burden differs and is specific to medical gas manufacturing.

FDA estimates the burden of this collection of information as follows:

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN
[Medical Gases] [1]

21 CFR section/activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping (in hours) [1]	Total hours
SOP Maintenance	2,284	0.65	1,485	25	37,125
New startup SOPs	100	25	2,500	20	50,000
211.34—Consultants	2,284	0.25	571	0.5 (30 minutes)	286
211.67(c)—Equipment cleaning and maintenance	2,284	32.5	74,230	0.25 (15 minutes)	18,558
211.68—Changes in master production and control records or other records.	2,284	2	4,568	1	4,568
211.68(a)—Automatic, mechanical, and electronic equipment	2,284	10	22,840	0.5 (30 minutes)	11,420
211.68(b)—Computer or related systems	2,284	5	11,420	0.25 (15 minutes)	2,855
211.72—Filters	2,284	.25	571	1	571
211.80(d)—Components and drug product containers or closures.	2,284	0.25	571	0.1 (6 minutes)	57
211.100(b)—Production and process controls	2,284	3	6,382	2	13,704
211.105(b)—Equipment identification	2,284	0.25	571	0.25 (15 minutes)	143
211.122(c)—Labeling and packaging material	2,284	50	114,200	0.25 (15 minutes)	28,550
211.130(e)—Labeling and packaging facilities	2,284	50	114,200	0.25 (15 minutes)	28,550
211.132(c)—Tamper-evident packaging	2,284	20	45,680	0.5 (30 minutes)	22,840
211.132(d)—Tamper-evident packaging	2,284	.2	457	0.5 (30 minutes)	229
211.137—Expiration dating	2,284	3.25	7,423	0.33 (20 minutes)	2,450
211.160(a)—Laboratory controls	2,284	2	4,568	1	4,568
211.165(e)—Test methodology	2,284	1	2,284	1	2,284
211.166—Stability testing	2,284	1.3	2,969	0.33 (20 minutes)	980
211.173—Laboratory animals	2,284	1	2,284	0.25 (15 minutes)	571
211.180(e)—Production, control, and distribution records	2,284	0.2	457	0.25 (15 minutes)	114
211.180(f)—Procedures for notification of regulatory actions	2,284	0.2	457	1	457
211.182—Equipment cleaning and use log	2,284	1.3	2,969	0.16 (10 minutes)	475
211.184—Component, drug product container, closure, and labeling records.	2,284	1.95	4,454	0.33 (20 minutes)	1,470
211.186—Master production and control records	2,284	10	22,840	2	45,680
211.188—Batch production and control records	2,284	16.25	37,115	1.3	48,250
211.192—Discrepancies in drug product production and control records.	2,284	2	4,568	1	4,568
211.194—Laboratory records	2,284	25	57,100	0.5 (30 minutes)	28,550
211.196—Distribution records	2,284	25	57,100	0.25 (15 minutes)	14,275
211.198—Complaint files	2,284	5	11,420	1	11,420
211.204—Returned drug products	2,284	10	22,840	0.5 (30 minutes)	11,420
Total					396,988

[1] Burden estimates of less than 1 hour are expressed as a fraction of an hour in the format "[number of minutes per response]/60".

The information collection reflects an increase in the number of respondents that results in a corresponding increase to the number of annual burden hours. This is consistent with our experience with the information collection.

Dated: April 2, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–07031 Filed 4–5–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Commission on Childhood Vaccines

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

ACTION: Notice—Request for nominations for voting members.

SUMMARY: HRSA is requesting nominations to fill vacancies on the Advisory Commission on Childhood Vaccines (ACCV). The ACCV was established by Title XXI of the Public Health Service Act (the Act), and advises the Secretary of HHS (the Secretary) on issues related to implementation of the National Vaccine Injury Compensation Program (VICP).

DATES: The agency will receive nominations on a continuous basis.

ADDRESSES: Submit your nominations to the Director, Division of Injury Compensation Programs (DICP), Healthcare Systems Bureau (HSB), HRSA, 5600 Fishers Lane, Room 08N146B, Rockville, Maryland 20857. Submit your electronic nomination package by email to Ms. Annie Herzog at *AHerzog@hrsa.gov*.

FOR FURTHER INFORMATION CONTACT: Ms. Annie Herzog, Principal Staff Liaison, DICP, HSB, HRSA, at (301) 443–6634 or email at *aherzog@hrsa.gov*.

SUPPLEMENTARY INFORMATION: Under the authorities that established the ACCV, the Federal Advisory Committee Act of October 6, 1972, (Pub. L. 92–463) and section 2119 of the Act, 42 U.S.C. 300aa–19, as added by Public Law 99–660 and amended, HRSA is requesting nominations for voting members of the ACCV.

The ACCV advises the Secretary on the implementation of the VICP. Other activities of the ACCV include: Recommending changes to the Vaccine Injury Table, at its own initiative or as the result of the filing of a petition; advising the Secretary on implementing section 2127 of the Act regarding the need for childhood vaccination products that result in fewer or no significant adverse reactions; surveying federal, state, and local programs and activities related to gathering information on injuries associated with the administration of childhood vaccines, including the adverse reaction reporting requirements of section 2125(b) of the Act; advising the

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 manufacturer 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