

process that FDA will use in working with sponsors of these tools to guide them as they refine the tools and rigorously evaluate them for use in the regulatory process.

A draft version of this guidance was issued in the **Federal Register** of October 25, 2010 (75 FR 65495). FDA received a number of comments, most of which focused on clarifications and further illustration of the qualification process. FDA reviewed all received comments carefully during the finalization process of the guidance; the Agency has made some clarifying changes in the final version of the guidance. Specifically, FDA provided general guidance on the qualification process, samples of what should be included in a qualification package, and examples of drug development tools. A new DDT, Animal Models under the Animal Rule, has been included and discussed in the final DDT guidance.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on the qualification process for drug development tools. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such an approach satisfies the requirements of the applicable statutes and regulations.

## II. The Paperwork Reduction Act of 1995

This guidance contains an information collection that is subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The information collection has been approved under the OMB control numbers 0910–0001 and 0910–0014. The information requested in the guidance is currently submitted to FDA to support medical product effectiveness (see 21 CFR 312.30, 21 CFR 314.50(d)(5), and 21 CFR 314.126(b)(6)).

## III. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and

will be posted to the docket at <http://www.regulations.gov>.

## IV. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: December 31, 2013.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

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**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](mailto: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](mailto: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:* Application and other forms utilized by

the National Health Service Corps (NHSC) Scholarship Program, the NHSC Students to Service Loan Repayment Program (S2S LRP), and the Native Hawaiian Health Scholarship Program (NHHSP).

**OMB No.:** 0915–0146—Revision.

**Abstract:** Administered by HRSA's Bureau of Clinician Recruitment and Service (BCRS), the National Health Service Corps (NHSC) Scholarship Program (SP), NHSC Students to Service Loan Repayment Program (S2S LRP), and the Native Hawaiian Health Scholarship Program (NHHSP), provide scholarships or loan repayment to qualified students who are pursuing primary care health professions education and training. In return, students agree to provide primary health care services in medically underserved communities located in federally designated Health Professional Shortage Areas (HPSAs) once they are fully trained and licensed health professionals. Awards are made to applicants who demonstrate the greatest potential for successful completion of their education and training, as well as commitment to providing primary health care services to communities of greatest need. The program applications, forms, and supporting documentation are used to collect necessary information from applicants and participants that will facilitate the selection of the best qualified candidates for these competitive awards, and to monitor participants' enrollment in school or in postgraduate training.

Although some program forms vary (see program-specific burden charts below), general forms include: The Program Application; Academic and Non-Academic Letters of Recommendation; the Authorization to Release Information; and the Acceptance/Verification of Good Standing Report. Additional forms for the NHSC SP include the Data Collection Worksheet, which is completed by the educational institutions of program participants; the Post Graduate Training Verification Form (formerly the Deferment Request Form applicable for S2S participants), which is completed by program participants and their residency director; and the Enrollment Verification Form, which is completed by program participants and the educational institution for each academic term of the program.

**Need and Proposed Use of the Information:** The NHSC SP, S2S LRP, and NHHSP applications, forms, and supporting documentation are used to collect necessary information from

applicants that will enable BCRS to make determinations about the competitive awards.

*Likely Respondents:* Qualified students who are pursuing primary care health professions education and training and are interested in working with underserved populations.

*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:*

*NHSC Scholarship Program*

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
NHSC Scholarship Program Application .....	1800	1	1800	2.00	3600
Letters of Recommendation .....	1800	2	3600	.50	1800
Authorization to Release Information .....	1800	1	1800	.10	180
Acceptance/Verification of Good Standing Report .....	1800	1	1800	.25	450
Receipt of Exceptional Financial Need Scholarship .....	200	1	200	.25	50
Data Collection Worksheet .....	400	1	400	1.00	400
Post Graduate Training Verification Form .....	100	1	100	.50	50
Enrollment Verification Form .....	600	2	1200	.50	600
Total .....	1100	.....	1700	.....	1050
Verification of Disadvantaged Background Status .....	300	1	300	.25	75
Total .....	7700	.....	9500	.....	6155

The annual estimate of burden for participants/schools/residency programs is as follows:

*NHSC Students to Service Loan Repayment Program*

*Native Hawaiian Health Scholarship Program*

Form name*	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Native Hawaiian Health Scholarship Program Application (includes Forms A–E: Applicant Resume Instructions and Guidelines; NHHSP Questionnaire and Narrative Statement; Conflicting Federal Service Memo; Debarment, Suspension, Disqualification and Related Matters Certification; and Delinquent Federal Debt) .....	250	1	250	1.00	250.00
NHSC Students to Service Program Application .....	100	1	100	2.00	200.00
Letters of Recommendation .....	100	2	200	.50	100.00
Authorization to Release Information .....	100	1	100	.10	10.00
Acceptance/Verification of Good Standing Report .....	100	1	100	.25	25.00
Receipt of Exceptional Financial Need Scholarship .....	4	1	4	.25	1.00
Verification of Disadvantaged Background Status .....	25	1	25	.25	6.25
Post Graduate Training Verification Form .....	150	1	150	.50	75.00
Total .....	579	.....	679	.....	417.25
Letters of Recommendation (includes Forms H and I: Academic Faculty/Advisor Evaluation of Applicant and Employer Evaluation of Applicant) .....	250	2	500	.25	125.00
Authorization to Release Information (Form F) .....	250	1	250	.25	62.50
Acceptance/Verification of Good Standing Report (includes Form G: Course Curriculum Worksheet) .....	30	12	360	.25	90.00
Total .....	780	.....	1360	.....	527.50

\*Please note that the forms listed above account for supporting documentation which may be uploaded as part of the application or associated with the supplemental forms.

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: December 30, 2013.  
**Bahar Niakan,**  
*Director, Division of Policy and Information Coordination.*  
[FR Doc. 2013–31590 Filed 1–6–14; 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 within 60 days of this notice.  
**ADDRESSES:** Submit your comments to [paperwork@hrsa.gov](mailto: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](mailto: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:* Assessment and Evaluation of the Public Health Training Center Program.  
*OMB No.:* 0915–xxxx–NEW.  
*Abstract:* The Public Health Training Center (PHTC) Program provides support to help improve the public health workforce by strengthening the competence of the existing and future public health workforce and addressing public health workforce shortages. Grantees of the PHTC Program include accredited schools and programs of public health and other private and non-profit entities that are required to provide competency-based training and educational programs—based on the Core Competencies for Public Health Professionals outlined by the Council on Linkages between Academia and Public Health—that support core public health functions and the Ten Essential Public Health Services.

*Need and Proposed Use of the Information:* The Bureau of Health Professions (BHP) is currently evaluating the PHTC Program to assess how grantees are meeting the needs of the public health workforce, improving the public health workforce by strengthening the competence of the existing and future public health workforce, and addressing shortages of the public health workforce. The specific purpose of this data collection activity is to obtain information from individuals who participate in continuing education courses offered by PHTC grantees in order to gauge and monitor changes in participants’ knowledge about public health-related issues.

*Likely Respondents:* Participants of continuing education courses offered by PHTC grantees.

*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.

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
CE Survey Form .....	3,000	1	3,000	.16	480
Total .....	3,000	1	3,000	.16	480

*Total Estimated Annualized burden hours:*  
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: December 30, 2013.  
**Bahar Niakan,**  
*Director, Division of Policy and Information Coordination.*  
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**BILLING CODE 4165–15–P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**  
  
**Health Resources and Services Administration**  
  
**Council on Graduate Medical Education; Notice of Meeting**

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), notice is hereby given of the following meeting:  
*Name:* Council on Graduate Medical Education (COGME).