Devices (Infectious Disease NGS Dx devices). Specifically, FDA recommends Infectious Disease NGS Dx devices that employ targeted or agnostic (metagenomics) sequencing to identify the presence or absence of infectious disease organisms, and/or detect the presence of absence of antimicrobial resistance and virulence markers.

The Agency received requests for a 30-day extension of the comment period for the document. Each request conveyed concern that the current 90-day comment period does not allow sufficient time to develop a meaningful or thoughtful response to the document on ''Infectious Disease Next Generation Sequencing Based Diagnostic Devices: Microbial Identification and Detection of Antimicrobial Resistance and Virulence Markers; Draft Guidance for Industry and Food and Drug Administration Staff.''

FDA has considered the request and is extending the comment period for the document on ''Infectious Disease Next Generation Sequencing Based Diagnostic Devices: Microbial Identification and Detection of Antimicrobial Resistance and Virulence Markers; Draft Guidance for Industry and Food and Drug Administration Staff'' for 30 days, until September 10, 2016. The Agency believes that a 30-day extension allows adequate time for interested persons to submit comments without significantly delaying regulation on these important issues.

Dated: August 5, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–19109 Filed 8–10–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[OMHA–1601–N]

Medicare Program; Administrative Law Judge Hearing Program for Medicare Claim and Entitlement Appeals; Quarterly Listing of Program Issuances—March Through June 2016

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

ACTION: Notice.

SUMMARY: This quarterly notice lists the OMHA Case Processing Manual (OCPM) manual instructions that were published from March through June, 2016. 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 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), 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 (PDPSs), 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 PDPSs 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 future published notices. The OCPM can be accessed at *http://www.hhs.gov/omha/OMHA_Case_Processing_Manual/index.html.*

IV. OCPM Releases for March Through June 2016

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 Web site at *http://www.hhs.gov/omha/OMHA_Case_Processing_Manual/index.html.*

OCPM Division II: Part A/B Claim Determinations

Chapter 6, Pre-Hearing Case Development. This new chapter describes the pre-hearing case development process for requests for hearing on Medicare Part A and Part B reconsiderations issued by Qualified Independent Contractors (QICs) and Quality Improvement Organizations (QIOs), and escalations of requests for reconsideration by a QIC. The pre-hearing case development process helps identify and address evidentiary issues prior to the hearing to avoid delays and helps to ensure legal requirements related to new evidence are observed. The process also assists staff in determining whether a hearing is necessary for a given case. In addition, the process guides OMHA staff on processes available to facilitate the hearing process, such as identifying special needs for hearing participants, discovery, using experts, and conducting pre-hearing conferences.

Dated: July 15, 2016.

Jason M. Green,

Chief Advisor, Office of Medicare Hearings and Appeals.

[FR Doc. 2016–18665 Filed 8–10–16; 8:45 am]

BILLING CODE 4152–01–P

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 (5 U.S.C. App.), 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 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: National Institute of Allergy and Infectious Diseases Special Emphasis Panel NIAID SBIR Phase II Clinical Trial Implementation Cooperative Agreement (U44).

Date: September 8, 2016.

Time: 1:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health Room 3G31B, 5601 Fishers Lane, Rockville, MD 20892 (Telephone Conference Call).

Contact Person: James T. Snyder, Ph.D., Scientific Review Officer Scientific Review Program, Division of Extramural Activities/Room 3G31B, National Institutes of Health, NIAID, 5601 Fishers Lane MSC 9823, Rockville, MD 20892, (240) 669–5060, *james.snyder@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: August 5, 2016.

Anna Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–19045 Filed 8–10–16; 8:45 am]

BILLING CODE 4140–01–P

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 (5 U.S.C. App.), 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 Emphasis Panel; NIAID Peer Review Meeting.

Date: September 7, 2016.

Time: 10:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, 3G61, 5601 Fishers Lane, Rockville, MD 20892 (Telephone Conference Call).

Contact Person: Travis J. Taylor, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, Room 3G62B, 5601 Fishers Lane, MSC 9823, Bethesda, MD 20892–9823, (240) 669–5082, *Travis.Taylor@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: August 4, 2016.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–19046 Filed 8–10–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Dental & Craniofacial Research; Notice of Closed Meeting

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 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 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: National Institute of Dental and Craniofacial Research Special