

In the **Federal Register** of August 29, 2022 (87 FR 52784), FDA published a notice announcing the availability of the draft guidances entitled “Q2(R2) Validation of Analytical Procedures” and “Q14 Analytical Procedure Development.” The notice gave interested persons an opportunity to submit comments by September 28, 2022.

After consideration of the comments received and revisions to the guideline, final drafts of the guidelines were submitted to the ICH Assembly and endorsed by the regulatory agencies in November 2023.

These guidances finalize the draft guidances issued on August 29, 2022. The final “Q2(R2) Validation of Analytical Procedures” guidance resolves issues on range, response, reference material, biologics, replicates, and dissolution. In addition, guidance on data requirements for accuracy, precision, and the combined approach (e.g., confidence intervals) were refined. The final “Q14 Analytical Procedure Development” guidance includes further clarification of concepts like minimum versus enhanced approach, the definition and description of the analytical targeting profile, and established conditions.

These guidances are being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on “Q2(R2) Validation of Analytical Procedures” and “Q14 Analytical Procedure Development.” These guidances do not establish any rights for any person and are not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

## II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information for investigational new drug applications have been approved under OMB control number 0910–0014; the collections of information for review of new drug applications have been approved under OMB control number 0910–0001; and the collections of information for review of biologics license applications have been approved under OMB control number 0910–0338.

## III. Electronic Access

Persons with access to the internet may obtain the guidance at <https://www.regulations.gov>, <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs>, <https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances>, or <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>.

Dated: March 4, 2024.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

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**BILLING CODE 4164–01–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; Information Collection Request Title: Advanced Nursing Education Program Specific Form OMB No. 0915–0375—Revision

**AGENCY:** Health Resources and Services Administration (HRSA), Department of Health and Human Services.

**ACTION:** Notice.

**SUMMARY:** In compliance with the Paperwork Reduction Act of 1995, HRSA 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. OMB may act on HRSA’s ICR only after the 30-day comment period for this notice has closed.

**DATES:** Comments on this ICR should be received no later than April 8, 2024.

**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](https://www.reginfo.gov/public/do/PRAMain). Find this particular information collection by selecting “Currently under Review—Open for Public Comments” or by using the search function.

**FOR FURTHER INFORMATION CONTACT:** To request a copy of the clearance requests submitted to OMB for review, email Joella Roland, the HRSA Information

Collection Clearance Officer, at [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or call (301) 443–3983.

#### SUPPLEMENTARY INFORMATION:

*Information Collection Request Title:* Advanced Nursing Education (ANE) Program Specific Form OMB No. 0915–0375—Revision.

*Abstract:* HRSA provides advanced nursing education grants to educational institutions to increase the supply, distribution, quality of, and access to advanced education nurses through the ANE Programs. The ANE Programs are authorized by section 811 of the Public Health Service Act (42 U.S.C. 296j), as amended. This clearance request is for continued approval of the information collection OMB No. 0915–0375 with revisions. This revision request seeks to add the ANE-Nurse Practitioner Residency and Fellowship Program and the Maternity Care Nursing Workforce Expansion Program to the ANE Program Specific Form, and to remove programs that have closed, which include the ANE-Nurse Practitioner Residency Program and the ANE-Nurse Practitioner Residency Integration Program. The activities previously supported under the ANE Nurse Practitioner Residency Program and the ANE-Nurse Practitioner Residency Integration Program are now supported under the ANE-Nurse Practitioner Residency and Fellowship Program.

A 60-day notice published in the **Federal Register** on December 28, 2023, 88 FR 89709–10. There were no public comments.

*Need and Proposed Use of the Information:* Section 811 of the Public Health Service Act provides the Secretary of Health and Human Services with the authority to award grants to and enter into contracts with eligible entities to meet the costs of: (1) projects that support the enhancement of advanced nursing education and practice; and (2) traineeships for individuals in advanced nursing education programs. Under this section, HRSA makes awards to entities who train and support nurses characterized as “advanced education nurses.” In awarding such grants, funding preference is given to applicants with projects that will substantially benefit rural or underserved populations, or help meet public health nursing needs in state or local health departments; special consideration is given to an eligible entity that agrees to extend the award to train advanced education nurses who will practice in designated Health Professional Shortage Areas.

The ANE Program Specific Form allows HRSA to effectively target

funding and measure the impact of the ANE Programs in meeting the legislative intent and program goals of supporting the enhancement of advanced nursing education and creating opportunities for individuals in advanced nursing education programs to increase the number of advanced practice nurses, especially in rural and underserved areas. Additionally, collecting this data assists HRSA in carrying out the most impactful program and ensuring resources are used responsibly. The proposed updates to this information

collection are to accurately list the current ANE Programs.

**Likely Respondents:** Likely respondents will be current ANE Programs awardees and new applicants to ANE Programs.

**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 (includes the ANE program specific tables and attachments)	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Advanced Nursing Education Workforce .....	156	1	156	7	1,092
Nurse Anesthetist Traineeship .....	64	1	64	7	448
ANE—Sexual Assault Nurse Examiners .....	54	1	54	7	378
ANE—Nurse Practitioner Residency and Fellowship .....	64	1	64	7	448
Maternity Care Nursing Workforce Expansion .....	10	1	10	7	70
<b>Total .....</b>	<b>348</b>	<b>.....</b>	<b>348</b>	<b>.....</b>	<b>2,436</b>

**Maria G. Button,**

*Director, Executive Secretariat.*

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**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; National Health Service Corps Scholar/Students to Service Travel Worksheet, OMB No. 0915-0278—Revision

**AGENCY:** Health Resources and Services Administration (HRSA), Department of Health and Human Services.

**ACTION:** Notice.

**SUMMARY:** In compliance with the Paperwork Reduction Act of 1995, HRSA 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. OMB may act on HRSA's ICR only after the 30-day comment period for this notice has closed.

**DATES:** Comments on this ICR should be received no later than April 8, 2024.

**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](http://www.reginfo.gov/public/do/PRAMain). Find this particular information collection by selecting "Currently under Review—Open for Public Comments" or by using the search function.

**FOR FURTHER INFORMATION CONTACT:** To request a copy of the clearance requests submitted to OMB for review, email Joella Roland, the HRSA Information Collection Clearance Officer, at [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or call (301) 443-3983.

#### SUPPLEMENTARY INFORMATION:

**Information Collection Request Title:** National Health Service Corps Scholar/Students to Service Travel Worksheet, OMB No. 0915-0278—Revision.

**Abstract:** Clinicians participating in the HRSA National Health Service Corps (NHSC) Scholarship Program and the Students to Service (S2S) Loan Repayment Program use the online Travel Request Worksheet to request and receive travel funds from the Federal Government to visit eligible NHSC sites to which they may be assigned in accordance with the Public Health Service Act, section 331(c)(1).

The travel approval process is initiated when an NHSC scholar or S2S participant notifies the NHSC of an

impending interview at one or more NHSC-approved practice sites. The Travel Request Worksheet is also used to initiate the relocation process after an NHSC scholar or S2S participant has successfully been matched to an approved practice site in accordance with the Public Health Service Act, section 331(c)(3). Upon receipt of a completed Travel Request Worksheet, the NHSC will review and approve or disapprove the request and promptly notify the NHSC scholar or S2S participant and the NHSC logistics contractor regarding travel arrangements and authorization of the funding for the site visit or relocation.

A 60-day notice published in the **Federal Register** on December 29, 2023, 88 FR 90190-91. There were no public comments.

**Need and Proposed Use of the Information:** This information will facilitate NHSC scholar and S2S participants' receipt of Federal travel funds that are used to visit high-need NHSC-approved practice sites. The Travel Request Worksheet is also used to initiate the relocation process after a NHSC scholar or S2S participant has successfully been matched to an approved practice site.

**Likely Respondents:** Clinicians participating in the NHSC Scholarship Program and the S2S Loan Repayment Program.

**Burden Statement:** Burden in this context means the time expended by persons to generate, maintain, retain,