effectiveness of the device. This section requires FDA to publish in the **Federal Register** a notice of intent to exempt a device, or of the petition, and to provide a 30-day comment period. Within 120 days of publication of this document, FDA must publish in the **Federal Register** its final determination regarding the exemption of the device that was the subject of the notice. If FDA fails to respond to a petition under this section within 180 days of receiving it, the petition shall be deemed granted.

II. Criteria for Exemption

There are a number of factors FDA may consider to determine whether a 510(k) is necessary to provide reasonable assurance of the safety and effectiveness of a class II device. These factors are discussed in the guidance the Agency issued on February 19, 1998, entitled ''Procedures for Class II Device Exemptions from Premarket Notification, Guidance for Industry and CDRH Staff.'' That guidance is available through the Internet at *http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM080199.pdf*. Send an email request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to 301–847–8149 to receive a hard copy. Please use the document number 159 to identify the guidance you are requesting.

III. Proposed Class II Device Exemptions

FDA has received the following petition requesting an exemption from premarket notification for a class II device: Dave Smith, on behalf of Adaptive Engineering, Inc., for its wheelchair elevator device (commonly known as a manually operated portable wheelchair lift), classified under 21 CFR 890.3930.

IV. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 12, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–14215 Filed 6–17–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects (Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995), the Health Resources and Services Administration (HRSA) announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this Information Collection Request must be received no later than August 18, 2014.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 10–29, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call the HRSA Information Collection Clearance Officer at (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

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, 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, 2014, 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 HRSA with other HHS 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, streamline data collection, and reduce the reporting burden. Eleven data elements will be deleted from the ADR and several variables were modified to reduce reporting burden. *Sex at Birth,* defined to 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, co-pays, and deductibles.

In addition to the new data elements noted above, other new variables will be added to the ADR to 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 DHHS 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 (ACS) 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 Information Collection Request 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	109	5,886
Total	54		54		6,210

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Dated: June 12, 2014.

Jackie Painter,

Deputy Director, Division of Policy and Information Coordination.

[FR Doc. 2014–14193 Filed 6–17–14; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects (Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995), the Health Resources and Services Administration (HRSA) announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this Information Collection Request must be received no later than August 18, 2014.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 10–29, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call the HRSA Information Collection Clearance Officer at (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: Federal Tort Claims Act Free Clinic Application OMB No. 0915–0293—Revision

Abstract: Under 42 U.S.C. 233(o) and HRSA Program Assistance Letter (PAL) 2014–04, ''Calendar Year 2015 Federal Tort Claims Act (FTCA) Deeming Application for Free Clinics,'' free clinics are required to submit annual, renewal, and supplemental applications for the process of deeming qualified health care professionals, board members, officers, and contractors for FTCA medical malpractice coverage for negligent acts and omissions that arise from the performance of medical, surgical, dental, or related functions within the scope of the covered individual's employment. HRSA proposes modifying the application forms to reflect changes to eligible personnel made by section 10608 of the Affordable Care Act, amending 42 U.S.C. 233(o)(1), which extended FTCA medical malpractice liability protection to free clinic board members, officers, employees, and contractors. Additionally, HRSA proposes upgrading the application to provide for electronic submissions. Specifically, the modifications include: (1) Inclusion of