

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Statement of Organization, Functions and Delegations of Authority

This notice amends Part R of the Statement of Organization, Functions and Delegations of Authority of the Department of Health and Human Services (HHS), Health Resources and Services Administration (HRSA) (60 FR 56605, as amended November 6, 1995; as last amended at 84 FR 49535–49540 dated September 20, 2019).

HRSA is making changes within their Healthcare Systems Bureau, Division of National Hansen's Disease Program, to improve the delivery of patient services, increase management and administrative efficiencies, and optimize use of staff resources within the Division.

Specifically this reorganization updates the functions of the Division of National Hansen's Disease Program (RRH).

Chapter RRH—Division of National Hansen's Disease Program

Section RRH.20 Function

Delete the functional statement for the Division of National Hansen's Disease Program (RRH) in its entirety and replace with the following:

Division of National Hansen's Disease Program (RRH)

The National Hansen's Disease Program (NHDP) in accordance with regulations and the Public Health Service (PHS) Act, Sec. 320 as amended by Public Law 105–78, Sec. 211, (1) provides care and treatment for persons with Hansen's Disease (leprosy), including managing a national short-term and outpatient health care delivery program providing specialized services to persons with Hansen's Disease; (2) conducts and promotes the coordination of research (including clinical research), investigations, demonstrations, and studies relating to the causes, diagnosis, treatment, control, and prevention of Hansen's disease and other mycobacterial diseases and complications related to such diseases; (3) conducts training in the diagnosis and management of Hansen's disease and related complications; (4) provides education and training to staff from the outpatient Hansen's Disease Clinics and to private physicians; (5) operates and oversees the National Hansen's Disease Museum and Cemetery; (6) consults on the coordination of activities within HRSA and HHS, and with other federal

agencies, state and local governments, and other public and private organizations involved in Hansen's Disease activities; (7) manages a network of contracted outpatient clinics providing care to persons with Hansen's Disease; and (8) manages and coordinates the National Hansen's Disease Program's administrative and operational activities with HRSA and HHS, other federal agencies, state and local governments, and other public and private organizations involved in Hansen's Disease activities.

Section RRH.30, Delegation of Authority

All delegations of authority and re-delegations of authority made to officials and employees of affected organizational components will continue in them or their successors pending further redelegation, if allowed, provided they are consistent with this reorganization.

This reorganization is effective upon date of signature.

(Authority: 44 U.S.C. 3101)

Dated: December 18, 2019.

Thomas J. Engels,
Administrator.

[FR Doc. 2019–28267 Filed 1–3–20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

[OMHA–1903–N]

Medicare Program; Administrative Law Judge Hearing Program for Medicare Claim and Entitlement Appeals; Quarterly Listing of Program Issuances—July Through September 2019

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 2019. 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 July through September 2019. 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 July Through September 2019

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 July through September 2019. 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

OMHA reorganized its Program Evaluation and Policy Division and Field Operations Division into two branches of a new Appeals Policy and Operations Division. References to the prior division names in OCPM chapters 6, 7, 11, 18, and 20 were updated to reflect the change in OMHA's organizational structure.

CMS's final rule entitled "Medicare Program; Changes to the Medicare Claims and Medicare Prescription Drug Coverage Determination Appeals Procedures" was published in the May 7, 2019 **Federal Register** (84 FR 19855) with an effective date of July 8, 2019. This final rule made a number of changes to help streamline the appeals process and reduce administrative burden, and to help ensure the regulations are clearly arranged and written to give stakeholders a better understanding of the appeals process. Among other things, these regulations corrected and clarified cross references, definitions, and terminology. To implement these changes, revisions were made to footnotes and citations in OCPM 9.3.6.1, 11.3.6.3, 17.1.5, 17.1.5.3 and 17.2.2.

OCPM Chapter 4: Parties—Section 4.4.1.1

This chapter was initially released on March 29, 2019, and was included in a quarterly notice published in the May 3, 2019 **Federal Register** (84 FR 19086). Section 4.4.1.1 of this chapter states that a Unified Program Integrity Contractor (UPIC) cannot elect party status in an appeal, and may only participate as a non-party. As initially published, this section cited to CMS's Medicare Program Integrity Manual (MPIM), internet-only manual publication 100–

08, chapter 4, section 4.8.2, which previously stated that a Zone Program Integrity Contractor (ZPIC) could not elect party status in an appeal, and section 4.1, which stated that all references to ZPICs shall also apply to UPICs, unless otherwise specified in the UPIC Statement of Work (SOW). Effective October 22, 2018, CMS revised the MPIM to directly state that a UPIC cannot invoke party status, and can only participate in OMHA proceedings as a non-party. This revision to OCPM 4.4.1.1 updates a footnote in this section to reflect the CMS manual's revised language. This revision does not change the way that OMHA interprets or implements the underlying policy that a UPIC cannot elect party status.

OCPM Chapter 5: Representatives—Section 5.2.1.2

This chapter was initially released on July 27, 2018, and was included in a quarterly notice published in the November 14, 2018 **Federal Register** (83 FR 56859). Section 5.2.1.2 of this chapter lists the required elements for a valid appointment of representative. This revision updates the required elements in accordance with revisions to 42 CFR 405.910(c) that became effective on July 8, 2019 (84 FR 19857 through 19858), and corresponding updates to CMS's Medicare Claims Processing Manual (MCPM), internet-only manual publication 100–04, chapter 29, section 270.1.2.

OCPM Chapter 6: CMS, CMS Contractor, and Plan Roles—Sections 6.5.3.1, 6.5.4.1, 6.5.10, 6.7.3.1, 6.7.3.3, 6.7.4

This chapter was initially released on July 27, 2018, and was included in a quarterly notice published in the November 14, 2018 **Federal Register** (83 FR 56859). Section 6.5.3.1 of this chapter previously stated that in a Part A, Part B, or Part C appeal, CMS or a CMS contractor may elect to be a party or non-party participant no later than 10 calendar days after "receiving the notice of hearing." This revision implements changes to 42 CFR 405.1010(b)(3)(ii) and 405.1012(a)(1) (84 FR 19862), and clarifies that the notice of hearing may be received by the Qualified Independent Contractor (QIC) or another contractor designated by CMS to receive the notice of hearing. Section 6.5.4.1 of this chapter is revised to clarify that CMS has designated the Administrative Qualified Independent Contractor (AdQIC) to receive notices of hearing. Sections 6.5.10 and 6.7.4 of this chapter previously stated written CMS or contractor elections and requests and evidentiary submissions must be sent to the parties who were sent a copy of the

reconsideration, if no hearing has been scheduled; or the parties who were sent a copy of the notice of hearing, if a hearing has been scheduled. This revision implements changes to 42 CFR 405.1010(b)(1) (84 FR19862), and identifies the copy requirement for appeals where an appeal has been escalated to OMHA, but has not been scheduled. Sections 6.7.3.1 and 6.7.3.3 of this chapter are revised to clarify that an attorney adjudicator may also grant additional time for submissions.

OCPM Chapter 9: Request and Correspondence Intake, Docketing, and Assignment—Section 9.3.4

This chapter was initially released on February 1, 2019, and was included in a quarterly notice published in the May 3, 2019 **Federal Register** (84 FR 19086). Section 9.3.4 of this chapter describes how OMHA appeal numbers are assigned for new appeals. This revision adds a note clarifying that if a single request for hearing or review identifies more than one reconsideration number, OMHA will process each reconsideration number as a separate request for purposes of assigning appeal numbers, but will assign the appeals to the same adjudicator to the extent possible for administrative efficiency.

OCPM Chapter 14: Scheduling and Noticing for Prehearing Conferences and Hearings—Sections 14.5.4, 14.6.7.4

This chapter was initially released on September 28, 2018, and was included in a quarterly notice published in the November 14, 2018 **Federal Register** (83 FR 56859). Section 14.5.4 is revised to clarify that CMS has designated the AdQIC to receive notices of hearing. Section 14.6.7.4 of this chapter describes when the hearing format may be changed. Previously, this section stated that if a party other than an unrepresented beneficiary who filed a request for hearing requests a VTC hearing or in-person hearing, concurrence of the Associate Chief ALJ was necessary to grant the request. This revision clarifies that the concurrence of the Associate Chief ALJ is only required to grant a request for an in-person hearing.

OCPM Chapter 18: Requests for Information and Remands—Sections 18.1.1.2, 18.1.5, 18.1.7.2, 18.2.2, 18.4.3

This chapter was initially released on November 30, 2018, and was included in a quarterly notice published in the January 31, 2019 **Federal Register** (84 FR 763). Sections 18.1.1.2 and 18.1.5 of this chapter describe how an OMHA adjudicator may issue a request for information if he or she believes that the

written record is missing information essential to resolving the issues on appeal. This revision clarifies that a request for information may be made for an official copy of a dismissal of a request for redetermination or reconsideration. Section 18.1.7.2 of this chapter lists actions an OMHA adjudicator may take if the missing information is not submitted within the applicable time frame. This revision added a note that a remand is authorized when the entity that conducted the reconsideration does not respond to a request for a case file, or does respond but is unable to furnish the requested case file. This note further states that case file requests are not requests for information made under 42 CFR 405.1034(a) or 423.2034(a). Rather, as discussed at 84 FR 19866, they are made in accordance with joint operating procedures between OMHA and the entity that conducted the reconsideration. Section 18.2.2 of this chapter explains that if the missing information is not provided, an OMHA adjudicator may remand the appeal. This revision clarifies that if an official copy of a dismissal of a request for redetermination or reconsideration is not received, an OMHA adjudicator may issue a remand to the entity that conducted the reconsideration, or its successor, to reconstruct the record or, if unable to do so, initiate a new appeal adjudication. Section 18.4.3 of this chapter explains the circumstances under which a remand may be reviewed. This revision clarifies that a remand issued because an official copy of a dismissal of a request for redetermination or reconsideration or case file cannot be obtained from the QIC may be subject to review by the Chief ALJ or designee in accordance with revisions to 42 CFR 405.1056(g) and 423.2056(g) that became effective on July 8, 2019 (84 FR 19866).

OCPM Chapter 20: Post-Adjudication Actions—Sections 20.7.1.3, 20.7.5.6, 20.7.7.3, 20.8.4, 20.8.5.6, 20.8.6.1, 20.8.7.2, 20.11.4

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). Sections 20.7.1.3 and 20.7.5.6 of this chapter previously stated a dismissal may be vacated within 6 months of the date of the notice of dismissal. This revision updates the time frame from 6 months to 180 calendar days in accordance with revisions to 42 CFR 405.1052(e) and 423.2052(e) that became effective on July 8, 2019 (84 FR 19857). Section 20.7.7.3 of this chapter updates the form number for the Order

Vacating Dismissal from OMHA–180 to OMHA–181. Section 20.8.4 of this chapter is revised to clarify that a request for review of a remand may only be filed with OMHA Central Operations. Section 20.8.5.6 of this chapter is revised to clarify that requests for a copy of administrative records are made directly through OMHA Central Operations. Section 20.8.6.1 of this chapter removed an incorrect statement that an OMHA adjudicator must make a request for information before issuing a remand for a missing case file. The remand order is authorized under 42 CFR 405.1056(a)(2). Chapter 20.8.7.2 of this chapter is revised to clarify that the re-established appeal number is used with the Notice of Vacated Remand and Order Vacating Remand. Chapter 20.11.4 of this chapter describes how an adjudicator responds to a Council remand order for missing evidence or information. Previously, this section stated that if the adjudicator is able to furnish the requested evidence or information, the complete administrative record was returned to the Council at the address specified in the Council's remand order. This revision states the records shall be returned to the Council at the address specified in OCPM 19.1.2.

Dated: December 31, 2019.

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

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special