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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10185 and CMS-10328]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid 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:

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. E-mail 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-10185 Medicare Part D Reporting Requirements and Supporting Regulations

## CMS-10328 Medicare Self-Referral Disclosure Protocol

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: Revision of a currently approved collection; Title of Information Collection: Medicare Part D Reporting Requirements and Supporting Regulations; Use: Data collected via Medicare Part D Reporting Requirements will be an integral resource for oversight, monitoring, compliance and auditing activities necessary to ensure quality provision of the Medicare Prescription Drug Benefit to beneficiaries. For all reporting sections, data are reported electronically to CMS. Each reporting section is reported at one of the following levels: Contract (data should be entered at the H#, S#, R#, or E# level) or Plan (data should be entered at the Plan Benefit Package (PBP level, e.g. Plan 001 for contract H#, R#, S#, or E). Sponsors should retain documentation and data records related to their data submissions. Data will be validated, analyzed, and utilized for trend reporting by the Division of Clinical and Operational Performance (DCOP) within the Medicare Drug Benefit and C & D Data Group. If outliers or other data anomalies are detected, DCOP will work in collaboration with other Divisions within CMS for follow-up and resolution. For CY2017 Reporting Requirements, the following 7 reporting sections will be reported

and collected at the Contract-level or Plan-level: Enrollment and Disenrollment, Retail, Home Infusion, and Long-Term Care Pharmacy Access, Medication Therapy Management (MTM) Programs, Grievances, Improving Drug Utilization Review Controls, Coverage Determinations and Redeterminations, and Employer/Union Sponsored Sponsors. Form Number: CMS-10185 (OMB control number: 0938-0992); Frequency: Annually and semi-annually; Affected Public: Private sector (Business or other for-profits); Number of Respondents: 561; Total Annual Responses: 11,438; Total Annual Hours: 14,750. (For policy questions regarding this collection contact Chanelle Jones at 410-786-8008).

2. Type of Information Collection Request: Revision of a currently approved collection; Title of Information Collection: Medicare Self-Referral Disclosure Protocol; Use: The Affordable Care Act (“ACA”) was enacted on March 23, 2010. Section 6409 of the ACA requires the Secretary of the Department of Health and Human Services (the “Secretary”), in cooperation with the Office of Inspector General of the Department of Health and Human Services, to establish a Medicare self-referral disclosure protocol (“SRDP”). The SRDP enables providers of services and suppliers to self-disclose actual or potential violations of the physicianself-referral statute, section 1877 of the Social Security Act (the “Act”). Section 6409(b) of the ACA gives the Secretary the authority to reduce the amount due and owing for all violations of section 1877 of the Act. In establishing the amount by which an overpayment may be reduced, the Secretary may consider: the nature and extent of the improper or illegal practice; the timeliness of the self-disclosure; the cooperation in providing additional information related to the disclosure; and such other factors as the Secretary considers appropriate.

In accordance with the ACA, CMS established the SRDP on September 23, 2010, and information concerning how to disclose an actual or potential violation of section 1877 of the Act was posted on the CMS website. The most recent approval of this information collection request (“ICR”) was issued

by the Office of Management and Budget on August 26, 2014.

We are now seeking approval to revise the currently approved ICR. Under the currently approved collection, a party must provide a financial analysis of overpayments arising from actual or potential violations of section 1877 of the Act based on a 4-year lookback period. On February 12, 2016, CMS published a final rule on the reporting and returning of overpayments. See CMS- 6037-F, Medicare Program; Reporting and Returning of Overpayments, 81 FR 7654 (Feb. 12, 2016) (the “final overpayment rule”). The final overpayment rule establishes a 6-year lookback period for reporting and returning overpayments. We are revising the information collection for the SRDP to reflect the 6-year lookback period established by the final overpayment rule. This revision is necessary to ensure that parties submitting self-disclosures to the SRDP report overpayments for the entire 6-year lookback period. The 6-year lookback period applies *only* to submissions to the SRDP received *on or after* March 14, 2016, the effective date of the final overpayment rule; parties submitting self-disclosures to the SRDP prior to March 14, 2016 need only provide a financial analysis of potential overpayments based on a 4-year lookback period.

We are also taking the opportunity to streamline and simplify the SRDP by issuing a required form for SRDP submissions. The SRDP Form will reduce the burden on disclosing parties by reducing the amount of information that is required for submissions to the SRDP and providing a streamlined and standardized format for the presentation of the required information. Form Number: CMS-10328 (OMB control number: 0938-1106); Frequency: Annually and semi-annually; Affected Public: Private sector (Business or other for-profits and Not-for-profits); Number of Respondents: 200; Total Annual Responses: 200; Total Annual Hours: 5,000. (For policy questions regarding this collection contact Matt Edgar at 410-786-0698).

Dated: May 3, 2016

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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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