2022 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	2022

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	02/19/2022	02/19/2024	

8a. Was Terminated During FiscalYear?	8b. Specific Termination Authority	8c. Actual Term Date
No	42 U.S.C. 217a	

9. Agency Recommendation for Next FiscalYear	10a. Legislation Req to Terminate?	10b. Legislation Pending?
Continue	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	17b. Closed	17c. Partially Closed	Other Activities	17d. Total
2	0	0	0	2

Meetings and Dates

Purpose	Start	End

The agenda included agency updates from CDC, CMS, and FDA. In addition to the general updates, agency presentations included an overview of the FDA's Center for Biologics Evaluation and Research, a laboratory safety update, and a status report on the new CLIA regulations assessment workgroup. Presentations and CLIAC discussion focused on next generation sequencing in clinical and public health laboratories and laboratory data exchange and harmonization.	11/03/2021 - 11/04/2021	
The agenda included agency updates from CDC, CMS, and FDA. In addition to the general updates, an update was provided on the ongoing CLIAC workgroups. Presentations and CLIAC discussion focused on the future of laboratory medicine, especially testing in non-traditional sites. There was an extended public comment session focusing on anticipated changes in testing practices, personnel issues, and emerging technologies used in non-traditional testing sites.	04/13/2022 - 04/14/2022	

Number of Committee Meetings Listed: 2

	Current FY	Next FY
18a(1). Personnel Pmts to Non-Federal Members	$18,250.00	$20,000.00
18a(2). Personnel Pmts to Federal Members	$8,112.00	$8,112.00
18a(3). Personnel Pmts to Federal Staff	$229,069.00	$212,567.00
18a(4). Personnel Pmts to Non-Member Consultants	$0.00	$0.00
18b(1). Travel and Per Diem to Non-Federal Members	$0.00	$68,950.00
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	$82,740.00
18c. Other(rents,user charges, graphics, printing, mail, etc.)	$10,791.00	$28,002.00
18d. Total	$266,222.00	$420,371.00
19. Federal Staff Support Years (FTE)	1.50	1.05

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, 2022, CLIAC has provided a total of 167 recommendations, which include five recommendations in the fiscal year 2022. Recent recommendations have addressed laboratory data exchange and harmonization, next generation sequencing, the laboratory workforce, and the

remote selection, interpretation, and reporting of patient results. In the fiscal year 2023, CDC, CMS, and FDA will continue to convene meetings of the CLIA Regulations Assessment Workgroup. This workgroup was recommended by CLIAC in 2019 to provide input to CLIAC for deliberation on how CLIA might specifically be updated based on the findings in the April 2019 reports by the Personnel Regulations, Non-Traditional Workflow Models, and Next Generation Sequencing (NGS) workgroups. The workgroup is charged with providing advice to CLIAC for consideration in making recommendations to the Department of Health and Human Services (HHS) on revising the CLIA regulations. The workgroup began meeting in April 2022 and provided an update during the April 13-14, 2022 CLIAC meeting. The CLIA Regulations Assessment Workgroup is scheduled to present its first workgroup report during the November 9-10, 2023 CLIAC meeting. Future resulting CLIAC recommendations will guide CDC and CMS in starting the regulatory revision process. Also, in the fiscal year 2023, CDC, CMS, and FDA will work together to assemble three new workgroups. The CLIA Certificate of Waiver and Certificate of Provider-performed Microscopy Workgroup is charged with providing input to CLIAC for consideration in making recommendations to the HHS on the potential need for expanding regulatory oversight of CLIA Certificate of Waiver sites. The workgroup will also provide input to CLIAC on the potential need for expanded regulatory oversight of Certificate for Provider-performed Microscopy Procedures sites. The Next Generation Sequencing (NGS) Workgroup was recommended by CLIAC in 2021 to define the scope of practice and the requisite CLIA qualifications for personnel performing bioinformatic data analysis and interpretation to

produce test results that inform clinical decision-making. The workgroup is charged with providing input to CLIAC for deliberation on how CLIA might specifically be updated, considering the CDC NGS request for information summary report, the April 2019 reports by the Personnel Regulations, Non-Traditional Workflow Models, and NGS workgroups, and the November 2021 CLIAC recommendation on personnel performing bioinformatic data analysis and interpretation. The focus of the workgroup is to define the scope of practice and the requisite CLIA qualifications for personnel performing NGS bioinformatic data analysis and interpretation to produce test results that inform clinical decision-making. The Biosafety of Laboratory Instrumentation Workgroup will be convened as a result of discussions during the CDC Town Hall Meeting on Laboratory Biosafety held on June 24, 2022. The workgroup will bring together diagnostic instrument manufacturers, clinical and public health laboratory professionals, federal partners, and industrial hygienists to provide input to CLIAC on solutions that will provide a safe working environment for the nation’s clinical and public health laboratories. Other CLIAC discussions and recommendations provide guidance and support for policy and research projects, such as emerging technologies in clinical and public health laboratories, laboratory data exchange and harmonization, the laboratory workforce, the laboratory's role in addressing health disparities, and the expansion of point-of-care testing. The Committee also provides a liaison to the CDC Board of Scientific Counselors, Deputy Director for Infectious Diseases to share the clinical laboratory perspective with that CDC Board and bring relevant information back to CLIAC.

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. The Committee 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, the identification and prioritization of significant research data gaps, and continued evaluation of 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. Approximately 15.76 billion laboratory tests are performed in the U.S. each year with at least one out of three patient encounters involving the ordering of one or more clinical laboratory tests; the volume of U.S. clinical laboratory testing is increasing at an average of 6-10% per year and 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 320,000 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?

During fiscal year 2022, 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. Monique Spruill, CMS ex officio resigned on 5/15/2022 and Gregg Brandush, CMS ex officio was appointed on 5/16/2022. Committee member Ewa King resigned on 5/23/2022.

Designated Federal Officer

Reynolds Mathewson Salerno Director, Division of Laboratory Systems

Committee Members	Start	End	Occupation	Member Designation
Archie, Birthale	07/01/2019	06/30/2023	Assistant Professor Graduate Nursing Program	Special Government Employee (SGE) Member
Black, Michael	07/01/2021	06/30/2025	Assistant Vice President, Clinical Laboratory System	Special Government Employee (SGE) Member
Brandush, Gregg	05/16/2022	05/15/2027	Director, Division of Laboratory Services, CMS	Ex Officio Member
Chapin, Kimberle	07/01/2021	06/30/2025	Medical and Scientific Affairs, Cepheid	Special Government Employee (SGE) Member
Crawford, James	07/01/2021	06/30/2025	Senior Vice President for Laboratory Services	Special Government Employee (SGE) Member
Duncan, Heather	11/21/2020	12/30/2022	Microbiology Manager	Special Government Employee (SGE) Member
Edgerton, Mary	07/01/2020	06/30/2024	Associate Professor, Department of Pathology	Special Government Employee (SGE) Member

Gross, Susan	09/26/2018	12/30/2022	Clinical Professor, Department of Genetics and Genomic Sciences	Special Government Employee (SGE) Member
Hilborne, Lee	09/20/2018	12/30/2022	Medical Director, Care Coordinator	Special Government Employee (SGE) Member
King, Ewa	07/01/2021	05/23/2022	Associate Director of Health, State Health Laboratories	Special Government Employee (SGE) Member
Koch, David	07/01/2021	06/30/2025	Director, Clinical Chemistry, Special Chemistry, Toxicology, and Point-of-Care Testing	Special Government Employee (SGE) Member
Leaumont, Collette	03/05/2018	03/04/2024	Associate Director for Science, DLS	Ex Officio Member
Middleton, Lavinia	09/17/2018	12/30/2022	Professor, Department of Pathology/Laboratory Medicine	Special Government Employee (SGE) Member
Moss, Carole	07/01/2019	06/30/2023	Founder/Patients Rights Activist	Special Government Employee (SGE) Member
Ng, Valerie	07/01/2020	12/30/2022	Chairman, Laboratory Medicine and Pathology	Special Government Employee (SGE) Member
Patel, Nirali	07/01/2020	06/30/2024	Physician, Tempus Labs	Special Government Employee (SGE) Member
Pentella, Michael	07/01/2020	06/30/2024	Physician, Tempus Labs	Special Government Employee (SGE) Member
Quintenz, Andy	09/25/2015	06/30/2023	Scientific & Professional Affairs Manager	Representative Member
Rhamy, Jennifer	07/01/2019	06/30/2023	Director, Blood Donor Center	Special Government Employee (SGE) Member
Sossaman, Gregory	09/20/2018	12/30/2022	System Chairman, Ochsner Health System	Special Government Employee (SGE) Member
Spruill, Monique	04/01/2021	05/15/2022	Director, Division of Laboratory Services, CMS	Ex Officio Member

Stenzel, Timothy	10/16/2020	10/15/2025	Director Office of In Vitro Diagnostics and Radiological Health, FDA	Ex Officio Member
Tuthill, J. Mark	07/01/2021	06/30/2025	Division Head, Pathology Informatics	Special Government Employee (SGE) Member
Watkins, R. W. (Chip)	07/01/2020	06/30/2024	Chief Medical Officer	Special Government Employee (SGE) Member
Wolk, Donna	10/09/2018	06/30/2022	System Director, Clinical and Molecular Microbiology	Special Government Employee (SGE) Member

Number of Committee Members Listed: 25

Narrative Description

The intention of the CLIA statute and its implementing regulations is 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 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

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?

167

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 five recommendations for the fiscal year 2022. During the November 3-4, 2021 meeting, there were three recommendations. One recommendation related to laboratory data exchange and harmonization is to encourage collaboration with CDC, CMS, FDA, other HHS organizations (e.g., The Office of the National Coordinator for Health Information Technology or ONC), In vitro diagnostics (IVD) and electronic health record (HER) vendors, and professional organizations to leverage current standards and fund a phased approach by which specimens, actionable test results, and methods are coded for interoperability. EHR vendors, bioindustry suppliers, and non-profit and commercial laboratories must implement the standard(s) within a specified timeline. HHS should identify an appropriate mechanism for compliance. Two recommendations on next generation sequencing: (1) CLIAC recommends that CDC, CMS, and FDA convene a workgroup to define the scope of practice and the requisite CLIA qualifications for personnel performing bioinformatic data analysis and interpretation to produce test results that inform clinical decision-making; and (2) CLIAC recommends that the CDC, CMS, and

FDA create a workgroup to review real-world practices as they apply to NGS for the end-to-end processing of data, including the acquisition, analysis, and transmittal of data (including the Admission, Discharge, Transfer (ADT) message, orders, and results) between instruments and health records, including but not limited to electronic communication between the electronic health record (EHR), laboratory information system (LIS) or laboratory information management system (LIMS), and IVD vendors, as well as interoperability between institutions, quality management systems, including documentation, regarding data security, fidelity, transmission, curation, retention, and retrieval, and validation of software algorithms used to generate interpretations During the April 13-14, 2022 CLIAC meeting there were two recommendations. One recommendation was made that CDC raise the recognition of laboratory professionals in health care through its outreach, communication, training, and guidance (partnerships with the laboratory science community to increase interest in laboratory careers), work with partners to create and expand access to educational content and resources and identify other opportunities to reduce the burden on individual training programs (create and oversee programs for clinical laboratory sciences training programs) and conduct a workplace survey of laboratory professionals to support and guide critical recruitment and retention activities. A second recommendation was made related to remote selection, interpretation, and reporting of patient results that augments the CLIAC 2019 recommendation that CMS and the U.S. Department of Health and Human Services permanently codify that a laboratory's CLIA certificate covers employees of that laboratory who are performing data analysis and interpretation of digital information under the quality oversight from a primary site when working remotely under the home laboratory's CLIA certificate.

What is the approximate Percentage of these recommendations that have been or will be Fully implemented by the agency?
96%

% of Recommendations Fully Implemented Comments
159 completed recommendations and 1 recommendation has no action/completed.

What is the approximate Percentage of these recommendations that have been or will be Partially implemented by the agency?
4%

% of Recommendations Partially Implemented Comments
There are 7 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/meeting.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 the fiscal year 2022, in response 23 personnel recommendations made over the span of several meetings including May 1993, November 2018, and April 2019, CMS and CDC published the Clinical Laboratory Improvement Amendments of 1988 (CLIA) Fees; Histocompatibility, Personnel, and Alternative Sanctions for Certificate of Waiver Laboratories Proposed Rule in the Federal Register on July 26, 2022 (https://www.federalregister.gov/documents/2022/07/26/2022-15300/clinical-laboratory-improver This proposed rule received 20,554 public comments. CDC and CMS will work in the fiscal year 2023 to address the comments and prepare the final rule for publication. In the fiscal year 2022, in response 20 proficiency testing (PT) recommendations made during the September 1-2, 2010 CLIAC meeting, CMS and CDC published the Clinical Laboratory Improvement Amendments of 1988 (CLIA) Proficiency Testing Regulations Related to Analytes and Acceptable Performance in the Federal Register on July 11, 2022 (https://www.federalregister.gov/documents/2022/07/11/2022-14513/clinical-laboratory-improver This final rule implements revised regulations that CMS and CDC proposed in 2019 to update CLIA PT regulations. The final rule includes: -The addition and deletion of analytes and microbiology tests that require PT, as well as updates to the criteria for acceptable performance and administrative processes for CLIA PT programs. -An update to align the CLIA regulations with the statute (42 U.S.C. 263a (i)(4)), which does not exclude waived

tests from the ban on improper PT referral. In the fiscal year 2022, the CDC had several accomplishments related to eight next generation sequencing (NGS) recommendations made during the CLIAC meeting held April 10-11, 2019, including: -CDC continued to convene the NGS Best Practices Forum in fiscal year 2022. The forum focused on encouraging professional societies and others to develop and/or update NGS guidelines and that CMS, CDC, and FDA create guidelines or best practices related to clinical and public-health NGS. The NGS Best Practices Forum will conclude in the fiscal year 2023. -The CLIA Regulations Assessment workgroup was established to provide input to CLIAC for deliberation on how CLIA might specifically be updated. Throughout 2022 and 2023, the workgroup will have discussions focused on the total testing process, data as a specimen, histopathology, analytical testing specifications, and digital pathology. The topics of data processing and quality management issues will be included in the workgroup discussions. The workgroup will present its first report to CLIAC during the November 9-10, 2022 CLIAC meeting. In the fiscal year 2022 in response to a CLIAC recommendation on health disparities made during the October 28-29, 2020 meeting, the CDC's Division of Laboratory Systems developed a journal article that has been accepted for publication in the Journal of Applied Laboratory Medicine entitled: Effective access to laboratory test results: A health equity issue that enhances diagnostic excellence. The article identifies gaps ranging from linguistic, cultural, and socioeconomic disparities to a lack of systematic approaches (e.g., implementation of specific support protocols, and policies) that affect limited English proficiency (LEP) patients' access to patient portals. It also summarizes initiatives healthcare providers, laboratory professionals, and portal developers can use to address disparities that affect more than 26 million LEPs while improving their health equity. In response to CLIAC recommendations on biosafety during April 2015 and April 2016, CDC's Division of Laboratory Systems hosted a town hall on June 24, 2022 (https://www.cdc.gov/safelabs/biosafety-townhall.html), in collaboration with clinical and public health laboratory partners and instrument manufacturers. The purpose of this meeting was to provide an overview and discussion on laboratory biosafety when using laboratory instruments to test human and biologic specimens. The publication Clinical Laboratory Biosafety Gaps: Lessons Learned from Past Outbreaks Reveal a Path to a Safer Future discussed critical gaps in clinical laboratory biosafety, including issues related to the use and disinfection of laboratory instruments.

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/