

**AMENDMENT
to the CHARTER**

of the

ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES

Advisory Committee's Official Designation.

Advisory Committee on Immunization Practices (ACIP or Committee).

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, (FACA), Public Law 92-463 (5 U.S.C. § 1001 et seq.), as amended.

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.

Vaccines have played an important role in public health around the globe. The Advisory Committee on Immunization Practices (ACIP) provides recommendations to the CDC Director on the use of vaccines and immunization program strategies to inform individuals, clinicians, and broader public health efforts. This committee convenes scientific and medical experts to provide recommendations based on the best available evidence of vaccine risks and benefits, and efficacy.

ACIP shall provide advice and guidance to the CDC Director ~~of the CDC~~ regarding use of vaccines and related agents for effective control of vaccine-preventable diseases and/or decreased symptomatology in the civilian population of the United States. and gaps in vaccine safety research including adverse effects following vaccination. Recommendations made by ~~the~~ ACIP are initially reviewed by the CDC Director, and if adopted, ~~are published as become~~ official CDC/HHS recommendations, and may be published in the *Morbidity and Mortality Weekly Report (MMWR)*. The CDC Director informs the HHS Secretary, HHS, ~~and the~~ Assistant Secretary for Health, of immunization recommendations. provided by the Committee. Upon the licensure or authorization 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 for the Committee's review.

Description of Duties.

The Committee shall provide advice for the control of diseases for which a vaccine is licensed or authorized 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. and the Committee is directed to develop such guidance by the CDC Director. For each vaccine, the Committee advises on population groups and/or circumstances in which a vaccine or related agent is recommended. The Committee shall also ~~provides~~ provide 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, use of specific antibody products for prevention of infectious diseases, and special situations or populations that may warrant modification of the routine recommendations.

The main tasks of the Committee can be organized into review and recommendations, immunization schedules, and public health strategies. ACIP shall review the latest scientific evidence on vaccine safety, efficacy, and effectiveness to make recommendations on the routine use of vaccines, including for specific populations such as pregnant women, elderly, and immunocompromised individuals. Such review may include evaluation of pre- and post-licensure data or if available, clinical trial data for vaccines under an Emergency Use Authorization. ACIP shall provide recommendations regarding revisions and updates to the CDC immunization schedules for children, adolescents, and adults, taking into account emerging diseases, new vaccines, cumulative exposures to vaccines and vaccine components, and changes in disease epidemiology. Furthermore, ACIP shall advise on vaccination strategies that promote optimal vaccine coverage, address health disparities, and ensure equitable access to immunizations across communities.

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 risks and benefits, 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.

Key responsibilities in developing committee recommendations can be organized into vaccine recommendations, vaccine safety and monitoring, emerging vaccines and technology, global health practices, and public engagement and transparency as part of ACIP public meetings. ACIP shall be responsible for formulating recommendations for routine vaccination schedules for different age groups and high-risk populations, advising on the use of vaccines in emergency situations (such as during disease outbreaks or public health emergencies), and reviewing immunization practices (including those related to vaccine storage, handling, and administration). ACIP shall also be responsible for reviewing data on vaccine safety and adverse events, providing recommendations to enhance vaccine safety surveillance systems, and advising CDC on gaps in vaccine safety research; evaluating the risk/benefit profiles of vaccines based on ongoing surveillance and new research findings; considering analysis of cumulative effects of vaccines and their constituent components; engaging in re-analysis of vaccine safety and efficacy as gaps are identified and new information becomes available; and evaluating the risks and benefits of tailoring immunization practices to maximize benefits and reduce risks and take into account variability in immune response for various populations. Furthermore, ACIP shall be responsible for considering on an ongoing basis the safety, efficacy, and public health impact of new vaccines, as well as novel vaccine platforms such as mRNA vaccines; and evaluating vaccines for new diseases or variants of concern, ensuring that recommendations adapt to new scientific evidence and evolving disease landscapes. ACIP shall also be responsible for reviewing global initiatives; and reviewing vaccination schedules by other countries and international organizations.

ACIP shall employ a transparent, evidence-driven decision-making process in developing recommendations. The Committee shall review clinical data, listen to expert presentations, and consult with subject matter experts to determine the benefits and risks of vaccines. ACIP decisions shall be based on rigorous scientific analysis and deliberation, with the goal of recommending immunization practices that protect and improve public health in the United States.

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 by 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 Federal Officer Receiving the Committee Reports Advisory Committee's Advice/Recommendations.

The Committee reports to the CDC Director, ~~CDC~~. The CDC Director informs the HHS Secretary, HHS and the Assistant Secretary for Health, HHS, of immunization recommendations provided by the Committee.

Support.

Management and support services shall be provided by the CDC's: Office of the ~~Director, Chief of Staff~~; National Center for Immunization and Respiratory Diseases; National Center for Emerging and Zoonotic Infectious Diseases; and National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention as instructed by the CDC Director, to support ACIP-related activities.

Estimated Annual Operating Costs and Staff Years.

Estimated annual ~~cost~~costs for operating the Committee, including (i) Federal personnel (3) and other Federal internal costs are \$1,080,340; (ii) proposed compensation and travel expenses~~expense payments~~ for up to 19 members, but excluding staff support, is \$42,750; and (iii) reimbursable costs are \$83,106,409,922. ~~Estimate of annual person-years of staff support required is 9.40, at an estimated annual cost of \$1,760,637.~~

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, 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. In the event that the DFO cannot fulfill the assigned duties of the Committee, one or more full-time or permanent part-time employees will be assigned as DFO and carry out these duties on a temporary basis.~~

Estimated Number and Frequency of Meetings.

Meetings ~~shall~~will be held ~~approximately three times per year~~ at the ~~call~~discretion of the ACIP DFO, in consultation with the Chair.

Meetings shall be open to the public except as determined otherwise by the CDC 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~~ (FACA (5 U.S.C. § 1009(d))). ~~Notice of all meetings shall be given to the public.~~

Notice of all meetings shall be given to the public.

Duration.

Continuing.

Termination.

Unless renewed by appropriate action, ~~the~~ ACIP will terminate ~~two~~ 2 years from the date this charter is filed.

Membership and Designation.

The Committee ~~shall consist~~ consists of up to 19 voting members, who are Special Government Employees, including the Chair and Vice Chair.

Members shall be selected from authorities who are knowledgeable in the fields of medicine, vaccines, immunization practices and, immunology, toxicology, pediatric neurodevelopment, epidemiology, data science, statistical analysis, health economics, recovery from serious vaccine injuries, or public health; have expertise in the use of vaccines ~~and/or~~ other immunobiologic agents in clinical practice or preventive medicine, have expertise with clinical or laboratory vaccine research, or have expertise in assessment of vaccine safety and efficacy ~~and safety~~.

The Committee shall include a person ~~or persons(s)~~ 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~~ non-voting ex-officio members from the Health Resources and Services Administration; the U.S. Food and Drug Administration; Centers for Medicare and Medicaid Services; National Institutes of Health; Indian Health Service; and the Office of Infectious Disease and HIV/AIDS Policy, National Vaccine Program at HHS; or their designees.

If fewer than a quorum of 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 33 non-voting liaison representatives from the American Academy of Family Physicians; American Academy of Pediatrics; American Academy of Physician Associates; 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 of American Physicians and Surgeons; Association for Prevention Teaching and Research; Association of State and Territorial Health Officials; Biotechnology Innovation Organization; Council of State and Territorial Epidemiologists; Canadian National Advisory Committee on Immunization; Infectious Diseases Society of America; Independent Medical Alliance; International Society of Travel Medicine; Medical Academy of Pediatrics and Special Needs; National Association of County and City Health Officials; National Association of Pediatric Nurse Practitioners; National Foundation for Infectious Diseases; National Medical Association; Pediatric Infectious Diseases Society; Pharmaceutical Research and Manufacturers of America; Physicians for Informed Consent; Society for Adolescent Health and Medicine; and 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, including the Chair and Vice Chair, shall be selected by the HHS 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 HHS 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, 2026_

APPROVED:

~~Amended Filing March 31, 2026 _____ **Date** _____~~

Approved:

12/3/2025_____

Date_____ Robert F. Kennedy, Jr.