DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

CHARTER

CLINICAL LABORATORY IMPROVEMENT ADVISORY COMMITTEE

Purpose

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, and maintenance of records that must be met by all clinical laboratories in the United States. These standards should ensure consistent, accurate, and reliable test results.

Authority

Section 222 of the Public Health Service Act (42 U.S.C. Section 217a), as amended. The committee is governed by the provisions of Public Law 92-463, as amended (5 U.S.C. App. 2), which sets forth standards for the formation and use of advisory committees.

Function

The Clinical Laboratory Improvement Advisory Committee shall provide scientific and technical advice and guidance to the Secretary, Department of Health and Human Services; the Assistant Secretary for Health; the Director, Centers for Disease Control and Prevention; the Commissioner, Food and Drug Administration; and the Administrator, Centers for Medicare and Medicaid Services, regarding the need for, and the nature of, revisions to the standards under which clinical laboratories are regulated; the impact on medical and laboratory practice of proposed revisions to the standards; and the modification of the standards to accommodate technological advances.

Structure

The committee shall consist of 20 members, including the Chair, and may include a Federal employee. 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, public health, and clinical practice; and consumer

representatives. Members shall be deemed Special Government Employees.

The committee shall also consist of three voting ex officio members, or designees: the Director, Centers for Disease Control and Prevention; the Commissioner, Food and Drug Administration; and the Administrator, Centers for Medicare and Medicaid Services; 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 committee shall also include a nonvoting liaison representative who is a member of the Advanced Medical Technology Association and such other nonvoting 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 may be established from time to time with the approval of the Secretary, HHS, or designee. There shall be four subcommittees of the committee. All subcommittees will include the three ex officio members, as well as any additional officers of the government that the Secretary deems are necessary to effectively carry out its functions. The Department Committee Management Officer will be notified upon establishment of any additional subcommittees, and will be provided information on its name, membership, function, and estimated frequency of meetings.

Management and support services shall be provided by the Division of Laboratory Systems, National Center for Preparedness, Detection, and Control of Infectious Diseases, Centers for Disease Control and Prevention.

Meetings

Meetings shall be held approximately two times per year at the call of the Designated Federal Official, in consultation with the Chair. The Designated Federal Official shall also approve the agenda and shall be present at all meetings.

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. 552b(c)) and Section 10(d) of the Federal Advisory Committee Act; notice of all meetings shall be given to the public.

Meetings shall be conducted, and records of the proceedings kept, as required by applicable laws and Departmental regulations.

Compensation

Members who are not full-time Federal employees shall be paid at the rate of $250 per day, or at the rate of $31.25 per hour, as determined by the agency, not to exceed $250 per day; plus per diem and travel expenses in accordance with standard government travel regulations.

Annual Cost Estimate

Estimated annual cost for operating the Committee, including compensation and travel expenses for members but excluding staff support, is $154,994. Estimate of annual person-years of staff support required is 2.3, at an estimated annual cost of $250,602.

Reports

In the event a portion of a meeting is closed to the public, as determined by the Secretary, HHS, in accordance with the Government in the Sunshine Act (5 U.S.C. 552b(c)) and Section 10(d) of the Federal Advisory Committee Act, a report shall be prepared which shall contain, as a minimum, a list of members and their business addresses, the committee's activities, and recommendations made during the fiscal year. A copy of the report shall be provided to the Department Committee Management Officer.

Termination Date

Unless renewed by appropriate action prior to its expiration, the Clinical Laboratory Improvement Advisory Committee and subcommittees will terminate on February 19, 2010.

APPROVED: