

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>.
2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to [Paperwork@cms.hhs.gov](mailto:Paperwork@cms.hhs.gov).
3. Call the Reports Clearance Office at (410) 786-1326.

**FOR FURTHER INFORMATION CONTACT:** Reports Clearance Office at (410) 786-1326.

**SUPPLEMENTARY INFORMATION:** Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Hospital and Hospital Health Care Complex Cost Report; *Use:* Providers of services participating in the Medicare program are required under sections 1815(a) and 1861(v)(1)(A) of the Social Security Act (42 U.S.C. 1395g) to submit annual information to achieve settlement of costs for health care services rendered to Medicare beneficiaries. In addition, regulations at 42 CFR 413.20 and 413.24 require adequate cost data and cost reports from providers on an annual basis.

We are requesting the Office of Management and Budget review and approve this revision to the Form CMS-2552-10, Hospital and Hospital Health Care Complex Cost Report. These cost reports are filed annually by hospitals participating in the Medicare program to determine the reasonable costs incurred

to provide medical services to patients. The revisions made to the hospital cost report are in accordance with the statutory requirement for hospice payment reform in § 3132 of the Patient Protection and Affordable Care Act (ACA) (March 23, 2010) and the statutory requirement establishing a prospective payment system for Federally Qualified Health Centers in § 10501(i)(3)(A) of the ACA, codified in section 1834(o) of the Act. *Form Number:* CMS-2552-10 (OMB control number 0938-0050); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal Governments, Private sector (For-profit and Not-for-profit institutions); *Number of Respondents:* 6,157; *Total Annual Responses:* 6,157; *Total Annual Hours:* 4,143,661. (For policy questions regarding this collection contact Gail Duncan at 410-786-7278).

Dated: September 15, 2015.

**William N. Parham, III,**

*Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.*

[FR Doc. 2015-23462 Filed 9-17-15; 8:45 am]

**BILLING CODE 4120-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10261]

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

**ACTION:** Notice and withdrawal of previous notice.

**SUMMARY:** The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the 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.

**DATES:** Comments on the collection(s) of information must be received by the OMB desk officer by October 19, 2015.

As of September 18, 2015 and as described below under "Partial Withdrawal of Previous Notice," the CMS-10261-related portion of the notice that published on August 24, 2015 (80 FR 51275) is withdrawn.

**ADDRESSES:** When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send 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) that are 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.

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**FOR FURTHER INFORMATION CONTACT:** Reports Clearance Office at (410) 786-1326.

**SUPPLEMENTARY INFORMATION:** Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C.

3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request*: Revision of a currently approved collection; *Title of Information Collection*: Part C Medicare Advantage Reporting Requirements and Supporting Regulations; *Use*: There are a number of information users of Part C reporting data, including our central and regional office staff that use this information to monitor health plans and to hold them accountable for their performance, researchers, and other government agencies such as the Government Accounting Office. Health plans can use this information to measure and benchmark their performance.

Based on internal review, this notice withdraws a portion of a prior notice (August 24, 2015) concerning the same subject matter and corrects that notice by adding a new requirement which was inadvertently omitted from that notice. Specifically, we propose to add a new Payments to Providers reporting section to capture data related to MA organizations' value-based payments. Upon OMB approval, the Payments to Providers section would add 10 data elements.

HHS has developed four categories of value based payment: (1) Fee-for-service with no link to quality; (2) fee-for-service with a link to quality; (3) alternative payment models built on fee-for-service architecture; and (4) population-based payment. To compliment HHS' action, CMS is seeking to collect data from MA organizations about the proportion of their payments to providers made based on these four categories. The collected information would help us understand the extent and use of alternate payment models in the MA industry.

*Form Number*: CMS-10261 (OMB Control Number 0938-1054); *Frequency*: Yearly and semi-annually; *Affected Public*: Private sector (business or other for-profits); *Number of Respondents*: 561; *Total Annual Responses*: 3,508; *Total Annual Hours*: 182,023. (For policy questions regarding this collection contact Terry Lied at 410-786-8973).

#### Partial Withdrawal of Previous Notice

This document also withdraws a portion of a prior notice concerning the same CMS-10261-specific subject matter.

Specifically, on page 51276, in the second column, in the second paragraph, information collection CMS-10261 (OMB Control Number 0938-1054) that published in the **Federal Register** on August 24, 2015 (80 FR 51275) is hereby withdrawn.

Dated: September 15, 2015.

**William N. Parham, III,**

*Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.*

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**BILLING CODE 4120-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2015-N-3230]

#### Consumer Comments—Public Posting and Availability of Comments Submitted to Food and Drug Administration Dockets

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

**ACTION**: Notice.

**SUMMARY**: The Food and Drug Administration (FDA or Agency) is changing the Agency's long standing practice of not publically posting on <http://www.regulations.gov> comments submitted by individuals in their individual capacity. These are generally comments from people who self-identify as an "individual consumer" under the field titled "Category (Required)" on the "Your Information" page on <http://www.regulations.gov>. Changing FDA's practice to routinely post these comments, as we do other comments, will increase the transparency and public utility of FDA's public dockets. It will better enable our public dockets to function as intended: To share information and encourage an open exchange of ideas.

**DATES**: All comments submitted to any FDA docket on or after October 15, 2015, will be publically posted, unless otherwise determined not to be subject to posting as described in the **SUPPLEMENTARY INFORMATION** section.

**FOR FURTHER INFORMATION CONTACT**: Kenneth R. Cohen, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 3324, Silver Spring, MD 20993-0002, 301-796-7001.

**SUPPLEMENTARY INFORMATION**:

#### I. Background

Historically, FDA generally has not publicly posted on <http://www.regulations.gov> comments submitted by individuals in their individual capacity (and not on behalf of an organization, corporation, or other entity). For comments submitted through <http://www.regulations.gov>, for example, such comments are identified as "Individual Consumer" under the field titled "Category (Required)" on the "Your Information" page. This non-posting practice has applied only to individual consumer comments which otherwise would be displayed on <http://www.regulations.gov>. These comments have been placed in the official FDA docket and are publicly available in FDA's Reading Room or through Freedom of Information Act requests and have been considered by the Agency in finalizing its regulatory actions.

FDA is changing this practice and will post such consumer comments on <http://www.regulations.gov>, as it posts other comments. FDA has made this change so that its public dockets better serve their purpose of promoting transparency and the sharing of information.

In 1995, FDA explained that it routinely reviewed all comments for obvious confidential information before placing the comments in the docket (60 FR 66982), but this practice is no longer feasible given factors such as the volume of comments FDA receives and the adoption of a government-wide electronic portal system for submitting and posting comments at <http://www.regulations.gov>. FDA developed the practice of not posting individual consumer comments largely because of concerns about disclosing personal information of individuals who may not have realized, when submitting their comments, that their name, address, and other identifying information would be publicly viewable. This public viewability became more obvious as the Internet gained popularity and particularly when FDA dockets system was merged with the government-wide portal system for submission of all public comments on government regulatory actions at <http://www.regulations.gov> in 2007. This practice has been precautionary because, as FDA has stated previously, "there can be no reasonable expectation of confidentiality for information submitted to a public docket in a rulemaking proceeding."<sup>1</sup> With the advent of <http://www.regulations.gov>,

<sup>1</sup> 60 FR 66981, at 66982 (December 27, 1995).