

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' website address at website address at <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing>.

FOR FURTHER INFORMATION CONTACT: William N. Parham at (410) 786-4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS-10507 State-based Exchange Annual Report Tool (SMART)
CMS-10105 National Implementation of the In-Center Hemodialysis CAHPS Survey

Under the PRA (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* State-based Exchange Annual Report Tool (SMART); *Use:* The annual report is the primary vehicle to insure comprehensive compliance with all reporting requirements contained in the Affordable Care Act (ACA). It is specifically called for in Section 1313(a)(1) of the Act which requires a State Based Exchange (including an Exchange using the Federal Platform) to keep an accurate accounting of all activities, receipts, and expenditures, and to submit a report annually to the

Secretary concerning such accounting. CMS will use the information collected from States to assist in determining if a State is maintaining a compliant operational Exchange. *Form Number:* CMS-10507 (OMB control number: 0938-1244); *Frequency:* Annually; *Affected Public:* State, Local, or Tribal governments; *Number of Respondents:* 21; *Total Annual Responses:* 21; *Total Annual Hours:* 4,281. (For policy questions regarding this collection contact Shilpa Gogna at 301-492-4257.)

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* National Implementation of the In-Center Hemodialysis CAHPS Survey; *Use:* The national implementation of the ICH CAHPS Survey is designed to allow third-party, CMS-approved survey vendors to administer the ICH CAHPS Survey using mail-only, telephone-only, or mixed (mail with telephone follow-up) modes of survey administration. Experience from previous CAHPS surveys shows that mail, telephone, and mail with telephone follow-up data collection modes work well for respondents, vendors, and health care providers. Any additional forms of information technology, such as web surveys, is under investigation as a potential survey option in this population.

Data collected in the national implementation of the ICH CAHPS Survey are used for the following purposes:

- To provide a source of information from which selected measures can be publicly reported to beneficiaries as a decision aid for dialysis facility selection.
- To aid facilities with their internal quality improvement efforts and external benchmarking with other facilities.
- To provide CMS with information for monitoring and public reporting purposes.
- To support the ESRD Quality Improvement Program.

Form Number: CMS-10105 (OMB control number: 0938-0926); *Frequency:* Semi Annually; *Affected Public:* Individuals and Households; *Number of Respondents:* 103,500; *Total Annual Responses:* 621,000; *Total Annual Hours:* 55,890. (For policy questions regarding this collection contact Israel H. Cross at 410-786-0619.)

Dated: March 22, 2022.

William N. Parham, III,
Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

[OMHA-2201-N]

Medicare Program; Administrative Law Judge Hearing Program for Medicare Claim and Entitlement Appeals; Quarterly Listing of Program Issuances—October Through December 2021

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 2021. 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 (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 October through December 2021. 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.

III. How To Use the Notice

This notice lists the OCPM chapters and subjects published during the quarter covered by the notice so the reader may determine whether any are of particular interest. The OCPM can be accessed at <https://www.hhs.gov/about/agencies/omha/the-appeals-process/case-processing-manual/index.html>.

IV. OCPM Releases for October Through December 2021

The OCPM is used by OMHA adjudicators and staff to administer the OMHA program. It offers day-to-day operating instructions, policies, and procedures based on statutes and regulations, and OMHA directives.

The following is a list and description of OCPM provisions that were issued or revised in the three-month period of October through December 2021. This information is available on our website at <https://www.hhs.gov/about/agencies/omha/the-appeals-process/case-processing-manual/index.html>.

General OCPM Updates

The Code of Federal Regulations (CFR) is the codification of the general and permanent rules published in the **Federal Register** by the executive

departments and agencies of the Federal Government. The OCPM frequently cites to the governing regulations for the Medicare Program contained in the CFR. The OCPM provides hyperlinks to those regulation citations at the Electronic Code of Federal Regulations (eCFR) website, available at <https://www.ecfr.gov>.

In late summer 2021, the eCFR website underwent significant updates. These updates rendered many of the eCFR hyperlinks embedded in the OCPM inoperable. To reconcile the OCPM with these updates, OMHA made revisions to footnotes and citations in the following sections: 4.4.1.3, 5.2.1.2, 5.4.1, 5.4.3, 7.1.1.1, 7.1.1.2, 7.1.4.1, 7.2.1, 7.2.2, 7.3.1, 7.3.2, 7.3.4, 7.4.3, 7.5.2, 7.5.4, 7.5.5, 7.5.6, 7.5.8, 7.5.9, 10.5.2, 10.5.3, 10.7.10.1, 10.7.11, 10.7.11.1, 10.7.11.2, 11.3.2, 11.4.5, 17.1.4, 17.1.5.2, 17.1.5.4, 17.1.11.1, 17.2.1, 20.1.4, 20.2.2, 20.4.3.

OCPM Chapter 11: Procedural Review and Determinations—Section 11.3.2

This chapter was initially released on May 24, 2019, and was included in a quarterly notice published in the July 16, 2019 **Federal Register** (84 FR 33956). Section 11.3 of this chapter describes the amount in controversy (AIC) that is the statutory threshold monetary amount that a party with standing to appeal must meet to be entitled to a hearing or review of a dismissal.

CMS issues annual adjustments to the AIC threshold amounts for ALJ hearings and judicial review under the Medicare appeals process. This revision to OCPM 11.3.2 updates the table in this section to reflect the AIC for the ten most recent calendar years.

OCPM Chapter 16: Decisions—Section 16.4.3

This chapter was initially released on October 9, 2019, and was included in a quarterly notice published in the July 1, 2020 **Federal Register** (85 FR 39571). Section 16.4.3 of this chapter describes when an adjudicator issues a stipulated decision. A stipulated decision may be issued when CMS, a CMS contractor, or a plan submits a written statement, or makes an oral statement at a hearing, indicating that an enrollee's at-risk determination should be reversed, or that the items or services at issue should be covered or payment may be made, and agreeing to the amount of payment that the parties believe should be made, if the amount of payment is at issue. This revision updates footnote 15 in section 16.4.3 to reflect the revised regulation at 42 CFR 422.562(d)(3) that became effective on March 22, 2021 (86

FR 6101), which provides that, “for the sole purpose of applying the regulations at § 405.1038(c) of this chapter, an MA organization is included in the definition of “contractors” as it relates to stipulated decisions.”

OCPM Chapter 20: Post-Adjudication Actions—Sections 20.5.3, 20.6.4, 20.7.4, 20.8.4, 20.9.2, 20.11.2

This chapter was initially released on May 25, 2018, and was included in a quarterly notice published in the August 7, 2018 **Federal Register** (83 FR 38700). Since the initial release, the OMHA Central Operations office relocated. This revision updates the Central Operations mailing address accordingly in sections 20.5.3, 20.6.4, 20.7.4, 20.8.4, 20.9.2, and 20.11.2.

Karen W. Ames,

Executive Director, Office of Medicare Hearings and Appeals.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request; Hazardous Waste Worker Training—National Institute of Environmental Health Sciences (NIEHS)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995 to provide opportunity for public comment on proposed data collection projects, the National Institute of Environmental Health Sciences (NIEHS) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Sharon D. Beard, Director, Worker Training Program (WTP), Division of Extramural Research and Training (DERT), NIEHS, P.O. Box 12233 MD: K3-14, Research Triangle Park, NC 27709 or call non-toll-free

number 984-287-3237 or Email your request, including your address to: beard1@niehs.nih.gov. Formal requests for additional plans and instruments must be requested in writing.

SUPPLEMENTARY INFORMATION: Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires: Written comments and/or suggestions from the public and affected agencies are invited to address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Proposed Collection Title: Hazardous Waste Worker Training Grantee Data Collection—42 CFR part 65, 0925-0348, Expiration Date 07/31/2022 REVISION, National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH).

Need and Use of Information Collection: The National Institute of Environmental Health Sciences (NIEHS) was given major responsibility for initiating a worker safety and health training program under section 126 of the Superfund Amendments and Reauthorization Act of 1986 (SARA) for hazardous waste workers and emergency responders. A network of non-profit organizations that are committed to protecting workers and their communities by delivering high-quality, peer-reviewed safety and health curricula to target populations of hazardous waste workers and emergency responders has been developed. The NIEHS Worker Training Program (WTP) contains the Hazardous Waste Worker Training Program (HWWTP) and the NIEHS/Department of Energy (DOE) Nuclear Worker Training Program to fund nonprofit organizations to develop and administer model health and safety training programs for hazardous materials or waste workers. The HWWTP provides occupational safety and health training for workers who may be engaged in activities related to hazardous waste

removal, containment, or chemical emergency response. This program is the core component of WTP. The other optional programs include the Environmental Career Worker Training Program (ECWTP) that focuses on delivering comprehensive training to increase the number of disadvantaged and underrepresented workers in areas such as environmental restoration, construction, hazardous materials/waste handling, and emergency response and the HAZMAT Disaster Preparedness Training Program (HDPTP) that supports the development and delivery of training for hazardous material and debris cleanup commonly needed after natural and man-made disasters. The purpose of the NIEHS/DOE Nuclear Worker Training Program is to support the development of model programs for the training and education of workers engaged in activities related to hazardous materials and waste generation, removal, containment, transportation and emergency response within the DOE nuclear weapons complex. In thirty-five years (FY 1987–2022) the WTP has successfully supported 25 primary grantees that have trained more than 4.5 million workers across the country and presented over 278,821 classroom, hands-on, and online training courses, which have accounted for over 55 million contact hours of actual training. Generally, the grant will initially be for one year, and subsequent continuation awards are also for one year at a time. Grantees must submit a separate application to have the support continued for each subsequent year. Grantees are to provide information in accordance with S65.4 (a), (b), (c) and 65.6(a) on the nature, duration, and purpose of the training, selection criteria for trainees’ qualifications and competency of the project director and staff, the adequacy of training plans and resources, including budget and curriculum, and response to meeting training criteria in OSHA’s Hazardous Waste Operations and Emergency Response Regulations (29 CFR 1910.120). As a cooperative agreement, there are additional requirements for the progress report section of the application. Grantees are to provide their information into the WTP Grantee Data Management System. The information collected is used by the Director through officers, employees, experts, and consultants to evaluate applications based on technical merit to determine whether to make awards and whether appropriate training is being conducted to support continuation of the grant into subsequent years.