

and guidance for programs addressing IVP have been provided through cooperative agreement funding and technical assistance administered by NCIPC. Awardees report progress and activity information to NCIPC on an annual schedule using three documents: Annual Progress Report, Evaluation and Performance Management Plan, and Injury Indicator Spreadsheet. Burden is expected to vary based on awardee funding type. For example all awardees who successfully compete will be funded for the BASE component.

However, awardees will also have the opportunity to compete to be funded for one or both of the Enhanced components. It is expected that those funded for Enhanced components will have a greater burden, given the requirement to report on more domains of activity.

Information to be collected will provide crucial data for program performance monitoring and provide CDC with the capacity to respond in a timely manner to requests for information about the program from the Department of Health and Human

Services (HHS), the White House, Congress, and other sources. Information to be collected will also strengthen CDC's ability to monitor awardee progress, provide data-driven technical assistance, and disseminate the most current surveillance data on unintentional and intentional injuries.

The total estimated annualized burden for this collection is 3,120 hours. OMB approval is requested for three years. The only cost to respondents will be time spent on responding to the progress reports.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Core SVIPP BASE Awardees	Initial Population—Annual Progress Report ..	20	1	22
	Annual Progress Report	20	1	11
	Evaluation and Performance Management Plan.	20	1	2
	Injury Indicator Spreadsheet	20	1	14
Core SVIPP 1—Enhanced Component Awardees.	Initial Population—Annual Progress Report ..	5	1	73
	Annual Progress Report	5	1	58
	Evaluation and Performance Management Plan.	5	1	3
	Injury Indicator Spreadsheet	5	1	14
Core SVIPP 2—Enhanced Component Awardees.	Initial Population—Annual Progress Report ..	5	1	146
	Annual Progress Report	5	1	116
	Evaluation and Performance Management Plan.	5	1	4
	Injury Indicator Spreadsheet	5	1	14

Leroy A. Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

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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 April 4, 2016.

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 Email: 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. Email 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 parts 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 parts 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.)

Dated: March 1, 2016.

William N. Parham, III,

Director, Paperwork Reduction Staff, 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-10152]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

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 May 3, 2016.

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.

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 the 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.

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-10152 Data Collection for Medicare Beneficiaries Receiving NaF-18 Positron Emission Tomography (PET) To Identify Bone Metastasis in Cancer

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.

1. *Type of Information Collection Request:* Extension of a previously approved collection; *Title:* Data Collection for Medicare Beneficiaries Receiving NaF-18 Positron Emission Tomography (PET) to Identify Bone Metastasis in Cancer; *Use:* In Decision Memorandum #CAG-00065R, issued on February 26, 2010, the Centers for Medicare and Medicaid Services (CMS) determined that the evidence is sufficient to conclude that for Medicare beneficiaries receiving NaF-18 PET scan to identify bone metastasis in cancer is reasonable and necessary only when the provider is participating in and patients are enrolled in a clinical study designed to information at the time of the scan to assist in initial antitumor treatment planning or to guide subsequent treatment strategy by the identification, location and quantification of bone metastases in beneficiaries in whom bone metastases are strongly suspected based on clinical symptoms or the results of other diagnostic studies. Qualifying clinical studies must ensure that specific hypotheses are addressed; appropriate data elements are collected; hospitals and providers are qualified to provide the PET scan and interpret the results; participating hospitals and