

Supporting Statement  
Report of a Hospital Death Associated with Restraint or Seclusion

A. Background

The regulation that was published on May 16, 2012 (77 FR 29074) included a reduction in the reporting requirement related to hospital deaths associated with the use of restraint or seclusion, §482.13(g). Furthermore, the Survey and Certification (S&C) Memo: 14-27-Hospital-CAH/DPU posted May 9, 2014 states, “Hospital Restraint/Seclusion Deaths to be Reported Using Form CMS-10455: Hospitals must use Form CMS-10455 to report those deaths associated with restraint and/or seclusion that are required by 42 CFR §482.13(g) to be reported directly to their Centers for Medicare & Medicaid Services (CMS) Regional Office (RO). This requirement also applies to rehabilitation or psychiatric distinct part units (DPUs) in Critical Access Hospitals (CAHs).” The RO must provide hospitals with instructions for submitting the form to the RO by fax and/or e-mail, based on RO preference. Hospitals are no longer required to report to CMS those deaths where there was no use of seclusion and the only restraint was 2-point soft wrist restraints beginning in May 9, 2014. This reporting requirement change resulted in no necessary edits to the CMS-10455 Form (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 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. Finally, the amount of information that CMS needs for each death report in order for CMS to determine whether further on-site investigation is needed was reduced.

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).

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.

## 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)((4)(ii) 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.

## 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 April 27, 2016. There were no public comments received.

#### 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 Citation, 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 6,225 hospitals 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.

We estimate that it will take hospital nursing administration staff approximately 15 minutes to complete this form. Total annual burden for the form is 0.25 hours per hospital. (15minutes (0.25 hours) per form x 1 forms/year = 15 minutes or 0.25 hours). The burden hours are 1,556 for all hospital reporting (6,225 hospitals x 0.25 annual hours= 1,556 total annual hospital burden hours).

We estimate that the information collection requirements will cost \$ 25.50 per hospital (0.25 hours x \$102.00 per hour= \$25.50). The rate of \$102.00 per hour is based on average hourly wage for nurse administrators of \$51.00 per hour as reported by the U. S. Bureau of Labor Statistics then doubled to include wages for overhead and benefits. The total annual burden for all hospitals is \$158,737.50 (\$25.50 per hospital x 6,225 Medicare hospitals = \$158,737.50).

Additionally, we estimate that the required record keeping will take hospital nursing staff 5 minutes for entering the time and date of report to CMS in the medical record. The total annual cost burden for this record keeping is 0.08 hours per hospital (5 minutes (0.08 hours) per report x 1 reports per year= 5 minutes or 0.08 hours). The total annual burden for record keeping for all hospitals is 498 hours (6,225 hospitals x 0.08 annual hours= 498 hospital annual hours)

We estimate that this record keeping will cost \$8.16 (0.08 hours x \$102.00 per hour=\$8.16). The rate of \$102.00 per hour is based on average hourly wage for nurse administrators as reported by the U. S. Bureau of Labor Statistics in May 2015 of \$51.00 per hour then wage rate doubled to include wages for overhead and benefits to total wage of \$102.00 per hour. The total cost annual burden for all Medicare hospitals for record keeping is \$50,796.00 (\$8.16 per hospital x 6,225 Medicare hospitals = \$50,796.00).

The total annual burden for all 6225 Medicare hospitals for reporting and record keeping is 2,054 annual hours (6,225 hospitals x 0.33 annual hours = 2,054.25 (rounded to 2,054) total annual hours).

The total annual cost burden for all Medicare hospitals to report and record deaths associated with restraint and seclusion is \$209,533.50 (\$158,737.50 for reporting + \$50,796.00 for record keeping = \$209,533.50).

	<b>Burden for Reporting</b>	<b>Burden for Recordkeeping</b>	<b>Total</b>
Number of Respondents	6225	6225	
Average number of responses	1	1	
<b>Total Number of responses</b>	<b>6225</b>	<b>6225</b>	
Hours per response (minutes/60)	0.25	0.08	

Annual hours of Burden (hours per response x number of responses)	0.25	0.08	
Total annual hours of burden x number of respondents)	1556	498	<b>2054</b>
Hourly cost per response	\$102.00	\$102.00	
Annual Cost of responses per hospital (annual hours of burden x hourly rate)	\$25.50	\$8.16	
Total Annual Cost (number of respondents x annual cost of response per hospital)	\$158,737.50	\$50,796.00	<b>\$209,533.50</b>

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 15 minutes to review the file; the Federal cost for each review is \$17.52 (\$70.07 x 0.25hours). The total number of reports annually is estimated to be 6,225 (6,225 hospitals x 1 annual reports). Thus, the total number of hours spent annually reviewing this report is 1,556 (0.25hours x 6,225 reports). The total federal cost for the RO review of the Report of a Hospital Death Associated with Restraint/Seclusion is estimated to be \$109,046.44 (1556.25 -Rounded to 1556 annual hours for review x \$70.07/hour).

TOTAL COSTS                      \$109,046

15. Burden Changes/Program changes

The estimated burden decreased with this collection. Survey and Certification (S&C) Memo (S&C Memo) :14-27-Hospital-CAH/DPU, under 42 CFR §482.13(g), requires Critical Access Hospitals (CAHs) with distinct part units (DPUs) to submit the hospital reporting of deaths associated with use of restraint or seclusion; since CAH DPUs are subject to the Hospital Conditions of Participation. This memo also excludes reporting of deaths in which only 2-point soft wrist restraints were used and the patient was not in seclusion at the time of death. The total number of hospitals and CAHs that are required to report deaths associated with restraint and seclusion increased based on this S&C memo release. Additionally, the total number of annual reports to the RO decreased following this S&C memo due to the reporting requirement change excluding 2-point soft wrist restraints in use at the time of deaths. Due to the decrease in the total number of annual reports required to be submitted to the RO, the federal cost burden was decreased with this collection.

16. Publication and Tabulation Dates

The results of this collection will not be published.

17. OMB Expiration Date

CMS does not object to displaying the OMB expiration date.