

Silver Spring, MD 20993-0002, 301-796-0963.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Opioid Use Disorder: Endpoints for Demonstrating Effectiveness of Drugs for Medication-Assisted Treatment." This guidance addresses the clinical endpoints acceptable to demonstrate effectiveness of drugs for medication-assisted treatment of opioid use disorder. FDA is also requesting comments on when the use of placebo or active controls is most appropriate in clinical trials for such drugs.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on endpoints for demonstrating effectiveness of drugs for medication-assisted treatment of opioid use disorder. 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. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 312 have been approved under OMB control number 0910-0014.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <https://www.regulations.gov>.

Dated: August 1, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

[OMHA-1801-N]

Medicare Program; Administrative Law Judge Hearing Program for Medicare Claim and Entitlement Appeals; Quarterly Listing of Program Issuances—April Through June 2018

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

ACTION: Notice.

SUMMARY: This quarterly notice announces the reorganization and revision of the OMHA Case Processing Manual (OCPM) and lists the OCPM manual instructions that were published from April through June 2018. 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.

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 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), 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 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 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 ensure nationwide consistency in that effort, OMHA established 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 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 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 three-month period of April through June 2018. 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 and coverage 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.

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 future published notices. The OCPM can be accessed at <https://www.hhs.gov/about/agencies/omha/the-appeals-process/case-processing-manual/index.html>.

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 future published notices. The OCPM can be accessed at <https://www.hhs.gov/about/agencies/omha/the-appeals-process/case-processing-manual/index.html>.

IV. Reorganization and Revision of the OCPM

OMHA is in the process of restructuring, reorganizing, and reformatting the OCPM to make it more user friendly. As part of this ongoing process, we are drafting new OCPM chapters and revising existing OCPM chapters to conform to the new format. Previously, the OCPM contained separate divisions for each Medicare part, and most chapters were repeated in each division. New and revised chapters provide information pertaining to all appeals arising under all Medicare parts. Plain language is used where possible and guidance is provided in a user-friendly, question-and-answer format. The manual is also being revised to reflect regulatory changes made by the final rule that was published in the

January 17, 2017 **Federal Register** and became effective on March 20, 2017 (82 FR 4974). New and revised chapters can be accessed at <https://www.hhs.gov/about/agencies/omha/the-appeals-process/case-processing-manual/index.html>. Unless inconsistent with a statute, regulation, or other controlling authority, provisions of chapters that were published before May 10, 2018, remain in effect until revised, and can be accessed at: <https://www.hhs.gov/about/agencies/omha/the-appeals-process/case-processing-manual/2017/index.html>.

IV. OCPM Releases for April Through June 2018

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. For future quarterly notices, we will list only the specific updates to the list of manual provisions that have occurred in the covered 3-month period. This information is available on our website at <https://www.hhs.gov/about/agencies/omha/the-appeals-process/case-processing-manual/index.html>.

OCPM Chapter 1: Manual Overview, Definition, and Governance

Chapter 1, Manual Overview, Definition, Governance. This chapter describes the OCPM's purpose and organization. It also describes how to navigate the OCPM, and when and how to cite an OCPM provision as an authority in an action issued by an OMHA adjudicator.

OMHA receives a variety of appeals, as discussed in section I above. This chapter describes when a specific OCPM provision may be read to apply to all or certain types of appeals, and describes OCPM conventions for citing to statutory, regulatory, and other applicable authorities. In addition, this chapter describes the process for updating an OCPM chapter, as well as how to determine when a revision was issued or became effective, and how to access prior versions of a chapter.

OCPM Chapter 19: Closing the Case

Chapter 19, Closing the Case. Timely notice of the disposition and closing of a case, in compliance with applicable laws and policy, is important to ensure that effectuation of a decision, or other necessary actions, can be undertaken by the parties to the appeal, CMS, CMS contractors, plans, SSA, or the Council.

Receipt of the disposition package also governs the timing for parties to file an appeal, and for the Council to initiate a review of a case on its own motion. In addition, the timely transfer of the administrative record helps ensure effectuation can occur, SSA, CMS, or CMS contractors can refer cases for review by the Council, and the record can be transitioned to storage. This revised chapter describes the necessary steps to timely and accurately close appeals pending at OMHA.

OCPM Chapter 20: Post-Adjudication Actions

Chapter 20, Post-Adjudication Actions. This new chapter describes the various potential actions that may occur after an OMHA adjudicator issues a decision, dismissal, or remand, and the procedures for responding to such actions. These actions include requests to correct a clerical error, reopen a decision, vacate a dismissal, or review a remand issued by an OMHA adjudicator. OMHA adjudicators take action to grant or deny such a request, and in some instances may initiate an action on their own motion.

In addition, parties may seek Council review of decisions and dismissals. CMS and its contractors, or SSA, may also refer decisions and dismissals to the Council for possible own motion review. The chapter also describes actions the Council may take on an appealed or referred case, including remanding the case to OMHA.

Dated: July 23, 2018.

Amanda M. Axeen,
Acting Chief Advisor, Office of Medicare Hearings and Appeals.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Declaration Under the Public Readiness and Emergency Preparedness Act for Zika Virus Vaccines

AGENCY: Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The Secretary is amending a Declaration pursuant to the Public Health Service Act to provide liability immunity protection for activities related to Zika virus vaccines consistent with the terms of the Declaration.

DATES: The declaration is effective as of August 1, 2018.