



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS-10110, CMS-10387, CMS-10400 and CMS-10593]

Agency Information Collection Activities: Submission for OMB Review; Comment Request
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 (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 **[Insert date 30 days after date of publication in the Federal Register]**:

ADDRESSES: When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and

recommendations must be received by the OMB desk officer via one of the following transmissions:

OMB, Office of Information and Regulatory Affairs

Attention: CMS Desk Officer

Fax Number: (202) 395-5806 OR

E-mail: OIRA_submission@omb.eop.gov

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. 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: 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: Reinstatement of a previously approved collection; Title of Information Collection: Skilled Nursing Facility (SNF) Prospective Payment System and Consolidated Billing; Use: 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. The 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. The 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: Revision of a currently approved collection; Title of Information Collection: Establishment of Exchanges and Qualified Health Plans; Use: The Patient Protection and Affordable Care Act, Public Law 111-148, enacted on March 23,

2010, and the Health Care and Education Reconciliation Act, Public Law 111-152, enacted on March 30, 2010 (collectively, “Affordable Care Act”), expand access to health insurance for individuals and employees of small businesses through the establishment of new Affordable Insurance Exchanges (Exchanges), including the Small Business Health Options Program (SHOP).

As directed by the rule *Establishment of Exchanges and Qualified Health Plans; Exchange Standards for Employers* (77 FR 18310) (Exchange rule), each Exchange will assume responsibilities related to the certification and offering of Qualified Health Plans (QHPs). To offer insurance through an Exchange, a health insurance issuer must have its health plans certified as QHPs by the Exchange. A QHP must meet certain minimum certification standards, such as network adequacy, inclusion of Essential Community Providers (ECPs), and non-discrimination. The Exchange is responsible for ensuring that QHPs meet these minimum certification standards as described in the Exchange rule under 45 CFR 155 and 156, based on the Affordable Care Act, as well as other standards determined by the Exchange. The reporting requirements and data collection in the Exchange rule address Federal requirements that various entities must meet with respect to the establishment and operation of an Exchange; minimum requirements that health insurance issuers must meet with respect to participation in a State based or Federally-facilitated Exchange; and requirements that employers must meet with respect to participation in the SHOP and compliance with other provisions of the Affordable Care Act. This proposed information collection was published in the Federal Register on November 23, 2015 (80 FR 72968). No comments were received. Form Number: CMS-10400;

Frequency: Monthly, Annual; Affected Public: Private Sector; Number of Respondents: 11,004; Number of Responses: 11,485; Total Annual Hours: 55,775. (For policy questions regarding this collection, contact Leigha Basini at 301-492-4380.)

4. Type of Information Collection Request: New collection (Request for a new OMB control number); Title of Information Collection: Establishment of an Exchange by a State and Qualified Health Plans; Use: The Patient Protection and Affordable Care Act, Public Law 111-148, enacted on March 23, 2010, and the Health Care and Education Reconciliation Act, Public Law 111-152, enacted on March 30, 2010 (collectively, “Affordable Care Act”), expand access to health insurance for individuals and employees of small businesses through the establishment of new Affordable Insurance Exchanges (Exchanges), including the Small Business Health Options Program (SHOP). As directed by the rule *Establishment of Exchanges and Qualified Health Plans; Exchange Standards for Employers* (77 FR 18310) (Exchange rule), each Exchange will assume responsibilities related to the certification and offering of Qualified Health Plans (QHPs). To offer insurance through an Exchange, a health insurance issuer must have its health plans certified as QHPs by the Exchange. A QHP must meet certain minimum certification standards, such as network adequacy, inclusion of Essential Community Providers (ECPs), and non-discrimination. The Exchange is responsible for ensuring that QHPs meet these minimum certification standards as described in the Exchange rule under 45 CFR 155 and 156, based on the Affordable Care Act, as well as other standards determined by the Exchange. The reporting requirements and data collection in the Exchange rule address Federal requirements that various entities must meet with respect to the establishment and operation of an Exchange;

minimum requirements that health insurance issuers must meet with respect to participation in a State based or Federally-facilitated Exchange; and requirements that employers must meet with respect to participation in the SHOP and compliance with other provisions of the Affordable Care Act. Comments have been received, however; there were no comments that impacted the burden, and therefore no additional changes were made. Form Number: CMS-10593 (OMB Control Number: 0938-NEW); Frequency: Annually, Monthly; Affected Public: Private Sector; Business or other for-profit; Number of Respondents: 20; Total Annual Responses: 400; Total Annual Hours: 36,900. (For policy questions regarding this collection contact Christy Woods at 301-492-5140.)

Date: March 1, 2016

William N. Parham, III

Director, Paperwork Reduction Staff

Office of Strategic Operations and Regulatory Affairs

Billing Code: 4120-01-U-P

[FR Doc. 2016-04841 Filed: 3/3/2016 8:45 am; Publication Date: 3/4/2016]