AHRQ convenes the PSWG to assist AHRQ with developing and maintaining the Common Formats. The PSWG includes major health agencies within HHS—the Centers for Disease Control and Prevention, Centers for Medicare and Medicaid Services, Food and Drug Administration, Health Resources and Services Administration, Indian Health Service, National Institutes of Health, National Library of Medicine, Office of the National Coordinator for Health Information Technology, Office of Public Health and Science, and Substance Abuse and Mental Health Services Administration—as well as the Department of Defense and Department of Veterans Affairs.

When developing Common Formats, AHRQ first reviews existing patient safety event reporting systems from a variety of health care organizations. In collaboration with the PSWG and Federal subject matter experts, AHRQ drafts and releases beta versions of the Common Formats for public review and comment.

Through a contract with AHRQ, the NQF solicits feedback on the initial and subsequent versions of the Common Formats from private sector organizations and individuals. The NQF, a nonprofit organization that focuses on health care quality, then convenes an expert panel to review the comments received and provide feedback to AHRQ. Based upon the expert panel's feedback, AHRQ, in conjunction with the PSWG, further revises the Common Formats.

The technical specifications promote standardization of collected patient safety event information by specifying rules for data collection and submission, as well as by providing guidance for how and when to create data elements, their valid values, conditional and go-to logic, and reports. These specifications will ensure that data collected by PSOs and other entities have comparable clinical meaning.

The technical specifications also provide direction to software developers, so that the Common Formats can be implemented electronically, and to PSOs, so that the Common Formats can be submitted electronically to the PSO Privacy Protection Center (PSOPPC) for data de-identification and transmission to the Network of Patient Safety Databases (NPSD).

Common Formats technical specifications consist of the following:

- Data dictionary—defines data elements and their attributes (data element name, answer values, field length, guide for use, etc.) included in Common Formats;
- clinical document architecture (CDA) implementation guide—provides instructions for developing a file to transmit the Common Formats Patient Safety data from the PSO to the PSOPPC using the Common Formats;
- validation rules and errors document—specifies and defines the validation rules that will be applied to the Common Formats data elements submitted to the PSOPPC;
- Common Formats flow charts—diagrams the valid paths to complete generic and event specific formats (a complete event report);
- local specifications—provides specifications for processing, linking and reporting on events and details specifications for reports; and
- metadata registry—includes descriptive facts about information contained in the data dictionary to illustrate how such data corresponds with similar data elements used by other Federal agencies and standards development organizations [*e.g.,* HL—7, International Standards Organization (ISO)].

Agenda, Registration, and Other Information About the Meeting

The 2015 meeting will be an interactive forum designed to allow meeting participants not only to provide input but also to respond to the input provided by others. The meeting agenda will include: An overview of Federal efforts related to the Common Formats; presentations and discussion of implementation of Common Formats Event Reporting—Hospital Versions 1.1 and 1.2; and, a review of data submission both by PSOs and by vendors on behalf of PSOs.

AHRQ requests that interested persons send an email to the PSOPPC at *support@psoppc.ORG* for registration information. The meeting space will accommodate approximately 150 participants. Before the meeting, a detailed agenda and logistical information will be provided to registrants. Prior to the meeting, AHRQ invites review of the technical specifications for Common Formats which can be accessed through AHRQ's PSO Web site at *http://www.pso.AHRQ.GOV/formats/commonfmt.htm.*

Dated: February 3, 2015.

Richard Kronick,

Director.

[FR Doc. 2015–02590 Filed 2–10–15; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Opportunity To Collaborate in the Evaluation of Simplified Nucleic Acid Tests for Detecting and Quantifying HIV

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (DHHS).

ACTION: General notice.

SUMMARY: The Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS) announces an opportunity for industry and the public to collaborate on a project to evaluate simplified nucleic acid tests. HHS/CDC is interested in evaluating simplified nucleic acid tests that (1) can be used near a patient with rapid turn-around of results (2) can be used to aid in the diagnosis of HIV–1 infection, and (3) have the potential to be used in moderately complex and/or waived laboratories as defined under the Clinical Laboratory Improvement Amendment (CLIA) regulations. Tests of interest include those that use whole blood, serum, plasma, or dried blood spots. Performance will be evaluated relative to HHS/Food and Drug Administration (FDA)-approved qualitative and quantitative nucleic acid tests as well as antibody immunoassays. More than one collaborator may be selected.

DATES: Formal proposals must be received on or before April 13, 2015.

ADDRESSES: Formal proposals should be submitted to Division of HIV/AIDS Prevention, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, Centers for Disease Control and Prevention, 1600 Clifton Road NE., Mailstop E–46, Atlanta, Georgia 30329, Attn: Simplified Nucleic Acid Tests Evaluation Project. If you are interested in submitting a proposal, please send a letter of interest to Dr. Michele Owen at *smo2@cdc.gov* by March 13, 2015. The letter of interest is not considered a formal proposal and is not required; however, it is highly recommended, as it will assist CDC in planning for the review process. The formal proposal will still need to be submitted according to the instructions in this notice.

FOR FURTHER INFORMATION CONTACT: Questions on the project should be addressed to: Laura Wesolowski, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, Centers for Disease Control and

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.

[FR Doc. 2015–02793 Filed 2–10–15; 8:45 am]

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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