Together; (9) FDA Conduct of Clinical Investigator Inspections; (10) Investigator Initiated Research; (11) Meetings with FDA—Why, When, and How; (12) Part 11 Compliance—Electronic Signatures; (13) IRB Regulations and FDA Inspections; (14) Informed Consent Regulations; (15) The Inspection is Over—What Happens Next? Possible FDA Compliance Actions; and (16) Question and Answer Session/Panel Discussion.

FDA has made education of the drug and device manufacturing community a high priority to help ensure the safety and effectiveness of FDA-regulated drugs and devices. The public workshop helps to achieve objectives set forth in section 406 of the FDA Modernization Act of 1997 (21 U.S.C. 393) which includes working closely with stakeholders and maximizing the availability and clarity of information to stakeholders and the public. The public workshop also is consistent with the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104–121), as outreach activities by Government Agencies to small businesses.

Dated: September 6, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–22115 Filed 9–10–13; 8:45 am]

BILLING CODE 4160–01–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 within 60 days of this notice.

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: Uniform Project Description and Application Guide—SF 424 Non-Construction.

OMB No. 0915-xxxx—New.

Abstract: The Health Resources and Services Administration is requesting clearance for the Uniform Project Description (UPD) and Application Guide to be used in conjunction with the SF–424 Non-Construction application kit by program offices to solicit application information for grants and cooperative agreements.

Need and Proposed Use of the Information: The HRSA SF–424 Application Guide provides detailed standard instructions to help applicants prepare and submit applications electronically to HRSA through Grants.gov. The Guide is used in conjunction with the HRSA UPD that provides a menu of narratives from which the program office can select for inclusion within a program-specific grant or cooperative agreement funding opportunity announcement (FOA). UPD text options selected for use in a given FOA define the required project description portion to the applicant. The ability to pick and choose standard language that is appropriate for any given FOA reduces the burden associated with application preparation by eliminating irrelevant portions of the application for a given announcement. In addition, it provides consistency in the application review process.

Much of the information required in applications for project grants and cooperative agreements is required by HHS Uniform Administrative Requirements for Grants and Cooperative Agreements at the following citations: 45 CFR part 74, 45 CFR part 92, applicable program regulations in 42 CFR chapters I and IV, and applicable administrative regulations in 45 CFR subtitle A.

HRSA program offices, grants management officials, and expert non-federal and federal panel reviewers use the collected information provided through grant applications to select and award discretionary grants. Program offices use the information to ensure that the authorizing legislation and applicable program regulations will be implemented through any funded project, and that applicant entities are eligible to receive HRSA funds. Expert non-federal and federal objective review panelists score the information provided in applications as they evaluate applications in the context of the FOA's published criteria to ensure that the best proposed projects are recommended for funding. Grants management officials use the information to ensure appropriate federal stewardship of federal grant funds and that proposed budgeted project costs are allowable, allocable, and reasonable.

Likely Respondents: Eligible organizations may include state, local, and Indian Tribal governments; institutions of higher education; other non-profit organizations (including faith-based, community-based, and Tribal organizations); and hospitals. In limited cases, foreign organizations may apply.

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 Information Collection Request 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
SF–424 Non-Construction UPD and SF–424 Application Guide	3,500	1	3,500	145	507,500
Total	3,500	1	3,500	145	507,500

HRSA specifically requests comments on (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.

Dated: September 5, 2013.

Bahar Niakan,

Director, Division of Policy and Information Coordination.

[FR Doc. 2013–22111 Filed 9–10–13; 8:45 am]

BILLING CODE 4165–15–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 within 30 days of this notice.

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: Evaluation and Initial Assessment of HRSA Teaching Health Centers.

OMB No. 0915–xxxx—NEW.

Abstract: Section 5508 of the Affordable Care Act of 2010 (ACA) amended section 340H of the Public Health Service (PHS) Act to establish the Teaching Health Center Graduate Medical Education (THCGME) program to support the expansion of new and existing primary care residency training programs in community-based settings. The primary goals of the THCGME program are to increase the production of primary care doctors who are well prepared to practice in community settings, particularly with underserved populations, and to improve the overall number and geographic distribution of primary care providers. To ensure these goals are achieved, the George Washington University (GW) will conduct an evaluation of the training, administrative and organizational structures, clinical service, challenges, innovations, costs associated with training, and outcomes of teaching health centers (THCs). GW has developed a program data collection tool that assesses basic organizational and training characteristics of the programs (including program specialty, numbers trained, training sites, educational partners, and residency program financing), educational initiatives (particularly around training for changing health care delivery systems and community experiences), and health center characteristics (including current workforce and vacancies, clinical service provided by residents, and participation in workforce programs such as the National Health Service Corps).

Questionnaires have also been developed for implementation with all THC matriculating residents, graduating residents, and graduated residents at 1 year post-graduation. The matriculation questionnaire aims to collect background information on THC residents to better understand the characteristics of individuals who apply and are accepted to THC programs. The graduation questionnaire collects information on career plans. The alumni questionnaire collects information on career outcomes (including practice in primary care and in underserved settings) following graduation, as well as feedback on the quality of training.

Need and Proposed Use of the Information: Statute requires that THC programs report annually on the types of primary care resident approved training programs provided, the number of approved training positions, the number who completed their residency at the end of the prior academic year and care for vulnerable populations living in underserved areas, and any other information as deemed appropriate by the Secretary (Section 340H(h)(1) of the PHS Act). The described data collection activities will serve to meet this statutory requirement for the THC programs in a uniform and consistent manner and will allow comparisons of this group to other trainees in non-THC programs (*See also* Section 241 of the PHS Act).

Likely Respondents: THC Program Directors will respond to the part of the data collection tool related to the characteristics of the programs, and THC matriculating residents, graduating residents, and graduated residents at 1 year post-graduation will respond to the questionnaires related to characteristics of the residents.

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