



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

CHARTER MEDICARE ADVISORY PANEL ON CLINICAL DIAGNOSTIC LABORATORY TESTS

AUTHORITY

The authority for the Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests (the Panel) is section 1834A (f)(1) of the Social Security Act (42 U.S.C. 1395m-1), (the Act) as amended by section 216(a) of the Protecting Access to Medicare Act of 2014 (Pub. L. 113-93), enacted April 1, 2014. The Panel is governed by the Federal Advisory Committee Act (FACA), as amended (5 U.S.C. App.), which sets forth standards for the formation and use of federal advisory committees.

OBJECTIVES AND SCOPE OF ACTIVITIES

The Secretary of the Department of Health and Human Services (HHS) shall consult with an expert outside advisory panel, established by the Secretary, composed of an appropriate selection of individuals with expertise in issues related to clinical diagnostic laboratory tests, including molecular pathologists, researchers, and individuals with expertise in laboratory science or health economics. The Panel may advise the Secretary of HHS and the Administrator, of the Centers for Medicare & Medicaid Services (CMS), on the following:

- 1) the establishment of payment rates under section 1834A of the Act for new clinical diagnostic laboratory tests, including whether to use crosswalking or gapfilling processes to determine payment for a specific new test; and
- 2) the factors used in determining coverage and payment processes for new clinical diagnostic laboratory tests.

In addition, the Panel will provide recommendations to the Secretary of HHS and the Administrator of CMS under section 1834A of the Act.

DESCRIPTION OF DUTIES

The Panel may advise on the following issues:

- Application of market rates to establish Medicare payment rates.
- Evaluation and designation of tests as advanced diagnostic laboratory tests.
- Whether to use crosswalking or gapfilling to determine payment for a specific new test.

AGENCY OR OFFICIAL TO WHOM THE PANEL REPORTS

The Panel shall report to the Secretary of HHS and the Administrator of CMS.

SUPPORT

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

ESTIMATED ANNUAL OPERATING COSTS AND STAFF YEARS

Estimated fiscal year 2019 annual cost for operating the Panel, including travel expenses for members but excluding staff support, is \$89,000.00 (up to 4 meetings per year).

The fiscal year 2019 staff support required for the Panel is 1.45 full-time equivalents at an estimated annual cost of \$228,483.12.

DESIGNATED FEDERAL OFFICER

CMS shall select a permanent full-time or part-time Federal employee to serve as the Designated Federal Officer (DFO) to attend each Panel meeting. The DFO shall approve and prepare all meeting agendas, approve and call all of the Panel 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 Panel reports. The DFO or his or her designee shall be present at all meetings of the full Panel and subcommittee(s).

ESTIMATED NUMBER AND FREQUENCY OF MEETINGS

Meetings shall be held up to 4 times a year. The Panel Chair shall facilitate meetings and 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 of 1976 (5 U.S.C. 552b(c)) and FACA. Notice of all meetings shall be published in the *Federal Register* as required by applicable laws and Departmental regulations. Meetings shall be conducted, and records of the proceedings kept, as required by applicable laws and departmental regulations.

In order to conduct the business of the Panel, a quorum is required. A quorum exists when a majority of currently appointed members is present at full Panel or subcommittee meetings or is participating in conference calls.

DURATION

Continuing.

TERMINATION

Unless renewed by appropriate action, the charter for the Panel will expire 2 years from the date this charter is filed.

MEMBERSHIP AND DESIGNATION

The Panel shall consist of up to 15 individuals with expertise in issues related to clinical diagnostic laboratory tests, which may include, molecular pathologists, laboratory researchers, and individuals with expertise in laboratory science or health economics, with regard to issues related to the development, validation, performance, safety, and application of such tests. Members shall be appointed by the Secretary's or CMS Administrator's designee.

For purposes of this Panel, consultants or independent contractors shall not be representatives of clinical laboratories. All members shall serve on a voluntary basis, without compensation, pursuant to advance written agreement. Members of the Panel shall be entitled to receive reimbursement for travel expenses and per diem in lieu of subsistence expenses, in accordance with standard Federal Travel Regulations.

Panel members shall serve a term of up to 3 years. A member may serve after the expiration of his/her term until a successor has been sworn in. A Panel member selected to replace another Panel member who has resigned prior to the end of his or her term, shall serve for the balance of the original Panel members' term.

A Federal official, or a current Panel member, designated by the Secretary or Administrator's designee, shall serve as the Chair and shall facilitate the Panel meetings. The Chair's term shall usually be for a period of 3 years, but it may be extended at the discretion of the Secretary or Administrator or his/her duly appointed designee.

SUBCOMMITTEES

With the approval of the Secretary or designee, subcommittees consisting of two or more Panel members may be established to assist the Panel in performing functions within the Panel's jurisdiction. One of the members will be designated by his/her peers as chair of the subcommittee. The Department Committee Management Officer will be notified upon establishment of each subcommittee and shall be provided information on its name, membership, function, and estimated frequency of meetings. The advice/recommendations of a subcommittee or working group must be deliberated by the Panel. A subcommittee may not report directly to a Federal official, but rather it must report to the parent Panel.

RECORDKEEPING

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 6.2 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

APR 26 2019

APPROVED

APR 17 2019

Date

Alex M. Azar II

