cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at *http://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: On October 8, the committee will discuss, make recommendations and vote on information related to the premarket approval application regarding the Boston Scientific Corporation's WATCHMAN Left Atrial Appendage (LAA) Closure Technology. FDA is seeking committee review and recommendations regarding new clinical data and associated additional adverse events including stroke that have become available since the previous advisory committee meeting on the WATCHMAN device, which was held December 11, 2013. The WATCHMAN LAA Closure Technology is a percutaneously delivered permanent cardiac implant placed in the left atrial appendage. This device is indicated to prevent thromboembolism (TE) from the left atrial appendage. It may be considered for use in patients with non-valvular atrial fibrillation who are eligible for warfarin therapy to reduce the risk of stroke and systemic embolism based on $CHADS_2$ (congestive heart failure, hypertension, age >75 years, diabetes, and prior stroke or transient ischemic attack (TIA)) or CHA_2DS_2-VASc (congestive heart failure, hypertension, age >75 years, diabetes mellitus, stroke/TIA/TE, vascular disease, age 65–74, and sex category) scores.

On October 9, the committee will discuss and make recommendations regarding the classification of more-than-minimally manipulated allograft heart valves (MMM Allograft HVs). A MMM Allograft HV is a human valve or valved conduit that has been aseptically recovered from qualified donors, dissected free from the human heart, and then subjected to a manufacturing process(es) that alters the original relevant characteristics of the tissue (21 CFR 1271.3(f), 21 CFR 1271.10(a)(1), and 21 CFR 1271.20). The valve is then stored until needed by a recipient. An example of such a manufacturing process is one that intentionally removes the cells and cellular debris with the goal of reducing in vivo antigenicity.

MMM Allograft HVs are considered preamendment devices because they were found substantially equivalent to devices in commercial distribution prior to May 28, 1976, when the Medical Device Amendments became effective. MMM Allograft HVs are currently regulated under Product Code OHA, ''Heart Valve, More than Minimally Manipulated Allograft,'' as unclassified devices and reviewed under the premarket notification, 510(k), authority (21 CFR part 807). FDA is seeking committee input on the safety and effectiveness of MMM Allograft HVs and the regulatory classification for MMM Allograft HVs.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before September 30, 2014. On October 8, oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. On October 9, oral presentations from the public will be scheduled between approximately 9:45 a.m. and 10:15 a.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before September 22, 2014. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by September 24, 2014.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact AnnMarie Williams, Conference Management Staff, 301–796–5966, *Annmarie.Williams@fda.hhs.gov* at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: August 20, 2014.

Peter Lurie,

Associate Commissioner for Policy and Planning.

[FR Doc. 2014–20165 Filed 8–25–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Health Resources and Services Administration (HRSA) has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

DATES: Comments on this ICR should be received no later than September 25, 2014.

ADDRESSES: Submit your comments, including the Information Collection Request Title, to the desk officer for HRSA, either by email to *OIRA_submission@omb.eop.gov* or by fax to 202–395–5806.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email the

HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443–1984.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: AIDS Drug Assistance Program Data Report OMB No. 0915–0345—Revision.

Abstract: HRSA's AIDS Drug Assistance Program (ADAP) is funded through The Ryan White HIV/AIDS Program, Part B, Title XXVI of the Public Health Service Act, which provides grants to states and territories. ADAP provides medications for the treatment of HIV/AIDS. Program funds may also be used to purchase health insurance for eligible clients and for services that enhance access, adherence, and monitoring of drug treatments.

Each of the 50 states, the District of Columbia, Puerto Rico, and several territories receive ADAP grants. As part of the funding requirements, ADAPs submit reports concerning information on patients served; eligibility requirements; pharmaceuticals prescribed; and pricing and other sources of support to provide AIDS medication treatment, cost data, and coordination with Medicaid. Since 2005, ADAPs have supplied aggregate data to HRSA using the ADAP Quarterly Report (AQR). However, aggregate data cannot be analyzed with the detail that is required to assess quality of care or to sufficiently account for the use of Ryan White HIV/AIDS Program Funds. To address this limitation, HRSA's HIV/AIDS Bureau (HAB) developed a client-level data system for ADAPs called the ADAP Data Report (ADR), and in 2013, ADAPs began submitting the ADR. As of April 30, 2104, HAB retired the AQR and now only requires the submission of the ADR. The ADR will be submitted annually and consists of a Grantee Report and a client-level data file.

Need and Proposed Use of the Information: The Ryan White HIV/AIDS Program requires the submission of annual reports by the Secretary of the Department of Health and Human Services (HHS) to the appropriate committees of Congress. The collection of grantee-level and client level data enables HRSA to more effectively respond to requests from the Secretary of HHS. In addition, client-level information is needed by HRSA in order to respond to the request for reviews of program performance and information for strategic planning. Client-level data is also needed to support the implementation and monitoring of the National HIV/AIDS Strategy (NHAS).

On April 11, 2012, a memo from the Secretary of HHS directed the Health Resources and Services Administration (HRSA) along with other Health and Human Services Operating Divisions (OpDivs) to work together to: (1) Identify seven common core HIV/AIDS indicators; (2) develop implementation plans to deploy these indicators; and (3) streamline data collection; and reduce reporting by at least 20 to 25 percent. In November 2012, the HIV/AIDS Indicators Implementation Group (HAIIG), comprised of representatives from HHS OpDivs, the Department of Housing and Urban Development, the Veterans' Health Administration, and community partners successfully identified the required common core HIV/AIDS indicators.

Revisions to the ADR are required to support implementation of the core indicators, streamlining data collection and reducing reporting burden. Eleven data elements will be deleted from the ADR and several variables were modified to reduce reporting burden. *Sex at Birth,* defined as the biological sex assigned to the client at birth, will be added to align with variables collected by other HHS OpDivs. *Type of ADAP-funded insurance assistance received* will also be added to track ADAP's payment of full or partial premium and co-pays and deductibles.

In addition to the new data elements noted above, other new variables will be added to the ADR address provisions set forth in Section 4302 of the Affordable Care Act (ACA). The ACA includes several provisions aimed at eliminating health disparities in America. Section 4302 (Understanding health disparities: Data collection and analysis) of the ACA focuses on the standardization, collection, analysis, and reporting of health disparities data. Section 4302 requires the Secretary of HHS to establish data collection standards for race, ethnicity, and sex. The race/ethnicity data elements include reporting of Hispanic, Asian, and Native Hawaiian/Pacific Islander subgroups. The categories for HHS data standards for race and ethnicity are based on the disaggregation of the OMB standard used in the American Community Survey and the 2000 and 2010 Decennial Census. The subgroup categories can be rolled-up to the OMB standard. These new data elements will be used in data analysis intended to identify and understand health disparities.

Likely Respondents: State ADAPs of Ryan White Part B grantees.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Grantee Report	54	1	54	6	324
Client-level Report	54	1	54	81	4,374
Total				87	4,698

Dated: August 19, 2014.

Jackie Painter,

Acting Director, Division of Policy and Information Coordination.

[FR Doc. 2014–20318 Filed 8–25–14; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Advisory Council on Migrant Health; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92–463), notice is hereby given of the following meeting:

Name: National Advisory Council on Migrant Health

Dates and Times: October 22, 2014, 8:00 a.m. to 5:00 p.m. October 23, 2014, 8:00 a.m. to 5:00 p.m.

Place: Sheraton Pittsburgh Hotel at Station Square, 300 W Station Square Drive, Pittsburgh, Pennsylvania 15219, Telephone: 412–261–2000, Fax: 412–261–2932.

Status: The meeting will be open to the public.

Purpose: The purpose of the meeting is to discuss services and issues related to the health of migratory and seasonal agricultural workers and their families and to formulate recommendations for the Secretary of Health and Human Services.

Agenda: The agenda includes an overview of the Council's general business activities. The Council will also hear presentations from experts on agricultural worker issues, including the status of agricultural worker health at the local and national levels.

In addition, the Council will be holding a public hearing at which migratory and seasonal agricultural workers will have the opportunity to testify before the Council regarding matters that affect the health of migratory and seasonal agricultural workers. The hearing is scheduled for Wednesday, October 22, 2014 from 1:30 p.m. to 4:30 p.m., at the Sheraton Pittsburgh Hotel at Station Square.

Agenda items are subject to change as priorities indicate.

FOR FURTHER INFORMATION CONTACT: Gladys Cate, Office of National Assistance and Special Populations, Bureau of Primary Health Care, Health Resources and Services Administration, 5600 Fishers Lane, Room 15–74, Maryland 20857; telephone (301) 594–0367.

Dated: August 19, 2014.

Jackie Painter,

Acting Director, Division of Policy and Information Coordination.

[FR Doc. 2014–20312 Filed 8–25–14; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Centers for Disease Control and Prevention (CDC)/Health Resources and Services Administration (HRSA) Advisory Committee on HIV, Viral Hepatitis, and Sexually Transmitted Disease (STD) Prevention and Treatment

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

ACTION: Notice; correction.

SUMMARY: HRSA is requesting nominations to fill three vacancies on the CDC/HRSA Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment (CHACHSPT). The action is to provide correction listed under addresses to provide more time for public input.

FOR FURTHER INFORMATION CONTACT: Shelley B. Gordon, Public Health, Analyst, HIV/AIDS Bureau, HRSA, 5600 Fishers Lane, Room 7C–26, Rockville, Maryland 20857, email at *sgordon@hrsa.gov,* or telephone at (301) 443–9684.

Correction

In the Federal Register, FR 2014–19199 (August 14, 2014), please make the following corrections:

In the **ADDRESSES** Section please change the date all nominations should be submitted by to no later than September 15, 2014.

Dated: August 19, 2014.

Jackie Painter,

Acting Director, Division of Policy and Information Coordination.

[FR Doc. 2014–20313 Filed 8–25–14; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources AND Services Administration

National Vaccine Injury Compensation Program; List of Petitions Received

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Health Resources and Services Administration (HRSA) is publishing this notice of petitions received under the National Vaccine Injury Compensation Program (the Program), as required by Section 2112(b)(2) of the Public Health Service (PHS) Act, as amended. While the Secretary of Health and Human Services is named as the respondent in all proceedings brought by the filing of petitions for compensation under the Program, the United States Court of Federal Claims is charged by statute with responsibility for considering and acting upon the petitions.

FOR FURTHER INFORMATION CONTACT: For information about requirements for filing petitions, and the Program in general, contact the Clerk, United States Court of Federal Claims, 717 Madison Place, NW., Washington, DC 20005, (202) 357–6400. For information on HRSA's role in the Program, contact the Director, National Vaccine Injury Compensation Program, 5600 Fishers Lane, Room 11C–26, Rockville, MD 20857; (301) 443–6593.

SUPPLEMENTARY INFORMATION: The Program provides a system of no-fault compensation for certain individuals who have been injured by specified childhood vaccines. Subtitle 2 of Title XXI of the PHS Act, 42 U.S.C. 300aa–10 *et seq.,* provides that those seeking compensation are to file a petition with the U.S. Court of Federal Claims and to serve a copy of the petition on the Secretary of Health and Human Services, who is named as the respondent in each proceeding. The Secretary has delegated this responsibility under the Program to HRSA. The Court is directed by statute to appoint special masters who take evidence, conduct hearings as appropriate, and make initial decisions as to eligibility for, and amount of, compensation.

A petition may be filed with respect to injuries, disabilities, illnesses, conditions, and deaths resulting from vaccines described in the Vaccine Injury Table (the Table) set forth at Section 2114 of the PHS Act or as set forth at 42 CFR 100.3, as applicable. This Table lists for each covered childhood vaccine the conditions which may lead to compensation and, for each condition, the time period for occurrence of the first symptom or manifestation of onset or of significant aggravation after vaccine administration. Compensation may also be awarded for conditions not listed in the Table and for conditions that are manifested outside the time periods specified in the Table, but only