



THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

CHARTER

MEDICARE EVIDENCE DEVELOPMENT & COVERAGE ADVISORY COMMITTEE

Purpose

The Secretary, and by delegation, the Administrator of the Centers for Medicare & Medicaid Services (CMS), and the Director of the Office of Clinical Standards and Quality, CMS, are charged with deciding which medical services and items are reasonable and necessary for Medicare beneficiaries under title XVIII of the Social Security Act. The Medicare Evidence Development & Coverage Advisory Committee (MEDCAC) formerly the Medicare Coverage Advisory Committee (MCAC) provides guidance and advice to CMS on specific clinical and policy topics under review for Medicare coverage.

Authority

42 U.S.C. 217a, section 222 of the Public Health Service Act, as amended. The Medicare Coverage Advisory Committee is governed by the provisions of Public Law (P.L.) 92-463, as amended (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory committees.

Function

The Medicare Evidence Development & Coverage Advisory Committee (MEDCAC) reviews and evaluates medical literature, reviews technology assessments, and examines data and information on the safety effectiveness and appropriateness of medical services and items that are covered under Medicare, or that may be eligible for coverage under Medicare. 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 applications of medical services and technology. The Committee may be asked to develop recommendations about specific issues of Medicare coverage, and/or to review and comment upon proposed or existing Medicare coverage policies. The Committee may also be asked to comment on pertinent aspects of proposals being considered and/or other policies.

Specific Committee tasks include:

- reviewing evidence regarding specific clinical topics and providing advice to CMS according to a framework of issues/questions established by CMS;
- considering and acting upon such other requests for assessments and tasks as may be requested by CMS during the year;
- working through the CMS liaison member, facilitating full and complete clinical and other technical staffing for the Committee meetings as specific issues indicate; and
- reviewing and submitting reports to CMS without undue delay.
- advising CMS as part of Medicare coverage evidence development activities.

Structure

The Committee shall consist of a maximum of 100 appointed Special Government Employees and Representative Members. Members shall be selected by the Secretary, or designee, from among authorities in clinical and administrative medicine, biologic and physical sciences, public health administration, advocates for patients, health care data and information management and analysis, the economics of health care, medical ethics, and other related professions. A maximum of 94 members shall be at large standing voting members, 6 of whom are patient advocates and 6 shall be nonvoting 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 invited to serve for 4-year terms. Terms of more than 2 years are contingent upon renewal of the Charter. 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 2 years. Agency may adjust terms of membership to ensure that MEDCAC member terms expiring do not exceed 25 percent per year.

The Committee members serving in the at-large expert pool may serve as voting members for any Committee meeting as issues/expertise call for. A roster will be developed and published in advance for each Committee meeting. Members will be chosen to serve on each Committee meeting as to their expertise and topic to be discussed.

The roster for each Committee meeting will be comprised of the standing Chair (or standing Vice-Chair) who will preside or in their absence an interim Chair delegated by

Secretary or designee; one nonvoting member (representing industry interests); one voting Patient Advocate; and the DFO as a nonvoting representative. The remaining members of the roster will be chosen from the standing pool of at-large voting members. There will be no more than 15 MEDCAC members serving at 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. In addition to the committee members, the committee may include nonvoting guests whose expertise pertains to the meeting topic.

With the approval of the Secretary or his/her designee, temporary subcommittees consisting of two or more members of the parent committee may be established as needed to address methodology and Committee procedural issues or other coverage related issues within their respective areas of expertise. A voting member will be designated as chair of the subcommittee. The Department Committee Management Officer (DCMO) will be notified upon establishment of each subcommittee and shall be provided information on its name, membership, function, and estimated frequency of meetings.

The Office of Clinical Standards and Quality, CMS, shall provide management and support services.

Designated Federal Officer (DFO)

A full-time federal employee, appointed in accordance with agency procedures, will serve as the DFO (or designee). The DFO will approve or call all of the advisory 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 official to whom the advisory committee reports.

Meetings

Meetings will be held approximately 6-8 times a year at the call of the DFO or designee, who shall approve the agenda. The DFO or designee shall be present at all meetings.

Meetings shall be open to the public except as determined otherwise by the Secretary or other government official to whom the authority has been delegated in accordance with the Government in the Sunshine Act (5 U.S.C. 552b(c)) and the Federal Advisory Committee Act; advance notice of all meetings shall be given to the public.

Meetings shall be conducted, and the records of the committee, formally and informally established subcommittees, or other subgroups of the committee, shall be handled in accordance with General Records Schedule 26, Item 2. These records shall be available for public inspection and copying, subject to the Freedom of Information Act, 5 U.S.C. 552.

Compensation

Members who are not employees of Federal, State, or local governments shall be paid at the rate of \$250 per day for each day (including travel time) during which they are performing committee business, plus travel and per diem expenses in accordance with Standard Government Travel Regulations.

Annual Cost Estimate

Estimated annual cost for operating the committee, including compensation and travel expenses for members, but excluding staff support, is \$134,720. Estimate of annual person-years of staff support required is 3.25, at an estimated annual cost of \$243,066

Reports

A transcript and minutes of the meeting will be posted on the MEDCAC website for the public.

In the event a portion of a meeting is closed to the public, as determined by the Secretary of HHS, in accordance with the Government in the Sunshine Act (5 U.S.C. 552b(c)) and the Federal Advisory Committee Act, a report shall be prepared which shall contain, at a minimum, a list of members and their business addresses, the committee's function, dates and places of meetings, and a summary of committee activities and recommendations made during the fiscal year. A copy of the report shall be provided to the DCMO.

Termination Date

Unless renewed by appropriate action prior to its expiration, the MEDCAC will terminate on November 24, 2010.

NOV 12 2008

Date



Secretary

CHARTER FILING DATE 11/24/08