



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

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

**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 (CDLT or 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 Public Law 113-93, enacted—April 1, 2014. The Panel is governed by the Federal Advisory Committee Act (FACA), as amended (5 U.S.C. App. 2).

**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 cross walking or gap filling 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.
- Evaluation and designation of tests as advanced diagnostic laboratory tests.
- Whether to use cross walking or gap filling 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 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 2021 annual cost for operating the CDLT Panel, including travel expenses for members but excluding staff support, is \$89,000.00 (up to 4 meetings per year).

The fiscal year 2021 staff support required for the Panel is 1.45 full-time equivalents at an estimated annual cost of \$241,244.18.

### **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 shall be present at all meetings of the full Panel and subcommittee(s). In the event that the DFO cannot fulfill the assigned duties of the committee, one or more full-time or permanent part-time employees will be assigned as DFO and carry out these duties on a temporary basis.

### **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 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 (14 Representative members and 1 Regular Government Employee (RGE)) 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 or CMS Administrator's designee.

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, 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 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 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.

**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**

April 26, 2021

**APPROVED**

**APR 19 2021**

Date

  
Xavier Becerra