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	03/31/2025

8a. Was Terminated During FiscalYear?	8b. Specific Termination Authority	8c. Actual Term Date
No	E.O. 14217	

9. Agency Recommendation for Next FiscalYear	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. Commitee 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 FiscalYear

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 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), provides scientific and technical advice to the Department of Health and Human Services (HHS). CLIAC provides timely and relevant advice and recommendations for refining and revising the Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulations and addressing new clinical laboratory

testing quality issues to meet the changing needs of a dynamic health care 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, 2024, CLIAC has provided a total of 224 recommendations, which include 14 recommendations in the fiscal year 2024. Recent recommendations have addressed standardization of test result communication, the role of the laboratory in diagnostic and antibiotic stewardship, efforts to address the CLIA top ten laboratory deficiencies, the revision of the CLIA regulations to reflect current laboratory testing practices, the use of clinical standards to improve laboratory quality, the role of artificial intelligence and machine learning in the clinical laboratory, and the applicability of CLIA personnel requirements to preanalytic testing. In the fiscal year 2025, CDC, CMS, and FDA will continue to work together on two CLIAC workgroups formed in fiscal year 2024, the Next Generation Sequencing (NGS) Workgroup and the Biosafety Workgroup. Both workgroups will present their reports during the November 6-7, 2024 CLIAC meeting. Future resulting CLIAC recommendations will guide CDC and CMS in starting the regulatory revision process. Also, CDC, CMS, and FDA will work to assemble a new workgroup, The Artificial Intelligence and Machine Learning in Clinical Laboratories Workgroup, which was recommended in April 2024 to explore the current and future intersection between artificial intelligence and machine learning in the clinical laboratory, specifically regarding implementing

and deploying tools in the clinical laboratory. Other CLIAC discussions and recommendations provide guidance and support for policy and research projects, such as emerging technologies in clinical and public health laboratories, cybersecurity requirements in the clinical laboratory, the determination of the clinically relevant range of values for proficiency testing analytes, the utilization of remote technologies for competency assessments, the use of artificial intelligence in the clinical laboratory, the role of the laboratory in diagnostic stewardship, and image standardization issues for digital pathology.

20b. How does the Committee balance its membership?

The Committee consists 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 meets at least once per year. It continues 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 control of disease to improve the health and safety of Americans. At least 70% of today’s medical decisions depend on the 14 billion laboratory tests conducted annually. One out of three patient encounters involve the ordering of 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 FDA-cleared or approved tests has increased by more than 400% resulting in a need to ensure that the nation's over 315,000 CLIA-certified laboratories can accurately and reliably conduct testing and report results. CLIAC is the only Federal advisory committee that provides scientific and technical advice and guidance related to laboratory testing quality and practices to HHS and its agencies, including CDC, CMS, and FDA. CLIAC's advice, recommendations, and guidance are crucial, and CLIAC has made recommendations for HHS to update CLIA regulations for laboratory testing and

personnel that have not been updated since 1992. CDC, CMS, and FDA are 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 is 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 2024, all CLIAC meetings were open to the public.

21. Remarks

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
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
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
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
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: 15

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	✓
Trust in government	
Major policy changes	
Advance in scientific research	
Effective grant making	
Improved service delivery	
Increased customer satisfaction	
Implementation of laws or regulatory requirements	✓
Other	

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	
Unable to Determine	✓

Under $100,000 ☐
$100,000 - $500,000 ☐
$500,001 - $1,000,000 ☐
$1,000,001 - $5,000,000 ☐
$5,000,001 - $10,000,000 ☐
Over $10,000,000 ☐
Cost Savings Other ☐

Cost Savings Comments
N/A

What is the approximate Number of recommendations produced by this committee for the life of the committee?
224

Number of Recommendations Comments
Recommendations address 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 14 recommendations for the fiscal year 2024. During the November 8-9, 2023, meeting, there were ten recommendations. One recommendation related to CLIAC deliberations on the CLIA Regulatory Assessment Workgroup related to the need to update CLIA to recognize histotechnicians, histotechnologists, and pathology assistants as testing personnel and define the educational requirements for each personnel category. Four recommendations related to efforts to address the CLIA top ten laboratory deficiencies: (1) CMS engage Accrediting Organizations to increase the granularity of data related to the CLIA top 10 deficiencies; (2) CDC and CMS engage with professional organizations and hospital and facility agencies to incorporate CLIA regulation requirements into the required training programs for hospital and laboratory quality organizational leaders; (3) CMS evaluate and consider modifications to the CLIA regulations for competency assessment to simplify the regulations and clarify the procedures while ensuring the competency of laboratory personnel; and (4) CMS consider requiring interim CLIA self-assessment and documentation of correction of self-identified deficiencies. Three recommendations related to the role of the laboratory in diagnostic and antibiotic stewardship: (1) To expand the influence of the CLIA quality program and strengthen clinical laboratory quality, CLIAC recommends that CMS and CDC develop an educational campaign promoting diagnostic stewardship programs targeting clinical laboratories; (2) CDC and FDA encourage in vitro diagnostics (IVD) manufacturers to harmonize results across different platforms, when possible, to allow for safe aggregation

of patient results from other institutions to trend results and reduce duplicate testing; and (3) updating the CLIA regulations to include blood culture contamination rate monitoring within the laboratory quality management system. Two recommendations related to the standardization of test result communication: (1) HHS require that all transmission of laboratory results throughout the healthcare ecosystem, at a minimum, adhere to the required discrete results defined in laboratory result reports in CLIA; and (2) the formation of a CLIAC workgroup, including key stakeholders, organizations/agencies from the provider, and health IT communities, to understand the opportunities for enhanced communication of laboratory results and to verify action upon those results. Four recommendations were made during the April 10, 2024, CLIAC meeting. One recommendation related to the applicability of CLIA personnel requirements to preanalytic testing and the need for the CLIA laboratory director's responsibilities to include determining the required competency of personnel who perform preanalytic phase processes, including documentation. One recommendation was made to create a workgroup to explore the current and future intersection between artificial intelligence and machine learning in the clinical laboratory, specifically regarding implementing and deploying tools in the clinical laboratory. Two recommendations were made on the use of clinical standards to improve laboratory quality: (1) CMS/CDC/FDA to engage professional societies (e.g., harmonization.net) to encourage test developers to participate in existing clinical standardization programs; and (2) CDC create a marketing campaign to raise awareness of standardization/harmonization efforts and their benefits.

What is the approximate Percentage of these recommendations that have been or will be Fully implemented by the agency?
77%

% of Recommendations Fully Implemented Comments
169 completed recommendations and 4 recommendations has no action/completed.

What is the approximate Percentage of these recommendations that have been or will be Partially implemented by the agency?
23%

% of Recommendations Partially Implemented Comments
There are 51 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 2024, in response to 23 personnel recommendations were made throughout several CLIAC meetings, including May 1993, November 2018, and April 2019. during the April 10-11, 2019, CMS and CDC published the Clinical Laboratory Improvement Amendments of 1988 (CLIA) Fees; Histocompatibility, Personnel, and Alternative Sanctions for Certificate of Waiver Laboratories Final Rule in the Federal Register on December 28, 2023 (https://www.federalregister.gov/documents/2023/12/28/2023-28170/clinical-laboratory-improver This final rule updates the CLIA fees and clarifies the CLIA fee regulations. This final rule also amends histocompatibility and personnel regulations under CLIA to address obsolete regulations and update the regulations to incorporate technological changes. In addition, this final rule amends the provisions governing alternative sanctions (including civil money penalties, a directed plan of correction, a directed portion of a plan of correction, and onsite State monitoring) to allow for the imposition of such sanctions on Certificate of Waiver laboratories. In response to recommendations made by CLIAC on histopathology and remote review of histopathology and cytology slides and images, CMS and CDC published the Histopathology, Cytology, and Clinical Cytogenetics Regulations under the Clinical Laboratory Improvement Amendments (CLIA) of 1988 Request for Information (RFI) on July 13, 2023 as part of the CY2024 Physician Fee Schedule proposed rule (CMS-1784-P) (https://www.federalregister.gov/documents/2023/08/07/2023-14624/medicare-and-medicaid-pro The RFI received 53 individual public commenters with 309 unique comments. In fiscal

year 2024, CDC reviewed these comments and created an RFI summary report. CDC and CMS will use the summary report to guide any potential regulatory revision processes. In response to a CLIAC recommendation made during the April 2023 meeting on the laboratory's role in advancing health equity, the CDC Division of Laboratory Systems hosted the Clinical Laboratory Partners Forum (CLPF) on May 22, 2024. This meeting's central theme focused on the early diagnosis of chronic kidney disease (CKD) and how the clinical laboratory can play a central role in identifying patients at risk for CKD. Participants participated in an open discussion on the standardization of the use of the CKD-EPI 2021 eGFR race-free equation across clinical laboratories, the creation of a specific Kidney Panel combining eGFR and the urine Albumin-Creatinine Ratio (ACR) for screening, and the standardization of the test name for ACR to Albumin-Creatinine Ratio, Urine. In response to a recommendation made during the November 2023 meeting on the role of the laboratory in diagnostic and antibiotic stewardship, the CDC Division of Laboratory Systems has created a Diagnostic Stewardship Toolkit intended for multidisciplinary healthcare teams, which include clinical laboratory professionals. It can help your organization form diagnostic stewardship teams and apply the principles of diagnostic stewardship. This toolkit also can help diagnostic stewardship teams save time and healthcare resources. Additionally, patients can benefit by receiving rapid and accurate diagnoses. In response to a recommendation made during the November 2022 meeting on CLIA Certificate of Waiver sites and the opening of the CLIA law to allow oversight of CLIA Certificate of Waiver testing sites, CDC and CMS collaborated to determine a path forward. As of August 2024, CMS and CDC will not pursue a CLIA law or regulation change related to the CLIA requirements for sites holding a Certificate of Waiver. This recommendation status has been updated to no action/complete. In response to two recommendations made during the April 2023 meeting on CLIA Certificate for Provider-performed Microscopy Procedures and the need for the CLIA regulations to be modified to implement routine inspection for CLIA Certificate for Provider-performed Microscopy sites, CDC and CMS collaborated to determine a path forward. As of August 2024, CMS and CDC will not pursue a CLIA law or regulation change related to the CLIA requirements for sites holding a Certificate for Provider-performed Microscopy Procedures. This recommendation status has been updated to no action/complete.

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	☐
Online Agency Web Site	☑
Online Committee Web Site	☑
Online GSA FACA Web Site	☑
Publications	☐
Other	☐

Access Comments

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