

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 January 7, 2014:

**ADDRESSES:** When commenting, please reference the document identifier or OMB control number (OCN). 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 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:**

**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-R-216 Procedures for Advisory Opinions Concerning Physicians' Referrals and Supporting Regulations**

Under the Paperwork Reduction Act (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 Collections**

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Procedures for Advisory Opinions Concerning Physicians' Referrals and Supporting Regulations; *Use:* The information collection requirements contained in 42 CFR 411.372 and 411.373 allow us to consider requests for advisory opinions and provide accurate and useful opinions. The information is read and analyzed to develop and issue an advisory opinion to the individual or entity that submitted the information. The primary office using the information is the Center for Medicare, which is responsible for the issuance of advisory opinions. *Form Number:* CMS-R-216 (OCN: 0938-0714); *Frequency:* Occasionally; *Affected Public:* Private sector—Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 25; *Total Annual Responses:* 25; *Total Annual Hours:* 500. (For policy questions regarding this collection contact Jacqueline Proctor at 410-786-0661).

Dated: November 5, 2013.

**Martique Jones**

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

[FR Doc. 2013-26829 Filed 11-7-13; 8:45 am]

**BILLING CODE 4120-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Medicare & Medicaid Services**

[Document Identifiers: CMS-10171, CMS-10207, CMS-10476, CMS-10497, CMS-10482, CMS-R-245 and CMS-10495]

**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 December 9, 2013.

**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) 395-6974 OR Email: [OIRA\\_submission@omb.eop.gov](mailto: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](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:* Coordination of Benefits Between Part D Plans and Other Prescription Coverage Providers; *Use:* We will use the information along with Part D plans, other health insurers or payers, and pharmacies to coordinate prescription drug benefits provided to Medicare beneficiaries. *Form Number:* CMS-10171 (OCN: 0938-0978); *Frequency:* Occasionally; *Affected Public:* Private sector—Business or other for-profits; *Number of Respondents:* 57,116; *Total Annual Responses:* 2,402,582; *Total Annual Hours:* 5,205,128. (For policy questions regarding this collection contact Heather Rudo at 410-786-7627.)

2. *Type of Information Collection Request:* Reinstatement without change of a previously approved collection; *Title of Information Collection:* Physician Self-Referral Exceptions for Electronic Prescribing and Electronic Health Records; *Use:* The collected information would be used for enforcement purposes. Specifically, if we were investigating the financial relationships between donors and physicians to determine whether the provisions in the exceptions at 42 CFR 411.357 (v) and (w) were met, first, we would review the written agreements

that indicate what items and services each entity intended to provide. *Form Number:* CMS-10207 (OCN: 0938-1009); *Frequency:* Monthly; *Affected Public:* Private sector—Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 9,409; *Total Annual Responses:* 17,744; *Total Annual Hours:* 1,896. (For policy questions regarding this collection contact Michael Zleit at 410-786-2050.)

3. *Type of Information Collection Request:* New collection (Request for a new OMB control number); *Title of Information Collection:* Medical Loss Ratio (MLR) Report for Medicare Advantage (MA) Plans and Prescription Drug Plans (PDP); *Use:* We will use the data collection of annual reports provided by plan sponsors for each contract to ensure that beneficiaries are receiving value for their premium dollar by calculating each contract's medical loss ratio (MLR) and any remittances due for the respective MLR reporting year. The recordkeeping requirements will be used to determine plan sponsors' compliance with the MLR requirements, including compliance with how plan sponsors' experience is to be reported, and how their MLR and any remittances are calculated. *Form Number:* CMS-10476 (OCN: 0938-New); *Frequency:* Yearly; *Affected Public:* Private sector—Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 616; *Total Annual Responses:* 616; *Total Annual Hours:* 130,004. (For policy questions regarding this collection contact Ilina Chaudhuri at 410-786-8628.)

4. *Type of Information Collection Request:* New collection (Request for a new OMB control number); *Title of Information Collection:* Evaluation of the Medicare Health Care Quality (MHCQ) Demonstration Evaluation: Focus Group and Interview Protocols; *Use:* The Medicare Health Care Quality (MHCQ) Demonstration was developed to address concerns about the U.S. health care system, which typically fragments care while also encouraging both omissions in and duplication of care. To rectify this situation, Congress has directed us to test major changes to the delivery and payment systems to improve the quality of care while also increasing efficiency across the health care system. This would be achieved through several types of interventions: adoption and use of information technology and decision support tools by physicians and their patients, such as evidence-based medicine guidelines, best practice guidelines, and shared decision-making programs; reform of payment methodologies; improved coordination of care among payers and

providers serving defined communities; measurement of outcomes; and enhanced cultural competence in the delivery of care.

The MHCQ Demonstration programs are designed to examine the extent to which major, multifaceted changes to traditional Medicare's health delivery and financing systems lead to improvements in the quality of care provided to Medicare beneficiaries without increasing total program expenditures. Each demonstration site uses a different approach for changing health delivery and financing systems, but all share the goal of improving the quality and efficiency of medical care provided to Medicare beneficiaries. Focus groups and individual interviews will be conducted at 2 demonstration sites that are active in the demonstration: Gundersen Health System (GHS) and Meridian Health System (MHS).

This MHCQ Demonstration evaluation will include analysis of both quantitative and qualitative sources of information. This multifaceted approach will enable this evaluation to consider a broad variety of evidence for evaluating the nature and impact of each site's interventions. We are seeking approval to conduct in-person focus groups and individual interviews with beneficiaries and their caregivers to inform our evaluation of the MHCQ Demonstration at the GHS and MHS demonstration sites. *Form Number:* CMS-10497 (OCN: 0938-New); *Frequency:* Occasionally; *Affected Public:* Individuals or households; *Number of Respondents:* 36; *Total Annual Responses:* 36; *Total Annual Hours:* 108. (For policy questions regarding this collection contact Normandy Brangan at 410-786-6640.)

5. *Type of Information Collection Request:* New Collection (Request for a new OMB control number); *Title of Information Collection:* Evaluation of the Physician Quality Reporting System (PQRS) and Electronic Prescribing (eRx) Incentive Program; *Use:* The Physician Quality Reporting System (PQRS) was first implemented in 2007 as an incentive for voluntary reporting of quality measures in accordance with a section of the Tax Relief and Health Care Act of 2006. The PQRS was further extended and enhanced by legislation such as the Medicare, Medicaid, and State Children's Health Insurance Program (SCHIP) Extension Act of 2007 (MMSEA) and the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA). A number of changes have been made to the PQRS, including group measures, the group reporting option, and

additional measures. The PQRS was extended further with the enactment of MMSEA. The MMSEA provided professionals greater flexibility for participating in the PQRS for 2008 and 2009 by authorizing us to establish alternative reporting criteria and alternative reporting periods for the reporting measures groups and for the submission of data on the PQRS quality measures through clinical data registries. The MIPPA, enacted in July 2008, made the PQRS program permanent, further enhanced the PQRS, and established a new standalone incentive program for successful electronic prescribers.

The eRx Incentive Program, the other program being evaluated in this project, was first implemented in 2009. The eRx is another incentive reporting program that uses a combination of incentive payments and payment adjustments to encourage eRx by eligible professionals. The program provides an incentive payment to practices with eligible professionals who successfully e-prescribe for covered Physician Fee Schedule services furnished to Medicare Part B Fee-For-Service (FFS) beneficiaries. Eligible professionals do not need to participate in PQRS to participate in the eRx Incentive Program.

In support of an evaluation the PQRS and the eRx Incentive Program, we will conduct three surveys. The surveys will include: Medicare beneficiaries, eligible professionals, and administrators. This evaluation is designed to determine how well the PQRS and the eRx Incentive Program are contributing to better and affordable health care for Medicare beneficiaries. The PQRS is a voluntary reporting program that provides an incentive payment to eligible professionals who satisfactorily report data on quality measures. We use quality measures to promote improvements in care delivery and payment and to increase transparency. The PQRS program rewards eligible professionals based on a percentage of the estimated Medicare Physician Fee Schedule of their allowed Part B charges if they meet the defined reporting requirements. The PQRS was initially referred to as the Physician Quality Reporting Initiative (PQRI).

Subsequent to the publication of the 60-day **Federal Register** notice (78 FR 35936), there has been an increase in burden due to the increase in the sample size of eligible professionals and administrators. Also, the surveys have been changed by revising lists of specialties and revising questions. *Form Number:* CMS-10482 (OCN: 0938-NEW); *Frequency:* Yearly; *Affected*

*Public:* Individuals and households, Private sector—Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 12,650; *Total Annual Responses:* 12,650; *Total Annual Hours:* 3,805. (For policy questions regarding this collection contact Lauren Fuentes at 410-786-2290.)

6. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* OASIS Collection Requirements as Part of the CoPs for HHAs and Supporting Regulations; *Use:* The Outcome and Assessment Information Set (OASIS) is currently mandated for use by Home Health Agencies (HHAs) as a condition of participation (CoP) in the Medicare program. Since 1999, the Medicare CoPs have mandated that HHAs use the OASIS data set when evaluating adult non-maternity patients receiving skilled services. The OASIS is a core standard assessment data set that agencies integrate into their own patient-specific, comprehensive assessment to identify each patient's need for home care that meets the patient's medical, nursing, rehabilitative, social, and discharge planning needs. Subsequent to the publication of the 60-day **Federal Register** notice (78 FR 37542), the data set was revised by rewording the text. *Form Number:* CMS-R-245 (OCN: 0938-0760); *Frequency:* Occasionally; *Affected Public:* Private Sector—Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 12,014; *Total Annual Responses:* 17,268,890; *Total Annual Hours:* 15,305,484. (For policy questions regarding this collection contact Robin Dowell at 410-786-0060.)

7. *Type of Information Collection Request:* New collection (Request for a new OMB control number); *Title of Information Collection:* Registration, Attestation, Dispute & Resolution, Assumptions Document and Data Retention Requirements for Open Payments; *Use:* Section 6002 of the Affordable Care Act added section 1128G to the Social Security Act (Act), which requires applicable manufacturers and applicable group purchasing organizations (GPOs) of covered drugs, devices, biologicals, or medical supplies to report annually to CMS certain payments or other transfers of value to physicians and teaching hospitals, as well as, certain information regarding the ownership or investment interests held by physicians or their immediate family members in applicable manufacturers or applicable GPOs.

Specifically, applicable manufacturers of covered drugs, devices, biologicals, and medical supplies are required to submit on an annual basis the information required in section 1128G(a)(1) of the Act about certain payments or other transfers of value made to physicians and teaching hospitals (collectively called covered recipients) during the course of the preceding calendar year. Similarly, section 1128G(a)(2) of the Act requires applicable manufacturers and applicable GPOs to disclose any ownership or investment interests in such entities held by physicians or their immediate family members, as well as information on any payments or other transfers of value provided to such physician owners or investors. Applicable manufacturers must report the required payment and other transfer of value information annually to CMS in an electronic format. The statute also provides that applicable manufacturers and applicable GPOs must report annually to CMS the required information about physician ownership and investment interests, including information on any payments or other transfers of value provided to physician owners or investors, in an electronic format by the same date. Applicable manufacturers and applicable GPOs are subject to civil monetary penalties (CMPs) for failing to comply with the reporting requirements of the statute. We are required by statute to publish the reported data on a public Web site. The data must be downloadable, easily searchable, and aggregated. In addition, we must submit annual reports to the Congress and each state summarizing the data reported. Finally, section 1128G of the Act generally preempts state laws that require disclosure of the same type of information by manufacturers.

We published a final rule in 2013 to implement this program, which included several information collections subject to the Paperwork Reduction Act. This information collection request is to inform the public about information collected that is necessary for registration, attestation, dispute resolution and corrections, record retention, and submitting an assumptions document within Open Payments. *Form Number:* CMS-10495 (OCN: 0938-New); *Frequency:* Once; *Affected Public:* Private sector—Business or other for-profits; *Number of Respondents:* 451,582; *Total Annual Responses:* 451,582; *Total Annual Hours:* 949,005. (For policy questions regarding this collection contact Melissa Heesters at 410-786-0618.)

Dated: November 5, 2013.

**Martique Jones,**

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

[FR Doc. 2013-26822 Filed 11-7-13; 8:45 am]

**BILLING CODE 4120-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Medicare & Medicaid Services**

[CMS-9081-N]

**Medicare and Medicaid Programs; Quarterly Listing of Program Issuances—July Through September 2013**

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

**ACTION:** Notice.

**SUMMARY:** This quarterly notice lists CMS manual instructions, substantive

and interpretive regulations, and other **Federal Register** notices that were published from July through September 2013, relating to the Medicare and Medicaid programs and other programs administered by CMS.

**FOR FURTHER INFORMATION CONTACT:** It is possible that an interested party may need specific information and not be able to determine from the listed information whether the issuance or regulation would fulfill that need. Consequently, we are providing contact persons to answer general questions concerning each of the addenda published in this notice.

Addenda	Contact	Phone Number
<b>I</b> CMS Manual Instructions	Ismael Torres	(410) 786-1864
<b>II</b> Regulation Documents Published in the <b>Federal Register</b>	Terri Plumb	(410) 786-4481
<b>III</b> CMS Rulings	Tiffany Lafferty	(410)786-7548
<b>IV</b> Medicare National Coverage Determinations	Wanda Belle	(410) 786-7491
<b>V</b> FDA-Approved Category B IDEs	John Manlove	(410) 786-6877
<b>VI</b> Collections of Information	Mitch Bryman	(410) 786-5258
<b>VII</b> Medicare -Approved Carotid Stent Facilities	Lori Ashby	(410) 786-6322
<b>VIII</b> American College of Cardiology-National Cardiovascular Data Registry Sites	Marie Casey, BSN, MPH	(410) 786-7861
<b>IX</b> Medicare's Active Coverage-Related Guidance Documents	Lori Ashby	(410) 786-6322
<b>X</b> One-time Notices Regarding National Coverage Provisions	Lori Ashby	(410) 786-6322
<b>XI</b> National Oncologic Positron Emission Tomography Registry Sites	Stuart Caplan, RN, MAS	(410) 786-8564
<b>XII</b> Medicare-Approved Ventricular Assist Device (Destination Therapy) Facilities	Marie Casey, BSN, MPH	(410) 786-7861
<b>XIII</b> Medicare-Approved Lung Volume Reduction Surgery Facilities	Marie Casey, BSN, MPH	(410) 786-7861
<b>XIV</b> Medicare-Approved Bariatric Surgery Facilities	Kate Tillman, RN, MAS	(410) 786-9252
<b>XV</b> Fluorodeoxyglucose Positron Emission Tomography for Dementia Trials	Stuart Caplan, RN, MAS	(410) 786-8564
<b>All Other Information</b>	Annette Brewer	(410) 786-6580

**I. Background**

The Centers for Medicare & Medicaid Services (CMS) is responsible for administering the Medicare and Medicaid programs and coordination and oversight of private health insurance. Administration and oversight of these programs involves the following: (1) Furnishing information to Medicare and Medicaid beneficiaries, health care providers, and the public; and (2) maintaining effective communications with CMS regional offices, state governments, state Medicaid agencies, state survey agencies, various providers of health care, all Medicare contractors that process claims and pay bills, National Association of Insurance Commissioners (NAIC), health insurers, and other stakeholders. To implement the various statutes on which the programs are based, we issue regulations under the authority granted to the Secretary of the Department of Health and Human Services under sections 1102, 1871, 1902, and related provisions of the Social Security Act (the Act) and Public Health Service Act. We also issue various manuals, memoranda, and

statements necessary to administer and oversee the programs efficiently.

Section 1871(c) of the Act requires that we publish a list of all Medicare manual instructions, interpretive rules, statements of policy, and guidelines of general applicability not issued as regulations at least every 3 months in the **Federal Register**.

**II. Revised Format for the Quarterly Issuance Notices**

While we are publishing the quarterly notice required by section 1871(c) of the Act, we will no longer republish duplicative information that is available to the public elsewhere. We believe this approach is in alignment with CMS' commitment to the general principles of the President's Executive Order 13563 released January 2011 entitled "Improving Regulation and Regulatory Review," which promotes modifying and streamlining an agency's regulatory program to be more effective in achieving regulatory objectives. Section 6 of Executive Order 13563 requires agencies to identify regulations that may be "outmoded, ineffective, insufficient, or excessively burdensome, and to modify, streamline, expand or repeal

them in accordance with what has been learned." This approach is also in alignment with the President's Open Government and Transparency Initiative that establishes a system of transparency, public participation, and collaboration.

Therefore, this quarterly notice provides only the specific updates that have occurred in the 3-month period along with a hyperlink to the full listing that is available on the CMS Web site or the appropriate data registries that are used as our resources. This information is the most current up-to-date information and will be available earlier than we publish our quarterly notice. We believe the Web site list provides more timely access for beneficiaries, providers, and suppliers. We also believe the Web site offers a more convenient tool for the public to find the full list of qualified providers for these specific services and offers more flexibility and "real time" accessibility. In addition, many of the Web sites have listservs; that is, the public can subscribe and receive immediate notification of any updates to the Web site. These listservs avoid the need to check the Web site, as notification of