

## 2023 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

2023

### 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

1

17b. Closed

0

17c. Partially Closed

0

Other Activities

0

17d. Total

1

### Meetings and Dates

Purpose

Start

End

**Number of Committee Meetings Listed: 1**

	<b>Current FY</b>	<b>Next FY</b>
<b>18a(1). Personnel</b>		
<b>Pmts to Non-Federal Members</b>	\$0.00	\$0.00
<b>18a(2). Personnel</b>		
<b>Pmts to Federal Members</b>	\$85,835.09	\$0.00
<b>18a(3). Personnel</b>		
<b>Pmts to Federal Staff</b>	\$190,867.99	\$200,793.13
<b>18a(4). Personnel</b>		
<b>Pmts to Non-Member Consultants</b>	\$0.00	\$0.00
<b>18b(1). Travel and Per Diem to Non-Federal Members</b>	\$0.00	\$40,000.00
<b>18b(2). Travel and Per Diem to Federal Members</b>	\$0.00	\$0.00
<b>18b(3). Travel and Per Diem to Federal Staff</b>	\$0.00	\$0.00
<b>18b(4). Travel and Per Diem to Non-member Consultants</b>	\$0.00	\$0.00
<b>18c. Other(rents,user charges, graphics, printing, mail, etc.)</b>	\$0.00	\$49,500.78
<b>18d. Total</b>	\$276,703.08	\$290,293.91
<b>19. Federal Staff Support Years (FTE)</b>	1.45	1.45

**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.

## Designated Federal Officer

Rasheeda Jameeka Arthur DFO

Committee Members	Start	End	Occupation	Member Designation
Baselski, Vickie	07/01/2015	08/31/2023	Professor Pathology	Representative Member
Chandra, Pranil	07/01/2018	07/31/2023	Chief Medical Officer;Molecular Genetic Pathology; Hematopathology	Representative Member
Chong, Yap-Yee (Chris)	04/01/2022	03/31/2025	Chief Medical Officer of Laboratory Services	Representative Member
Clarke, William	07/01/2015	08/31/2023	Professor of Pathology	Representative Member
Contis, Lydia	07/01/2019	08/31/2023	Hematopathologist	Representative Member
Hamilton, Stanley	07/01/2015	08/31/2023	Gastrointestinal and Molecular Pathologist	Representative Member
Harris, Elizabeth	07/01/2019	08/31/2023	Pathology	Representative Member
Jiang, Jennifer	04/01/2022	03/31/2025	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	Representative Member
Lennerz, Jochen	04/01/2022	03/31/2025	Diagnostic; Associate Chief of Path; Associate Professor	Representative Member
Nakano, Karen	02/22/2017	02/22/2023	Centers for Medicare and Medicaid Services	Regular Government Employee (RGE) Member
Rumpler, Marc	04/01/2022	03/31/2025	Division Director for Chemistry, Toxicology and Newborn Screening at the Public Health Laboratory (Tennessee Dept. of Health) Clinical Laboratory Dir.; Clinical Consultant	Representative Member

**Number of Committee Members Listed: 12**

### **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?**

819

### **Number of Recommendations Comments**

Approximately 819 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