

Agency for Toxic Substances and Disease Registry.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10455]

#### Agency Information Collection Activities: Submission for OMB Review; Comment Request

**AGENCY:** Centers for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the Agency's function; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* New collection; *Title of Information Collection:* Report of a Hospital Death Associated with Restraint or Seclusion; *Use:* 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.

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).

The 60-day **Federal Register** notice published on November 21, 2012, (77 FR 69848). Subsequently, there was a minor revision to the Health Death Report form. *Form Number:* CMS-10455 (OCN: 0938—New); *Frequency:* Occasionally; *Affected Public:* Private Sector. *Number of Respondents:* 4,900. *Number of Responses:* 24,500. *Total Annual Hours:* 8,085. (For policy questions regarding this collection contact Danielle Miller at 410-786-8818. For all other issues call 410-786-1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS Web Site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>, or Email your request, including your address, phone number, OMB number, and CMS document identifier, to [Paperwork@cms.hhs.gov](mailto:Paperwork@cms.hhs.gov), or call the Reports Clearance Office on (410) 786-1326.

To be assured consideration, comments and recommendations for the

proposed information collections must be received by the OMB desk officer at the address below, no later than 5 p.m. on *March 1, 2013*.

OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395-6974, Email: [OIRA\\_submission@omb.eop.gov](mailto:OIRA_submission@omb.eop.gov).

Dated: January 24, 2013.

**Martique Jones,**

*Deputy Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[Document Identifier: CMS-276 and CMS-339]

#### Agency Information Collection Activities: Proposed Collection; Comment Request

**AGENCY:** Centers for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS) is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* Reinstatement with change of a previously approved collection; *Title:* Prepaid Health Plan Cost Report; *Use:* Health Maintenance Organizations and Competitive Medical Plans (HMO/CMPs) contracting with the Secretary under Section 1876 of the Social Security Act are required to submit a budget and enrollment forecast, semi-annual interim report, interim final cost report, and a final certified cost report in accordance with 42 CFR 417.572-417.576. Health Care Prepayment Plans

(HCPPs) contracting with the Secretary under Section 1833 of the Social Security Act are required to submit a budget and enrollment forecast, semi-annual interim report, and final cost report in accordance with 42 CFR 417.808 and 42 CFR 417.810. CMS is requesting approval for the reinstatement with change of Form CMS-276 (OCN: 0938-0165). This Cost Report outlines the provisions for implementing Section 1876(h) and Section 1833(a)(1)(A) of the Social Security Act. The purposes of the revisions were to implement some changes in response to the Affordable Care Act, clarify certain instructions, and update outdated issues within the Cost Report. *Form Number:* CMS-276 (OMB# 0938-0165); *Frequency:* Annually; *Affected Public:* Private Sector—Business or other for-profits and not-for-profit institutions; *Number of Respondents:* 29; *Total Annual Responses:* 106; *Total Annual Hours:* 1,384. (For policy questions regarding this collection contact Temeshia Johnson at 410-786-8692. For all other issues call 410-786-1326.)

2. *Type of Information Collection Request:* Reinstatement with change of a previously approved collection; *Title of Information Collection:* Medicare Provider Cost Report Reimbursement Questionnaire; *Use:* The purpose of Form CMS-339 is to assist the provider in preparing an acceptable cost report and to minimize subsequent contact between the provider and its Medicare Administrative Contractor (MAC). Form CMS-339 provides the basic data necessary to support the information in the cost report. Exhibit 1 of Form CMS-339 contains a series of reimbursement-oriented questions which serve to update information on the operations of the provider. It is arranged topically regarding financial activities such as independent audits, provider organization and operation, etc. The MAC is responsible for the settlement of the Medicare cost report and must determine the reasonableness and the accuracy of the reimbursement claimed. This process includes performing both a desk review of the cost report and an analysis leading to a decision to settle the cost report with or without further audit. Form CMS-339 provides essential information to enable the MAC to make the audit or no audit decision, scope of the audit if one is necessary, and to update the provider documentation (i.e., documentation to support the financial profile of the provider). If the information is not collected, the MAC will have to go onsite to each provider to get this information. Consequently, it

is far less burdensome and extremely cost effective to capture this information through the Form CMS-339.

Exhibit 2 of Form CMS-339 is a listing of bad debts pertaining to uncollectible Medicare deductible and coinsurance amounts. Preparation of the listing is a convenient way for providers to supply the MAC with information needed to determine the allow ability of the bad debts for reimbursement. Some items required to determine allow ability that are included on this exhibit are patient's name, dates of service, date first bill sent to beneficiary, and date the collection effort ceased. Supplying the MAC with this information may be all that is required for the MAC to determine whether or not the bad debt is allowable. This too may eliminate a visit to the provider to gather this needed data. *Form Number:* CMS-339 (OCN: 0938-0301); *Frequency:* Yearly; *Affected Public:* Private Sector—Business or other for-profits and not-for-profit institutions; *Number of Respondents:* 17,939; *Total Annual Responses:* 17,939; *Total Annual Hours:* 53,817. (For policy questions regarding this collection contact Christine Dobrzycki at 410-786-3389. For all other issues call 410-786-1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>, or Email your request, including your address, phone number, OMB number, and CMS document identifier, to [Paperwork@cms.hhs.gov](mailto:Paperwork@cms.hhs.gov), or call the Reports Clearance Office on (410) 786-1326.

In commenting on the proposed information collections please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in one of the following ways by *April 1, 2013*:

1. *Electronically.* You may submit your comments electronically to <http://www.regulations.gov>. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number \_\_\_\_\_, Room C4-26-05, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: January 24, 2013.

**Martique Jones,**

*Deputy Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No: FDA-2013-N-0001]

#### Science Board to the Food and Drug Administration; Notice of Meeting

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

*Name of Committee:* Science Board to the Food and Drug Administration (Science Board).

*General Function of the Committee:* The Science Board provides advice primarily to the Commissioner of Food and Drugs and other appropriate officials on specific complex scientific and technical issues important to the FDA and its mission, including emerging issues within the scientific community. Additionally, the Science Board provides advice to the Agency on keeping pace with technical and scientific developments including in regulatory science; and input into the Agency's research agenda; and on upgrading its scientific and research facilities and training opportunities. It will also provide, where requested, expert review of Agency-sponsored intramural and extramural scientific research programs.

*Date and Time:* The meeting will be held on Wednesday, February 27, 2013, from approximately 8:30 a.m. to 5:15 p.m.

*Location:* FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993. For those unable to attend in person, the meeting will also be webcast. The link for the webcast is available at <https://collaboration.fda.gov/scienceboard/>. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <http://www.fda.gov/AdvisoryCommittees/default.htm>; under the heading "Resources for You," click on "Public Meetings at the FDA White