



[Billing Code: 4120-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-3395-N]

Medicare Program; Virtual Meeting of the Medicare Evidence Development and Coverage Advisory Committee—July 22, 2020

AGENCY: Centers for Medicare & Medicaid Services (CMS), 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, July 22, 2020. This meeting will focus on the home use of noninvasive positive pressure ventilation in patients with chronic respiratory failure (CRF) consequent to chronic obstructive pulmonary disease (COPD). We are seeking the MEDCAC's recommendations regarding the characteristics that define those patient selection and usage criteria, concomitant services, and equipment parameters necessary to best achieve positive patient health outcomes in beneficiaries with CRF consequent to COPD. This meeting is open to the public in accordance with the Federal Advisory Committee Act (5 U.S.C. App. 2, section 10(a)).

DATES: Meeting Date: The virtual meeting will be held on Wednesday, July 22, 2020 from 8:00 a.m. until 4:30 p.m., Eastern Daylight Time (EDT).

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 Daylight Time (EDT), on Monday, June 22, 2020. 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., EDT, on Monday, June 22, 2020. Speakers may register by phone or via e-mail 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 e-mail to MedCACpresentations@cms.hhs.gov section of this notice by Monday June 22, 2020.

Deadline for All Other Attendees Registration: Individuals who want to join the meeting may register online at <https://letsmeet.webex.com/letsmeet/onstage/g.php?MTID=e6f9d4471a6f1f77e29f5c34c64ccdc4d> by 11:59 p.m. EDT, on Sunday, July 19, 2020.

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=BAAAAAAAAAAAA&>. Participants in the MEDCAC meeting will require the following: a computer, laptop or smartphone where the WebEx 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., EDT on Friday, June 26, 2020.

ADDRESSES: Due to the current COVID-19 public health emergency, the Panel meeting will be held virtually.

FOR FURTHER INFORMATION CONTACT: Tara Hall, MEDCAC Coordinator, via e-mail 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, July 22, 2020, virtual public meeting of the Committee. This meeting will focus on the home use of noninvasive positive pressure ventilation in patients with CRF consequent to COPD. Devices to be considered are home mechanical ventilators (HMs), bi-level positive airway pressure (BPAP) devices and continuous positive airway pressure (CPAP) devices. We are seeking the MEDCAC's recommendations regarding the characteristics that define those patient selection and usage criteria, concomitant services, and equipment parameters necessary to best achieve positive patient health outcomes in beneficiaries with CRF consequent to COPD. The MEDCAC will specifically focus on the scientific evidence associated with the outcomes most pertinent to the affected patient population. Outcomes of interest will include decreased mortality, decreased frequency of exacerbations requiring ER or hospital admission, increased time to hospital re-admission for respiratory related disease, and improved function and quality of life.

Background information about this topic, including panel materials, is available at <http://www.cms.gov/medicare-coverage-database/indexes/medcac-meetings-index.aspx?bc=BAAAAAAAAAAAA&>. 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 with expertise in the appraisal of the state of evidence for the use of HMV, BPAP, and CPAP equipment in the home for the affected patient population. This meeting is open to the public. The Committee will hear oral

presentations from the public for approximately 60 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 by June 29, 2020. 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 web site prior to the meeting: <http://www.cms.gov/medicare-coverage-database/indexes/medcac-meetings-index.aspx?bc=BAAAAAAAAAAAA&>. 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 <http://www.cms.gov/apps/events/upcomingevents.asp?strOrderBy=1&type=3> 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 e-mail 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 Acting Director for the Center for Clinical Standards and Quality, at the Centers for Medicare & Medicaid Services, Jean Moody-Williams, having reviewed and approved this document, authorizes Evell J. Barco Holland, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

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Authority: 5 U.S.C. App. 2, section 10(a).

Dated: June 8, 2020

Evell J. Barco Holland,
Federal Register Liaison,
Department of Health and Human Services.

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