

CHARTER

MEDICARE EVIDENCE DEVELOPMENT & COVERAGE ADVISORY COMMITTEE

ADVISORY COMMITTEE'S OFFICIAL DESIGNATION

Medicare Evidence Development & Coverage Advisory Committee (MEDCAC or the Committee)

AUTHORITY

42 U.S.C. 217a, section 222 of the Public Health Service Act, as amended. The Medicare Evidence Development & Coverage Advisory Committee, is also governed by the provisions of the Federal Advisory Committee Act Public Law (P.L.) 92-463, as amended (5 U.S. Code 10).

OBJECTIVES AND SCOPE OF ACTIVITIES

The MEDCAC shall provide independent advice and recommendations regarding the clinical evidence presented to Centers for Medicare & Medicaid Services (CMS) on topics under review by Medicare. The Secretary, and by delegation, the Administrator of (CMS), and the Director of the Center for Clinical Standards and Quality, CMS, are charged with deciding which medical items and services are reasonable and necessary, or otherwise covered, for Medicare beneficiaries under title XVIII of the Social Security Act.

DESCRIPTION OF DUTIES

The duties of the Committee are solely advisory and shall include providing advice and recommendations on the evidence-based determination process for Medicare's coverage policies. The Committee shall provide advice to CMS on the strength of the evidence available for specific medical treatments and technologies through a public, participatory and accountable process. The Committee shall develop technical advice in order to assist CMS in determining reasonable and necessary uses of medical items and services. The Committee may be asked to develop recommendations about the quality of the evidence for specific issues of Medicare coverage or related policies, to review and comment upon proposed or existing Medicare coverage policies, and/or review and comment on the evidence that is used to support the policies. The Committee may comment on pertinent aspects of proposals being considered and/or other policies.

Specific Committee tasks may include:

- Reviewing and assessing evidence regarding specific clinical topics, and providing advice to CMS according to a framework of issues/questions established by CMS;
- Considering and acting upon requests for assessments and tasks as may be requested by CMS during the year;
- Reviewing and submitting reports to CMS in accordance with agreed-upon timetables.

AGENCY OR FEDERAL OFFICER RECEIVING THE ADVISORY COMMITTEE'S ADVICE/RECOMMENDATIONS

The Committee reports to the Secretary of the Department of Health & Human Services (HHS) and the Administrator of CMS.

SUPPORT

CMS is responsible for providing the necessary support for the Committee. CMS facilitates all Committee operations and logistics.

ESTIMATED ANNUAL OPERATING COSTS AND STAFF YEARS

Estimated annual cost for operating the committee, including compensation and travel expenses for members, but excluding CMS staff support, is \$63,360. The estimate of required annual person-years of CMS staff support is 2.17, at an estimated annual cost of \$412,165.

DESIGNATED FEDERAL OFFICER

A full-time or permanent part-time Federal employee, appointed in accordance with agency procedures, will serve as the Designated Federal Officer (DFO) to attend each Committee meeting and ensure that all Committee policies and procedures comply with applicable statutory and regulatory requirements, including those under FACA. The DFO will approve or call all the Committee's and subcommittees' meetings, prepare and approve all meeting agendas, attend all Committee and subcommittee meetings, adjourn any meeting when the DFO determines adjournment to be in the public interest, and chair meetings when directed to do so by the officials to whom the Committee reports. In the event the DFO cannot fulfill the assigned duties of the Committee, one or more full-time or permanent part-time employees will be assigned as DFO and carry out these duties on a temporary basis.

ESTIMATED NUMBER AND FREQUENCY OF MEETINGS

The Committee will hold approximately 2-4 meetings per year. Meetings are open to the public, except as determined otherwise by the Secretary of HHS, or a designee of the Secretary.

Adequate advance notice of all meetings shall be published in the Federal Register, as required by applicable laws and departmental regulations, stating reasonable, accessible, and convenient locations and times.

DURATION

The duration of the advisory committee is continuing, subject to the Termination section below.

TERMINATION

Unless renewed by appropriate action prior to its expiration, the MEDCAC will terminate two years from the date the charter is filed.

MEMBERSHIP AND DESIGNATION

The Committee shall consist of a maximum of 100 members who will be appointed as Special Government Employees or Representatives. A maximum of 90 members shall be at-large standing members (20 of whom are patient advocates), and 10 shall be members representing the industry interests. The Secretary or designee will appoint a Chair and Vice-Chair from among the pool of at-large members. Members shall be selected by the Secretary, or designee, from among authorities in clinical medicine including subspecialties, administrative medicine, public health, biological and physical sciences, epidemiology and biostatistics, clinical trial design, health care data management and analysis, patient advocacy, health care economics, health disparities, medical ethics, those with an understanding of sociodemographic bias and resulting limitations of scientific evidence, or other relevant professions.

Members shall be invited to serve for overlapping two-year terms. Terms of more than two years are contingent upon renewal of the Charter and membership. Members may serve after the expiration of their terms until successors have taken office. The period of service for the Chair and Vice-Chair shall be no more than 4 years. CMS may adjust terms of membership to ensure that expiring MEDCAC member terms do not exceed 25 percent per year.

For each Committee meeting, CMS staff select members for the panel roster and the roster is posted on CMS' website in advance of each Committee meeting. Members will

be chosen for each Committee meeting based upon their expertise and the topic to be discussed.

The panel roster for each Committee meeting will be comprised of at least the following:

- Standing chair (or standing vice-chair) who will preside, or in their absence, an interim chair delegated by the Secretary or designee;
- One industry representative;
- One patient advocate;
- The remaining members of the panel roster are chosen from the standing pool of at-large members. There will be no more than 15 MEDCAC members serving on a panel for a particular meeting.

A quorum is required for all meetings and shall consist of a majority of the members designated for service at each meeting. Each Committee meeting may also include guests whose expertise pertains to the meeting topic.

SUBCOMMITTEES

Subcommittees composed of members of the MEDCAC and other subject matter experts may be established with the approval of the Secretary or designee. The subcommittees must report back to the parent committee and not provide advice or work products directly to the agency. The Department Committee Management Officer (DCMO) will be notified upon establishment of each standing subcommittee and will be provided information on its name, membership, function, and estimated frequency of meetings.

RECORDKEEPING

The records of the Committee, established subcommittees, or other subgroups of the Committee, shall be managed in accordance with General records Schedule 26, Item 2 or other approved agency records disposition schedule. These records shall be available for public inspection and copying, subject to the Freedom of Information Act (5 U.S.C. 552).

FILING DATE

November 24, 2024

APPROVED

11/20/2024

Date


Xavier Becerra



DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator

Washington, DC 20201

DATE: November 14, 2024

TO: Xavier Becerra, Secretary

THROUGH: Angel Ramirez; Deputy Chief of Staff
Manuel Joe Carrillo, White House Liaison
Elizabeth J. Gramling, Executive Secretary

FROM: Chiquita Brooks-LaSure, Administrator
Centers for Medicare & Medicaid Services

SUBJECT: DECISION - Request to Renew the Centers for Medicare & Medicaid Services
Medicare Evidence Development & Coverage Advisory Committee Charter

ACTION REQUESTED

This memorandum recommends that you approve the attached renewal to the Centers for Medicare & Medicaid Services (CMS) charter of the Medicare Evidence Development & Coverage Advisory Committee (MEDCAC). The current charter expires on November 24, 2024.

RECOMMENDATION

I recommend that the Secretary approve the Notice of Renewal, the Charter and the Delegation of Authority.

EXECUTIVE SUMMARY

The Secretary of Health and Human Services (HHS), and by delegation, the Administrator of the Centers for Medicare & Medicaid Services (CMS), and the Director of the Center for Clinical Standards and Quality, CMS, are charged with deciding which medical items and services are reasonable and necessary, or otherwise covered, for Medicare beneficiaries under title XVIII of the Social Security Act. The MEDCAC, which is a Federal Advisory Committee Act (FACA) compliant advisory committee, originally chartered in 1998, provides advice regarding the clinical evidence presented to CMS on topics under review by Medicare. The Committee's purpose is to support the evidence-based determination process for Medicare's coverage policies. MEDCAC panels provide advice to CMS on the strength of the evidence available for specific medical treatments and technologies through a public, participatory and accountable process.

The MEDCAC currently functions as one FACA committee consisting of a pool of a maximum of 100 expert members. Members will be selected from among authorities in clinical and administrative medicine, biologic and physical sciences, public health administration, patient

advocates, health care data and information management and analysis, health care economics, medical ethics, and other related professions.

The MEDCAC meeting roster will take maximum advantage of the expert skills housed in the 100-member expert pool. Each Committee meeting will deal with one or more specific clinical topics, and will include no more than 15 MEDCAC members. Members will be selected from the expert pool based on the topic and their expertise.

Notable Timing Factors:

The current charter begins on November 24, 2022 and expires on November 24, 2024. Unless renewed by appropriate action prior to its expiration, the MEDCAC will terminate two years from the date the charter is filed.

Noteworthy Elements about Equity:

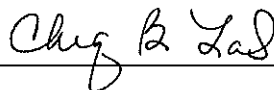
We wish to increase the likelihood of adequate representation of those enrolled in the Medicare program including but not limited to, racial and ethnic groups, individuals with disabilities, and from across the gender spectrum. Therefore, we encourage nominations of qualified candidates who can represent these lived experiences.

ANTICIPATED STAKEHOLDER REACTION

Federal partners and stakeholders will react positively to the renewal the proposed charter.

ROLLOUT

The updated charter will be shared with stakeholders and posted on the MEDCAC website.



Chiquita Brooks-LaSure, Administrator

DECISION

I recommend that the Secretary approve the Notice of Renewal, Charter and the Delegation of Authority.

Approved [☒]
Disapproved [☐]
Briefing Needed [☐]

Additional Comments:



Xavier Becerra

November 20, 2024

Date

ATTACHMENTS:

TAB A: Current Charter
TAB B: Proposed Renewed Charter
TAB C: Proposed Renewed Charter Redline
TAB D: Notice of Charter Renewal
TAB E: Legislative Authority
TAB F: Membership Balance Plan
TAB G: Financial Operating Plan
TAB H: Current Membership Roster
TAB I: Delegation of Authority
TAB J: Filing Letters