



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 established by section 216 of Public Law 113-93, enacted April 1, 2014. The Panel is governed by Federal Advisory Committee Act (FACA), as amended (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory panels.

OBJECTIVES AND SCOPE OF ACTIVITIES

Section 1834A(f)(1) of the Act directs the Secretary to 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, which may include representatives of clinical laboratories, molecular pathologists, clinical laboratory researchers, and individuals with expertise in clinical laboratory science or health economics. The Panel may advise the Secretary of the Department of Health and Human Services (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 may provide recommendations to the Secretary of HHS and the Administrator of CMS under section 1834A of the Act.

DESCRIPTION OF DUTIES

In carrying out the activities outlined above, the Panel may consider and advise on the following issues:

- Calculation of weighted medians of private payor rates for laboratory tests.
- Phase-in of reductions in Medicare payment rates based on private payor rates, as required.
- Application of market rates to establishment of Medicare payment rates.

- Evaluation and designation of tests as advanced diagnostic laboratory tests as defined in section 1834A of the Act.
- Whether to use crosswalking or gapfilling to determine payment for a specific new test.
- The factors used in determining coverage or payment processes for new clinical diagnostic laboratory tests.

The subject matter before the Panel shall be limited to these and related topics. Unrelated topics are not subjects for discussion. Unrelated topics may include, but are not limited to, the following topics referenced in section 1834A of the Act: definition of an applicable laboratory, definition of a data collection period, treatment of discounts, reporting of more than one payment rate for the same payor, certification of data, definition of private payor, use civil money penalties, and generally, Medicare conditions of payment for clinical diagnostic laboratory tests.

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 annual cost for operating the Panel, including travel expenses for members but excluding staff support, is \$94,700. The annual staff support required for the Panel is 1.95 full-time equivalents at an estimated annual cost of \$267,463.

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 and ensure that all procedures meet applicable statutory and regulatory directives. The DFO shall approve and prepare all meeting agendas, call all 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. 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 prior to its expiration, 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 representatives of clinical laboratories, molecular pathologists, clinical laboratory researchers, and individuals with expertise in clinical 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, or CMS Administrator, or CMS Administrator's designee.

For purposes of this Panel, consultants or independent contractors are not considered to be representatives of clinical laboratories. All members shall serve on a voluntary basis, without compensation, pursuant to advance written agreement. All members who are not current federal employees shall be designated special government employees.

Panel members shall serve a term of up to 3 years, contingent upon the renewal of the Panel by appropriate action prior to its termination. A member may serve after the expiration of his/her term until a successor has been sworn in.

The Secretary or designee will appoint a Chair who 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 designee.

SUBCOMMITTEES

With the approval of the Secretary or designee, subcommittees consisting of two or more Panel members may be established to perform 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; rather it must report to the parent Panel.

RECORDKEEPING

The records of the Panel and established subcommittees 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

APR 16 2015

APPROVED

APR 15 2015

Date



Sylvia M. Burwell