Liabilities attributable to the U.S. operations of a foreign financial company that is not a foreign banking organization are calculated in a similar manner to the method described for foreign banking organizations, and liabilities of a U.S. subsidiary not subject to the risk-based capital rule are calculated based on the U.S. subsidiary's liabilities under applicable accounting standards. The Federal Reserve used information collected on the Capital and Asset Report for Foreign Banking Organizations (''FR Y–7Q''), the FR Y–9C, and the FR XX–1 to calculate liabilities of these institutions.

*By order of the Board of Governors of the Federal Reserve System, acting through the Director of Supervision and Regulation under delegated authority.*

**Ann E. Misback,**

*Secretary of the Board.*

[FR Doc. 2023–12389 Filed 6–9–23; 8:45 am]

**BILLING CODE P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

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

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

**ACTION:** General notice.

**SUMMARY:** The Centers for Disease Control and Prevention (CDC), within the Department of Health and Human Services (HHS), announces an opportunity for industry and the public to collaborate on a project to evaluate nucleic acid and serologic tests. CDC is interested in evaluating serologic and nucleic acid tests that can be used to aid in the diagnosis of HIV–1 infection, including serologic tests that can secondarily differentiate recent infection, and nucleic acid tests for the quantitation or semi-quantitation of HIV RNA. Tests of interest include those that use whole blood, serum, plasma, or dried blood spots. Performance will be evaluated relative to Food and Drug Administration (FDA)-approved qualitative and quantitative nucleic acid tests as well as serologic immunoassays. More than one collaborator may be selected.

**DATES:** Letters of interest must be received on or before Friday, September 15, 2023. Formal proposals must be received on or before Friday, November 10, 2023.

**ADDRESSES:** Send Letters of Interest and Formal Proposals to Division of HIV Prevention, National Center for HIV, Viral Hepatitis, STD, and TB Prevention, Centers for Disease Control and Prevention, 1600 Clifton Road NE, Mailstop H18–2, Atlanta, Georgia 30329. Attn: HIV Serologic and Nucleic Acid Tests Evaluation Project.

**FOR FURTHER INFORMATION CONTACT:** Jeffrey Johnson, National Center for HIV, Viral Hepatitis, STD, and TB Prevention, Centers for Disease Control and Prevention, 1600 Clifton Road NE, Mailstop 18–2, Atlanta, GA 30329; Telephone 404–639–4976; Email: *jlj6@cdc.gov.*

**SUPPLEMENTARY INFORMATION:**

#### Background

Priority for technical evaluations are rapid tests or mail-in sample collection methods that can be self-administered outside of clinic settings. Secondarily, tests or collection methods that have the potential for both HIV–1 diagnostic and prognostic use for monitoring responses to therapy are preferred.

The objective of the collaboration is timely collection of data to evaluate the performance characteristics of simplified nucleic acid and serologic tests or protocols when used in their intended applications. Only tests that are under or near production (*i.e.,* not first-generation prototypes) will be eligible for the collaboration. Companies that are interested in collaborating must be planning to market a test protocol for distribution in the United States and to seek FDA approval for diagnostic or prognostic use.

Currently, nucleic acid testing conducted as part of CDC's laboratory algorithm has 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. Moreover, there are significant financial stability, geographic isolation, and stigma barriers to accessing testing in clinical settings that prevent sustained continuum of care for many populations, including the most vulnerable. Methods to support rapid identification of HIV–1 infection or viral suppression using a simplified nucleic acid or serologic test, or use of self-collection methods, may have a significant impact on individuals by allowing them to obtain care and services more quickly.

Tests should be simple to use on unprocessed specimens (*e.g.,* whole blood) or include specimen processing in the design of the test. For nucleic acid tests, preference may also be given to tests that are capable of both qualitative and quantitative applications. Key benchmarks are the ability to demonstrate improved sensitivity of diagnostic tests over current FDA-approved laboratory-based tests and nucleic acid monitoring test protocols that are suitable for lower complexity settings.

#### CDC and Collaborator Roles and Responsibilities

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 assistance with project management and data analysis;

(3) Providing testing support as determined by CDC as needed; and

(4) Publishing research results.

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 Prevention access to necessary data about the diagnostic tests in support of the evaluation 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, DNA, antibody, or antigen.

(3) Information on:

a. the time required to perform the test or sample collection method;

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 or sample collection method;

(4) Information on the storage requirements and stability of the test.

(5) Plans, capability, and clinical trial designs 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, for appropriate tests, if FDA approved.

**Letters of Interest**

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.

**Formal Proposals**

Confidential proposals, preferably six pages or less (excluding appendices), are solicited from companies which have a product that is suitable for regulatory approval and commercialization. This collaboration will have an expected duration of 1 to 4 years.

Dated: June 7, 2023.

**Tiffany Brown,**

*Executive Secretary, Centers for Disease Control and Prevention.*

[FR Doc. 2023–12435 Filed 6–9–23; 8:45 am]

**BILLING CODE 4163–18–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

**[Document Identifier: CMS–4040 and CMS–R–297]**

### Agency Information Collection Activities: Submission for OMB Review; Comment Request

**AGENCY:** Centers for Medicare & Medicaid Services, Health and Human 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 (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 the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and 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 July 12, 2023.

**ADDRESSES:** Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain*. Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, please access the CMS PRA website by copying and pasting the following web address into your web browser: *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing*.

**FOR FURTHER INFORMATION CONTACT:** William Parham at (410) 786–4669.

**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:* Request for Enrollment in Supplementary Medical Insurance (SMI); *Use:* CMS regulations 42 CFR 407.11 lists the CMS–4040 as the application to be used by individuals who are not eligible for monthly Social Security/Railroad Retirement Board benefits or free Part A. The CMS–4040 solicits the information that is used to determine entitlement for individuals who meet the requirements in section 1836 as well as the entitlement of the applicant or their spouses to an annuity paid by OPM for premium deduction purposes. The application follows the application questions and requirements used by SSA. This is done not only for consistency purposes but to comply with other Title II and Title XVIII requirements because eligibility to Title II benefits and free Part A under Title XVIII must be ruled out in order to qualify for enrollment in Part B only. *Form Number:* CMS–4040 (OMB control number: 0938–0245); *Frequency:* Once; *Affected Public:* Individuals or households; *Number of Respondents:* 42,011; *Total Annual Responses:* 42,011; *Total Annual Hours:* 10,503. (For policy questions regarding this collection contact Carla Patterson at 410–786–8911.)

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Request for Employment Information; *Use:* The form CMS–L564, also referred to as CMS–R–297, is used, in conjunction with form CMS–40–B, Application for Supplementary Medical Insurance, during an individual's special enrollment period (SEP). Completed by an employer, the CMS–L564 provides proof of an applicant's employer group health coverage. The Social Security Administration (SSA) uses it to obtain information from employers regarding whether a Medicare beneficiary's coverage under a group health plan is based on current employment status. The form is available online via *Medicare.gov* and *CMS.gov* for individuals who are requesting the SEP to obtain and submit to their employer for completion. The employer must complete and sign the form, and submit it to the individual to accompany their enrollment or late enrollment penalty reduction request. The information on the completed form is reviewed manually by SSA. *Form Number:* CMS–R–297 (OMB control number: 0938–0787); *Frequency:* Once; *Affected Public:* Individuals or households, Business or other for-profits, Not-for-profit institutions; *Number of Respondents:* 676,526; *Total Annual Responses:* 676,526; *Total Annual Hours:* 56,355. (For policy questions regarding this collection contact Carla Patterson at 410–786–8911.)