

VIII. Category of Disease, Health Condition, or Threat

42 U.S.C. 247d–6d(b)(2)(A)

The category of disease, health condition, or threat for which I recommend the administration or use of the Covered Countermeasures is Ebola disease (EBOD).

IX. Administration of Covered Countermeasures

42 U.S.C. 247d–6d(a)(2)(B)

Administration of the Covered Countermeasure means physical provision of the countermeasures to recipients, or activities and decisions directly relating to public and private delivery, distribution and dispensing of the countermeasures to recipients, management and operation of countermeasure programs, or management and operation of locations for purpose of distributing and dispensing countermeasures.

X. Population

42 U.S.C. 247d–6d(a)(4), 247d–6d(b)(2)(C)

The populations of individuals include any individual who uses or is administered the Covered Countermeasures in accordance with this Declaration.

Liability immunity is afforded to manufacturers and distributors without regard to whether the countermeasure is used by or administered to this population; liability immunity is afforded to program planners and qualified persons when the countermeasure is used by or administered to this population, or the program planner or qualified person reasonably could have believed the recipient was in this population.

XI. Geographic Area

42 U.S.C. 247d–6d(a)(4), 247d–6d(b)(2)(D)

Liability immunity is afforded for the administration or use of a Covered Countermeasure without geographic limitation.

Liability immunity is afforded to manufacturers and distributors without regard to whether the countermeasure is used by or administered in any designated geographic area; liability immunity is afforded to program planners and qualified persons when the countermeasure is used by or administered in any designated geographic area, or the program planner or qualified person reasonably could have believed the recipient was in that geographic area.

XII. Effective Time Period

42 U.S.C. 247d–6d(b)(2)(B)

Liability immunity for Covered Countermeasures began on February 27, 2015 and extends through December 31, 2023.

XIII. Additional Time Period of Coverage

42 U.S.C. 247d–6d(b)(3)(B) and (C)

I have determined that an additional 12 months of liability protection is reasonable to allow for the manufacturer(s) to arrange for disposition of the Covered Countermeasure, including return of the Covered Countermeasures to the manufacturer, and for Covered Persons to take such other actions as are appropriate to limit the administration or use of the Covered Countermeasures.

Covered Countermeasures obtained for the Strategic National Stockpile (SNS) during the effective period of this Declaration are covered through the date of administration or use pursuant to a distribution or release from the SNS.

XIV. Countermeasures Injury Compensation Program

42 U.S.C. 247d–6e

The PREP Act authorizes the Countermeasures Injury Compensation Program (CICP) to provide benefits to certain individuals or estates of individuals who sustain a covered serious physical injury as the direct result of the administration or use of the Covered Countermeasures, and benefits to certain survivors of individuals who die as a direct result of the administration or use of the Covered Countermeasures. The causal connection between the countermeasure and the serious physical injury must be supported by compelling, reliable, valid, medical and scientific evidence in order for the individual to be considered for compensation. The CICP is administered by the Health Resources and Services Administration, within the Department of Health and Human Services. Information about the CICP is available at the toll-free number 1–855–266–2427 (toll-free) or <http://www.hrsa.gov/cicp/>.

XV. Amendments

42 U.S.C. 247d–6d(b)(4)

Any amendments to this Declaration will be published in the **Federal Register**.

Authority: 42 U.S.C. 247d–6d.

Dated: January 24, 2019.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

[OMHA–1803–N]

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

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 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: Jason Green, by telephone at (571) 777–2723, or by email at jason.green@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 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 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, 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. 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. OCPM Releases for October Through December 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 OCPM provisions that were revised in the three-month period of October through December 2018. 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 17: Dismissals

Chapter 17, Dismissals. This chapter addresses the reasons an OMHA adjudicator may dismiss a request for

hearing or a request for review of a CMS contractor's dismissal of a request for a reconsideration, the contents of a dismissal order and its associated notice, and the effect of a dismissal. This chapter also addresses a party's rights to appeal a dismissal and an adjudicator's authority to vacate his or her own dismissal.

OCPM Chapter 18: Requests for Information and Remands

Chapter 18, Requests for Information and Remands. When authorized by the applicable regulations, OMHA adjudicators may use requests for information and remands to obtain information that is missing from an appeal, or request that a prior adjudicating entity take an action or issue a new appeal determination. In addition, an appellant and CMS or a CMS contractor in a Part A, B, or C appeal; an enrollee and CMS, the IRE, or a PDPS in a Part D appeal; or an appellant and SSA in an appeal of an SSA reconsideration may jointly request that a case be remanded to the prior adjudicator. This chapter describes the circumstances in which an OMHA adjudicator may issue a request for information or remand, and the requirements for requesting that an OMHA adjudicator remand a case. In addition, this chapter describes the right of a party, CMS, a CMS contractor, a PDPS, or SSA to request that the OMHA Chief Administrative Law Judge or a designee review a remand and, if it was not authorized by regulation, vacate the remand order.

Dated: January 22, 2019.

Jason M. Green,
Chief Advisor, Office of Medicare Hearings and Appeals.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Ebola Virus Disease Vaccines—Amendment

ACTION: Notice of Amendment to the December 3, 2014, Declaration under the Public Readiness and Emergency Preparedness Act for Ebola Virus Disease Vaccines, as amended.

SUMMARY: The Secretary is amending the Declaration issued pursuant to the Public Health Service Act on December 3, 2014, as amended on December 1, 2015 and December 2, 2016, to update the term “Ebola Virus Disease” to