

Prevention, 1600 Clifton Road NE., Mailstop E-46, Atlanta, GA 30329, telephone: (404) 639-6007, email: lig7@cdc.gov.

Scientific questions should be addressed to Michele Owen, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, Centers for Disease Control and Prevention, 1600 Clifton Road NE., Mailstop A-25, Atlanta, GA 30329; Phone 404-639-1046, email smo2@cdc.gov.

SUPPLEMENTARY INFORMATION: HHS/CDC seeks to collaborate with one or more companies that have developed a simplified nucleic acid test that can detect acute or established HIV-1 infection. Acute HIV infection is the early infection period associated with high viral load that occurs before the development of HIV antibodies, and established infection is that which occurs once antibodies are detectable.

The objective of the collaboration is timely collection of data to evaluate the performance characteristics of simplified nucleic acid tests when used in their intended applications. The evaluation will be conducted in phases. The first round of evaluation will be done on well characterized stored or mock laboratory specimens. Following the initial round of evaluation, a subset of tests with high performance will be evaluated with prospectively collected specimens. Only tests that are near production (*i.e.*, not first generation prototypes) will be eligible for the collaboration. Companies that are interested in collaborating must be planning to produce a simplified nucleic acid test for distribution in the United States and to seek FDA approval for diagnostic or prognostic use (priority given to tests with both applications). Confidential proposals, preferably six pages or less (excluding appendices), are solicited from companies which have a product that is suitable for commercial distribution. This collaboration will have an expected duration of 1 to 6 years.

Currently, nucleic acid testing conducted as part of HHS/CDC's laboratory algorithm is associated with a delay in returning results because testing is often conducted in referral laboratories. Likewise, pooled nucleic acid testing causes delays due to the time required to create and break down pools in the event of a positive pool. Rapid identification of acute and established HIV-1 infection using a simplified nucleic acid test may have a significant impact on patients with positive test results obtaining care and services more quickly. Therapeutic monitoring could also be conducted

more efficiently using a simplified nucleic acid test.

For this project, preference may be given to manufacturers that have produced rapid nucleic acid tests that can aid in HIV-1 diagnosis, and be used for monitoring responses to therapy. Tests should be simple to use on unprocessed specimens (*e.g.*, whole blood) or include specimen processing in the design of the test. Preference will also be given for tests that can be performed in 60 minutes or less, that have the potential to be designated moderately complex or waived under the Clinical Laboratory Improvement Amendments (CLIA), and that are capable of both qualitative and quantitative applications.

HHS/CDC and Collaborator Responsibilities

HHS/CDC's role may include, but will not be limited to, the following:

- (1) Providing scientific and technical expertise needed for the research project;
- (2) Providing appropriate panels of specimens, and conducting the tests;
- (3) Planning and conducting research studies of the diagnostic tests and interpreting results; and
- (4) Publishing research results.

HHS/CDC anticipates that the role of the successful collaborator(s) will include the following:

- (1) Providing tests and finalized protocols that can be used in the evaluation; and
- (2) Providing the CDC Division of HIV/AIDS Prevention access to necessary data about the diagnostic tests in support of the research activities.

Selection Criteria

Proposals submitted for consideration should address, as fully as possible and to the extent relevant to the proposal, each of the following:

- (1) Data available on the performance of the test in persons with acute and established HIV-1 infection.
- (2) Information on the technology used for the test and its basic operating principals for detecting HIV RNA and/or DNA.
- (3) Information on:
 - a. the time required to perform the test;
 - b. whether the test is performed on whole blood, serum, plasma, or dried blood spots; and
 - c. the steps involved in performing the test on each specimen type;
- (4) Information on the storage requirements and stability of the test.
- (5) Plans and capability of the company to seek HHS/FDA approval and whether the company intends to

seek a diagnostic claim, a prognostic claim (for patient monitoring) or both.

(6) Plans the company has for seeking CLIA waiver status, if FDA approved.

Dated: February 6, 2015.

Ron A. Otten,

Acting Deputy Associate Director for Science, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS-10433]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

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 April 13, 2015.

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.
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-10433 Initial Plan Data Collection To Support Qualified Health Plan (QHP) Certification and Other Financial Management and Exchange Operations

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.

Information Collection

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Initial Plan Data Collection to Support Qualified Health Plan (QHP) Certification and Other Financial Management and Exchange Operations; *Use:* As required by the CMS-9989-F, Patient Protection and Affordable Care Act; Establishment of Exchanges and Qualified Health Plans; Exchange Standards for Employers (77 FR 18310) (Exchange Establishment Rule), each Exchange must assume responsibilities related to the certification and offering of Qualified Health Plans (QHPs). In addition to data collection for the certification of QHPs, the reinsurance and risk adjustment programs outlined by the Affordable Care Act, detailed in 45 CFR part 153, as established by CMS-9975-F, Patient Protection and Affordable Care Act; Standards for Reinsurance, Risk Corridors, and Risk Adjustment (77 FR 17220), have general information reporting requirements that apply to issuers, group health plans, third party administrators, and plan offerings outside of the Exchanges. Subsequent regulations for these programs including the final HHS Notice of Benefit and Payment Parameters for 2014 and the Program Integrity: Exchange, Premium Stabilization Programs, and Market Standards; Amendments to the HHS Notice of Benefit and Payment Parameters for 2014, and the final HHS Notice of Benefit and Payment Parameters for 2015 provide further reporting requirements. *Form Number:* CMS-10433 (OMB control number 0938-1187); *Frequency:* Once; *Affected Public:* Individuals and households, private sector—business or other for-profits and not-for-profit institutions, State, Local or Tribal Governments; *Number of Respondents:* 900; *Total Annual Responses:* 900; *Total Annual Hours:* 150. (For policy questions regarding this collection contact Jaya Ghildiyal at 301-492-5149.)

Dated: February 6, 2015.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2015-02852 Filed 2-10-15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Tribal Consultation Meeting

AGENCY: Office of Head Start (OHS), Administration for Children and Families, HHS.

ACTION: Notice of meeting.

SUMMARY: Pursuant to the Improving Head Start for School Readiness Act of 2007, Public Law 110-134, notice is hereby given of one 1-day Tribal Consultation Session to be held between the Department of Health and Human Services, Administration for Children and Families, Office of Head Start leadership and the leadership of Tribal Governments operating Head Start (including Early Head Start) programs. The purpose of this Consultation Session is to discuss ways to better meet the needs of American Indian and Alaska Native children and their families, taking into consideration funding allocations, distribution formulas, and other issues affecting the delivery of Head Start services in their geographic locations [42 U.S.C. 9835, Section 640(l)(4)].

DATES: March 16, 2015, from 1:00 p.m. to 5:00 p.m.

Location: Southwest Consortium of Indian Head Start, Native American Child and Family Conference, Hotel Albuquerque at Old Town, 800 Rio Grande Boulevard Northwest, Albuquerque, New Mexico 87104.

FOR FURTHER INFORMATION CONTACT: Robert Bialas, Regional Program Manager, Region XI, Office of Head Start, email Robert.Bialas@acf.hhs.gov or phone (202) 205-9497. Additional information and online meeting registration is available at <http://eclkc.ohs.acf.hhs.gov/hslc/hs/calendar/tc2015>.

SUPPLEMENTARY INFORMATION: The Department of Health and Human Services (HHS) announces an Office of Head Start (OHS) Tribal Consultation for leaders of Tribal Governments operating Head Start and Early Head Start programs.

The agenda for the scheduled OHS Tribal Consultation in Albuquerque, New Mexico, will be organized around the statutory purposes of Head Start Tribal Consultations related to meeting the needs of American Indian/Alaska Native children and families, taking into consideration funding allocations, distribution formulas, and other issues affecting the delivery of Head Start services in their geographic locations. In