

10.115). The draft guidance, when finalized, will represent the current thinking of FDA on “Human User Safety in New and Abbreviated New Animal Drug Applications.” It does not establish any rights for any person and is 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. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 511 have been approved under OMB control number 0910–0117; in 21 CFR part 514 have been approved under OMB control numbers 0910–0032 and 0910–0284; in 21 CFR part 516 have been approved under OMB control numbers 0910–0605 and 0910–0620; and in section 512(n)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(n)(1)) have been approved under OMB control number 0910–0669.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at <https://www.fda.gov/animal-veterinary/guidance-regulations/guidance-industry>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, or <https://www.regulations.gov>.

Dated: March 27, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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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; The National Health Service Corps and Nurse Corps Interest Capture Form—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 May 5, 2023.

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. 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 Samantha Miller, the HRSA Information Collection Clearance Officer, at paperwork@hrsa.gov or call 301–594–4394.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: The National Health Service Corps and Nurse Corps Interest Capture Form OMB No. 0915–0337—Revision.

Abstract: The National Health Service Corps (NHSC) and the Nurse Corps Scholarship and Loan Repayment Programs of HRSA are both committed to improving the health of the nation’s underserved by uniting communities in need with caring health professionals and by supporting communities’ efforts to build better systems of care. The NHSC and Nurse Corps Interest Capture Form, which can be accessed on the HRSA website at <https://bhwh.hrsa.gov/about-us/ask-question>, is an optional form that a health profession student, licensed clinician, faculty member, clinical site administrator, or other interested individual can complete and submit to HRSA online. The purpose of the form is to enable individuals and clinical sites to ask questions about the NHSC and/or Nurse Corps Scholarship and Loan Repayment Programs, and to provide their contact information so that HRSA may provide them with periodic program updates and other general information via email. Completed forms

will contain information such as the names and roles of the individual(s), their phone number(s) and email address(es), and the HRSA program(s) in which they are interested or about which they have questions.

The revisions in this ICR are as follows:

a. The discontinuation of the print version of the NHSC and Nurse Corps Interest Capture Form, previously used by HRSA staff for sharing HRSA program information with health profession students and providers at national and regional conferences and campus recruiting events.

b. The addition of an online version of the NHSC and Nurse Corps Interest Capture Form, located on the HRSA website at <https://bhwh.hrsa.gov/about-us/ask-question>.

A 60-day notice published in the **Federal Register** on January 11, 2023, vol. 88, No. 7; pp. 1600–01. There were no public comments.

Need and Proposed Use of the Information: The need and purpose of this information collection is to share resources and information regarding the NHSC and Nurse Corps Scholarship and Loan Repayment Programs with interested HRSA website (<https://www.hrsa.gov/>) visitors.

Likely Respondents: Individuals and potential service sites interested in the NHSC or Nurse Corps Scholarship and Loan Repayment 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	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
NHSC and Nurse Corps Interest Capture Form	16,144	1	16,144	.025	404
Total	16,144	16,144	404

Maria G. Button,

Director, Executive Secretariat.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

[OMHA-2301-N]

Medicare Program; Administrative Law Judge Hearing Program for Medicare Claim and Entitlement Appeals; Quarterly Listing of Program Issuances—October Through December 2022

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 October through December 2022. 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.

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 (PDPSs), 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 PDPSs 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 October through December 2022. 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 available earlier than we publish our quarterly notice. We believe the OMHA website provides more timely access to the current OCPM chapters for those involved in the Medicare claim; organization, coverage, and at-risk determination; and entitlement appeals processes. We also believe the website offers the public a more convenient tool for real time access to current OCPM provisions. In addition, OMHA has a listserv to which the public can subscribe to receive notification of certain updates to the OMHA website, including when new or revised OCPM chapters are posted. If accessing the OMHA website proves to be difficult, the contact person listed above can provide the information.