matured to the point that their introduction into the clinic appears practical and useful. Fundamental to using IVDs in the clinic is the need to demonstrate that the tests are safe and effective—that the results claimed are accurate and precise and that the interpretation of the results are supported by science. FDA's regulatory process is designed to ensure that intended use claims are supported with appropriate data. However, the range of variables that can be included in proteomic IVDs such as technological approaches, variety of sample types and preparation methods, data capture, and analysis algorithms, poses unique regulatory challenges, as more complex the information gathered, more challenging is the validation of results. At this point, what we need is a regulatory framework, tuned to proteomic technologies, which will facilitate the introduction of validated IVDs into the clinic.

The intent of this workshop is not to discuss the limitations and strengths of the proteomic discovery process. The theoretical analytical performance of proteomic technologies have been well demonstrated, and in the past few years a number of initiatives have been launched to bring standardization and quality control to the discovery and pre-clinical development of proteomic-based assays. However, this level of quality control does not ensure that these assays have been validated for their intended use as IVDs tests that are used for diagnosis of disease and clinical management of patients; e.g., assessment of risk, monitoring of disease, prediction of response to therapy, and selection of treatment.

Strategies are needed that will guide the successful transfer of research and discovery-level assays into the clinic. This includes their use in clinical trials, so that the analytical and clinical validity of the test procedure and outcome are assured. As a general rule, the requirements for analytical and clinical validation of IVDs are much greater than the studies that are commonly performed in a research and development setting. To support the least burdensome approach to assay development, FDA is willing to discuss unconventional approaches to IVD validation driven by, for example, the theoretical precision of multiple reaction monitoring assays. However, theoretical performance must be balanced by the recognition that there are few, if any, recognized reference standards for the analytes or the assays with which to assess the performance of proteomic IVDs. The impact of the lack of standards may be substantial: Assays that combine the measurements of several, if not dozens, of individual analytes into a single, actionable ''score'' may require validation of each individual analyte separately and in combination. Thus, the objective of this public workshop is to obtain feedback from academia, government, industry, clinical laboratories, and other stakeholders on the development of a regulatory approach that may reduce the burden of assay validation while assuring that the assays are safe and effective.

II. Topics for Discussion at the Public Workshop

We plan to include the following topics at the public workshop.

- State of the art: Current state of proteomic IVD landscape and FDA's perspectives;
- Community initiatives: Overview of community (governmental and non-governmental) initiatives to help standardize proteomic technologies and provide quality control to discovery;
- Success stories: Description of FDA experience in the clearance of IVDs that use proteomic technologies, with lessons learned and challenges discovered in bringing proteomic-based assays to the clinic; and
- Case study open discussion: In an open discussion, FDA will present a hypothetical case study that includes assay design and validation issues with which FDA has experience. The goal is to stimulate discussion with attendees regarding what expectations from FDA are reasonable, what validation by manufacturers is possible and other challenges inherent in bringing these tests to the clinic and the Agency. Possible points of discussion will be solicited from the attendees, and may include:
  - How can or should the FDA use community-developed reference standards/assays to assess IVD validity?
  - How can manufacturers assess accuracy in a multiplex/multipeak assay without a reference standard for the analytes?
  - Are there general rules for assay validation that cannot or should not be applied to different platforms?
  - How can or should late-stage validation considerations be incorporated into early-stage assay development?

Dated: May 7, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–10787 Filed 5–9–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Health Resources and Services Administration (HRSA) has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

DATES: Comments on this ICR should be received no later than June 11, 2014.

ADDRESSES: Submit your comments, including the Information Collection Request Title, to the desk officer for HRSA, either by email to *OIRA_submission@omb.eop.gov* or by fax to 202–395–5806.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443–1984.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Rural Health Care Services Outreach Supplement Performance Measures.

OMB No.: 0915–xxxx—NEW.

Abstract: The fiscal year (FY) 2013 Supplemental Funding to the Rural Health Care Services Outreach Program grantees is a one-time supplemental funding under Section 330A(e) of the Public Health Service (PHS) Act (42 U.S.C. 254c(e)) to promote rural health care services outreach by expanding the delivery of health care services to include new and enhanced services in rural areas. The supplemental funding will specifically focus on supporting the current scope of their project, allowing grantees to further enhance outreach and enrollment assistance activities in their communities. This supplemental funding will support the Affordable Care Act's outreach and enrollment activities to the Health Insurance Marketplaces. Grantees will be able to raise awareness of affordable insurance options and provide assistance and

information to the uninsured about enrolling in available sources of insurance, such as Medicare, Medicaid, the Children's Health Insurance Program, and private insurance in the Marketplace through this supplemental funding.

The overarching goal is to increase the number of eligible individuals educated about their coverage options and enrollees to the Health Insurance Marketplaces or other available sources of insurance, such as Medicare, Medicaid, and the Children's Health Insurance Program as a result of this supplemental funding.

Need and Proposed Use of the Information: For this program, performance measures were drafted to provide data to the program and to enable HRSA to provide aggregate program data. These measures cover the principal topic areas of interest to the Office of Rural Health Policy, including: (a) Organizational information; (b) outreach and enrollment personnel; (c) outreach and education; (d) enrollment; and (e) additional resources. Several measures will be used for this program. A 60-day **Federal Register** notice was published in the **Federal Register** on February 18, 2014 (see, 79 Fed. Reg. 9235). There were no comments.

Likely Respondents: The respondents would be recipients of the Rural Health Care Services Outreach supplemental funding award.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Rural Health Care Services Outreach Supplement Performance Measures	52	1	52	1.5	78
Total	52	1	52	1.5	78

Dated: May 6, 2014.

Bahar Niakan,

Director, Division of Policy and Information Coordination.

[FR Doc. 2014–10875 Filed 5–9–14; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects (Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995), the Health Resources and Services Administration (HRSA) announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this Information Collection Request must be received no later than July 11, 2014.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 10–29, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call the HRSA Information Collection Clearance Officer at (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: Health Education Assistance Loan (HEAL) Program: Lender's Application for Insurance Claim Form and Request for Collection Assistance Form OMB No. 0915–0036—Extension.

Abstract: The clearance request is for an extension of two forms that are currently approved by OMB. HEAL lenders use the Lenders Application for Insurance Claim to request payment from the federal government for federally insured loans lost due to borrowers' death, disability, bankruptcy, or default. The Request for Collection Assistance form is submitted by HEAL lenders to request federal assistance with the collection of delinquent payments from HEAL borrowers.

Need and Proposed Use of the Information: Lender's Application for Insurance Claim Form—This form is used to obtain information about the claim and to determine if the lending institution has complied with statutory and regulatory requirements for payment of the insurance claim.

Failure to submit the required documentation or not filing the form promptly may result in a claim being penalized or denied. *Request for Collection Assistance Form*—When a borrower is 90 days delinquent, the lender must immediately request pre-claims assistance from the Public Health Service. Pre-claims assistance consists of three progressively stronger letters urging the borrower to contact his or her lender before litigation is initiated against the borrower. The Secretary does not pay a default claim if the lender fails to request pre-claims assistance.

Likely Respondents: HEAL Lenders and Servicers.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to