

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

A. Background

Executive Order 13563, Improving Regulation and Regulatory Review, was signed on January 18, 2011. The order recognized the importance of a streamlined, effective, and efficient regulatory framework designed to promote economic growth, innovation, job creation, and competitiveness. Each agency was directed to establish an ongoing plan to reduce or eliminate burdensome, obsolete, or unnecessary regulations to create a more efficient and flexible structure.

The regulation that was published on May 16, 2012 (77 FR 29034) included a reduction in the reporting requirement related to hospital deaths associated with the use of restraint or seclusion, §482.13(g). 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. It is estimated that this will 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 has been 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 information from this form will be entered into the ASPEN Complaint Tracking System (ACTS) and related survey and certification databases and serve as the information base for the creation of a record for future survey and analytical activity.

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

The information collection requirements do not significantly affect small businesses as hospitals are not considered small business entities.

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 5 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 21, 2012. There were no 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 4900 hospitals currently enrolled in Medicare are required to report deaths associated with restraints and seclusion. The average number of reports per hospital is 5 per year. The total hospital annual responses are 24,500.

We estimate that it will take hospital nursing staff approximately 15 minutes to complete this form. Total annual burden for the form is 1.25 hours per hospital. (15minutes (0.25 hours) per form x 5 forms/year = 75 minutes or 1.25 hours). The burden hours are 6,125 for all hospital reporting (4900 hospitals x 1.25 annual hours= 6125 total annual hospital burden hours).

We estimate that the information collection requirements will cost \$56.25 per hospital (1.25 hours x \$45.00 per hour= \$56.25). The rate of \$45.00 per hour is based on average hourly wage for nurses as reported by the Department of Labor. The total annual burden for all hospitals is \$275,625 (\$56.25 per hospital x 4900 Medicare hospitals = \$275,625).

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 0.40 hours per hospital (5 minutes (0.08 hours) per report x 5 reports per year= 25 minutes or 0.40 hours). The total annual burden for record keeping for all hospitals is 1960 hours (4900 hospitals x 0.40 annual hours= 1960 hospital annual hours)

We estimate that this record keeping will cost \$18.00 (0.40 hours x \$45.00 per hour=\$18.00). The rate of \$45.00 per hour is based on average hourly wage for nurses as reported by the Department of Labor. The total cost annual burden for all Medicare hospitals for record keeping is \$88,200 (\$18.00 per hospital x 4900 Medicare hospitals = \$88,200).

The total annual burden for all 4900 Medicare hospitals for reporting and record keeping is 8085 annual hours (4900 hospitals x 1.65 annual hours = 8085 total annual hours).

The total annual cost burden for all Medicare hospitals to report and record deaths associated with restraint and seclusion is \$363,825 (\$275,625 for reporting + \$88,200 for record keeping = \$363,825).

	Burden for Reporting	Burden for Recordkeeping	Total
Number of Respondents	4900	4900	
Average number of responses	5	5	
Total Number of responses			24500
Hours per response (minutes/60)	0.25	0.08	
Annual hours of Burden (hours per response x number of responses)	1.25	0.4	
Total annual hours of burden x number of respondents)	6125	1960	8085
Hourly cost per response	\$45	\$45	
Annual Cost of responses per hospital (annual hours of burden x hourly rate)	\$56	\$18	
Total Annual Cost (number of respondents x annual cost of response per hospital)	\$275,625	\$88,200	\$363,825

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 \$25.00/hour for a Regional Office reviewer, and assuming it would take 15 minutes to review the file; the Federal cost for each review is \$6.25/hour (\$25.00x 0.25hours). The total number of reports annually is estimated to be 24,500 (4900 hospitals x 5 annual reports). Thus, the total number of hours spent annually reviewing this report is 6125 (0.25hours x 24500 reports). The total federal cost for the RO review of the Report of a Hospital Death Associated with Restraint/Seclusion is estimated to be \$153,125 (6125 annual hours for review x \$25.00/hour).

TOTAL COSTS	\$153,125
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15. Burden Changes/Program changes

This is a new 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.