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 **[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) 395-6974 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: 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 website. 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

Billing Code: 4120-01-U-P

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