

2025 Current Fiscal Year Report: Clinical Laboratory Improvement Advisory Committee

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1. Department or Agency	2. Fiscal Year
Department of Health and Human Services	2025

3. Committee or Subcommittee	3b. GSA Committee No.
Clinical Laboratory Improvement Advisory Committee	826

4. Is this New During Fiscal Year?	5. Current Charter	6. Expected Renewal Date	7. Expected Term Date
No	02/19/2024	02/19/2026	

8a. Was Terminated During Fiscal Year?	8b. Specific Termination Authority	8c. Actual Term Date
Yes	Per 2025 Secretary Directive	04/01/2025

9. Agency Recommendation for Next Fiscal Year	10a. Legislation Req to Terminate?	10b. Legislation Pending?
Terminate	Not Applicable	Not Applicable

11. Establishment Authority Authorized by Law

12. Specific Establishment Authority	13. Effective Date	14. Committee Type	14c. Presidential?
42 U.S.C. 217a	02/28/1992	Continuing	No

15. Description of Committee Scientific Technical Program Advisory Board

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
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The agenda included CDC, CMS, and FDA agency updates. Presentations and CLIAC discussions focused on reports from two CLIAC workgroups, the Biosafety Workgroup and the Next Generation Sequencing Workgroup; cybersecurity requirements in the clinical laboratory; the determination of clinically relevant range of values for proficiency testing samples; and the utilization of remote technology for competency assessments.

11/06/2024 - 11/07/2024

Number of Committee Meetings Listed: 1

	Current FY	Next FY
18a(1). Personnel Pmts to Non-Federal Members	\$8,750.00	\$0.00
18a(2). Personnel Pmts to Federal Members	\$0.00	\$0.00
18a(3). Personnel Pmts to Federal Staff	\$62,740.00	\$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. Administrative Costs (FRNs, contractor support, In-person/hybrid/virtual meetings)	\$0.00	\$0.00
18d. Other (all other funds not captured by any other cost category)	\$3,069.00	\$0.00
18e. Total Costs	\$74,559.00	\$0.00
19. Federal Staff Support Years (FTE)	0.59	0.00

20a. How does the Committee accomplish its purpose?

The Clinical Laboratory Improvement Advisory Committee (CLIAC), hosted by the Centers for Disease Control and Prevention (CDC) in collaboration with the Centers for Medicare & Medicaid Services (CMS) and the Food and Drug Administration (FDA), provided scientific and technical advice to the Department of Health and Human Services (HHS). CLIAC provided timely and relevant advice and recommendations for refining and revising the Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulations, as well as addressing new clinical laboratory testing quality issues, to meet the changing needs of a dynamic healthcare system. Its role and functions are in the CLIA regulations (42 CFR part 493.2001) to meet the CLIA statutory requirement for consultation with private organizations and public agencies [42 USC 263a section 353 (q)]. Laboratory certificate fees support CLIAC through an interagency agreement between CMS and CDC, not through congressional appropriation. As of September 30, 2025, CLIAC has provided a total of 236 recommendations, which included 12 recommendations in the fiscal year 2025. Recent recommendations have addressed the revision of the CLIA regulations to reflect current laboratory testing practices for biosafety and next generation sequencing, cybersecurity requirements in the clinical laboratory, the determination of clinically relevant range of values for proficiency testing and the utilization of remote technology for competency assessments. Consistent with Executive Order (E.O.) 14217, entitled "Commencing the Reduction of the Federal Bureaucracy," the CLIAC was declared terminated by the Secretary of HHS on March 31, 2025.

20b. How does the Committee balance its membership?

The Committee consisted of 20 members who are knowledgeable in the fields of microbiology (including bacteriology, mycobacteriology, mycology, parasitology, and virology); immunology (including histocompatibility); chemistry; hematology; pathology (including histopathology and cytology); genetic testing (including cytogenetics); representatives from the fields of medical technology, bioinformatics, public health, and clinical practice; and consumer representatives. This representation is accompanied by an equal emphasis on diversity and qualified females and minorities are represented. The Committee also consists of three non-voting ex officio members and a non-voting liaison representative from the Advanced Medical Technology Association, which plays an important role in interacting and coordinating activities relating to the development of new devices/technology

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

The Committee met at least once per year. CLIAC met once in fiscal year 2025. While active CLIAC continued to play a critical role in recommending changes to CLIA program policy, standards, and guidelines by providing direction on the policy and procedures used in the development of and modifications to the CLIA regulations, identifying and prioritizing significant research data gaps, and continuing to evaluate the procedures used in the implementation and administration of the program.

20d. Why can't the advice or information this committee provides be obtained elsewhere?

Clinical laboratories are the backbone of the healthcare system and provide the foundation for accurate and timely diagnosis, prevention, and disease control to improve Americans' health and safety. At least 70% of today's medical decisions depend on the 15 billion laboratory tests conducted annually. One out of three patient encounters involve ordering one or more clinical laboratory tests, and the volume of U.S. clinical laboratory testing is increasing at an average of 6-10% per year while the scope of testing is becoming increasingly complex. Over the past 30 years since the implementation of the Clinical Laboratory Improvement Amendments of 1988 (CLIA), the number of Food and Drug Administration (FDA)-cleared or approved tests has increased by more than 400%, resulting in a need to ensure that the nation's over 308,000 CLIA-certified laboratories can accurately and reliably conduct testing and report results. CLIAC was the only Federal advisory committee that provided scientific and technical advice and guidance related to laboratory testing quality and practices to HHS and its agencies, including CMS and FDA. CLIAC's advice, recommendations, and guidance were crucial to the establishment of standards for quality assurance and quality control, personnel, proficiency testing, and maintenance of records, equipment, and facilities that must be met by all clinical laboratories in the U.S. CLIA regulations provided the standards that laboratories must meet when performing testing any disease or infection. CLIAC has made recommendations for HHS to update CLIA regulations as related to personnel, proficiency testing, remote testing, and preanalytical and analytical processes. CDC, CMS, and FDA were working together to act on these recommendations to revise the CLIA regulations;

future CLIAC recommendations will provide additional guidance to HHS regarding both regulatory and non-regulatory actions needed for ensuring quality and safe laboratory practices. The Committee was essential for providing HHS with timely and relevant advice and recommendations for refining and revising the CLIA regulations and addressing issues of clinical laboratory testing quality to meet the changing needs of a dynamic healthcare system.

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

N/A. During fiscal year 2025, all CLIAC meetings were open to the public.

21. Remarks

Per Secretary Directive the committee was terminated 04.01.2025. No formal reports are required in the charter; the Committee provides advice and recommendations through various means other than formal reports.

Designated Federal Officer

Heather Leigh Stang Senior Advisor for Clinical Laboratories

Committee Members	Start	End	Occupation	Member Designation
Babady, Esther	01/09/2023	03/31/2025	Chief, Clinical Microbiology Service, Memorial Sloan Kettering Cancer Center	Special Government Employee (SGE) Member
Black, Michael	07/01/2021	03/31/2025	Assistant Vice President, Clinical Laboratory System, Avera McKennan Hospital	Special Government Employee (SGE) Member
Brandush, Gregg	05/16/2022	03/31/2025	The Centers for Medicare & Medicaid Services (CMS)	Ex Officio Member

Brown, Chester	01/18/2023	03/31/2025	Pediatrics and Genetics, Genomics, and Informatics, University of Tennessee Health Science Center	Special Government Employee (SGE) Member
Campbell-Lee, Sally	01/07/2025	03/31/2025	Interim Head, Department of Pathology, University of Illinois at Chicago	Special Government Employee (SGE) Member
Chapin, Kimberle	07/01/2021	03/31/2025	Medical and Scientific Affairs, Cepheid, Lifespan Academic Medical Center	Special Government Employee (SGE) Member
Crawford, James	07/01/2021	03/31/2025	Senior Vice President for Laboratory Services, Northwell Health Laboratories	Special Government Employee (SGE) Member
Eisenstaedt, Richard	01/07/2025	03/31/2025	Chair, Department of Medicine, Jefferson Abington Hospital	Special Government Employee (SGE) Member
Hagelstrom, Tanner	01/17/2023	03/31/2025	Senior Laboratory Director, Natera	Special Government Employee (SGE) Member
Heher, Yael	01/06/2023	03/31/2025	Director, Quality and Patient Safety, Massachusetts General Hospital	Special Government Employee (SGE) Member
Kadel, Santosh	01/03/2025	03/31/2025	Clinical Architect, Laboratory Medicine, ChristianaCare Health System	Special Government Employee (SGE) Member

Koch, David	07/01/2021	03/31/2025	Director, Clinical Chemistry, Special Chemistry, Toxicology, and Point-of-Care Testing, Grady Memorial Hospital	Special Government Employee (SGE) Member
Laser, Jordan	01/09/2023	03/31/2025	Founder, Laser Laboratory Consulting, LLC, Everly Health	Special Government Employee (SGE) Member
Leaumont, Collette	03/05/2018	03/31/2025	Centers for Disease Control and Prevention (CDC)	Ex Officio Member
Lias, Courtney	03/14/2024	03/31/2025	US Food and Drug Administration (FDA)	Ex Officio Member
Lockwood, Christina	01/03/2025	03/31/2025	Professor, Department of Laboratory Medicine and Pathology, The University of Washington	Special Government Employee (SGE) Member
Luu, Hung	01/09/2023	03/31/2025	Associate Professor, University of Texas Southwestern Medical Center	Special Government Employee (SGE) Member
Tuthill, J. Mark	07/01/2021	03/31/2025	Division Head, Pathology Informatics, Henry Ford Hospital	Special Government Employee (SGE) Member
Veoukas, April	10/12/2023	03/31/2025	Director, Regulatory Affairs, Abbott Laboratories	Representative Member

Number of Committee Members Listed: 19

Narrative Description

The CLIA statute and its implementing regulations aim to ensure the quality and reliability of medical tests performed by clinical laboratories throughout the nation. The Committee's advice and

recommendations relative to the CLIA program are consistent with and supportive of the CDC's vision of equitably protecting health, safety, and security.

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

	Checked if Applies
Improvements to health or safety	<input checked="" 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 checked="" type="checkbox"/>
Other	<input type="checkbox"/>

Outcome Comments

Implementation of laws or regulatory requirements for CLIA-certified laboratories.

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

N/A

What is the approximate Number of recommendations produced by this committee

for the life of the committee?

236

Number of Recommendations Comments

Recommendations addressed general issues related to improvement in clinical laboratory quality and laboratory medicine practice. Recommendations generally provide guidance to assure quality laboratory testing and support for policies, studies, and evaluation activities. There were 12 recommendations for the fiscal year 2025. During the November 5-6, 2024, meeting, there were twelve recommendations. Five recommendations related to CLIAC deliberations on the CLIA Biosafety Workgroup report: (1) revising the CLIA requirements to include general biosafety training as part of the competency requirements for testing personnel; (2) a standardized definition of a biosafety risk assessment should be developed and added to 42 CFR 493.2; (3) CDC provide educational tools and resources on how laboratories can develop and perform biosafety risk assessments; (4) that it is best practice that laboratories should be required to perform a biosafety risk assessment on all instrumentation currently in use; and (5) that 42 CFR 493.1804(a)(2) should be expanded to clarify that laboratory workers and, in turn, the general population should be safeguarded. Three recommendations related to CLIAC deliberations on the CLIA Next Generation Sequencing Workgroup: (1) the CLIA testing personnel qualifications for laboratories performing high complexity testing should be modified to add a qualification route for the responsibilities of bioinformaticians, which are not burdensome for laboratories; (2) a CLIA personnel carve-out be created to allow individuals who perform bioinformatics data analysis to qualify under CLIA, similar to how the current blood gas analysis carve-out is at § 493.1461 and § 493.1489; and (3) using the existing CLIA personnel roles (testing personnel, general supervisor, technical supervisor, and director), along with the experience and degree requirements, as a framework to build upon. Two recommendations related to the cybersecurity requirements in the clinical laboratory: (1) a regulation that requires laboratories to have a documented cybersecurity plan; and (2) updating the existing CLIA regulations to reflect modern cybersecurity and information management issues. One recommendation related to the determination of clinically relevant range of values for proficiency testing stating that the CLIA requirements for proficiency testing programs be updated to include consideration for analytical measurement ranges, including those values that may be medically relevant, if possible, for regulated analytes. One recommendation related to the utilization of remote technology for competency assessments stating that CMS allows remote assessment to be utilized in the direct observation component of competency assessment.

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

74%

% of Recommendations Fully Implemented Comments

171 completed recommendations and 4 recommendations have no action/completed.

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

26%

% of Recommendations Partially Implemented Comments

There are 61 recommendations with partial implementation.

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

Yes No Not Applicable

Agency Feedback Comments

Yes, through agency updates provided at the beginning of each Committee meeting. A recommendations table with the date of the recommendation, category, the recommendation text, and current status is updated and can be found at <https://www.cdc.gov/cliac/php/meetings/index.html>.

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

Checked if Applies

- Reorganized Priorities
- Reallocated resources
- Issued new regulation
- Proposed legislation
- Approved grants or other payments
- Other

Action Comments

In fiscal year 2025, in response to two recommendations made during the November 2024 meeting on the biosafety workgroup report, the CDC Division of Laboratory Systems has created the Introduction to Laboratory Risk Management (LRM) training course. This course is the first in a series of courses focused on developing risk management strategies for laboratory settings. This basic level eLearning course provides details on applying risk management principles and briefly describes related practices to emphasize

the importance of risk management in laboratory settings. Topics covered include risk management goals, terminology, processes, and associated activities.

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

No

Grant Review Comments

N/A

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

Checked if Applies

- | | |
|---------------------------|-------------------------------------|
| Contact DFO | <input 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 type="checkbox"/> |
| Other | <input type="checkbox"/> |

Access Comments

<https://www.cdc.gov/cliac/php/about/index.html>