Resource (eSTAR) is the only electronic submission template available to prepare a complete 510(k) electronic submission using the guided prompts for the collection of structured and unstructured data.

All 510(k) submissions, including original submissions for Traditional, Special, and Abbreviated 510(k)s, and subsequent Supplements and Amendments (amendments include add-to-files and appeals), and any other subsequent submissions to an original submission unless exempted in this final guidance, will be required to be submitted as electronic submissions as specified in the guidance. Section 745A(b)(2) of the FD&C Act allows for FDA to set forth criteria for exemptions and waivers from electronic submission requirements. FDA has identified such criteria in the final guidance document. FDA is identifying October 1, 2023, as the date on which the 510(k) electronic submission requirements will take effect.

A notice of availability of the draft guidance appeared in the **Federal Register** of September 29, 2021 (86 FR 53965). FDA considered comments received and revised the guidance as appropriate in response to the comments, including updated criteria for exemptions; clarification of the technical screening hold; and description of the transition period and effective date on which 510(k) electronic submissions will be required.

In section 745A(b) of the FD&C Act, Congress granted explicit statutory authorization to FDA to specify in guidance the statutory requirement for electronic submissions solely in electronic format by providing standards, a timetable, and criteria for waivers and exemptions. To the extent that this final guidance provides such requirements under section 745A(b)(3) of the FD&C Act (*i.e.,* standards, timetable, criteria for waivers of and exemptions), indicated by the use of the mandatory words, such as must or required, this document is not subject to the usual restrictions in FDA's good guidance practice regulations, such as the requirement that guidances not establish legally enforceable responsibilities. (See § 10.115(d).)

To the extent that this final guidance describes recommendations that are not standards, timetable, criteria for waivers of, or exemptions under section 745A(b)(3) of the FD&C Act, it is being issued in accordance with FDA's good guidance practices regulation (§ 10.115). This guidance represents the current thinking of FDA on this topic. 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. This final guidance contains both binding and nonbinding provisions.

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, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics.* Persons unable to download an electronic copy of ''Electronic Submission Template for Medical Device 510(k) Submissions'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 19006 and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

While this guidance contains no new collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (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 collections of information in the following FDA regulations and forms have been approved by OMB as listed in the following table:

21 CFR part or FDA form	Topic	OMB control No.
807 subpart E, including forms FDA 4062 eSTAR and FDA 4078 eSTAR (for In Vitro Diagnostic (IVD) 510(k) submissions).	Premarket Notification Submission, including submissions via eSTAR.	0910–0120
800, 801, and 809	Medical Device Labeling Regulations	0910–0485

Dated: September 16, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–20512 Filed 9–21–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: HRSA Ryan White HIV/AIDS Program HIV Quality Measures Module, OMB No. 0906–0022—Extension

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

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 October 24, 2022.

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 Samantha Miller, the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov,* or call (301) 443–9094.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: HIV Quality Measures (HIVQM) Module OMB No. 0906–0022—Extension.

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 HIV care, treatment, and support services to low-income people with HIV. Since 1990, the RWHAP has developed a comprehensive system of safety net 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 diagnosed with HIV in the United States. Nearly two-thirds of clients live at or below 100 percent of the federal poverty level and approximately three-quarters of RWHAP clients are racial/ethnic minorities.[1]

RWHAP Parts A, B, C and D recipients and subrecipients must follow the legislative requirements for the establishment of clinical quality management programs to assess the extent to which their HIV services are consistent with the most recent HHS Clinical Treatment guidelines. In support of these requirements, HRSA created the RWHAP HIVQM Module as an online tool to assist recipients in meeting the clinical quality management program requirement by allowing recipients to input data for the HRSA performance measures. HRSA maintains over 40 performance measures across the following categories: (1) core, (2) all ages, (3) adolescent/adult, (4) HIV-infected children, (5) HIV-exposed children, (6) medical case management, (7) oral health, (8) AIDS drug assistance program, and (9) systems-level. The RWHAP HIVQM Module also supports the requirement imposed by the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Award (45 CFR 75.301) that recipients relate performance accomplishments of their federal awards. The RWHAP HIVQM Module helps recipients set goals and monitor performance measures and quality improvement projects. The use of the RWHAP HIVQM Module is voluntary for RWHAP recipients but strongly encouraged.

A 60-day notice published in the **Federal Register**, 87 FR 34887–88 (June 8, 2022). There were were no public comments.

Need and Proposed Use of the Information: The RWHAP HIVQM Module supports recipients and sub-recipients in their clinical quality management programs, performance measurement, service delivery, and monitoring of client health outcomes and quality HIV services. The RWHAP HIVQM Module is accessible via the RWHAP Services Report, an existing online portal that RWHAP recipients use for required data collection of their services. Recipients may enter performance measures data into the RWHAP HIVQM Module four times a year and then generate reports to assess their performance. Recipients have the option to enter data for specific populations for a subset of performance measures based on age, gender, race/ethnicity, and risk factor. Recipients may also compare their performance against other recipients in their state, regionally, and nationally. Additionally, recipients can choose the performance measures they want to monitor and enter data accordingly. For recipients and sub-recipients participating in the Centers for Medicare & Medicaid Incentive Programs, such as the Medicare Promoting Interoperability Program and the Merit-based Incentive Payment System, the RWHAP HIVQM Module may be used to monitor the HRSA measures that qualify and comply with the requirements to receive incentives from these programs.

Likely Respondents: RWHAP Part A, Part B, Part C, and Part D recipients and their sub-recipients.

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. There is a decrease in burden due to improved burden calculation obtained through conducting a pilot program.

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
HIVQM Report	2,063	4	8,252	* .216/60	1,788
Total	2,063		8,252		1,788

* Exact number is .216674745.

[1] HRSA. Ryan White HIV/AIDS Program Data Report (RSR) 2020.

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. 2022–20572 Filed 9–21–22; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Meeting of the CDC/HRSA Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment

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

ACTION: Notice.

SUMMARY: In accordance with the Federal Advisory Committee Act, this notice announces that the Secretary's Centers for Disease Control and Prevention (CDC)/HRSA Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment (CHAC) has scheduled a public meeting. Information about CHAC and the agenda for this meeting can be found on the CHAC website at *https://www.cdc.gov/maso/facm/facmCHACHSPT.html* and the meeting website at *https://targethiv.org/ta-org/chac*.

DATES:

- November 1, 2022, 12:30 p.m.–5:00 p.m. Eastern Time (ET);
- November 2, 2022, 12:30 p.m.–5:30 p.m. ET; and
- November 3, 2022, 12:30 p.m.–4:00 p.m. ET.

ADDRESSES: This meeting will be held virtually. Advance registration is required to attend. Please visit the meeting website to register. The registration deadline is Friday, October 28, 2022, at 12:00 p.m. ET. Prior to the meeting, each individual registrant will receive a registration confirmation along with an access link to the virtual meeting location.

- Meeting website link: *https://targethiv.org/ta-org/chac*.

FOR FURTHER INFORMATION CONTACT: Theresa Jumento, Senior Public Health Advisor, HIV/AIDS Bureau, HRSA, 301–443–5807; or *CHACAdvisoryComm@hrsa.gov*.

SUPPLEMENTARY INFORMATION: CHAC provides advice and recommendations to the Secretary of HHS (Secretary) on policy, program development, and other matters of significance concerning the activities under Section 222 of the Public Health Service Act, 42 U.S.C. 217a.

The purpose of the CHAC is to advise the Secretary of HHS, the Director of CDC, and the HRSA Administrator regarding objectives, strategies, policies, and priorities for the prevention and treatment of HIV, viral hepatitis, and other STDs, including: surveillance, epidemiologic, behavioral, health services, and laboratory research, identification of policy issues related to professional eduction, patient healthcare delivery, and prevention services; Agency policies regarding health care delivery, research and training; strategic issues influencing the ability of CDC and HRSA to fulfill their missions programmatic efforts to prevent and treat HIV, viral hepatitis, and other STDs; and support to the CDC and HRSA in their development of responses to emerging health needs related to these issues.

During the November 1–3, 2022, meeting, CHAC will discuss issues related to HIV and the workforce, including non-traditional partnerships to address people with HIV who are out of care, AIDS Education and Training Center program and integrating innovative programs to address HIV workforce challenges into the Ryan White HIV/AIDS Program, and how to more effectively use community health workers and disease intervention specialists in HIV and STD prevention, care, and treatment, along with a federal update on Monkeypox. Agenda items are subject to change as priorities dictate. Refer to the CHAC meeting information page for any updated information concerning the meeting.

Members of the public will have the opportunity to provide comments. Public participants may also submit written statements as further described below. Oral comments will be honored in the order they are requested and may be limited as time allows. Requests to submit a written statement or make oral comments to CHAC should be sent via the meeting website at *https://targethiv.org/ta-org/chac*. Requests for oral comment must be received by October 25, 2022, at 5 p.m. ET to be considered. Written comments may be submitted to Theresa Jumento at the email address and/or phone number listed above prior to and up to ten business days after the meeting. Visit the meeting information page for additional details: *https://targethiv.org/ta-org/chac*.

Individuals who plan to attend and need special assistance or another reasonable accommodation should notify Theresa Jumento at the email address and/or phone number listed above at least 10 business days prior to the meeting.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2022–20528 Filed 9–21–22; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–4040–0004]

Agency Information Collection Request. 30-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before October 24, 2022

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 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Sagal Musa, *sagal.musa@hhs.gov* or (202) 205–2634. When submitting comments or requesting information, please include the document identifier 4040–0004–30D and project title for reference.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (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