# CHARTER

# MEDICARE EVIDENCE DEVELOPMENT & COVERAGE ADVISORY COMMITTEE

## COMMITTEE'S OFFICIAL DESIGNATION

Medicare Evidence Development & Coverage Advisory Committee (MEDCAC)

## 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.C. Appendix 2) which set forth standards for the formation and use of advisory committees.

## OBJECTIVES AND SCOPE OF ACTIVITIES

The MEDCAC provides advice regarding the clinical evidence presented to CMS on topics under review by Medicare. The Secretary, 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.

## DESCRIPTION OF DUTIES

The Committee's purpose is to support the evidence-based determination process for Medicare's coverage policies. The Committee provides 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 will work from an agenda provided by the Designated Federal Official (DFO) that lists specific issues and will 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. CMS may also ask the Committee to 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 OFFICIAL TO WHOM THE COMMITTEE REPORTS

The Committee reports to CMS.

## SUPPORT

Coordination, management, and operational services shall be provided by CMS staff.

## 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 $293,904.

## DESIGNATED FEDERAL OFFICER

CMS will select a full-time or permanent part-time Federal employee to serve as the DFO to attend each Committee meeting and ensure that all procedures are consistent with applicable statutory and regulatory directives. The DFO will approve all meeting agendas, call to order all of the 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 official to whom the Committee reports. The DFO and/or the designee shall be present at all meetings of the full Committee and subcommittee(s).

## ESTIMATED NUMBER AND FREQUENCY OF MEETINGS

Meetings shall be held approximately 2-4 times per year. Meetings shall be open to the public, except as determined otherwise by the Secretary or other official to whom the authority has been delegated in accordance with the Government in the Sunshine Act (5 U.S.C. 552b(c)).

Adequate advance notice of all meetings, with a reasonably accessible location and time, shall be published in the *Federal Register*, as required by law and Departmental regulations.

## DURATION

Continuing

## 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 (10 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 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

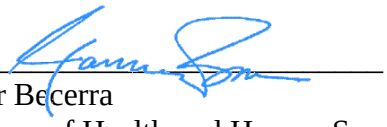
The records of the Committee, established subcommittees, or other subgroups of the Committee, shall be managed in accordance with General records Schedule 26, Item 2 or other approved agency records disposition schedule. These records shall be available for public inspection and copying, subject to the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

## FILING DATE

November 24, 2022

## APPROVED

November 23, 2022
Date



Xavier Becerra
Secretary of Health and Human Services