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

CHARTER

MEDICARE EVIDENCE DEVELOPMENT COVERAGE ADVISORY COMMITTEE
formerly the Medicare 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 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 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 under CMS' demonstration authority.

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;

-reviewing and submitting reports to CMS without undue delay; and

-advising CMS as part of Medicare coverage evidence development activities.

Structure

The Committee shall consist of a maximum of 100 appointed 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 88 members shall be at large standing voting members, and 12 shall be nonvoting members, 6 of whom shall be representatives of consumer interests, and 6 shall be representatives of 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 overlapping 4-year terms; terms of more than 2 years are contingent upon renewal of the Committee by appropriate action prior to its termination. 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 1 year. The incumbent Chair and Vice-Chair may serve no more than 2 consecutive years in their respective capacity.

Each Committee meeting will deal with one or more specific clinical topics, and will generally include 13-15 MedCAC members. A quorum for conduct of business shall consist of a majority of the members designated for service at each meeting. The Chair or the Vice-Chair will preside. The consumer and industry representatives will be selected from the pool of 12, based on clinical relevancy. The remaining positions on the MedCAC meeting roster will be filled from the pool of at-large members, taking into account their training, experience, and the topic(s) under review.

The Committee members serving in the at-large expert pool may serve as voting members for any Committee meeting as needed. 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. A primary and secondary reviewer will be chosen from the Committee at-large pool to serve as technical experts for the presiding official and DFO. The reviewers will assist the presiding official in facilitating effective technical consideration of the meeting topic and will serve as the members of a particular meeting that brings recognized outstanding expertise concerning the topic(s) under review.

The roster for each Committee meeting will be comprised of the standing Chair (or standing Vice-Chair) who will preside; two nonvoting members (one representing consumer interests and the other representing industry interests); two voting Committee members specifically designated as primary and secondary reviewers for the meeting; 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.

Temporary subcommittees consisting of two or more members of the parent committee may be established as needed to address methodology and committee procedural 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.

Meetings

Meetings will be held approximately 6-8 times a year at the call of the Designed Federal Official or designee who shall also 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 official to whom the authority has been delegated; in accordance with the Government in the Sunshine Act (5U.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 records of the proceedings kept, as required by applicable laws and Departmental regulations.

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 $363,485. Estimate of annual person-years of staff support required is 3.25, at an estimated annual cost of $230,142.

Reports

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 (5U.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 23, 2008.

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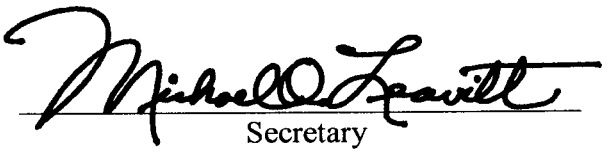
Date



Secretary