

**CHARTER
MEDICARE ADVISORY PANEL ON CLINICAL
DIAGNOSTIC LABORATORY TESTS**

ADVISORY COMMITTEE’S OFFICIAL DESIGNATION

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 of Public Law 113-93—April 1, 2014. The renewal of the Panel is governed by the Federal Advisory Committee Act (FACA), as amended (5 U.S.C. Ch. 10).

OBJECTIVES AND SCOPE OF ACTIVITIES

The Secretary of the Department of Health and Human Services (Secretary of 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 1834(A) of the Act.

DESCRIPTION OF DUTIES

The Panel may advise on the following issues:

- Application of market rates to establish Medicare payment rates.
- 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.

**AGENCY OR FEDERAL OFFICER RECEIVING THE ADVISORY COMMITTEE’S
ADVICE/RECOMMENDATIONS**

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 four meetings per year, for all 15 members but excluding staff support, is \$89,000.00.

The fiscal year 2025 staff support required for the Panel is 1.45 full-time equivalents at an estimated annual cost of \$298,796.41.

The estimated annual cost reflects four (4), in-person meetings per year for 15 panel members. Over the past several years, we have had one (1) meeting per year and held virtual-only meetings. Therefore, the actual annual expenses for the past several years have been significantly less than the estimated annual expenses.

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 Alternate DFO 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 four-times within a fiscal year. The Panel Chair shall facilitate meetings and the DFO 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

The duration of the Panel is continuing, subject to the Termination section below.

TERMINATION

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

MEMBERSHIP AND DESIGNATION

The Panel shall consist of up to 15 individuals; 14 Special Government Employees (SGEs) or Representative members and 1 Regular Government employee (RGE). They will have 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 which may include the development, validation, performance, and application of such tests.

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 three-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 member's 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 three-years, but it may be extended at the discretion of the 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 objectives and scope of activities. One of the members will be designated by fellow subcommittee members 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, or parent committee.

RECORDKEEPING

The records of the committee, established subcommittees, or other subgroups of the Panel, 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

April 24, 2025

APPROVED

Date

Robert F. Kennedy, Jr.