

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS-10387, CMS-10110 and CMS-10393]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Department of Health and Human

Services.

ACTION: 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 (the 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 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates 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 must be received by **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

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:

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.

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:

- Access CMS' Web Site address at http://www.cms.hhs.gov/PaperworkReductionActof1995.
- 2. E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to 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:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see ADDRESSES).

- CMS-10387 Skilled Nursing Facility (SNF) Prospective Payment System and Consolidated
 Billing
- CMS-10110 Manufacturer Submission of Average Sales Price (ASP) Data for Medicare Part B

 Drugs and Biologicals
- CMS-10393 Medicare Beneficiary and Family-Centered Satisfaction Survey

Under the 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 requires federal agencies to publish a 60-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.

Information Collection

1. <u>Type of Information Collection Request</u>: Reinstatement of a previously approved collection; <u>Title of Information Collection</u>: Skilled Nursing Facility (SNF) Prospective Payment System and Consolidated Billing; <u>Use</u>: We are requesting approval of a reinstatement of a Change of Therapy OMRA for Skilled Nursing Facilities (SNFs). As described in CMS-1351-F, we finalized the assessment effective October 1, 2011. SNFs are required to submit this

assessment. The COT OMRA is comprised of a subset of resident assessment information developed for use by SNFs to satisfy a Medicare payment requirement. The burden associated with this is the SNF staff time required to complete the COT OMRA, SNF staff time to encode the data, and SNF staff time spent in transmitting the data. SNFs are required to complete a COT OMRA when a SNF resident was receiving a sufficient level of rehabilitation therapy to qualify for an Ultra High, Very High, High, Medium, or Low Rehabilitation category and when the intensity of therapy (as indicated by the total reimbursable therapy minutes (RTM) delivered, and other therapy qualifiers such as number of therapy days and disciplines providing therapy) changes to such a degree that it would no longer reflect the RUG-IV classification and payment assigned for a given SNF resident based on the most recent assessment used for Medicare payment. The COT OMRA is a type of required PPS assessment which uses the same item set as the End of Therapy (EOT) OMRA. Form Number: CMS-10387 (OMB Control Number: 0938-1140); Frequency: Yearly; Affected Public: Private sector (Business or other For-profits and Not-for-profit institutions); Number of Respondents: 15,421; Total Annual Responses: 678,524; Total Annual Hours: 701,119. (For policy questions regarding this collection contact Penny Gershman at 410-786-6643).

2. Type of Information Collection Request: Reinstatement of a previously approved collection; Title of Information Collection: Manufacturer Submission of Average Sales Price (ASP) Data for Medicare Part B Drugs and Biologicals; Use: In accordance with section 1847A of the Social Security Act (the Act), Medicare Part B covered drugs and biologicals not paid on a cost or prospective payment basis are paid based on the average sales price (ASP) of the drug or biological, beginning in Calendar Year (CY) 2005. The ASP data reporting requirements are specified in section 1927 of the Act. The reported ASP data are used to establish the Medicare

payment amounts. The reporting template was revised in CY 2011 in order to facilitate accurate collection of ASP data. An accompanying user guide with instructions on the template's use was also created and included an explanation of the data elements in the template. Form

Number: CMS-10110 (OMB Control Number: 0938-0921); Frequency: Quarterly; Affected Public: Private sector (Business or other For-profits); Number of Respondents: 180; Total Annual Responses: 720; Total Annual Hours: 34,560. (For policy questions regarding this collection contact Amy Gruber at 410-786-1542).

- 3. Type of Information Collection Request: Extension of a previously approved collection; Title of Information Collection: Medicare Beneficiary and Family-Centered Satisfaction Survey; Use: The data collection methodology used to determine Beneficiary Satisfaction flows from the proposed sampling approach. Based on recent literature on survey methodology and response rates by mode, we recommend using a data collection that is done primarily by mail. A mail-based methodology will achieve the goals of being efficient, effective, and minimally burdensome for beneficiary respondents. We anticipate that a mail-based methodology could yield a response rate of approximately 60 percent. In order to achieve this response rate, we would recommend a 3 staged approach to data collection:
- (1) Mailout of a covering letter, the paper survey questionnaire, and a postage-paid return envelope.
- (2) Mailout of a post card that thanks respondents and reminds the non-respondents to please return their survey.
- (3) Mailout of a follow-up covering letter, the paper survey questionnaire, and a postage-paid return envelope.

Through the pilot test, we will determine the response rate that can be achieved using this

approach. If it is deemed necessary, a prenotification letter, additional mailout reminders and a

telephone non-response step can be added to the protocol to achieve desired response rate.

Form Number: CMS-10393 (OMB Control number: 0938-1177); Frequency: Once; Affected

<u>Public</u>: Individuals or households; <u>Number of Respondents</u>: 16,010; <u>Number of Responses</u>:

16,010; <u>Total Annual Hours</u>: 4,002. (For policy questions regarding this collection, contact

Coles Mercier at 410-786-2112.)

Dated: July 16, 2015.

William N. Parham, III,

Director,

Paperwork Reduction Staff,

Office of Strategic Operations and Regulatory Affairs.

Billing Code: 4120-01-U-P

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