

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

AMENDMENT to the CHARTER of the ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES

Structure

The committee shall consist of 15 members, including the Chair. Members and the Chair shall be selected by the Secretary, HHS, 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 eight non-voting ex-officio members: the Director, Division of Vaccine Injury Compensation, Bureau of Health Professions, Health Resources and Services Administration; the Deputy Director for Scientific Activities, Office of the Assistant Secretary of Defense for Health Affairs, Department of Defense; the Under Secretary for Health, Department of Veterans Affairs; the Director, Center for Biologics Evaluation and Research, Food and Drug Administration; the Director, Center for Medicaid and State Operations, 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, National Vaccine Program Office, HHS; or their designees.

The committee shall not take a vote unless at least eight ACIP members are present. If fewer than eight ACIP members are eligible to vote due to absence or a financial or other conflict of interest, the Executive Secretary, or designee, shall have the authority to temporarily designate the ex-officio members as voting members.

There also shall be non-voting liaison representatives from the American Academy of Family Physicians; the American Academy of Pediatrics; the American College Health Association; the American College of Obstetricians and Gynecologists; the American College of Physicians; the American Geriatrics Society; the America's Health Insurance Plans; the American Medical Association; the American Osteopathic Association; the American Pharmacists Association; the

Association for Prevention Teaching and Research; the Biotechnology Industry Organization; the Canadian National Advisory Committee on Immunization; the Council of State and Territorial Epidemiologists; the Department of Health of the United Kingdom; the Healthcare Infection Control Practices Advisory Committee, CDC; the Infectious Diseases Society of America; the National Association of County and City Health Officials; the National Association for Pediatric Nurse Practitioners; the National Foundation for Infectious Diseases; the National Immunization Council and Child Health Program, Mexico; the National Medical Association; the National Vaccine Advisory Committee, HHS; the Pharmaceutical Research Manufacturers of America; the Society for Adolescent Medicine; the Society for Healthcare Epidemiology of America; 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 renewal of the committee by appropriate action prior to its termination. A member may serve 180 days after expiration of that member's term if a successor has not taken office.

The Chair shall be appointed for a 3-year term. The Chair shall be chosen from among persons who have had at least one year experience as a voting member and have demonstrated ability both to lead the work of similar bodies and to work effectively in partnership with federal agencies and partner organizations.

Subcommittees may be established from time to time with the approval of the Secretary, HHS, or designee. 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.

Management and support services shall be provided by the Office of the Director, Immunization Services Division, National Center for Immunization and Respiratory Diseases, CDC.

Approved:

10/7/08 Date

Director Management Analysis and Services Office



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

CHARTER

ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES

Purpose

The Secretary, the 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, as amended, 42 U.S.C. 243 and 42 U.S.C. 247b, 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.

Authority

42 U.S.C. 217a, Section 222 of the Public Health Service Act, 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.

The Advisory Committee on Immunization Practices has been given a statutory role under Section 13631 of the Omnibus Budget Reconciliation Act of 1993, Public Law 103-66 (42 U.S.C. 1396s(c)(2)(B)(i) and (e), subsections 1928(c)(2)(B)(i) and 1928(e) of the Social Security Act).

Function

The Advisory Committee on Immunization Practices shall provide advice and guidance to the Secretary, HHS, the Assistant Secretary for Health, and the Director, CDC, regarding the most appropriate selection of vaccines and related agents for effective control of vaccine-preventable diseases in the civilian population. The committee shall specifically provide advice for the control of diseases for which a vaccine is licensed in the U.S. The guidance will cover the appropriate use of the vaccine and may include recommendations for administration of immune globulin preparations and/or antimicrobial therapy shown to be effective in controlling the same disease. Guidance for use of unlicensed vaccines may be developed if circumstances warrant.

For each recommended vaccine, the committee shall advise on population groups and/or circumstances in which a vaccine or related agent is recommended. The committee shall develop guidance on the appropriate route, dose and frequency of administration of the vaccine, associated immune globulin, or antimicrobial agent. The committee also shall provide recommendations on contraindications and precautions for use of the vaccine and related agents and provide information on recognized adverse events. Committee deliberations on the appropriate use of vaccines to control disease in the U.S. should include consideration of population based studies such as efficacy, cost:benefit and risk:benefit analyses. The committee may alter or withdraw their recommendation(s) regarding a particular vaccine as new information becomes available or the risk of disease changes.

The committee also may provide recommendations that address the general use of vaccines and immune globulins as a class of biologic agents. These general recommendations may address the principles that govern administration technique, dose and dosing interval, recognized contraindications and precautions, reporting adverse events, the correct storage, handling, and recording of vaccines and immune globulins, and special situations or populations that may warrant modification of the routine recommendations.

In accordance with Section 1928 of the Social Security Act, the committee also shall establish and periodically review and, as appropriate, revise a 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 shall use, for the purpose of the purchase, delivery, and administration of pediatric vaccines in the Vaccines for Children Program, the list established by the committee.

Structure

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Institute of Allergy and Infectious Diseases, National Institutes of Health; the Director, Indian Health Service; and the Director, National Vaccine Program Office, HHS; or their designees.

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Management and support services shall be provided by the Office of the Director, Immunization Services Division, National Center for Immunization and Respiratory Diseases, CDC.

Meetings

Meetings shall be held approximately three times per year at the call of the Designated Federal Official, in consultation with the Chair. The Designated Federal Official also shall 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 of operating the committee, including compensation and travel expenses for members but excluding staff support, is \$122,138. Estimate of annual person-years of staff support required is 3.9 at an estimated annual cost of \$477,068.

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 Advisory Committee on Immunization Practices will terminate on April 1, 2010.

Approved:

3/12/08

Director Management Analysis and Services Office

CHARTER FILING DATE 4/1/08

PUBLIC HEALTH SERVICE ACT

ADVISORY COUNCILS OR COMMITTEES

SEC. 222. [217a] (a) The Secretary may, without regard to the provisions of title 5, United States Code, governing appointments in the competitive service, and without regard to the provisions of chapter 51 and subchapter ill of chapter 53 of such title relating to classification and General Schedule pay rates, from time to time, appoint such advisory councils or committees (in addition to those authorized to be established under other provisions of law), for such periods of time, as he deems desirable with such period commencing on a date specified by the Secretary for the purpose of advising him in connection with any of his functions.

- (b) Members of any advisory council or committee appointed under this section who are not regular full-time employees of the United States shall, while attending meetings or conferences of such council or committee or otherwise engaged on business of such council or committee receive compensation and allowances as provided in section 208(c) for members of national advisory councils established under this Act.
- (c) Upon appointment of any such council or committee, the Secretary may delegate to such council or committee such advisory functions relating to grants-in-aid for research or training projects or programs, in the areas or fields with which such council or committee is concerned, as the Secretary determines to be appropriate.