

approved under OMB control number 0910–0014; the collections of information in 21 CFR 600.14 have been approved under OMB control number 0910–0458; and the collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0338.

### III. Electronic Access

Persons with access to the internet may obtain the draft guidance at 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

Dated: December 21, 2023.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2023–28596 Filed 12–27–23; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Agency Information Collection Activities: Proposed Collection: 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 requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, 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 ICR should be received no later than February 26, 2024.

**ADDRESSES:** Submit your comments to [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or mail the HRSA Information Collection Clearance Officer, Room 14N39, 5600 Fishers Lane, Rockville, Maryland 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 Joella Roland, the HRSA Information Collection Clearance Officer, at (301) 443–3983.

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

*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 Advanced Nursing Education-Nurse Practitioner Residency and Fellowship (ANE-NPRF) 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 Advanced Nursing Education-Nurse Practitioner Residency (ANE-NPR) Program and the Advanced Nursing Education-Nurse Practitioner Residency Integration Program. The activities previously supported under the ANE-NPR and the Advanced Nursing Education-Nurse Practitioner Residency Integration Program are now supported under the ANE-NPRF Program.

*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

## TOTAL ESTIMATED ANNUALIZED BURDEN HOURS—Continued

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 Sexual Assault Nurse Examiners .....	54	1	54	7	378
ANE-NPRF .....	64	1	64	7	448
Maternity Care Nursing Workforce Expansion .....	10	1	10	7	70
Total .....	348	.....	348	.....	2,436

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.

**Maria G. Button,**

*Director, Executive Secretariat.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

[OMHA-2302-N]

### Medicare Program; Administrative Law Judge Hearing Program for Medicare Claim and Entitlement Appeals; Quarterly Listing of Program Issuances—July Through September 2023

**AGENCY:** Office of Medicare Hearings and Appeals (OMHA), HHS.

**ACTION:** Notice.

**SUMMARY:** This quarterly notice lists the OMHA Case Processing Manual (OCPM) instructions that were published from July through September 2023. This manual standardizes the day-to-day procedures for carrying out adjudicative functions, in accordance with applicable statutes, regulations, and OMHA directives, and gives OMHA staff direction for processing appeals at the OMHA level of adjudication.

**FOR FURTHER INFORMATION CONTACT:** Jon Dorman, by telephone at (571) 457-7220, or by email at [jon.dorman@hhs.gov](mailto:jon.dorman@hhs.gov).

#### SUPPLEMENTARY INFORMATION:

#### I. Background

The Office of Medicare Hearings and Appeals (OMHA), a staff division within the Office of the Secretary within the

U.S. Department of Health and Human Services (HHS), administers the nationwide Administrative Law Judge hearing program for Medicare claim; organization, coverage, and at-risk determination; and entitlement appeals under sections 1869, 1155, 1876(c)(5)(B), 1852(g)(5), and 1860D-4(h) of the Social Security Act (the Act). OMHA ensures that Medicare beneficiaries and the providers and suppliers that furnish items or services to Medicare beneficiaries, as well as Medicare Advantage organizations (MAOs), Medicaid State agencies, and applicable plans, have a fair and impartial forum to address disagreements with Medicare coverage and payment determinations made by Medicare contractors, MAOs, or Part D plan sponsors (PDPs), and determinations related to Medicare eligibility and entitlement, Part B late enrollment penalty, and income-related monthly adjustment amounts (IRMAA) made by the Social Security Administration (SSA).

The Medicare claim, organization determination, coverage determination, and at-risk determination appeals processes consist of four levels of administrative review, and a fifth level of review with the Federal district courts after administrative remedies under HHS regulations have been exhausted. The first two levels of review are administered by the Centers for Medicare & Medicaid Services (CMS) and conducted by Medicare contractors for claim appeals, by MAOs and an Independent Review Entity (IRE) for Part C organization determination appeals, or by PDPs and an IRE for Part D coverage determination and at-risk determination appeals. The third level of review is administered by OMHA and conducted by Administrative Law Judges and attorney adjudicators. The fourth level of review is administered by the HHS Departmental Appeals Board (DAB) and conducted by the Medicare Appeals Council (Council). In addition, OMHA and the DAB administer the second and third levels of appeal,

respectively, for Medicare eligibility, entitlement, Part B late enrollment penalty, and IRMAA reconsiderations made by SSA; a fourth level of review with the Federal district courts is available after administrative remedies within SSA and HHS have been exhausted.

Sections 1869, 1155, 1876(c)(5)(B), 1852(g)(5), and 1860D-4(h) of the Act are implemented through the regulations at 42 CFR part 405 subparts I and J; part 417, subpart Q; part 422, subpart M; part 423, subparts M and U; and part 478, subpart B. As noted above, OMHA administers the nationwide Administrative Law Judge hearing program in accordance with these statutes and applicable regulations. To help ensure nationwide consistency in that effort, OMHA established a manual, the OCPM. Through the OCPM, the OMHA Chief Administrative Law Judge establishes the day-to-day procedures for carrying out adjudicative functions, in accordance with applicable statutes, regulations, and OMHA directives. The OCPM provides direction for processing appeals at the OMHA level of adjudication for Medicare Part A and B claims; Part C organization determinations; Part D coverage determinations and at-risk determinations; and SSA eligibility and entitlement, Part B late enrollment penalty, and IRMAA determinations.

Section 1871(c) of the Act requires that the Secretary publish a list of all Medicare manual instructions, interpretive rules, statements of policy, and guidelines of general applicability not issued as regulations at least every three months in the **Federal Register**.

#### II. Format for the Quarterly Issuance Notices

This quarterly notice provides the specific updates to the OCPM that have occurred in the three-month period of July through September 2023. A hyperlink to the available chapters on the OMHA website is provided below. The OMHA website contains the most current, up-to-date chapters and revisions to chapters, and will be