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

CHARTER
MEDICARE EVIDENCE DEVELOPMENT & COVERAGE ADVISORY COMMITTEE

Authority

42 U.S.C. 217a, section 222 of the Public Health Service Act, as amended. The Medicare Evidence Development & Coverage Advisory Committee (MEDCAC), 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.

Objective and Scope of Activities

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

Description of Duties

The MEDCAC reviews and evaluates medical literature, reviews technology assessments, public testimony and examines data and information on the benefits, harms, and appropriateness of medical items and services 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 uses of medical services and technology. The Committee may be asked to develop recommendations about the quality of the evidence for specific issues of Medicare coverage or related policies, and/or to review and comment upon proposed or existing Medicare coverage policies and the evidence the policies rely. CMS may also ask the Committee 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;

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

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

Agency or Official to Whom the Committee Reports

The Committee reports to CMS.

Support

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

Estimated Annual Operating Costs and Staff Years

Estimated annual cost for operating the committee, including compensation and travel expenses for members, but excluding staff support, is $168,980. Estimate of annual person-years of staff support required is 2.17, at an estimated annual cost of $246,012.

Designated Federal Officer

Centers for Medicare & Medicaid Services will select a fulltime 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 and prepare all meeting agendas, call 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 or his/her designee shall be present at all meetings of the full committee and subcommittee.

Estimated Number and Frequency of Meetings

Meetings shall be held approximately 2-4 times during the 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 shall be published in the *Federal Register*, as required by applicable law and Departmental regulations, stating reasonably accessible and convenient locations and times.

Duration

Continuing

Termination

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

Membership and Designation

The Committee shall consist of a maximum of 100 members that will be appointed as Special Government Employees or Representatives. Members shall be selected by the Secretary, or the Administrator or Administrator's 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 members, (6 of whom are patient advocates), and 6 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 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 4 years. The Agency may adjust terms of membership to ensure that MEDCAC member terms expiring do not exceed 25 percent per year. A panel roster will be developed and published in advance for each Committee meeting. Members will be chosen to serve on each Committee meeting according to their expertise and the topic to be discussed.

The panel 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 the Secretary or designee; one industry representative; and one Patient Advocate. The remaining members of the panel roster will be chosen from the standing pool of at-large 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 guests whose expertise pertains to the meeting topic.

Subcommittees

Subcommittees composed of members of the parent committee 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 6.2, 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, 2016

Approved:

OCT 21 2016
Date

Sylvia M. Burwell
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