

FDA will do its best to accommodate requests to present. FDA urges individuals and organizations with common interests to consolidate or coordinate their comments, and request a single time for a joint presentation. For those requesters with Internet access, Caryn Cohen (see **FOR FURTHER INFORMATION CONTACT**) will email you regarding your request to speak by March 1, 2016.

#### IV. Transcripts

Please be advised that as soon as a transcript is available, it will be accessible at <http://www.regulations.gov>. It may be viewed at the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. The Freedom of Information office address is available on the Agency's Web site at <http://www.fda.gov>. It will also be available after the workshop at <http://www.fda.gov/TobaccoProducts/NewsEvents/ucm238308.htm> as soon as the official transcript is finalized.

Dated: February 18, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

[OMHA-1503-N]

### Medicare Program; Administrative Law Judge Hearing Program for Medicare Claim and Entitlement Appeals; Quarterly Listing of Program Issuances—October Through December 2015

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

**ACTION:** Notice.

**SUMMARY:** This quarterly notice lists of the OMHA Case Processing Manual (OCPM) manual instructions that were published from October through December, 2015. 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:** Amanda Axeen, by telephone at (571)

777-2705, or by email at [amanda.axeen@hhs.gov](mailto:amanda.axeen@hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

The Office of Medicare Hearings and Appeals (OMHA), a staff division within the Office of the Secretary of the U.S. Department of Health and Human Services (HHS), administers the nationwide Administrative Law Judge hearing program for Medicare claim, organization and coverage 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) and Medicaid State Agencies, 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 and coverage 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 for Part C organization determination appeals, or by PDPs and an independent review entity for Part D coverage determination appeals. The third level of review is administered by OMHA and conducted by Administrative Law Judges. The fourth level of review is administered by the HHS Departmental Appeals Board (DAB) and conducted by the Medicare Appeals 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. As part of that effort, OMHA is establishing a manual, the OMHA Case Processing Manual (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 SSA eligibility and entitlement, Part B late enrollment penalty, and IRMAA determinations.

Section 1871(c) of the Act requires that we 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 3 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 3-month period. A hyperlink to the available chapters on the OMHA Web site is provided below. The OMHA Web site 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 Web site list provides more timely access to the current OCPM chapters for those involved in the Medicare claim, organization and coverage determination and entitlement appeals processes. We also believe the Web site 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 immediate notification of any updates to the OMHA Web site. This listserv avoids the need to check the OMHA Web site, as update notifications are sent to subscribers as they occur. If accessing the OMHA Web site 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. We expect this notice to be used in concert with the previously published notices. The OCPM can be accessed at [http://www.hhs.gov/omha/OMHA\\_Case\\_Processing\\_Manual/index.html](http://www.hhs.gov/omha/OMHA_Case_Processing_Manual/index.html).

#### IV. OCPM Releases for October Through December 2015

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 new OCPM provisions and the subject matter that have been implemented in the covered 3-month period. The full text of current OCPM provisions is available on our Web site at [http://www.hhs.gov/omha/OMHA\\_Case\\_Processing\\_Manual/index.html](http://www.hhs.gov/omha/OMHA_Case_Processing_Manual/index.html).

##### OCPM Division I: General Matters

*Chapter 7, Adjudication Time Frames.* This new chapter describes the cases subject to statutory time frames, tolling and waivers of adjudication time frames, and provides instruction on how to handle cases escalated from the Qualified Independent Contractor (QIC) to OMHA and from OMHA to the Medicare Appeals Council.

##### OCPM Division II: Part A/B Claim Determinations

*Chapter 4, Administrative Record.* This new chapter describes the minimum organization and exhibiting structure for documents and evidence received in support of Medicare Part A and B requests for hearing filed with OMHA. This chapter standardizes the way that OMHA prepares these files for further processing.

*Chapter 7, Scheduling and Notices of Hearing.* This new chapter describes the scheduling and notice of hearing process in Medicare Part A and Part B cases and provides guidance on sending amended notices of hearing, rescheduling or cancelling hearings and issuing notices for supplemental hearings.

*Chapter 13, Closing the Case.* This new chapter describes the necessary administrative steps to finalize and close a Medicare Part A or Part B case. The chapter also provides guidance on mailing the notice of disposition and shipping the case file.

##### OCPM Division III: Part C Organization Determinations

*Chapter 4, Administrative Record.* This new chapter describes the minimum organization and exhibiting

structure for documents and evidence received in support of Medicare Part C requests for hearing filed with OMHA. This chapter standardizes the way that OMHA prepares these files for further processing.

*Chapter 7, Scheduling and Notices of Hearing.* This new chapter describes the scheduling and notice of hearing process in Medicare C cases and provides guidance on sending amended notices of hearing, rescheduling or cancelling hearings and issuing notices for supplemental hearings.

*Chapter 13, Closing the Case.* This new chapter describes the necessary administrative steps to finalize and close a Medicare Part C case. The chapter also provides guidance on mailing the notice of disposition and shipping the case file.

##### OCPM Division IV: Part D Coverage Determinations

###### *Chapter 4, Administrative Record.*

This new chapter describes the minimum organization and exhibiting structure for documents and evidence received in support of Medicare Part D requests for hearing filed with OMHA. This chapter standardizes the way that OMHA prepares these files for further processing.

*Chapter 7, Scheduling and Notices of Hearing.* This new chapter describes the scheduling and notice of hearing process in Medicare D cases and provides guidance on sending amended notices of hearing, rescheduling or cancelling hearings and issuing notices for supplemental hearings.

*Chapter 13, Closing the Case.* This new chapter describes the necessary administrative steps to finalize and close a Medicare Part D case. The chapter also provides guidance on mailing the notice of disposition and shipping the case file.

##### OCPM Division V: SSA Determinations

###### *Chapter 4, Administrative Record.*

This new chapter describes the minimum organization and exhibiting structure for documents and evidence received in support of requests for hearing filed with OMHA following reconsiderations of Medicare eligibility and entitlement, Part B late enrollment penalties, and Part B and Part D IRMAAs issued by SSA. This chapter standardizes the way that OMHA prepares these files for further processing.

*Chapter 7, Scheduling and Notices of Hearing.* This new chapter describes the scheduling and notice of hearing process for requests for hearing filed following reconsideration of Medicare eligibility and entitlement, Part B late

enrollment penalties, and Part B and Part D IRMAAs issued by SSA. The chapter also provides guidance on sending amended notices of hearing, rescheduling or cancelling hearings and issuing notices for supplemental hearings.

*Chapter 13, Closing the Case.* This new chapter describes the necessary administrative steps to finalize and close a case on appeal at OMHA following reconsideration of Medicare eligibility and entitlement, Part B late enrollment penalties, and Part B and Part D IRMAAs issued by SSA. The chapter also provides guidance on mailing the notice of disposition and shipping the case file.

Dated: February 8, 2016.

**Jason M. Green,**

Chief Advisor, Office of Medicare Hearings and Appeals.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings 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 grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Member Conflict: Ethology, Addiction and Development.

*Date:* March 14, 2016.

*Time:* 11:00 a.m. to 1:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* Wind Cowles, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive Room 3172, Bethesda, MD 20892, [cowleshw@csr.nih.gov](mailto:cowleshw@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Small Business: Cardiovascular Sciences.