2018 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	2018

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	02/19/2018	02/19/2020	

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

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 2 **17b. Closed** 0 **17c. Partially Closed** 0 **Other Activities** 0 **17d. Total** 2

Meetings and Dates

Purpose	Start	End
This Committee is charged with providing scientific and technical advice and guidance to the Secretary of Health and Human Services (HHS); the Assistant Secretary for Health; the Director, Centers for Disease Control and Prevention; the Commissioner, Food and Drug Administration (FDA); and the Administrator, Centers for Medicare and Medicaid Services (CMS). The advice and guidance pertain to general issues related to improvement in clinical laboratory quality and laboratory medicine practice and specific questions related to possible revision of the Clinical Laboratory Improvement Amendment (CLIA) standards. The agenda included agency updates from CDC, CMS, and FDA. Presentations and discussions focused on laboratory testing in the era of telemedicine; antibiotic resistance testing issues; culture independent diagnostic tests; and a report from the Institute of Medicine (IOM) CLIAC workgroup.	11/01/2017	11/02/2017

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Number of Committee Meetings Listed: 2

	Current FY	Next FY
18a(1). Personnel Pmts to Non-Federal Members	$15,000.00	$20,000.00
18a(2). Personnel Pmts to Federal Members	$0.00	$0.00
18a(3). Personnel Pmts to Federal Staff	$222,678.00	$250,327.00
18a(4). Personnel Pmts to Non-Member Consultants	$0.00	$18,000.00
18b(1). Travel and Per Diem to Non-Federal Members	$42,328.00	$107,904.00
18b(2). Travel and Per Diem to Federal Members	$0.00	$0.00
18b(3). Travel and Per Diem to Federal Staff	$3,527.00	$8,456.00
18b(4). Travel and Per Diem to Non-member Consultants	$15,190.00	$70,198.00
18c. Other(rents,user charges, graphics, printing, mail, etc.)	$6,779.00	$16,736.00
18d. Total	$305,502.00	$491,621.00
19. Federal Staff Support Years (FTE)	1.90	1.65

20a. How does the Committee accomplish its purpose?

The Clinical Laboratory Improvement Advisory Committee (CLIAC) provides the Department of Health and Human Services (HHS) scientific and technical advice and guidance. The advice and guidance pertain to general issues related to improvement in clinical laboratory quality and laboratory medicine. In addition, the Committee provides advice and guidance on specific questions related to possible revision of the CLIA standards. For example, the Committee has recommended that CDC convene a cross-agency coordinating group to assess the impact of CIDTs on public health surveillance. The Committee has also provided recommendations on laboratory interoperability, such as requesting that HHS encourage the development and evaluation of team-based care innovations that include CLIA covered specialties (and engage patients) in reducing diagnostic error and creating a process for standards utilization field studies across a wide range of clinical laboratories. Other CLIAC discussions and recommendations provide guidance and support for policy and research projects, such as a recent recommendation related to interoperability, and the laboratory workforce shortage. The Committee also provides a liaison to the CDC Office of Infectious Diseases Board of Scientific Counselors 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; chemistry; hematology; pathology (including histopathology and cytology) and genetics (including biochemical, molecular and cytogenetics); representatives of medical technology, public health, clinical practice; and consumers. 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 development of new devices/technology.

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

The Committee meets approximately two times 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?

CLIA is among the most complex and challenging regulations that HHS has ever implemented. The intention of the CLIA statute is to ensure the quality and reliability of medical tests performed by clinical laboratories throughout the Nation, and the statute mandated a significant increase in Federal regulatory oversight. All of those involved in implementing the statute recognized the potential for unintended consequences that could possibly hinder rather than improve patient care, especially in light of the fact that laboratory testing is a dynamic science, with new tests and technology evolving continually. The Committee is essential for providing HHS 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 health care system.

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

N/A

21. Remarks

No formal reports are required in the charter; the committee provides advice and

recommendations through various means other than formal reports. Ms. Susan Sheridan was listed on the fiscal year 2017 report. She retired from CLIAC on 07/20/2017 and did not serve on the Committee during fiscal year 2018.The following CLIAC members Dr. Marc Couturier, Dr. Jordan Laser, Dr. Thomas Lorey, Dr. Katherine Perez, and Dr. Thomas Williams had term beginning dates of 7/1/2017. They were inadvertently left off the FY17 ACR but included in the FY18 ACR. The first meeting that these members attended was in November 2017 (FY18) and their costs are accounted for in FY18.

Designated Federal Officer

Reynolds Mathewson Salerno Director, Division of Laboratory Systems

Committee Members	Start	End	Occupation	Member Designation
Arnaout, Ramy	07/26/2015	06/30/2019	Medical Director, Beth Israel Medical Center	Special Government Employee (SGE) Member
Campbell, Sheldon	07/01/2015	06/30/2019	Director, Clinical Pathologist, VA Community Healthcare System	Special Government Employee (SGE) Member
Couturier, Marc	07/01/2017	06/30/2021	Medical Director, Parasitology/Fecal Testing, Infectious Disease, Antigen Testing and Microbial Immunology	Special Government Employee (SGE) Member
Davis, Keith	09/19/2016	06/30/2020	Medical Director, Shoshone Family Medical Center	Special Government Employee (SGE) Member
Delaney, Gwendolyn	10/27/2014	09/25/2018	Senior Pediatrician/Owner, Vickery Pediatrics, LLC	Special Government Employee (SGE) Member
Dyer, Karen	01/01/2015	06/04/2025	Director, Division of Laboratory Services, CMS	Ex Officio Member
Gross, Susan	09/26/2018	06/30/2022	Clinical Professor, Department of Genetics and Genomic Sciences	Special Government Employee (SGE) Member
Hilborne, Lee	09/20/2018	06/30/2022	Medical Director, Care Coordinator	Special Government Employee (SGE) Member
Hinrichs, Steven	01/19/2017	06/30/2021	Chair, Department of Pathology and Microbiology	Special Government Employee (SGE) Member
Karon, Bradley	09/26/2016	06/30/2020	Consultant, Dept of Laboratory Svcs, Mayo Clinic	Special Government Employee (SGE) Member
Laser, Jordan	07/01/2017	06/30/2021	Medical Director, Department of Pathology	Special Government Employee (SGE) Member
Leaumont, Collette	03/05/2018	03/04/2024	Associate Director for Science, DLS	Ex Officio Member
Lorey, Thomas	07/01/2017	06/30/2021	Medical Director, Regional Reference Laboratory Services	Special Government Employee (SGE) Member
Marlowe-Goslow, Elizabeth	07/09/2013	12/31/2017	Assistant Director, Microbiology-Molecular Testing, Southern California Permanente Medical Group	Special Government Employee (SGE) Member
Massingale, Sharon	09/19/2016	06/30/2020	Public Health Director, Alabama Department of Health	Special Government Employee (SGE) Member
Middleton, Lavinia	09/17/2018	06/30/2022	Professor, Department of Pathology/Laboratory Medicine	Special Government Employee (SGE) Member
Mills, Helen	07/01/2015	06/30/2019	Medical Assisting Program Coordinator and Advisor, Kaiser University	Special Government Employee (SGE) Member
Ng, Valerie	09/21/2016	06/30/2020	Chairman, Clinical Laboratory, Alabama Health Systems	Special Government Employee (SGE) Member
Palavecino, Elizabeth	10/27/2014	12/31/2018	Medical Director of Clinical Microbiology, Wake Forest Baptist Medical Center	Special Government Employee (SGE) Member
Perez, Katherine	07/01/2017	06/30/2021	Clinical Specialist-Infectious Diseases	Special Government Employee (SGE) Member
Quintenz, Andy	09/25/2015	08/24/2019	Scientific & Professional Affairs Manager	Representative Member

Roberson, Anita	10/29/2014	09/06/2018	Manager, Anatomic Pathology, University of AL, Birmingham	Special Government Employee (SGE) Member
Rubin, Bonnie	09/22/2016	06/30/2020	Sr. Associate Director, State Hygenic Laboratory	Special Government Employee (SGE) Member
Rushenberg, Maureen	10/30/2014	09/19/2018	Administrative Lab Director, PathLab LTD	Special Government Employee (SGE) Member
Salerno, Reynolds	03/29/2016	03/04/2018	Director, Division of Laboratory Services (DLS)	Ex Officio Member
Singh, Hardeep	07/09/2013	12/31/2017	Chief, Health Policy, Quality and Informatics Program, Houston VA HSR&D Center Excellence	Special Government Employee (SGE) Member
Sossaman, Gregory	09/20/2018	06/30/2022	System Chairman, Ochsner Health System	Special Government Employee (SGE) Member
Tobin, Peter	11/07/2017	11/06/2021	Chemist, Division of Program Operations and Management	Ex Officio Member
Wilkerson, Cynthia	09/07/2018	06/30/2022	Administrator, Department of Laboratory Medicine	Special Government Employee (SGE) Member
Williams, Thomas	07/01/2017	06/30/2021	Chief Medical Officer and Director - retired	Special Government Employee (SGE) Member
de Baca, Monica	11/03/2014	09/16/2018	Director of Hematopathology, HematoLogics, Inc.	Special Government Employee (SGE) Member

Number of Committee Members Listed: 31

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 mission to promote health and quality of life by preventing and controlling disease, injury, and disability.

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?

120

Number of Recommendations Comments

Recommendations address potential rulemaking to revise the CLIA regulations; the development of criteria for the approval of waived tests; good laboratory practices in waived testing sites and for genetic testing; and other recommendations for voluntary laboratory practice standards. Recommendations generally provide guidance to assure quality laboratory testing and support for policies, studies, and evaluation activities. There were nine recommendations for fiscal year 18: 1) a recommendation pertaining to the development and evaluation of team-based care innovations and to create a process for standards utilization field studies; 2) a recommendation addressing culture-independent diagnostic tests (CIDTs); 3) a recommendation to create implement guidelines for in vitro diagnostic devices and laboratory information systems; 4) a recommendation to generate a laboratory interoperability report; 5) a recommendation to address the shortfall of trained laboratory professionals; 6) a recommendation to HHS to address training skills needed for laboratory professionals; 7) a recommendation to fund a study of the opportunity costs of the two decades of reduction in the laboratory workforce; 8) a recommendation to form a next-generation sequencing workgroup; and 9) a recommendation to form a workgroup to address non-traditional testing models.

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

78%

% of Recommendations Fully Implemented Comments
88 completed recommendations and 5 recommendations have no action/completed.

What is the approximate Percentage of these recommendations that have been or will be Partially implemented by the agency?
22%

% of Recommendations Partially Implemented Comments
There are 27 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/docs/CLIAC_Recommendations_Web_10012018.pdf.

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
On February 6, 2018, two letters were sent to the Secretary of HHS to express the Committee’s recommendations from the November 1-2, 2017 meeting. The first letter provided HHS with background information on CLIAC discussions on culture-independent diagnostic tests (CIDTs) and stated the Committee's recommendation that CDC urgently convene a cross-agency coordinating group to assess the impact of CIDTs on public health surveillance, and to recommend impactful solutions that are brought to the attention of agency and government leaders. The second letter provided HHS with

background information on laboratory interoperability. The letter stated the Committee's recommendation to encourage the development and evaluation of team-based care innovations that include CLIA covered specialties (and engage patients) in reducing diagnostic error and to create a process for standards utilization field studies across a wide range of clinical laboratories (varying size and complexity). In addition to the HHS letter on CIDTS, CDC co-sponsored the "2018 Forum on Culture-Independent Diagnostics: Charting a Path for Public Health" with the Pew Charitable Trusts, the Association of Public Health Laboratories (APHL), the Council of State and Territorial Epidemiologists (CSTE), and The Ohio State University. This forum was held on May 8-9, 2018 at The Pew Charitable Trusts' Washington, DC office. On July 24, 2018, two letters were sent to the Secretary of HHS to express the Committee's recommendations from the April 10-11, 2018 meeting. The first letter provided HHS with background information on past CLIAC discussions on laboratory interoperability and stated the Committee's recommendations on implementing guidelines for in vitro diagnostic devices and laboratory information systems and the development of a report to determine the landscape of laboratory interoperability. The second letter provided HHS with background information on CLIAC discussions on the laboratory workforce. The letter stated the Committee's recommendation to CDC, CMS, and FDA to prioritize approaches to address the 20-year shortfall of trained laboratory professionals, include laboratory science professions in the science, technology, engineering, and mathematics programming addressing resources needed to address the laboratory workforce shortage, and supporting the funding of a study of the opportunity costs of the two decades of reduction in the laboratory workforce.

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/