

2025 Current Fiscal Year Report: Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests

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1. Department or Agency

Department of Health and Human Services

2. Fiscal Year

2025

3. Committee or Subcommittee

Medicare Advisory Panel on Clinical
Diagnostic Laboratory Tests

3b. GSA

Committee

No.

2529

4. Is this New During Fiscal Year?

No

5. Current Charter

04/26/2023 04/26/2025

6. Expected Renewal Date

7. Expected Term Date

8a. Was Terminated During Fiscal Year?

No

8b. Specific Termination Authority

8c. Actual Term Date

9. Agency Recommendation for Next Fiscal Year

Continue

10a. Legislation Req to Terminate?

Not Applicable

10b. Legislation Pending?

Not Applicable

11. Establishment Authority

Statutory (Congress Created)

12. Specific Establishment Authority

Section 1834A(f)(1) of the
Social Security Act (the Act)
(42 USC 1395m-1)

13. Effective Date

07/01/2015

14. Committee Type

Continuing

14c. Presidential?

No

15. Description of Committee

16a. Total Number of Reports

No Reports for
this Fiscal Year

17a. Open

0

17b. Closed

0

17c. Partially Closed

0

Other Activities

0

17d. Total

0

Meetings and Dates

No Meetings

	Current FY	Next FY
18a(1). Personnel Pmts to Non-Federal Members	\$0.00	\$0.00
18a(2). Personnel Pmts to Federal Members	\$0.00	\$0.00
18a(3). Personnel Pmts to Federal Staff	\$0.00	\$0.00
18a(4). Personnel Pmts to Non-Member Consultants	\$0.00	\$0.00
18b(1). Travel and Per Diem to Non-Federal Members	\$0.00	\$0.00
18b(2). Travel and Per Diem to Federal Members	\$0.00	\$0.00
18b(3). Travel and Per Diem to Federal Staff	\$0.00	\$0.00
18b(4). Travel and Per Diem to Non-member Consultants	\$0.00	\$0.00
18c. Other(rents,user charges, graphics, printing, mail, etc.)	\$0.00	\$0.00
18d. Total	\$0.00	\$0.00
19. Federal Staff Support Years (FTE)	0.00	0.00

20a. How does the Committee accomplish its purpose?

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 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 may provide recommendations to the Secretary of HHS and the Administrator of CMS under section 1834A of the Act.

20b. How does the Committee balance its membership?

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.

20c. How frequent and relevant are the Committee Meetings?

Estimated Number of Meetings per Year - 4. The Panel is relevant because it considers and advises 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.

20d. Why can't the advice or information this

committee provides be obtained elsewhere?

The Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests (the Panel) is required by law under 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.

20e. Why is it necessary to close and/or partially closed committee meetings?

Meetings are not closed; in fact, they are open to the public. Notices of meetings are given to the public in the Federal Register, and there will be records of the meeting proceedings kept, as required by applicable laws and departmental regulations. In the event that a portion of a meeting is closed to the public, a report will be prepared that contains at a minimum a list of members and their business addresses, the Panel's function, dates and places of meetings, and a summary of Panel activities and recommendations made during the fiscal year. A copy of the report will be provided to the Department Committee Management Officer.

21. Remarks

The Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests does not currently have a Chairperson. The former Chairperson retired in 2023 and a new Chairperson has not yet been selected. We currently have two panel members that are serving as the "interim co-chairs" until a Chairperson is selected.

Designated Federal Officer

Rasheeda Jameeka Arthur DFO

Committee Members	Start	End	Occupation	Member Designation
Baselski, Vickie	07/01/2015	08/31/2026	Professor Pathology	Representative Member

Chandra, Prnil	07/01/2015	08/31/2026	Chief Medical Officer; Molecular Genetic Pathology; Hematopathology	Representative Member
Chong, Yap-Yee (Chris)	04/01/2022	03/31/2026	Chief Medical Officer of Laboratory Services	Representative Member
Garner, Jerry	10/01/2024	10/01/2027	Senior Director of Global Market Access, Health Economics and Policy	Representative Member
Hooker, Gillian	10/01/2024	10/01/2027	Chief Scientific Officer Concert Genetics	Representative Member
Jiang, Jennifer	04/01/2022	03/31/2026	Full- Time Medical Consultant of Hematopathology- Mayo Clinic Florida; Assistant Prof in Dept of Laboratory Med. & Path; Med. Dir of Flow Cytometry Med Dir Ctr for Integrated Diagnostic;	Representative Member
Lennerz, Jochen	04/01/2022	03/31/2026	Associate Chief of Path; Associate Professor Division Director for Chemistry, Toxicology and Newborn Screening at the Public Health Laboratory (Tennessee Dept. of Health) Clinical Laboratory Dir.; Clinical Consultant	Representative Member
Rumpler, Marc	04/01/2022	03/31/2026	Professor	Representative Member
Schoonmaker, Michele	07/01/2015	08/31/2026	Professor	Representative Member
Shappell, Heather	07/01/2019	03/31/2026	Lab and Pharmacy Benefit Manager	Representative Member

Number of Committee Members Listed: 10

Narrative Description

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.

What are the most significant program outcomes associated with this committee?

Checked if
Applies

- | | |
|---|--------------------------|
| Improvements to health or safety | <input type="checkbox"/> |
| Trust in government | <input type="checkbox"/> |
| Major policy changes | <input type="checkbox"/> |
| Advance in scientific research | <input type="checkbox"/> |
| Effective grant making | <input type="checkbox"/> |
| Improved service delivery | <input type="checkbox"/> |
| Increased customer satisfaction | <input type="checkbox"/> |
| Implementation of laws or regulatory requirements | <input type="checkbox"/> |
| Other | <input type="checkbox"/> |

Outcome Comments

Not Applicable

What are the cost savings associated with this committee?

Checked if Applies

- | | |
|----------------------------|-------------------------------------|
| None | <input type="checkbox"/> |
| Unable to Determine | <input checked="" type="checkbox"/> |
| Under \$100,000 | <input type="checkbox"/> |
| \$100,000 - \$500,000 | <input type="checkbox"/> |
| \$500,001 - \$1,000,000 | <input type="checkbox"/> |
| \$1,000,001 - \$5,000,000 | <input type="checkbox"/> |
| \$5,000,001 - \$10,000,000 | <input type="checkbox"/> |
| Over \$10,000,000 | <input type="checkbox"/> |
| Cost Savings Other | <input type="checkbox"/> |

Cost Savings Comments

Not Applicable

What is the approximate Number of recommendations produced by this committee for the life of the committee?

1,004

Number of Recommendations Comments

Approximately 1004 recommendations since 2015 were generated for the life of the committee.

What is the approximate Percentage of these recommendations that have been or will be Fully implemented by the agency?

85%

% of Recommendations Fully Implemented Comments

Approximately 85 percent of the CDLT Panel recommendations are fully implemented by the Agency.

What is the approximate Percentage of these recommendations that have been or will be Partially implemented by the agency?

10%

% of Recommendations Partially Implemented Comments

Of the 15 percent that are not fully implemented, approximately 10 percent are partially implemented. For the remaining 5 percent, CMS may not be able to address these issues due to statutory constraints, or they may be addressed in future years as we are able to do so.

Does the agency provide the committee with feedback regarding actions taken to implement recommendations or advice offered?

Yes ☒ No ☐ Not Applicable ☐

Agency Feedback Comments

Panel recommendations are verified before they are made final and then posted on CMS website.

What other actions has the agency taken as a result of the committee's advice or recommendation?

Checked if Applies

- | | |
|-----------------------------------|--------------------------|
| Reorganized Priorities | <input type="checkbox"/> |
| Reallocated resources | <input type="checkbox"/> |
| Issued new regulation | <input type="checkbox"/> |
| Proposed legislation | <input type="checkbox"/> |
| Approved grants or other payments | <input type="checkbox"/> |
| Other | <input type="checkbox"/> |

Action Comments

Not Applicable

Is the Committee engaged in the review of applications for grants?

No

Grant Review Comments

Not Applicable

How is access provided to the information for the Committee's documentation?

Checked if Applies

- | | |
|---------------------------|-------------------------------------|
| Contact DFO | <input checked="" type="checkbox"/> |
| Online Agency Web Site | <input checked="" type="checkbox"/> |
| Online Committee Web Site | <input checked="" type="checkbox"/> |
| Online GSA FACA Web Site | <input checked="" type="checkbox"/> |
| Publications | <input checked="" type="checkbox"/> |
| Other | <input type="checkbox"/> |

Access Comments

Not Applicable