U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30329-4027

CHARTER
of the
CLINICAL LABORATORY IMPROVEMENT ADVISORY COMMITTEE

Committee's Official Designation (Title).

Clinical Laboratory Improvement Advisory Committee.

Authority.

The Clinical Laboratory Improvement Advisory Committee was established under Section 222 of the Public Health Service Act [42 U.S.C. § 217a], as amended. The committee is governed by the provisions of the Federal Advisory Committee Act, as amended, 5 U.S.C. App., which sets forth standards for the formation and use of advisory committees.

Objective and Scope of Activities.

The Secretary is authorized under Section 353 (42 U.S.C. Section 263a) of the Public Health Service Act, as amended, to establish standards for quality assurance and quality control; personnel; proficiency testing; maintenance of records, equipment, and facilities that must be met by all clinical laboratories in the United States. These standards should ensure consistent, accurate, and reliable test results. The Clinical Laboratory Improvement Advisory Committee shall provide scientific and technical advice and guidance to the Secretary, Department of Health and Human Services (HHS); the Assistant Secretary for Health, HHS; the Director, Centers for Disease Control and Prevention (CDC); the Commissioner, Food and Drug Administration (FDA); and the Administrator, Centers for Medicare & Medicaid Services (CMS). The advice and guidance pertain to general issues related to improvement in clinical laboratory quality and laboratory medicine and specific questions related to possible revision of the Clinical Laboratory Improvement Amendments of 1988 (CLIA) standards.

Description of Duties.

The Committee provides guidance on studies designed to improve safety, effectiveness, efficiency, timeliness, equity, and patient-centeredness of laboratory services; revisions to the standards under which clinical laboratories are regulated; the impact of proposed revisions to the standards on medical and laboratory practice; the modification of the standards and provision of non-regulatory guidelines to accommodate technological advances, such as new test methods,

the electronic transmission of laboratory information, and mechanisms to improve the integration of public health and clinical laboratory practices.

Agency or Official to Whom the Committee Reports.

The Committee reports to the Secretary, HHS; the Assistant Secretary for Health, HHS; the Director, CDC; the Commissioner, FDA; and the Administrator, CMS.

Support.

Management and support services shall be provided by the Center for Surveillance, Epidemiology, and Laboratory Services, Division of Laboratory Systems, CDC.

Estimated Annual Operating Costs and Staff Years.

Estimated annual cost for operating the committee, including compensation and travel expenses for members, but excluding staff support, is $161,883. Estimate of annual person-years of staff support required is 1.45 at an estimated annual cost of $237,284.

Designated Federal Officer.

CDC will select a fulltime or permanent part-time Federal employee to serve as the Designated Federal Officer (DFO) to attend each committee meeting and ensure that all procedures are within applicable statutory, regulatory, and HHS General Administration Manual directives. The DFO will approve and prepare all meeting policies and agendas, call all of the committee and subcommittee meetings, adjourn any meeting when the DFO deems adjournment to be in the public interest, and chair meetings when directed to do so by the official to whom the committee reports. The DFO or his/her designee shall be present at all meetings of the full committee and subcommittees.

Estimated Number and Frequency of Meetings

Meetings shall be held at least once per year at the call of the DFO, in consultation with the Chair.

Meetings shall be open to the public except as determined otherwise by the Secretary, HHS, or other official, to whom the authority has been delegated, in accordance with the Government in the Sunshine Act [5 U.S.C. Section 552b(c)] and Section 10(d) of the Federal Advisory Committee Act, as amended. Notice of all meetings shall be given to the public.

Duration.

Continuing

Termination.

Unless renewed by appropriate action, the Clinical Laboratory Improvement Advisory Committee will terminate two years from the date this charter is filed.

Membership and Designation.

The Committee shall consist of 20 members, including the Chair. Members shall be selected by the Secretary from authorities 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. These members shall be deemed Special Government Employees or Regular Government Employees.

The committee shall also consist of three non-voting ex officio members, or designees: the Director, CDC; the Commissioner, FDA; and the Administrator, CMS; and such additional officers of the United States government that the Secretary deems are necessary for the committee to effectively carry out its functions. The CDC, FDA, and CMS ex officio members are non-voting members, but they will be considered part of the quorum required to conduct a committee meeting. The Committee shall also include a non-voting liaison representative who is a member of the Advanced Medical Technology Association and such other non-voting liaison representatives as the Secretary deems necessary to effectively carry out the functions of the committee. Liaisons shall be deemed representatives.

Members shall be invited to serve for overlapping terms of up to four years, except that any member appointed to fill a vacancy for an unexpired term shall be appointed for the remainder of that term. Terms of more than two years are contingent upon the renewal of the committee by appropriate action prior to its termination. A member may serve 180 days after the expiration of that member's term if a successor has not taken office.

Subcommittees.

Subcommittees composed of members of the parent committee and other subject matter experts may be established with the approval of the Secretary, HHS, or his/her designee. The subcommittees must report back to the parent committee and do not provide advice or work products directly to the agency. The Department Committee Management Officer will be notified upon establishment of each subcommittee and will be provided information on its name, membership, function, and estimated frequency of meetings.

Record Keeping.

The records of the committee, established subcommittees, or other subgroups of the committee, shall be managed in accordance with General Records Schedule 6.2, Federal Advisory Committee Records, or other approved agency records disposition schedule. These records shall be available for public inspection and copying, subject to the Freedom of Information Act, 5 U.S.C. §552.

Filing Date.

February 19, 2020

Approved:

7 FEB 2020
Date

Kalwant S Smagh
Director
Strategic Business Initiatives Unit