

Information Collection

1. Type of Information Collection

Request: Revision of a currently approved collection; *Title of Information Collection:* Solicitation for Applications for Medicare Prescription Drug Plan 2015 Contracts; *Use:* The information will be collected under the solicitation of proposals from PDP, MA-PD, Cost Plan, PACE, and EGWP applicants. We will use the information to ensure that applicants meet our requirements and support the determination of contract awards. Participation in the Part D program is voluntary in nature. Only organizations that are interested in participating in the program will respond to the solicitation. The MA-PDs that voluntarily participate in the Part C program must submit a Part D application and successful bid. *Form Number:* CMS-10137 (OMB control number: 0938-0936); *Frequency:* Yearly; *Affected Public:* Private sector—Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 254; *Total Annual Responses:* 254; *Total Annual Hours:* 2,193. (For policy questions regarding this collection contact Arianne Spaccarelli at 410-786-5715).

2. Type of Information Collection

Request: Revision of a currently approved collection; *Title of Information Collection:* Part C—Medicare Advantage and 1876 Cost Plan Expansion Application; *Use:* The information will be collected under the solicitation of Part C applications from MA, EGWP Plan, and Cost Plan applicants and will be used to ensure that applicants meet our requirements and support the determination of contract awards. Participation in all programs is voluntary in nature; only organizations that are interested in participating in the program will respond to the solicitation. The MA-PDs that voluntarily participate in the Part C program must submit a Part D application and successful bid. *Form Number:* CMS-10237 (OMB control number: 0938-0935); *Frequency:* Yearly; *Affected Public:* Private sector—Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 566; *Total Annual Responses:* 566; *Total Annual Hours:* 22,625. (For policy questions regarding this collection contact Melissa Staud at 410-786-3669).

3. Type of Information Collection

Request: Revision of a currently approved collection; *Title of Information Collection:* Generic Clearance for Medicaid and CHIP State Plan, Waiver, and Program Submissions;

Use: State Medicaid and CHIP agencies are responsible for developing submissions to CMS, including State plan amendments and requests for waivers and program demonstrations. States use templates when they are available and submit the forms to review for consistency with statutory and regulatory requirements (or in the case of waivers and demonstrations whether the proposal is likely to promote the objectives of the Medicaid program). If the requirements are met, we approve the States' submissions giving the States the authority to implement the flexibilities. For a State to receive Medicaid Title XIX funding, there must be an approved Title XIX State plan.

The development of streamlined submissions forms enhances the collaboration and partnership between States and CMS by documenting our policy for States to use as they are developing program changes. Streamlined forms improve efficiency of administration by creating a common and user-friendly understanding of the information we need to quickly process requests for State plan amendments, waivers, and demonstration, as well as ongoing reporting. *Form Number:* CMS-10398 (OMB control number: 0938-1148); *Frequency:* Collection specific, but generally the frequency is yearly, once, and occasionally; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 56; *Total Annual Responses:* 1,120; *Total Annual Hours:* 28,747. (For policy questions regarding this collection contact Annette Pearson at 410-786-6858).

4. *Type of Information Collection Request:* New collection (Request for a new OMB control number); *Title of Information Collection:* Executive Summary Form for Research Identifiable Data; *Use:* The Centers for Medicare & Medicaid Services (CMS) is responsible for administering the Medicare, Medicaid and State Children's Health Insurance Programs. We collect data to support the Agency's mission and operations. These data include information about Medicare beneficiaries, Medicare claims, Medicare providers, and Medicaid eligibility and claims. We disclose the identifiable data consistent with the routine uses identified in the Privacy Act Systems of Records notices that are published in the **Federal Register** and the limitations on uses and disclosures that are set out in the HIPAA Privacy Rule.

All requests for identifiable data are received and reviewed by the Division of Privacy Operations & Compliance (DPOC) in the Office of E-Health

Standards and Services. The DPOC staff and the CMS Privacy Officer review the requests to determine if there is legal authorization for disclosure of the data. If legal authorization exists, the request is reviewed to ensure that the minimal data necessary is requested and approved for the project. Requests for identifiable data for research purposes must be submitted to and approved by the CMS Privacy Board. To assist the CMS Privacy Board with its review of research data requests, OIPDA has developed the Executive Summary (ES) forms. The ES collects all the information that the CMS Privacy Board needs to review and make a determination on whether the request meets the requirements for release of identifiable data for research purposes. We currently have three versions of the ES Form and an ES Supplement for Requestors of the National Death Index (NDI) Causes of Death Variables. Each meets the need for a different type of requestor. *Form Number:* CMS-10522 (OMB control number: 0938-New); *Frequency:* On occasion; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 325; *Total Annual Responses:* 325; *Total Annual Hours:* 650. (For policy questions regarding this collection contact Kim Elmo at 410-786-0161).

Dated: July 3, 2014.

Martique Jones,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS-304/CMS-304a, CMS-368/CMS-R-144 and CMS-10517]

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 August 11, 2014.

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:* Extension of a currently approved collection; *Title of Information Collection:* Reconciliation of State Invoice and Prior Quarter Adjustment Statement; *Use:* Form CMS-304 (Reconciliation of State Invoice) is used by manufacturers to respond to the state's rebate invoice for current quarter utilization. Form CMS-304a (Prior Quarter Adjustment Statement) is required only in those instances where a change to the original rebate data submittal is necessary. *Form Number:* CMS-304 and -304a (OMB control number: 0938-0676); *Frequency:* Quarterly; *Affected Public:* Private sector—Business or other for-profits; *Number of Respondents:* 1,037; *Total Annual Responses:* 4,148; *Total Annual Hours:* 187,880. (For policy questions regarding this collection contact Andrea Wellington at 410-786-3490.)

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Medicaid Drug Rebate Program Forms; *Use:* We develop the rebate amount per drug unit from information supplied by the drug manufacturers and distributes these data to the states. States then must report quarterly to the drug manufacturers and report to us the total number of units of each dosage form/strength of their covered outpatient drugs reimbursed during a quarter and the rebate amount to be refunded. This report is due within 60 days of the end of each calendar quarter. The information in the report is based on claims paid by the state Medicaid agency during a calendar quarter. Form CMS-R-144 (Quarterly Report Data) is required from states quarterly to report utilization for any drugs paid for during that quarter. Form CMS-368 (Administrative Data) is required only in those instances where a change to the original data submittal is necessary. *Form Number:* CMS-368 and -R-144 (OMB control number: 0938-0582); *Frequency:* Quarterly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 56; *Total Annual Responses:* 224; *Total Annual Hours:* 12,101. (For policy questions regarding this collection contact Andrea Wellington at 410-786-3490.)

3. *Type of Information Collection Request:* New collection (Request for a

new control number); *Title of Information Collection:* The Predictive Learning Analytics Tracking Outcome (PLATO™); *Use:* The Predictive Learning Analytics Tracking Outcome (PLATO™) is a web-based application tool that will serve as the centerpiece of the advanced analytics initiative with the Centers for Medicare & Medicaid Services (CMS) and Health Integrity, LLC, the National Benefit Integrity Medicare Integrity Contractor (NBI MEDIC). Developed by Health Integrity, LLC and licensed for one of its contracts—the NBI MEDIC—PLATO™ utilizes a cutting-edge advanced analytics fraud detection process in conjunction with a state-of-the-art web-based user interface tool to present fraud and abuse lead information visually to Medicare Part D plan sponsors. Summary data, based on National Prescription Drug Event Data and actions from all Part D plan sponsors, is shared with law enforcement, CMS, NBI MEDIC, and Part D plan sponsors to review historic actions taken against providers who are enrolled in the Medicare Part D program, which will assist in detecting and preventing fraud, waste, and abuse. *Form Number:* CMS-10517 (OMB control number: 0938—New); *Frequency:* Monthly; *Affected Public:* Private sector—Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 1,550; *Total Annual Responses:* 1,550; *Total Annual Hours:* 18,600. (For policy questions regarding this collection contact Delois Newkirk at 410-786-1247.)

Dated: July 3, 2014.

Martique Jones,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-D-0125]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry on Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.