CLIAC Federal Advisory Committee 'Refresher'

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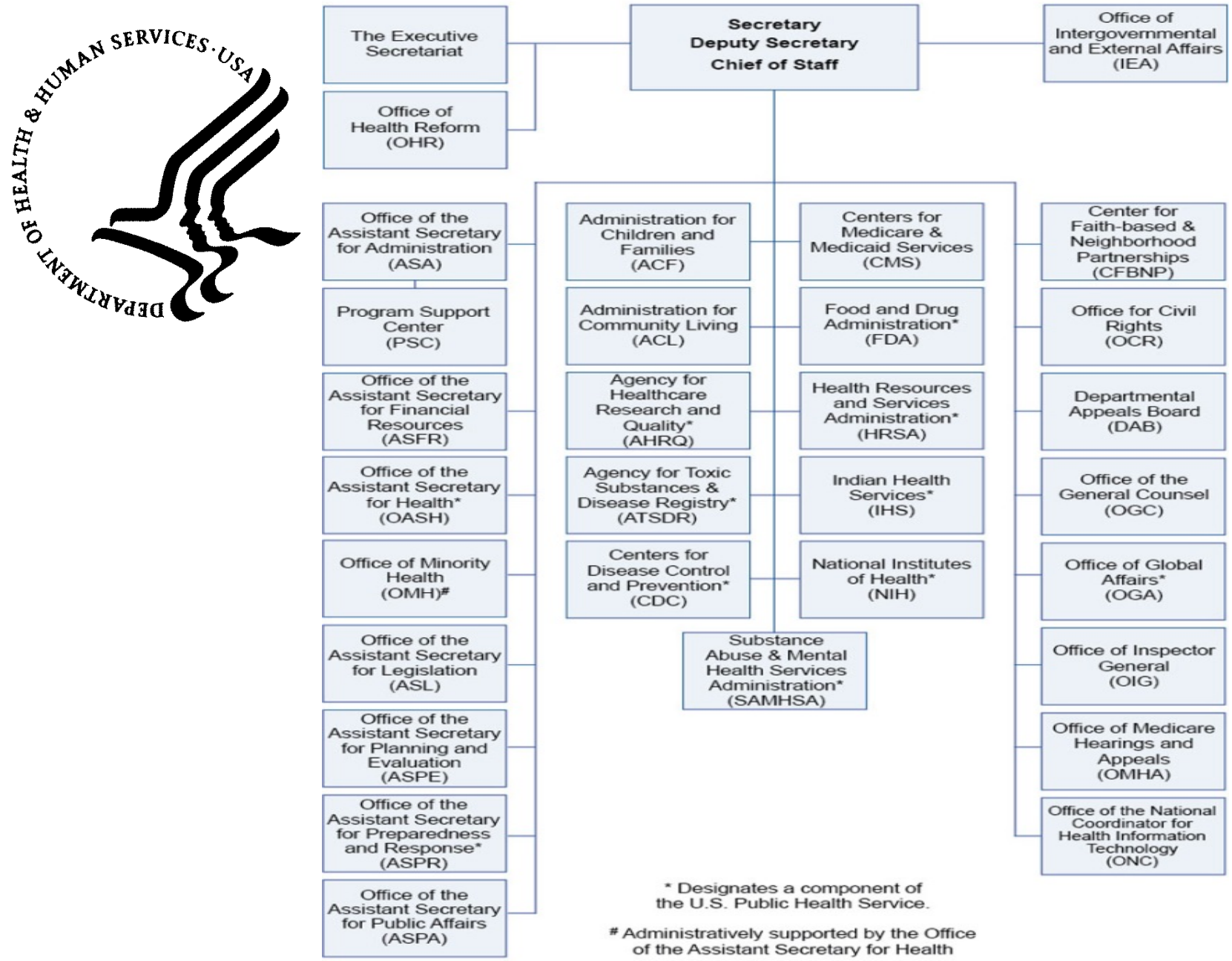
Clinical Laboratory Improvement Advisory Committee Meeting
November 5, 2014


The Executive Secretariat
Office of Health Reform (OHR)
Secretary
Deputy Secretary
Chief of Staff
Office of Intergovernmental and External Affairs (IEA)
Office of the Assistant Secretary for Administration (ASA)
Program Support Center (PSC)
Office of the Assistant Secretary for Financial Resources (ASFR)
Office of the Assistant Secretary for Health* (OASH)
Office of Minority Health (OMH)#
Office of the Assistant Secretary for Legislation (ASL)
Office of the Assistant Secretary for Planning and Evaluation (ASPE)
Office of the Assistant Secretary for Preparedness and Response* (ASPR)
Office of the Assistant Secretary for Public Affairs (ASPA)
Administration for Children and Families (ACF)
Administration for Community Living (ACL)
Agency for Healthcare Research and Quality* (AHRQ)
Agency for Toxic Substances & Disease Registry* (ATSDR)
Centers for Disease Control and Prevention* (CDC)
Substance Abuse & Mental Health Services Administration* (SAMHSA)
Centers for Medicare & Medicaid Services (CMS)
Food and Drug Administration* (FDA)
Health Resources and Services Administration* (HRSA)
Indian Health Services* (IHS)
National Institutes of Health* (NIH)
Center for Faith-based & Neighborhood Partnerships (CFBNP)
Office for Civil Rights (OCR)
Departmental Appeals Board (DAB)
Office of the General Counsel (OGC)
Office of Global Affairs* (OGA)
Office of Inspector General (OIG)
Office of Medicare Hearings and Appeals (OMHA)
Office of the National Coordinator for Health Information Technology (ONC)
* Designates a component of the U.S. Public Health Service.
# Administratively supported by the Office of the Assistant Secretary for Health

CLIAC Basics

- Established by regulation (42 CFR Subpart T. § 493.2001)
- HHS advisory committee serving 3 agencies responsible for the CLIA program – CDC, CMS and FDA
- Managed by CDC
- Charter renewed every 2 years
- Meetings approximately two times per year
- Members selected by HHS from a slate of potential candidates provided by CDC
  - 20 members; knowledge in clinical laboratory disciplines, public health, clinical practice and consumer representation
  - Serve overlapping 4 year terms
  - Industry liaison (non-voting)
  - 3 ex-officio members – CDC, CMS, FDA

Role of CLIAC

*Provide scientific/technical advice to HHS on:

- General issues related to improvement in clinical laboratory quality
- Revisions to the CLIA standards
- Impact of revisions on medical and laboratory practice
- Modification of the standards and provision of non-regulatory guidelines to accommodate technological advances
- Guidance on studies designed to evaluate and improve safety, effectiveness, efficiency, timeliness, equity, and patient-centeredness of laboratory services

*CLIAC scope spelled out in the charter

CLIAC Operations

- Meeting agenda established by the agencies
- Agenda topics published in a Federal Register Notice at least 15 days prior to each meeting (public notice)
- CLIAC deliberation and recommendations must align with the agenda
- DFO responsible for ensuring procedures are followed; must be present at all full committee meetings
- Meetings follow Robert's Rules of Order
- Webcasting allows broader access
- Meeting summaries posted on the CLIAC website within 90 days of each meeting
- Website - http://wwwn.cdc.gov/CLIAC/default.aspx

CLIAC Recommendations

- Advice to government; agencies not required to implement
- Workgroups cannot make recommendations; information to CLIAC and CLIAC makes recommendations
- Any CLIAC member can initiate a recommendation related to the meeting agenda through a motion that is seconded
- Committee must vote on recommendations; majority rules
- CDC tracks recommendations and their status
- Recommendations typically focus on changes to standards or development of guidance
- Committee can recommend law changes; if desired, agencies can follow through via a formal process

Questions?

Website - http://wwwn.cdc.gov/CLIAC/default.aspx

Email - CLIAC@cdc.gov