).

There are currently 6,389 hospitals and CAHs with DPUs. In 2017 the CMS Regional Offices received 2,617 CMS-10455 forms. Statistically, this would mean that only 41% of these 6,389 hospitals and CAHs submitted CMS-10455 forms to the CMS regional offices.

However, we estimate that the addition of instructions to the Form CMS-10455 that informs

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

C. Burden Related to Entering Information Related to Use of 2 Point Soft Cloth Restraints into the Hospital or CAH with DPUs Logs.

We estimate that the time required for the hospital or CAH with DPUs to enter information about deaths related to use of soft cloth restraints into the hospital/CAH records would be approximately 5 minutes. We believe that approximately 40% of the 6,389 hospitals/CAHs or 1,981 hospitals/CAHs would have a death related to the use of soft restraints that would require the need to document this information. We further estimate that each of these 1,981 hospitals would only have one incident per year.

We believe that this task would be performed by a Registered Nurse. According to the U.S. Bureau of Labor Statistics, the mean hourly wages for a registered nurse is \$33.65 (<https://www.bls.gov/ooh/healthcare/registered-nurses.htm>).

1. Time Burden For Each Hospital or CAH with DPUs Related to Documenting Information Related to Death Associated with Use of 2 Point Soft Cloth Restraints In the Hospital/CAH Record.

- 10 minutes per report x 1 report per year = **10 minutes**

2. Time Burden Across The 2,556 Hospitals or CAHs with DPUs Related to Documenting Information Related to Death Associated with Use of 2 Point Soft Cloth Restraints In the Hospital/CAH Record.

- 10 minutes per report x 2,556 hospital required to report = 25,560 minutes
- 25,560 minutes divided 60 minutes per hour = **426 hours**

3. Cost Burden for Each Hospital or CAH with DPUs Related to Documenting Information Related to Death Associated with Use of 2 Point Soft Cloth Wrist Restraints In the Hospital or CAH with DPUs Logs.

- 10 minutes per report x 1 report per year = 10 minutes
- \$33.65 per hour divided by 60 minutes per hour = \$0.56 per minute
- \$0.56 per minute x 10 minutes = **\$5.60**

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

4. Cost Burden Across the 2,556 Hospitals or CAH with DPUs Related to Documenting Information Related to Death Associated with Use of 2 Point Soft Cloth Wrist Restraints In the Hospital or CAH with DPUs Logs.

- 10 minutes per report x 2,556 hospitals = 25,560 minutes
- 25,560 minutes divided by 60 minutes per hour = 426 hours
- \$33.65 per hour x 426 hours = **\$14,335**

D. Cost Burden Related to Fringe Benefits

To account for fringe benefits of employment we would add an additional amount in the amount of 100% of the hourly wages for the time required to perform all tasks. Therefore, we would add an additional cost burden for fringe benefits in the amounts stated below:

1. Total Fringe Benefits Per Each Hospital Or CAH w/ DPU

- | | |
|---|-----------------|
| • Cost Burden for Training | \$336.50 |
| • Cost Burden Across Each Hospitals That Submitted CMS-10455 Forms | \$ 8.41 |
| • <u>Cost Burden Across Each hospital for documenting death info in the hospital record</u> | <u>\$ 5.60</u> |
| Total Amount of Fringe Benefits | \$350.51 |

2. Total Fringe Benefits Across All Hospitals & CAHS W/ DPUs

- | | |
|---|-----------------|
| • Cost Burden Across All Hospitals for Training | \$ 2,150 |
| • Cost Burden Across All Hospitals That Submitted CMS-10455 Forms | \$16,509 |
| • <u>Cost burden across all hospital for doc. death info in the hospital record</u> | <u>\$14,335</u> |
| TOTAL Amount of Fringe Benefits | \$32,994 |

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

E. Total Time Burden Associated With This ICR

1. Total Time Burden Per Each Hospital or CAH w/ DPU:

• Training	60 minutes
• Submission of Form CMS-10455	15 minutes
• <u>Documentation of info of deaths related to 2 point soft cloth wrist restraints</u>	<u>10 minutes</u>
TOTAL:	85 minutes

2. Total Time Burden Across All Hospitals or CAHs w/ DPU:

• Training	6,389 hours
• Submission of Form CMS-10455	491 hours
• <u>Documentation of info of deaths related to 2 point soft cloth wrist restraints</u>	<u>426 hours</u>
TOTAL:	7,306 hours

F. Total Cost Burden Associated With This ICR

1. Total Cost Burden Per Each Hospital:

• Training	\$336.50
• Submission of Form CMS-10455	\$ 8.41
• Documentation of information of deaths related to 2 point soft cloth wrist restraints	\$ 5.60
• <u>Fringe Benefits:</u>	<u>\$350.51</u>
TOTAL:	\$701.02

2. Total Time Burden Across All Hospitals:

• Training	\$ 2,150
• Submission of Form CMS-10455	\$16,509
• Documentation of information of deaths related to soft cloth restraints	\$14,335
• <u>Fringe Benefits</u>	<u>\$32,994</u>
TOTAL:	\$65,988

13. Capital Costs

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

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 CMS ROs are responsible for reviewing the *Report of Hospital Death Associated with Restraint/Seclusion*. The amount for review of the form was calculated using an average salary of \$70.07 per hour for a Regional Office reviewer, and assuming it would take 20 minutes to review the file; the Federal cost for each review is \$23 (\$70.07 x 0.33 hours).

The total number of reports annually is estimated to be 6,389 (6,389 hospitals x 1 annual reports). Thus, the total number of hours spent annually reviewing this report is 2,108 (0.33 hours x 6,389 reports). The total federal cost for the RO review of the Report of a Hospital Death Associated with Restraint/Seclusion is estimated to be \$147,708 (2,108 annual hours for review x \$70.07/hour).

TOTAL ESTIMATED FEDERAL COSTS	\$147,708
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15. Burden Changes/Program changes

The total time burden associated with the submission of the electronic CMS-10455 form will increase from 2,619 hours to 7,306 hours. The time burden associated with the use of the electronic CMS-10455 form has decreased from 2,108 hours to 491 hours. Also, we estimate that the time burden associated with the recording in the internal hospital record of deaths that

occur during the use of 2 point soft wrist restraints will decrease from 511 hours to 426 hours. However, there will be an increase of an additional 6,389 burden hours due to the training that each hospital and CAH with DPU must take to learn how to use the electronic CMS-10455 form.

We further estimate that the use of the electronic version of the CMS-10455 form will reduce the time required to complete and submit this form from 30 minutes for paper submissions to 15 minutes for electronic submission. This decrease in the time burden for submission of the electronic CMS-10455 form creates a decrease in the estimated cost associated with submission of the electronic CMS-10455 form from \$275,047 to \$65,988.

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

16. Publication and Tabulation Dates

The results of this collection will not be published.

17. OMB Expiration Date

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