

Secretary on the methods of obtaining, compiling, publishing, and using credible data related to the frequency and severity of adverse reactions associated with childhood vaccines; consulting on the development or revision of Vaccine Information Statements; and recommending to the Director of the National Vaccine Program research related to vaccine injuries which should be conducted to carry out the VICP.

The ACCV consists of nine voting members appointed by the Secretary as follows: (1) Three health professionals, who are not employees of the United States Government, and who have expertise in the health care of children, the epidemiology, etiology, and prevention of childhood diseases, and the adverse reactions associated with vaccines, of whom at least two shall be pediatricians; (2) three members from the general public, of whom at least two shall be legal representatives (parents or guardians) of children who have suffered a vaccine-related injury or death; and (3) three attorneys, of whom at least one shall be an attorney whose specialty includes representation of persons who have suffered a vaccine-related injury or death, and of whom one shall be an attorney whose specialty includes representation of vaccine manufacturers. In addition, the Director of the National Institutes of Health, the Assistant Secretary for Health, the Director of the Centers for Disease Control and Prevention, and the Commissioner of the Food and Drug Administration (or the designees of such officials) serve as nonvoting ex officio members.

HHS will consider nominations of all qualified individuals with a view to ensure that the ACCV includes the areas of subject matter expertise noted above. As indicated above, at least two of the three ACCV members of the general public must be legal representatives (parents or guardians) of children who have suffered a vaccine-related injury or death. Because those members must be the legal representatives of children who have suffered a vaccine-related injury or death, to be considered for appointment to the ACCV in that category there must have been a finding (*i.e.*, a decision) by the U.S. Court of Federal Claims or a civil court that a VICP-covered vaccine caused, or was presumed to have caused, the represented child's injury or death. Additionally, based on a recommendation made by the ACCV, the Secretary will consider having a health professional with expertise in obstetrics as one of the members of the general public.

ACCV members are appointed as Special Government Employees. As such, they are covered by the federal ethics rules, including the criminal conflict of interest statutes governing executive branch employees. For example, an ACCV member may be prohibited from discussions about making changes to the Vaccine Injury Table and Vaccine Information Statements for the Hepatitis B vaccine if he/she or his/her spouse owns stock valued above a certain amount in companies that manufacture this vaccine, affecting their own pecuniary interests—including interests imputed to them. To evaluate possible conflicts of interest, potential candidates will be asked to fill out the U.S. Office of Government Ethics (OGE) Confidential Financial Disclosure Report, OGE Form 450, to provide detailed information concerning financial interests, consultancies, research grants, and/or contracts that might be affected by recommendations made by the ACCV.

Interested persons may nominate one or more qualified persons for membership on the ACCV. Nominations shall state that the nominee is willing to serve as a member of the ACCV. Nominees will be invited to serve a 3-year term beginning the date of appointment. A nomination package should be submitted as hard copy or email communication and should include the following information for each nominee: (1) A letter of nomination stating the name, affiliation, and contact information for the nominee, the basis for the nomination (*i.e.*, what specific attributes, perspectives, and/or skills does the individual possess that would benefit the workings of the ACCV) and the nominee's field(s) of expertise; (2) a biographical sketch of the nominee and a copy of his/her curriculum vitae; and (3) the name, address, daytime telephone number, and email address at which the nominator can be contacted. Nomination packages will be collected and retained to create a pool of possible future ACCV voting members. When a vacancy occurs, nomination packages from the appropriate category will be reviewed and nominees may be contacted at that time.

HHS strives to ensure that the membership of the ACCV is balanced in terms of points of view presented and the committee's function. Every effort is made to ensure that the views of women, all ethnic and racial groups, and people with disabilities are represented on HHS Federal Advisory Committees and, therefore, HHS encourages nominations of qualified candidates from these groups. HHS also encourages geographic diversity in the

composition of the Committee. Appointment to the ACCV shall be made without discrimination on basis of age, race, ethnicity, gender, sexual orientation, disability, and cultural, religious, or socioeconomic status. HHS encourages nominations of qualified candidates from all groups and locations.

Dated: March 30, 2018.

Lori A. Roche,

Acting Deputy, Division of the Executive Secretariat.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Solicitation of Nominations for Membership To Serve on the Advisory Committee on Heritable Disorders in Newborns and Children

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Request for nominations.

SUMMARY: HRSA is seeking nominations of qualified candidates to be considered for appointment as members of the Advisory Committee on Heritable Disorders in Newborns and Children (Committee). The Committee provides advice, recommendations, and technical information about aspects of heritable disorders and newborn and childhood screening to the Secretary of HHS. HRSA is seeking nominations of qualified candidates to fill up to three positions on the Committee.

DATE: Written nominations for membership on the Committee must be received on or before April 30, 2018.

ADDRESSES: Nomination packages must be submitted electronically as email attachments to Alaina Harris, Genetic Services Branch, Maternal and Child Health Bureau (MCHB), HRSA, AHarris@hrsa.gov.

FOR FURTHER INFORMATION CONTACT: Alaina Harris. Address: MCHB, HRSA, 5600 Fishers Lane, Room 18W66, Rockville, MD 20857; phone number: (301) 443–0721; email: AHarris@hrsa.gov. A copy of the Committee Charter and list of the current membership can be obtained by accessing the Committee website at www.hrsa.gov/advisory-committees/heritable-disorders.

SUPPLEMENTARY INFORMATION: The Committee was established in 2003 to advise the Secretary of HHS regarding newborn screening tests, technologies, policies, guidelines, and programs for

effectively reducing morbidity and mortality in newborns and children having or at risk for heritable disorders. In addition, the Committee provides advice and recommendations to the Secretary concerning the grants and projects authorized under section 1109 of the PHSA and technical information to develop policies and priorities for grants, including those that will enhance the ability of the state and local health agencies to provide for newborn and child screening, counseling and health care services for newborns, and children having or at risk for heritable disorders.

The Committee reviews and reports regularly on newborn and childhood screening practices for heritable disorders, recommends improvements in the national newborn and childhood heritable screening programs, and recommends conditions for inclusion in the Recommended Uniform Screening Panel (RUSP). The Committee's recommendations regarding additional conditions/inherited disorders for screening that have been adopted by the Secretary are included in the RUSP and constitute part of the comprehensive guidelines supported by HRSA pursuant to section 2713 of the PHSA, codified at 42 U.S.C. 300gg-13. Under this provision, non-grandfathered health plans and group and individual health insurance issuers are required to cover screenings included in the HRSA-supported comprehensive guidelines without charging a co-payment, co-insurance, or deductible for plan years (*i.e.*, in the individual market, policy years) beginning on or after the date that is one (1) year from the Secretary's adoption of the condition for screening.

Nominations: HRSA is requesting nominations to fill up to three (3) positions for voting members to serve on the Committee. The Secretary appoints committee members with the expertise needed to fulfill the duties of the Committee established under section 1111(b) of the PHSA, as amended by the Newborn Screening Saves Lives Reauthorization Act of 2014 (Act; 42 U.S.C. 300b-10(b)). Areas of expertise include medical, technical, or scientific professionals with special expertise in the field of heritable disorders or in providing screening, counseling, testing, or specialty services for newborns and children with, or at risk for having, heritable disorders; and/or who have expertise in ethics (*e.g.*, bioethics) and infectious diseases and who have worked and published material in the area of newborn screening; and/or are members of the public having special expertise about or concern with heritable disorders; and/or

representatives from such federal agencies, public health constituencies, and medical professional societies. Interested applicants may self-nominate or be nominated by another individual or organization. Nominees must reside in the United States.

Individuals selected for appointment to the Committee will be invited to serve for up to four (4) years. Members who are not federal officers or permanent federal employees are appointed as special government employees and receive a stipend and reimbursement for per diem and travel expenses incurred for attending Committee meetings and/or conducting other business on behalf of the Committee, as authorized by section 5 U.S.C. 5703 for persons employed intermittently in government service. Members who are officers or employees of the United States Government shall not receive additional compensation for service on the Committee, but receive per diem and travel expenses incurred for attending Committee meetings and/or conducting other business on behalf of the Committee.

The following information must be included in the package of materials submitted for each individual being nominated for consideration: (1) A statement that includes the name and affiliation of the nominee and a clear statement regarding the basis for the nomination, including the area(s) of expertise that may qualify a nominee for service on the Committee, as described above; (2) confirmation the nominee is willing to serve as a member of the Committee; (3) the nominee's contact information (include home address, work address, daytime telephone number, and an email address); and (4) a current copy of the nominee's curriculum vitae. Nomination packages may be submitted directly by the individual being nominated or by the person/organization recommending the candidate.

HHS will endeavor to ensure that the membership of the Committee is fairly balanced in terms of points of view represented and that individuals from a broad representation of geographic areas, gender, ethnic and minority groups, as well as individuals with disabilities, are considered for membership. Appointments shall be made without discrimination on the basis of age, ethnicity, gender, sexual orientation, and cultural, religious, or socioeconomic status.

Individuals who are selected to be considered for appointment will be required to provide detailed information regarding their financial holdings, consultancies, and research grants or

contracts. Disclosure of this information is necessary in order to determine if the selected candidate is involved in any activity that may pose a potential conflict with the official duties to be performed as a member of the Committee.

Authority: Section 1111 of the Public Health Service Act (PHSA), as amended by the Newborn Screening Saves Lives Reauthorization Act of 2014 (42 U.S.C. 300b-10). The Committee is governed by the Federal Advisory Committee Act (FACA), as amended (5 U.S.C. App.), and 41 CFR part 102-3, which set forth standards for the formation and use of advisory committees.

Dated: March 30, 2018.

Lori A. Roche,

Acting Deputy Director, Division of the Executive Secretariat.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Interagency Coordinating Committee on the Validation of Alternative Methods; Notice of Public Meeting; Request for Public Input

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) will hold a public forum to share information and facilitate direct communication of ideas and suggestions from stakeholders. Interested persons may attend in person or view the meeting remotely by webcast. Time will be set aside for questions and public statements on the topics discussed. Registration is requested for both public attendance and oral statements, and required for remote access. Information about the meeting and registration are available at <http://ntp.niehs.nih.gov/go/iccvamforum-2018>.

DATES:

Meeting: May 24, 2018, 9:00 a.m. to approximately 4:00 p.m. Eastern Daylight Time (EDT).

Registration for Onsite Meeting: Deadline is May 11, 2018.

Registration for Webcast: Deadline is May 24, 2018.

Submission of Oral Public Statements: Deadline is May 11, 2018.

ADDRESSES: *Meeting Location:* William H. Natcher Conference Center, National Institutes of Health, Bethesda, MD 20892. *Meeting web page:* The