elements of these messages will include the unique public health laboratory specimen ID and a summary of specimen testing results to date.

Sites participating in detection and characterization of AR Neisseria gonorrhoeae, including antimicrobial susceptibility testing of *Neisseria gonorrhoeae* will provide the following to the STD Laboratory Reference and Research Branch (SLRRB) at CDC—Division of STD Prevention (DSTDP):

1. Annually, participating laboratories will provide an Evaluation and Performance Measure Report. Data will be used to indicate progress made toward program objectives and challenges encountered.

2. Participating laboratories will notify CDC DTSDP of any isolate(s) identified to demonstrate an ''alert'' MIC as defined by SLRRB within one working day. Laboratories will utilize REDCap to communicate these findings. The elements of these messages will include the unique public health laboratory specimen ID and a summary of specimen testing results to date.

3. Participating laboratories will report all testing results to CDC, requested at least monthly, by email, REDCap, or HL7 using an online web-portal transmission. This information will be used to: (a) identify and track antibiotic resistant pathogens and emerging patterns of resistance; and (b) aid public health departments and healthcare facilities in timely responding to antibiotic resistant public health threats and outbreaks. Participating laboratories will utilize secure public health messaging protocols to transfer results data to CDC, submitting facilities and clinical laboratories. For messaging to CDC, these messaging protocols will be based in REDCap or the AIMS platform. The REDCap and AIMS platforms are secure environments that provide shared services to assist public health laboratories in the transport, validation, and routing of electronic data. AIMS is transitioning to the use of HL7 messaging for data to be transmitted in real-time, allowing more frequent reporting of results while simultaneously lessening burden on public health laboratories.

CDC requests OMB approval for an estimated 4,705 annualized burden hours. There is no cost to respondents other than their time to participate.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Public Health Laboratories	Annual Report of Bacterial Specimen Testing Methods.	56	1	6/60	6
Public Health Laboratories	Annual Evaluation and Performance Measurement Report for Bacterial Specimen Testing.	56	1	4	224
Public Health Laboratories	Monthly Testing Results Reports—Bacterial Specimen Testing.	56	12	4	2688
Public Health Laboratories	AR Lab Network Alerts—Bacterial Specimen Testing.	56	34	6/60	190
Public Health Laboratories	Annual Evaluation and Performance Measurement Report (*Candida* identification).	Up to 56	1	2	112
Public Health Laboratories	Monthly Testing Results Reports—*Candida* identification.	Up to 56	12	2	1344
Public Health Laboratories	AR Lab Network Alerts—*Candida auris*.	Up to 56	13	6/60	73
Public Health Laboratories	Annual Evaluation and Performance Measurement Report (*Neisseria gonorrhoeae*).	Up to 56	1	1	56
Public Health Laboratories	Monthly Testing Results Reports—*Neisseria gonorrhoeae*.	Up to 56	1	6/60	6
Public Health Laboratories	AR Lab Network Alerts—*Neisseria gonorrhoeae*.	Up to 56	1	6/60	6
Total					4705

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2022–22027 Filed 10–7–22; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3431–N]

Medicare Program; Virtual Meeting of the Medicare Evidence Development and Coverage Advisory Committee—December 7, 2022

AGENCY: Centers for Medicare & Medicaid Services (CMS), Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: This notice announces a virtual public meeting of the Medicare Evidence Development & Coverage Advisory Committee (MEDCAC) (''Committee'') will be held on Wednesday, December 7, 2022. National Coverage Determinations resulting in coverage with evidence development (CED) can expedite earlier Medicare beneficiary access to innovative technology while ensuring that systematic patient safeguards are in place to reduce the risks inherent to new technologies, or to new

applications of older technologies. This meeting will examine the general requirements for clinical studies submitted for CMS coverage requiring CED. The MEDCAC will evaluate the CED criteria to assure that CED studies are evaluated with consistent, feasible, transparent and methodologically rigorous criteria and advise CMS on whether the criteria are appropriate to ensure that CED-approved studies will produce reliable evidence that CMS can rely on to help determine whether a particular item or service is reasonable and necessary. This meeting is open to the public in accordance with the Federal Advisory Committee Act.

DATES:

Meeting Date: The virtual meeting will be held on Wednesday, December 7, 2022 from 10:00 a.m. until 5:00 p.m., Eastern Standard Time (EST).

Deadline for Submission of Written Comments: Written comments must be received at the email address specified in the **ADDRESSES** section of this notice by 5:00 p.m., Eastern Standard Time (EST), on Monday, November 7, 2022. Once submitted, all comments are final.

Deadlines for Speaker Registration and Presentation Materials: The deadline to register to be a speaker and to submit PowerPoint presentation materials and writings that will be used in support of an oral presentation is 5:00 p.m., EST, on Monday, November 7, 2022. Speakers may register by phone or via email by contacting the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice. Presentation materials must be received at the email address specified in the **ADDRESSES** section of this notice.

Submission of Presentations and Comments: Presentation materials and written comments that will be presented at the meeting must be submitted via email to *MedCACpresentations@cms.hhs.gov* section of this notice by Monday November 7, 2022.

Deadline for All Other Attendees Registration: Individuals who want to join the meeting may register online at *https://cms.zoomgov.com/webinar/register/WN_CsJL7k7kQcyY0Z20OR6eqw* by 11:59 p.m. EST, on Tuesday, December 6, 2022.

Webinar and Teleconference Meeting Information: Teleconference dial-in instructions, and related webinar details will be posted on the meeting agenda, which will be available on the CMS website *http://www.cms.gov/medicare-coverage-database/indexes/medcac-meetings-index.aspx?bc=BAAAAAAAAAAA&.* Participants in the MEDCAC meeting will require the following: A computer, laptop or smartphone where the Zoom application needs to be downloaded; a strong Wi-Fi or an internet connection and access to use Chrome or Firefox web browser and a webcam if the meeting participant is scheduled to speak or make a presentation during the meeting.

Deadline for Submitting a Request for Special Accommodations: Individuals viewing or listening to the meeting who are hearing or visually impaired and have special requirements, or a condition that requires special assistance, should send an email to the MEDCAC Coordinator as specified in the **FOR FURTHER INFORMATION CONTACT** section of this notice no later than 5:00 p.m., EST on Monday, November 14, 2022.

ADDRESSES: Due to the current COVID–19 public health emergency, the Panel meeting will be held *virtually* and *will not* occur at the campus of the Centers for Medicare & Medicaid Services (CMS), Central Building, 7500 Security Boulevard, Baltimore, Maryland 21244.

FOR FURTHER INFORMATION CONTACT: Tara Hall, MEDCAC Coordinator, via email at *Tara.Hall@cms.hhs.gov* or by phone 410–786–4347.

SUPPLEMENTARY INFORMATION:

I. Background

MEDCAC, formerly known as the Medicare Coverage Advisory Committee (MCAC), is advisory in nature, with all final coverage decisions resting with CMS. MEDCAC is used to supplement CMS' internal expertise. Accordingly, the advice rendered by the MEDCAC is most useful when it results from a process of full scientific inquiry and thoughtful discussion, in an open forum, with careful framing of recommendations and clear identification of the basis of those recommendations. MEDCAC members are valued for their background, education, and expertise in a wide variety of scientific, clinical, and other related fields. (For more information on MEDCAC, see the MEDCAC Charter (*http://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/Downloads/medcaccharter.pdf*) and the CMS Guidance Document, *Factors CMS Considers in Referring Topics to the MEDCAC* (*http://www.cms.gov/medicare-coverage-database/details/medicare-coverage-document-details.aspx?MCDId=10*).

II. Meeting Topic and Format

This notice announces the Wednesday, December 7, 2022, virtual public meeting of the Committee. This meeting will examine the requirements for clinical studies submitted for CMS coverage under CED. It has been nearly 8 years since the criteria for CED were last evaluated and codified. In that time, not only have technologies become more complex, but there has been growing appreciation and commitment to transparency in decision-making, to making certain that study methodologies are ''fit to purpose'' as determined by the topic, questions asked, health outcomes studied, and to making certain that the populations studied are representative of the diversity in the Medicare beneficiary population. For example, some questions may be sufficiently answered through analysis of real-world evidence including data from clinical registries, electronic health records, and administrative claims. Any decision about whether an item or service is reasonable and necessary must, minimally, be sensitive to these commitments as well as to ensuring that study participants' interests are respected and protected. The MEDCAC will evaluate the CED criteria to assure that CED studies are evaluated with consistent, feasible, transparent and methodologically rigorous criteria and advise CMS on whether the criteria are appropriate to ensure that CED-approved studies will produce reliable evidence that CMS can rely on to help determine whether a particular item or service is reasonable and necessary.

Background information about this topic, including panel materials, is available at *http://www.cms.gov/medicare-coverage-database/indexes/medcac-meetings-index.aspx?bc=BAAAAAAAAAAA&.* Electronic copies of all the meeting materials will be on the CMS website no later than 2 business days before the meeting. We encourage the participation of organizations, researchers and people with expertise or interest in the thoughtful, efficient design and implementation of clinical studies whose goals are to improve the health of people, especially Medicare beneficiaries. This meeting is open to the public. The Committee will hear oral presentations from the public for approximately 45 minutes. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than what can be reasonably accommodated during the scheduled open public hearing session, we may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their

request to speak no later than 1 week from the speaker registration deadline specified in the **DATES** section of this notice. Your comments must focus on issues specific to the list of topics that we have proposed to the Committee. The list of research topics to be discussed at the meeting will be available on the following website prior to the meeting *http://www.cms.gov/medicare-coverage-database/indexes/medcac-meetings-index.aspx?bc=BAAAAAAAAAAA&.* We require that you declare at the meeting whether you have any financial involvement with manufacturers (or their competitors) of any items or services being discussed. Speakers presenting at the MEDCAC meeting must include a full disclosure slide as their second slide in their presentation for financial interests (for example, type of financial association—consultant, research support, advisory board, and an indication of level, such as minor association <$10,000 or major association >$10,000) as well as intellectual conflicts of interest (for example, involvement in a federal or nonfederal advisory committee that has discussed the issue) that may pertain in any way to the subject of this meeting. If you are representing an organization, we require that you also disclose conflict of interest information for that organization. If you do not have a PowerPoint presentation, you will need to present the full disclosure information requested previously at the beginning of your statement to the Committee.

The Committee will deliberate openly on the topics under consideration. Interested persons may observe the deliberations, but the Committee will not hear further comments during this time except at the request of the chairperson. The Committee will also allow a 15-minute unscheduled open public session for any attendee to address issues specific to the topics under consideration. At the conclusion of the day, the members will vote and the Committee will make its recommendation(s) to CMS.

III. Registration Instructions

CMS' Coverage and Analysis Group is coordinating meeting registration. While there is no registration fee, individuals must register to attend. You may register online at *https://cms.zoomgov.com/webinar/register/WN_CsJL7k7kQcyY0Z20OR6eqw* or by phone by contacting the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice by the deadline listed in the **DATES** section of this notice. Please provide your full name (as it appears on your state-issued driver's license), address, organization, telephone number(s), and email address. You will receive a registration confirmation with instructions for your participation at the virtual public meeting.

IV. Collection of Information

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35).

The Chief Medical Officer and Director of the Center for Clinical Standards and Quality for the Centers for Medicare & Medicaid Services (CMS), Lee A. Fleisher, having reviewed and approved this document, authorizes Lynette Wilson, who is the **Federal Register** Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Dated: October 5, 2022.

Lynette Wilson,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

[FR Doc. 2022–22067 Filed 10–7–22; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–437A and CMS–437B]

Agency Information Collection Activities: Proposed Collection; Extension of Comment Period

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Agency information collection activities: Proposed collection; comment request; extension of comment period.

SUMMARY: This notice extends the comment period for a 60-day notice request for proposed information collection request associated with the notice [Document Identifier: CMS–437A and CMS–437B] entitled ''Rehabilitation Unit and Hospital Criteria Worksheet'' that was published in the August 9, 2022 **Federal Register**. The comment period for the information collection request, which would have ended on October 11, 2022, is extended to November 16, 2022.

DATES: The comment period for the information collection request published in the August 9, 2022 **Federal Register** (87 FR 48482) is extended to November 16, 2022.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to *http://www.regulations.gov*. Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number ____, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, please access the CMS PRA website by copying and pasting the following web address into your web browser: *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.*

FOR FURTHER INFORMATION CONTACT: William N. Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION: In the FR Doc. 2022–17063 of August 9, 2022 (87 FR 48482), we published a Paperwork Reduction Act notice requesting a 60-day public comment period for the document entitled ''Rehabilitation Unit and Hospital Criteria Worksheet.'' There were technical delays associated with making the information collection request publicly available; therefore, in this notice we are extending the comment period from the date originally listed in the August 9, 2022, notice.

Dated: October 5, 2022.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2022–22066 Filed 10–7–22; 8:45 am]

BILLING CODE 4120–01–P