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

A. Background

The regulations at 42 CFR 482.13(g) require that hospitals must report deaths associated with the use of seclusion or restraint by telephone, facsimile, or electronically, as determined by CMS, no later than the close of business on the next business day following knowledge of the patient's death for each of the following circumstances: (1) Each death that occurs while a patient is in restraint or seclusion; (2) Each death that occurs within 24 hours after the patient has been removed from restraint or seclusion; (3) Each death known to the hospital that occurs within 1 week after restraint or seclusion where it is reasonable to assume that use of restraint or placement in seclusion contributed directly or indirectly to a patient's death, regardless of the type(s) of restraint used on the patient during this time. The term "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 information about patient deaths associated with the use of seclusion or restraints must be reported to CMS in the CMS-10455 form which is titled ***"Report Of A Hospital Death Associated With The Use Of Restraint Or Seclusion"***

42 CFR 482.13(g) provides that a hospital does not have to report, to CMS by telephone, fax or electronically, deaths that occur 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. Under these circumstances, the hospital staff are required to record in an internal log or other system, the following information: (1) any death that occurs while a patient is in such restraints; (2) any death that occurs within 24 hours after a patient has been removed from such restraints; (3) documentation in the patient's medical record of the date and time the death was reported to CMS (for deaths required to be reported under 42 CFR 482.13(g)(1); or (4) a record in the internal log or other system for deaths described in paragraph (g)(2) of this section (i.e. – deaths that are not required to be reported to CMS). In addition, the hospital is required to make this information available to CMS upon request.

The provision in 482.13(g) that hospitals are not required to immediately report via telephone, fax or electronically to CMS, the deaths that occur 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 was implemented as a result of a final rule titled ***"Medicare and Medicaid Programs; Reform of Hospital and Critical Access Hospital Conditions of Participation"*** dated May 16, 2012 (77 FR 29040). In this rule we finalized our proposals to modify the reporting requirements for hospitals when the circumstances of a patient's death involve only the use of soft two-point wrist restraints and no use of seclusion. We further finalized a proposal to modify to require that hospitals would be required to report to CMS the death involving soft two-point wrist restraints and no use of seclusion by having hospital staff record the

information about the death into an internal log or other system (482.13(g)(2)). Finally, we finalized our proposal that each entry in the record must be made no later than seven days after the date of death of the patient and that the record must include the patient's name, date of birth, date of death, attending physician, primary diagnosis(es), and medical record number. We also proposed that hospitals must make this information available to CMS in either written or electronic form immediately upon request (482.13(g)(4)).

For deaths involving all other types of restraints and all forms of seclusion, we noted that we would retain the current, more extensive death reporting requirements to CMS by telephone no later than the close of business on the next business day following knowledge of the patient's death. In addition to reporting the deaths by telephone, we proposed to revise § 482.13(g)(1) to provide additional reporting options, which would include the use of facsimile and electronic reporting.

This reporting requirement change resulted in no necessary edits to the form CMS-10455 (OMB 0938-1210) as soft wrist restraints may be used in combination with other types of restraints. It was estimated that this would reduce the volume of reports that must be submitted by 90 percent for hospitals. In addition, the final rule (77 FR 290974) replaced the previous requirement for reporting via telephone to CMS, which proved to be cumbersome for both CMS and hospitals, with a requirement that allows submission of reports via telephone, facsimile or electronically, as determined by CMS.

CMS is revising the CMS-10455 form in order to obtain the necessary information for the CMS Regional Offices (ROs) to make a determination whether or not to authorize an on-site investigation related to the details surrounding the death of individuals associated with restraint and/or seclusion. The revised CMS-10455 form contains additional requests for information that is specifically needed for the ROs to assess whether the case warrants an on-site investigation based on the situation involving a violation of 42 CFR 482.13(e) through 42 CFR 482.13(g).

The revised CMS-10455 form also displays instructions which outline the submission requirements of the CMS-10455 form. These instructions were added to assist in reducing the burden to providers related to death reporting using the CMS-10455 form. It is important to note that there are 2 separate reporting requirements associated with the use of the CMS-10455 form. When there has been a death associated with the use of non-cloth restraints and/or seclusion, the hospital staff must complete the CMS-10455 form and submit it to the CMS RO via telephone, fax or electronically. However, when there has been a death but there was no seclusion used or only soft cloth wrist restraints were used, the hospital is only required to document the information required by 482.13(g)(4) in an internal log or record. The hospital only has to report this information to CMS upon request.

The situations in which hospitals submitted CMS-10455 forms to the CMS ROs when not required (e.g.: 2 point soft wrist restraint reporting) accounted for nearly half of the unnecessary CMS-10455

forms received by the ROs since the reporting requirement changed in May 2016. CMS anticipates the number of form submissions to decrease based on the addition of the instructions to the revised 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 as 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 restraints 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) 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 in general.

We would perform an on-site investigation if we find that a hospital's rate of death's 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 is properly meeting the Conditions of Participation for patient's rights, they would be constantly monitoring patients when they put in restraints or seclusion, so that they can intervene if a problem arises, especially a problem that is potentially life threatening to the patient. If a hospital has 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

The CMS-10455 form must be completed by the hospital staff and either faxed or emailed to the Regional Office (RO) based on the RO preference. The information from this CMS-10455 form will be entered into the ASPEN Complaint Tracking System (ACTS) and related survey and certification databases by the RO staff only in instances when a survey is authorized based on the RO's staff triage of the CMS-10455 data.

4. Duplication of Similar Information

The Report of a Hospital Death Associated with Restraint/Seclusion does not duplicate any external information collection, but contains similar elements required by the regulation at 42 CFR 482.13(g)(3) and (g)(4) for an internal hospital log for deaths of patients for whom 2-point soft wrist restraints were used. The external and internal reporting are mutually exclusive and therefore not duplicative. When there has been a death associated with the use of non-cloth restraints and/or seclusion, the hospital staff must complete the CMS-10455 form and submit it to the CMS RO via telephone, fax or electronically. However, when there has been a death but there was no seclusion used or only soft cloth wrist restraints were used, the hospital is only

required to document the information required by 482.13(g)(4) in an internal log or record. The hospital only has to report this information to CMS upon request.

5. Small Business

These requirements do affect small businesses; however, the information collection is necessary for the business to participate in the Medicare program. These paperwork requirements are minimal and are necessary to meet the participation requirements of the law.

6. Less Frequent Collection

This information is collected within the close of business of the next business day following the hospital's knowledge of a reportable patient death. The estimated number of information collections per hospital is 1 annually. This could vary based on the size of the hospital, 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 November 7, 2017 (82 FR 51630). No comments were received as a result of this notice.

The 30-day Federal Register notice published on January 19, 2018 (83 FR 2784). No comments were received.

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.

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 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 average number of reports per hospital is 1 per year. The total hospital annual responses for 2015 was 2,708 as Regional Office (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 stated 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 Completion of the CMS-10455 Form

We estimate that it will take hospital nursing administration staff approximately 20 minutes to complete the CMS-10455 form. 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 2016 the CMS Regional Offices received 2,617 CMS-10455 forms. Statistically, this would means 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 CMS-10455 form that informs hospital staff that the CMS-10455 form does not need to be submitted for deaths related to the use of soft cloth wrist restraints and no seclusion will reduce the number of CMS-10455 forms submitted to the CMS ROs by approximately 25%. We believe that this 25% reduction will occur approximately one year after the revised CMS-10455 has been implemented. The ROs received 2,617 CMS-10455 forms in 2017. Therefore, we estimate that the RO would receive approximately 1,963 CMS-10455 forms in 2019 and thereafter. Statistically, this would means that only 31% (or 1,981) of the 6,389 hospitals and CAHs would be submitting CMS-10455 forms to the CMS regional offices beginning in 2019 (6,389 hospitals divided by 100 = 63.89 / 63.89 x 31 = 1,981).

1. Time Burden Per Each Hospital that Submitted CMS-10455 forms

   - 20 minutes x 1 CMS-10455 submission per year = 20 minutes

2. Time Burden Across the 31% of Hospitals that Submitted CMS-10455 forms
   - 20 minutes x 1,963 CMS-10455 forms submitted per year = 39,260 minutes
   - 39,260 minutes divided by 60 minutes per hour = 654 hours

3. Cost Burden Per Each Hospital That Submitted a CMS-10455 Form

   - $33.65 per hour divided by 60 minutes per hour = $0.56 per minute
   - $0.56 per minute x 20 minutes = $11.20

4. Cost Burden Across the 31% of Hospitals That Submitted CMS-10455 Forms

   - $33.65 per hour divided by 60 minutes per hour = $0.56 per minute
   - $0.56 per minute x 20 minutes = $11.20 per 20 minutes
   - $11.20 x 1,963 = $21,986

B. Burden Related to Entering Information Related to Use of Soft Cloth Restraints into the Hospital Records.

We estimate that the time required for the hospital to enter information about deaths related to use of soft cloth restraints into the hospital records would be approximately 5 minutes. We believe that approximately 40% of the 6,389 hospitals or 1,981 hospitals 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 Related to Documenting Information Related to Death Associated with Use of Soft Cloth Restraints In the Hospital Record.

   - 5 minutes per report x 1 report per year = 5 minutes

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

   - 5 minutes per report x 2,556 hospital required to report = 12,780 minutes
   - 12,780 minutes divided 60 minutes per hour = 213 hours

3. Cost Burden For Each Hospital Related to Documenting Information Related to Death Associated with Use of Soft Cloth Restraints In the Hospital Record.

   - 5 minutes per report x 1 report per year = 5 minutes
   - $33.65 per hour divided by 60 minutes per hour = $0.56 per minute
   - $0.56 per minute x 5 minutes = $2.80

4. Cost Burden Across the 2,556 Hospitals Related to Documenting Information Related to Death Associated with Use of Soft Cloth Restraints In the Hospital Record.

   - 5 minutes per report x 2,556 hospitals = 12,780 minutes
   - 12,780 minutes divided by 60 minutes per hour = 213 hours
   - $33.65 per hour x 213 hours = $7,167

C. Cost Burden Related to Fringe Benefits

We have estimated that it would take approximately 20 minutes for a registered nurse to complete the CMS-10455 form. We have further estimated that it would take approximately 5 minutes for a registered nurse to document death information in the hospital records.

Above we have estimated the following cost burdens:

• Cost Burden Across All Hospitals That Submitted CMS-10455 Forms	$21,986
• Cost burden across all hospital for documenting death info in the hospital record	$ 7,167
TOTAL	$29,153

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 amount of $29,153 ($21,986 + $7,167)

D. Total Burden Associated With This ICR

1. Total Time Burden Per Each Hospital:

• Submission of CMS-10455	20 minutes
• Documentation of information of deaths related to soft cloth restraints	5 minutes
TOTAL:	**25 minutes**

2. Total Time Burden Across All Hospitals:

• Submission of CMS-10455	654 hours
• Documentation of information of deaths related to soft cloth restraints	213 hours
TOTAL:	**873 hours**

3. Total Cost Burden Per Each Hospital:

• Submission of CMS-10455	$11.20
• Documentation of information of deaths related to soft cloth restraints	$ 2.80
• Fringe Benefits:	$14.00
TOTAL:	**$28.00**

4. Total Time Burden Across All Hospitals:

• Submission of CMS-10455	$21,986
• Documentation of information of deaths related to soft cloth restraints	$ 7,167
• Fringe Benefits	$29,153

TOTAL: **$58,306**

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 CMS Regional Offices 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**

15. Burden Changes/Program changes

Factors Contributing to Burden/Program Changes	**Previous PRA package**	**Current Estimate**	**Changes**
Decrease in number of reports submitted due to change in policies	2708	2617	-91 in 2018 -654 in 2019 and thereafter
Annual Burden Hours	2,054	2,619	+565
Increase in reporting elements		13	+13

Increase in number of Respondents (Hospitals)	6225	6389	+164

The changes to the collection tool include directions which clarify the exclusion of the reporting of deaths in which only 2-point soft wrist restraints were used, the patient was not in seclusion at the time of death and it is reasonable to assume that the use of those restraints did not contribute to the death of the patient. We expect this clarification of the reporting requirements will decrease the number of unnecessary reports by approximately 25 percent, in turn, reducing the overall burden to providers. This decrease in the total number of annual reports that are required to be submitted to the RO will also result in a decrease of the federal cost burden associated with this collection.

Based on information gathered from CMS Regional Offices (ROs), the current collection tool associated with this package did not provide the needed information to thoroughly evaluate whether the case warrants an on-site investigation. The ROs provided feedback for data needed on the CMS-10455 form to evaluate whether the case warrants an on-site investigation. The collection tool was revised based on the ROs need for additional information.

The estimated burden for reporting would be expected to increase to 2,619 hours from 2,054 hours due to the request for additional information with the revisions to the collection tool (CMS-10455: Report of a Hospital Death Associated with Restraint or Seclusion: *see crosswalk for identified changes) However, review of data collected from May 2014 through November 2016 revealed that a high number of reports were submitted by hospitals that were unnecessary according to regulation requirements. To help decrease the number of unnecessary reports being submitted, we have revised the CMS-10455 form to add instructions which advise the hospital staff that it is not necessary to submit a CMS-10455 form for deaths associated with the use of soft cloth wrist restraints and no seclusion. We estimate that the addition of these instructions to the CMS-10455 form will decrease the number of CMS-10455 forms received by the CMS ROs by approximately 25%. It is important to note that this 25% reduction applies only to the number of CMS-10455 forms submitted to the CMS ROs and does not apply to the number of respondents or other burden factors.

Also, the number of respondents has increased from 6,225 to 6,389. This increase is due to new hospitals and CAHs with DPUs having opened since the time of the filing of the last PRA package. Also, the number of respondents cited in section 12 of this PRA package includes the number of 6,389 hospitals and the estimated number of CAHs with DPUs) currently enrolled in Medicare are required to report deaths associated with restraints and seclusion. The number of hospital and CAHs is in a given year is dependent on the number of new hospitals and CAHs

that opened and the number of hospitals and CAHs that closed during that year. This information is obtained from the Survey and Certification Quality, Certification and Oversight Reports (S&C OCOR) system (https://qcor.cms.gov/main.jsp).

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.