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
ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES

Committee's Official Designation.

Advisory Committee on Immunization Practices (ACIP).

Authority.

The ACIP 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.

The ACIP has been given statutory roles under subsections 1928(c)(2)(B)(i) and 1928(e) of the Social Security Act (42 U.S.C. § 1396s(c)(2)(B)(i) and 1396s(e)) and subsection 2713(a)(2) of the Public Health Service Act (42 U.S.C. § 300gg-13(a)(2)).

Objective and Scope of Activities.

The Secretary, Department of Health and Human Services (HHS), and by delegation the Director, Centers for Disease Control and Prevention (CDC), are authorized under Section 311 and Section 317 of the Public Health Service Act, [42 U.S.C. §243 and 42 U.S.C. §247b], as amended, to assist states and their political subdivisions in the prevention and control of communicable diseases; to advise the states on matters relating to the preservation and improvement of the public's health; and to make grants to states and, in consultation with the state health authorities, to agencies and political subdivisions of states to assist in meeting the costs of communicable disease control programs.

The ACIP shall provide advice and guidance to the Director of the CDC regarding use of vaccines and related agents for effective control of vaccine-preventable diseases in the civilian population of the United States. Recommendations made by the ACIP are reviewed by the CDC Director, and if adopted, are published as official CDC/HHS recommendations in the Morbidity and Mortality Weekly Report (MMWR). The CDC Director informs the Secretary, HHS, and the Assistant Secretary for Health, of immunization recommendations. Upon the licensure of any vaccine or any new indication for a vaccine, the committee shall, as appropriate, consider the use of the vaccine at its next regularly scheduled meeting. If the committee does not make a recommendation at the

committee's first regularly scheduled meeting, the committee shall provide an update on the status of such committee's review.

Description of Duties.

The committee shall provide advice for the control of diseases for which a vaccine is licensed in the U.S. The guidance will address use of vaccines and may include recommendations for administration of immune globulin preparations and/or antimicrobial therapy shown to be effective in controlling a disease for which a vaccine is available. Guidance for use of unlicensed vaccines may be developed if circumstances warrant. For each vaccine, the committee advises on population groups and/or circumstances in which a vaccine or related agent is recommended. The committee also provides recommendations on contraindications and precautions for use of the vaccine and related agents and provides information on recognized adverse events. The committee also may provide recommendations that address the general use of vaccines and immune globulin preparations as a class of biologic agents, as well as special situations or populations that may warrant modification of the routine recommendations.

Committee deliberations on use of vaccines to control disease in the U.S. shall include consideration of disease epidemiology and burden of disease, vaccine safety, vaccine efficacy and effectiveness, the quality of evidence reviewed, economic analyses, and implementation issues. The committee may revise or withdraw their recommendation(s) regarding a particular vaccine as new information on disease epidemiology, vaccine effectiveness or safety, economic considerations, or other data become available.

In accordance with Section 1928 of the Social Security Act, the ACIP also shall establish and periodically review and, as appropriate, revise the list of vaccines for administration to children and adolescents eligible to receive vaccines through the Vaccines for Children Program, along with schedules regarding the appropriate dose and dosing interval, and contraindications to administration of the pediatric vaccines. The Secretary, and as delegated the CDC Director, shall use the list established by the ACIP for the purpose of the purchase, delivery, and administration of pediatric vaccines in the Vaccines for Children Program.

Further, under provisions of the Affordable Care Act (Section 2713 of the Public Health Service Act, as amended), immunization recommendations of the committee that have been adopted by the Director of the Centers for Disease Control and Prevention must be covered by applicable health plans.

Agency or Official to Whom the Committee Reports.

The committee reports to the Director, CDC. The CDC Director informs the Secretary, HHS and the Assistant Secretary for Health, HHS, of immunization recommendations.

Support.

Management and support services shall be provided by the Office of the Director, National Center for Immunization and Respiratory Diseases, Deputy Director of Infectious Diseases, 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 $245,873. Estimate of annual person-years of staff support required is 2.5, at an estimated annual cost of $372,378.

Designated Federal Officer.

CDC will select a full-time 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 approximately three times 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 Director, CDC, 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.

Duration.

Continuing.

Termination.

Unless renewed by appropriate action, the ACIP will terminate two years from the date this charter is filed.

Membership and Designation.

The committee shall consist of 15 special government employee members, including the Chair. Members shall be selected from authorities who are knowledgeable in the fields of immunization practices and public health, have expertise in the use of vaccines and other immunobiologic agents in clinical practice or preventive medicine, have expertise with clinical or laboratory vaccine research, or have expertise in assessment of vaccine efficacy and safety. The committee shall include a person or persons knowledgeable about consumer perspectives and/or social and community aspects of immunization programs. Members shall be deemed Special Government Employees.

The committee also shall consist of six nonvoting ex-officio members: the Director, Division of Injury Compensation Programs, Healthcare Systems Bureau, Health Resources and Services Administration; the Director, Center for Biologics Evaluation and Research, Food and Drug Administration; the Director, Center for Medicaid and CHIP Services, Centers for Medicare and Medicaid Services; the Director, Division of Microbiology and Infectious Diseases, National Institute of Allergy and Infectious Diseases, National Institutes of Health; the Director, Indian Health Service; and the Director, Office of Infectious Disease and HIV/AIDS Policy, HHS; or their designees.

If fewer than eight ACIP members are eligible to vote due to absence or a financial or other conflict of interest, the DFO, or designee, shall have the authority to temporarily designate the ex-officio members as voting members.

There also shall be non-voting liaison representative members from the American Academy of Family Physicians; American Academy of Pediatrics; American Academy of Physician Assistants; American College Health Association; American College of Nurse Midwives; American College of Obstetricians and Gynecologists; American College of Physicians; American Geriatrics Society; America's Health Insurance Plans; American Immunization Registry Association; American Medical Association; American Nurses Association; American Osteopathic Association; American Pharmacists Association; Association of Immunization Managers; Association for Prevention Teaching and Research; Association of State and Territorial Health Officials; Biotechnology Industry Organization; Council of State and Territorial Epidemiologists; Canadian National Advisory Committee on Immunization; Infectious Diseases Society of America; International Society for Travel Medicine; National Association of County and City Health Officials; National Association for Pediatric Nurse Practitioners; National Foundation for Infectious Diseases; National Medical Association; Pediatric Infectious Diseases Society; Pharmaceutical Research Manufacturers of America; Society for Adolescent Health and Medicine; Society for Healthcare Epidemiology of America 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, including the Chair, shall be selected by the Secretary and 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. A member may serve 180 days after the expiration of that member's term if a successor has not taken office.

Subcommittees.

Subcommittees composed, in part, 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.

Recordkeeping.

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.

April 1, 2020

Approved:

March 22, 2020
Date

s/ Kalwant S. Smagh
Director
Strategic Business Initiatives Unit