

study, such as protocols, instructions, participant-specific data, statistical analyses, and contracts with the test's researchers. There is an exception for a "Reliably Reported" test, defined as a test published in a peer-reviewed journal that was not conducted, controlled, or sponsored by HLS, its affiliates, or others in the manufacturing and supply chain. Also, the published report must provide sufficient information about the test for experts in the relevant field to assess the reliability of the results.

Parts VII through X of the proposed order require HLS to: Deliver a copy of the order to principals, officers, directors and other employees having responsibilities with respect to the subject matter of the order; notify the Commission of changes in corporate structure that might affect compliance obligations under the order; and file compliance reports with the Commission.

Part XI provides that the order will terminate after twenty (20) years, with certain exceptions.

The purpose of this analysis is to facilitate public comment on the proposed order, and it is not intended to constitute an official interpretation of the complaint or proposed order, or to modify the proposed order's terms in any way.

By direction of the Commission.

Donald S. Clark,

Secretary.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS-10137, CMS-10305, CMS-10068 and CMS-10343]

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 October 20, 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:* 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:* Medicare Part C and Part D Data Validation; *Use:* Organizations contracted to offer Medicare Part C and Part D benefits are required to report data to us on a variety of measures. For the data to be useful for monitoring and performance measurement, the data must be reliable, valid, complete, and comparable among sponsoring organizations. To meet this goal, we have developed reporting standards and data validation specifications with respect to the Part C and Part D reporting requirements. These standards provide a review process for Medicare Advantage Organizations, Cost Plans, and Part D sponsors to use to conduct data validation checks on their reported Part C and Part D data. The currently approved information collection is being revised to reflect decreases in the number of reporting sections being validated and an increase in the average number of data elements per reporting section for 2015-2017. The package has been revised subsequent to the publication of the 60-day **Federal**

Register notice (June 13, 2014; 79 FR 33927). *Form Number:* CMS-10305 (OMB control number: 0938-1115); *Frequency:* Yearly; *Affected Public:* Private sector—Business or other for-profits; *Number of Respondents:* 706; *Total Annual Responses:* 706; *Total Annual Hours:* 202,578. (For policy questions regarding this collection contact Terry Lied at 410-786-8973).

3. Type of Information Collection
Request: Reinstatement with change of a previously approved collection; *Title of Information Collection:* Medicare Ombudsman Customer Service Feedback Survey; *Use:* The Centers for Medicare and Medicaid Services stresses a continuing need for setting customer service goals that include providing accurate, timely, and relevant information to its customers. With these goals in mind, we periodically survey our customers to ensure that the needs of Medicare beneficiaries are being met. This survey will be used to measure overall satisfaction of the customer service that the Medicare Ombudsman Group (MOG) within CMS provides to Medicare beneficiaries and their representatives. The information provided will be used by management and staff to measure and improve the quality and timeliness of responses to written and verbal correspondence. *Form Numbers:* CMS-10068 (OMB control number: 0938-0894); *Frequency:* Annually, occasionally; *Affected Public:* Private Sector; Business or other for-profit and not-for-profit institutions; *Number of Respondents:* 2,380; *Total Annual Responses:* 2,380; *Total Annual Hours:* 317. (For policy questions regarding this collection contact Nancy Conn at 410-786-8374.)

4. Type of Information Collection
Request: Reinstatement without change of a previously approved collection; *Title of Information Collection:* State Plan Preprint for Medicaid Recovery Audit Contractors (RACs); *Use:* Under section 1902(a)(42)(B)(i) of the Social Security Act, States are required to establish programs to contract with one or more Medicaid Recovery Audit Contractors (RACs) for the purpose of identifying underpayments and recouping overpayments under the State plan and any waiver of the State plan with respect to all services for which payment is made to any entity under such plan or waiver. Further, the statute requires States to establish programs to contract with Medicaid RACs in a manner consistent with State law, and generally in the same manner as the Secretary contracts with Medicare RACs. State programs contracted with Medicaid RACs are not required to be fully operational until after December

31, 2010. States may submit, to CMS, a State Plan Amendment (SPA) attesting that they will establish a Medicaid RAC program. States have broad discretion regarding the Medicaid RAC program design and the number of entities with which they elect to contract. Many States already have experience utilizing contingency-fee-based Third Party Liability recovery contractors. *Form Number:* CMS-10343 (OMB control number: 0938-1126); *Frequency:* Once; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 56; *Total Annual Responses:* 56; *Total Annual Hours:* 56. (For policy questions regarding this collection contact Yolanda Green at 410-786-0798.)

Dated: September 16, 2014.

Martique Jones,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request, Process Assessment Review of the Division of Acquired Immunodeficiency Syndrome (DAIDS) Critical Events, Policy Implementation (CEPI) Program (NIAID)

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health, has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on April 9, 2013, page 19633 and allowed 60-days for public comment. No comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health, may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office

of Management and Budget, Office of Regulatory Affairs, *OIRA_submission@omb.eop.gov* or by fax to 202-395-6974, Attention: NIH Desk Officer.

Comment Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, or request more information on the proposed project, contact: Lynda Lahl, RN, MS, Office for Policy in Clinical Research Operations, DAIDS, NIAID, 5601 Fishers Lane, 9B25, Rockville, MD 20852, or call non-toll-free number 240-292-4887, or Email your request, including your address to: *Lynda.Lahl@nih.gov*. Formal requests for additional plans and instruments must be requested in writing.

Proposed Collection: Process Assessment Review of the Division Of Acquired Immunodeficiency Syndrome (DAIDS) Critical Events Policy Implementation (CEPI) Program, 0925-New, National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH).

Need and Use of Information Collection: This is a new data collection to assess the CEPI program's progression to fulfillment of its program goals and will assess whether the CEPI program is implemented and functioning as intended. The program goals for CEPI are: 1) Awareness & Accessibility—The target populations (DAIDS Staff, extramural researchers, external stakeholders) are aware of the DAIDS Critical Events (CE) policy and manual and associated documents and whether the policy and associated documents are readily accessible.; 2) Understandability—The Critical Events policy and manual clearly articulate DAIDS expectations for CE policy implementation by the target populations. The CE policy and manual should establish a common base of understanding and promote positive attitudes towards event reporting; and 3) Applicability—Target populations are able to correctly identify which Critical Events have occurred at their sites and are able to apply the CE policy and manual to their events.

Findings will provide data to inform DAIDS and Protection of Participants, Evaluation and Policy (ProPEP) leadership regarding further policy deployment decisions. Information collected will be used to determine how effectively the CEPI Program meets extramural researchers' needs. By assessing the CEPI Program, DAIDS will