MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Jessica Paulsen, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2108, Silver Spring, MD 20993–0002, 301–796–6883.

SUPPLEMENTARY INFORMATION:

I. Background

In February 2015, FDA published a final order requiring the submission of premarket approval (PMA) applications for new and existing AEDs and necessary AED accessories. The final order required the submission of a PMA application for any preamendments and substantially equivalent AED necessary accessory—such as batteries, pad electrodes, adapters, and hardware keys for pediatric use—within 90 days of the date of the final order; however, the final order also stated that FDA did not intend to enforce compliance with the PMA submission requirement for these necessary AED accessories for 60 months following the date of the final order, which was February 3, 2020.

For the reasons described in the guidance, at this time FDA does not intend to enforce compliance with the PMA submission requirement for these necessary AED accessories until February 3, 2022.

This guidance is being implemented without prior public comment because the Agency has determined that prior public participation is not feasible or appropriate (see section 701(h)(1)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371(h)(1)(C)) and 21 CFR 10.115(g)(2)). FDA has determined that this guidance document presents a less burdensome policy that is consistent with public health. Although this guidance is immediately in effect, FDA will consider all comments received and revise the guidance document as appropriate.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on Necessary Automated External Defibrillator Accessories: Policy Regarding Compliance Date. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products.* This guidance document is also available at *https://www.regulations.gov.* Persons unable to download an electronic copy of ''Necessary Automated External Defibrillator Accessories: Policy Regarding Compliance Date'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 20043 and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collection of information in the following FDA regulations have been approved by OMB as listed in the following table:

21 CFR part	Topic	OMB control No.
814, subparts A through E	Premarket approval	0910–0231

Dated: October 22, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–23841 Filed 10–27–20; 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; Information Collection Request Title: Enhancing Linkage of Sexually Transmitted Infection and Human Immunodeficiency Virus Surveillance Data in the Ryan White HIV/AIDS Program Evaluation, OMB No. 0906–New

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

ACTION: Notice.

SUMMARY: In compliance with of the Paperwork Reduction Act of 1995, 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. OMB may act on HRSA's ICR only after the 30 day comment period for this Notice has closed.

DATES: Comments on this ICR should be received no later than November 27, 2020.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function.

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

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

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Enhancing Linkage of Sexually Transmitted Infection and Human Immunodeficiency Virus Surveillance Data in the Ryan White HIV/AIDS Program Evaluation, OMB No. 0906–xxxx–NEW

Abstract: HRSA's Ryan White HIV/AIDS Program (RWHAP) funds and coordinates with cities, states, and local clinics/community-based organizations to deliver efficient and effective Human Immunodeficiency Virus (HIV) care, treatment, and support to low-income people with HIV. Nearly two-thirds of clients (patients) live at or below 100 percent of the Federal poverty level and approximately three-quarters of RWHAP clients are racial and ethnic minorities. Since 1990, the RWHAP has developed a comprehensive system of HIV service providers who deliver high quality direct health care and support services to over half a million people with HIV—more than 50 percent of all people with diagnosed HIV in the United States.

HRSA's HIV/AIDS Bureau is conducting a multi-year evaluation of the Enhancing Linkage of Sexually Transmitted Infection (STI) and HIV Surveillance Data in the RWHAP (Enhancing STI Linkage) demonstration project. The Enhancing STI Linkage demonstration project is a capacity building cooperative agreement that seeks to improve linkage, re-engagement in care, and health outcomes for people with HIV in the RWHAP. Through this demonstration project, a Technical Assistance Provider is collaborating with four RWHAP Part B jurisdictions to provide them with tailored training and technical assistance to facilitate data sharing across STI and HIV surveillance systems. A persistent barrier to addressing HIV and STI infections simultaneously and jointly is the lack of data systems linking HIV and STI surveillance data. Aside from helping to address problems around coinfection, there are substantial opportunities—particularly for the RWHAP—associated with linking HIV and STI surveillance data, including, but not limited to, identifying people with HIV currently out of care and identifying people with STIs who could be tested for HIV and promptly linked to care. This clearance request is for approval of data collection activities associated with the Enhancing STI Linkage evaluation which will occur simultaneously with the demonstration project, over a 3-year project period.

A 60-day notice published in the **Federal Register** on August 20, 2020, vol. 85 No. 162; pp. 51454–51455. There were no public comments.

Need and Proposed Use of the Information: This mixed methods evaluation will assess the achievement and effectiveness of the Enhancing STI Linkage demonstration project. HRSA will collect quantitative and qualitative data to inform the HRSA on how to enhance jurisdictions' use of STI and HIV surveillance data to improve service delivery and HIV-related health outcomes. Information gleaned from the Enhancing STI Linkage evaluation may be used to enhance and coordinate health departments' responses to HIV and STI epidemics and affect change in HIV care continuum outcomes.

Likely Respondents: Multiple respondents from four HRSA RWHAP Part B recipients, including data end-users identified by the Part B recipients within their jurisdiction.

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

ANNUALIZED DATA COLLECTION BURDEN—YEARS 2 AND 3

Type of respondent	Form name	Number of respondents	Number of responses per respondent *	Total responses	Average burden per response (in hours)	Total burden hours
Jurisdiction TA Recipient	Jurisdiction TA Recipient Semi-Structured Interview Guide.	12	2	24	1.00	24
Policy Stakeholder	Policy Stakeholder Semi-Structured Interview Guide	12	2	24	.50	12
Data End-User	Data End-User Survey	105	2	210	.17	36
Total	.....	129	.....	258	.....	72

* Note: Burden hours represent responses for both years 2 and 3; and there are 2 responses per respondent, indicating one in each year (one in year 2 and another in year 3).

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.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2020–23871 Filed 10–27–20; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Charter Renewal of the Secretary's Advisory Committee on Human Research Protection

AGENCY: Office for Human Research Protections, Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.