Further, section 340B(a)(5)(B) prohibits a covered entity from reselling or otherwise transferring a discounted drug to a person who is not a patient of the entity.

Because of the potential for disputes involving covered entities and participating drug manufacturers, the HRSA Office of Pharmacy Affairs (OPA) has developed a dispute resolution process for manufacturers and covered entities as well as manufacturer guidelines for audits of covered entities.

Audit guidelines: A manufacturer will be permitted to conduct an audit only when there is reasonable cause to believe a violation of section 340B(a)(5)(A) or (B) has occurred. The manufacturer must notify the covered entity in writing when it believes the covered entity has violated these provisions of section 340B. If the problem cannot be resolved, the manufacturer must then submit an audit work plan describing the audit and evidence in support of the reasonable cause standard to the HRSA OPA for review. The office will review the documentation to determine if reasonable cause exists. Once the audit is completed, the manufacturer will submit copies of the audit report to the HRSA OPA for review and resolution of the findings, as appropriate. The manufacturer will also submit an informational copy of the audit report to the HHS Office of Inspector General.

Dispute resolution guidelines: Because of the potential for disputes involving covered entities and participating drug manufacturers, the HRSA OPA has developed a dispute resolution process which can be used if an entity or manufacturer is believed to be in violation of section 340B. Prior to filing a request for resolution of a dispute with the HRSA OPA, the parties must attempt, in good faith, to resolve the dispute. All parties involved in the dispute must maintain written documentation as evidence of a good faith attempt to resolve the dispute. If the dispute is not resolved and dispute resolution is desired, a party must submit a written request for a review of the dispute to the HRSA OPA. A committee appointed to review the documentation will send a letter to the party alleged to have committed a violation. The party will be asked to provide a response to or a rebuttal of the allegations.

To date, there have been no requests for audits, and no disputes have reached the level where a committee review was needed. As a result, the estimates of annualized hour burden for audits and disputes have been reduced to the level shown in the table below.

Reporting requirement	Number of respondents	Responses per respondent	Total responses	Hours/ response	Total burden hours
Audits:					
Audit Notification of Entity [1]	2	1	2	4	8
Audit Workplan [1]	1	1	1	8	8
Audit Report [1]	1	1	1	1	1
Entity Response	0	0	0	16	0
Dispute Resolution:					
Mediation Request	5	1	5	8	40
Rebuttal	2	1	2	16	32
Total	9	1.2	11	8.1	89

[1] Prepared by the manufacturer

Recordkeeping requirement	Number of recordkeepers	Hours of recordkeeping	Total burden
Dispute records	10	.5	5

The total burden is 94 hours.

Send comments to Susan G. Queen, HRSA Reports Clearance Officer, Room 14–33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: June 1, 2000.

James J. Corrigan,

Associate Administrator for Management and Program Support.

[FR Doc. 00–14215 Filed 6–5–00; 8:45 am]

BILLING CODE 4160–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Commission on Childhood Vaccines; Request for Nominations for Voting Members

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Health Resources and Services Administration (HRSA) is requesting nominations to fill three vacancies on the Advisory Commission on Childhood Vaccines (ACCV). The ACCV was established by Title XXI of the Public Health Service Act (the Act), as enacted by Public Law (Pub. L.) 99–660 and as subsequently amended, and advises the Secretary of Health and Human Services (the Secretary) on issues related to implementation of the National Vaccine Injury Compensation Program (VICP).

FOR FURTHER INFORMATION CONTACT: Ms. Shelia Tibbs, Principal Staff Liaison, Policy Analysis Branch, Division of Vaccine Injury Compensation, at (301) 443–4036.

DATES: Nominations are to be submitted by July 6, 2000.

ADDRESSES: All nominations are to be submitted to the Director, Division of Vaccine Injury Compensation, Bureau of Health Professions, HRSA, Parklawn Building, Room 8A–46, 5600 Fishers Lane, Rockville, Maryland 20857.

SUPPLEMENTARY INFORMATION: Under the authorities that established the ACCV, viz., 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 three voting members of the ACCV.

The ACCV advises the Secretary on the implementation of the VICP; on its own initiative or as the result of the filing of a petition, recommends changes in the Vaccine Injury Table; advises the Secretary in implementing the Secretary's responsibilities under section 2127 regarding the need for childhood vaccination products that result in fewer or no significant adverse reactions; surveys Federal, State, and local programs and activities relating to the gathering of information on injuries associated with the administration of childhood vaccines, including the adverse reaction reporting requirements of section 2125(b); advises the Secretary on means to obtain, compile, publish, and use credible data related to the frequency and severity of adverse reactions associated with childhood vaccines; and recommends to the Director, National Vaccine Program Office, 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: three health professionals, of whom at least two are pediatricians, who are not employees of the United States, who have expertise in the health care of children, the epidemiology, etiology and prevention of childhood diseases, and the adverse reactions associated with vaccines; three members from the general public, of whom at least two are legal representatives (parents or guardians) of children who have suffered a vaccine-related injury or death; and 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 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.

Specifically, HRSA is requesting nominations for three voting members of the ACCV representing: (1) a health professional with special experience in childhood diseases; (2) an attorney whose specialty includes representation of a vaccine manufacturer and (3) a member from the general public. Nominees will be invited to serve 3-year terms beginning January 1, 2001, and ending December 31, 2003.

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 and appears to have no conflict of interest that would preclude the ACCV membership. Potential candidates will be asked to provide detailed information concerning such matters as financial holdings, consultancies, and research grants or contracts to permit evaluation of possible sources of conflicts of interest. A curriculum vitae or resume should be submitted with the nomination.

The Department of Health and Human Services has special interest in assuring that women, minority groups, and the physically handicapped are adequately represented on advisory committees and therefore extends particular encouragement to nominations for appropriately qualified female, minority, or physically handicapped candidates.

Dated: May 30, 2000.

Claude Earl Fox,

Administrator, HRSA.

[FR Doc. 00–14041 Filed 6–5–00; 8:45 am]

BILLING CODE 4160–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Commission on Childhood Vaccines (ACCV); Notice of Meeting; Cancellation

Federal Register Document 00–11251, in the issue dated Friday, May 5, 2000, on the following pages 26219–26220, the Advisory Commission on Childhood Vaccines meeting scheduled for June 7, 2000, has been cancelled due to lack of quorum.

Dated: May 31, 2000.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 00–14107 Filed 6–5–00; 8:45 am]

BILLING CODE 4160–15–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Availability of Draft Comprehensive Conservation Plan and Environmental Assessment for Tewaukon National Wildlife Refuge Complex, Cayuga, ND.

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability.

SUMMARY: Pursuant to the Refuge Improvement Act of 1997, the U.S. Fish and Wildlife Service has published the Tewaukon National Wildlife Refuge Complex Draft Comprehensive Conservation Plan and Environmental Assessment. This Plan describes how the FWS intends to manage the Tewaukon NWR and Wetland Management District for the next 10–15 years.

DATES: Submit written comments by July 6, 2000. All comments need to be addressed to Allison Banks, Refuge Planner, Land Acquisition and Refuge Planning, U.S. Fish and Wildlife Service, P.O. Box 25486 DFC, Denver, Colorado 80225.

ADDRESSES: A copy of the Plan may be obtained by writing to U.S. Fish and Wildlife Service, 9754 143½ Avenue SE, Cayuga, ND 58013–9764; or download from http://www.r6.fws.gov/larp/.

FOR FURTHER INFORMATION CONTACT: Allison Banks, U.S. fish and Wildlife Service, P.O. Box 25486 DFC, Denver, CO 80225, 303/236–8145 extension 626; fax 303/236–4792.

SUPPLEMENTARY INFORMATION: Tewaukon NWR Complex is located in southeast North Dakota. Implementation of the Plan will focus on adaptive resource management of glaciated prairie wetlands, tall and mixed grass prairie grasslands, riparian woodlands, and opportunities for compatible wildlife-dependent recreation. Habitat monitoring and evaluation will be emphasized as the Plan is implemented. Opportunities for compatible wildlife-dependent recreation will continue to be provided.

Dated: May 31, 2000.

Ralph O. Morgenweck,

Regional Director, Denver, Colorado.

[FR Doc. 00–14100 Filed 6–5–00; 8:45 am]

BILLING CODE 4310–55–M