were considered as the guidance was finalized.

The guidance announced in this notice finalizes the draft guidance entitled ''Recommendations for Requalification of Blood Donors Deferred Because of Reactive Test Results for Antibodies to Human T-Lymphotropic Virus Types I and II (anti-HTLV–I/II)'' dated September 2018. The guidance also consolidates FDA's other previously issued recommendations on HTLV–I/II into one document. Therefore, the guidance also supersedes the recommendations specific to HTLV–1 contained in the memorandum to blood establishments, entitled ''Recommendations for the Quarantine and Disposition of Units from Prior Collections from Donors with Repeatedly Reactive Screening Tests for Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), and Human T-Lymphotropic Virus Type I (HTLV–I)'' dated July 1996. In addition, the guidance supersedes the memorandum to blood establishments entitled ''HTLV–I Antibody Testing, Memorandum'' dated November 1988; the memorandum to blood establishments entitled ''HTLV–I Antibody Testing, Memorandum'' dated July 1989; and the document entitled ''Guidance for Industry: Donor Screening for Antibodies to HTLV–II'' dated August 1997.

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 the use of serological tests to reduce the risk of transfusion-transmitted human T-lymphotropic virus types I and II. 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. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 601 and Form FDA 356h have been approved under OMB control number 0910–0338, and the collections of information in 21 CFR parts 610 and 606 have been approved under OMB control number 0910–0116.

## III. Electronic Access

Persons with access to the internet may obtain the guidance at either *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances* or *https://www.regulations.gov.*

Dated: February 3, 2020.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

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**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; Ending the HIV Epidemic (EHE), OMB No. 0906–xxxx—New

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

**ACTION:** Notice.

**SUMMARY:** In compliance with 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 March 9, 2020.

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

A 60-day notice was published in the **Federal Register** on October 15, 2019, vol. 84, No. 199; pp. 55163–64. There was one public comment.

**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:* Ending the HIV Epidemic (EHE) Triannual Module, 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 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/ethnic minorities. 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 with diagnosed HIV in the United States.

### Ending the HIV Epidemic: A Plan for America

In February 2019, the Administration announced a new initiative, *Ending the HIV Epidemic: A Plan for America* (EHE). Authorized by section 311(c) and title XXVI of the Public Health Service Act, this 10-year initiative beginning in FY 2020 seeks to achieve the important goal of reducing new HIV infections in the United States to fewer than 3,000 per year by 2030. EHE will focus on 48 counties, Washington, DC, San Juan, Puerto Rico, and 7 states that have a substantial rural HIV burden. By focusing on these jurisdictions in the first phase of the EHE, HHS plans to reduce new HIV infections by 75 percent within 5 years. Across the United States, the EHE will promote and implement four Pillars to substantially reduce HIV transmissions—diagnose, treat, prevent, and respond. EHE is a collaborative effort among key HHS agencies, primarily HRSA, the Centers for Disease Control and Prevention, the National Institutes of Health, the Indian Health Service, and the Substance Abuse and Mental Health Services Administration. RWHAP will focus on implementing activities in the *Pillar Two: Treat* and supporting *Pillar Four: Respond* for this important initiative.

HRSA identified proposed data collection needs to support HRSA's efforts toward ending the HIV epidemic. To reach this goal, HRSA needs to have the ability to monitor initiative activities including funding allocations, expenditures, service utilization, and clients served; and assess progress toward meeting national goals for ending the HIV epidemic. HRSA proposes that recipients and service providers (subrecipients) who receive EHE initiative funding report on the

reach of EHE initiative activities in a new EHE Triannual Module.

*Need and Proposed Use of the Information:* HRSA proposes that service providers who receive EHE Initiative funding report aggregate information on the number of clients receiving specific services and the number of clients who were prescribed antiretroviral medications in the previous four months (beginning in March 2020). This information would complement the annual information collected through the Ryan White Services Report (RSR) and other reporting mechanisms. Service providers will report three times per year on clients who received at least one service during the previous four month period.

This module will provide HRSA with frequent and timely data on EHE Initiative progress by providing information on the number of clients who are reached through the EHE Initiative during each four month reporting period. In addition, HRSA can calculate the number of clients who did not receive services in the previous year by subtracting the number of clients who received services in the previous year and the number of new clients from the total number of clients. This will provide valuable information on the scope of outreach to new clients and clients who have had a lapse in service which could be an indication of reengagement in care. These calculations will be similar to calculations using the new RSR variables. This module will support project officer monitoring and HRSA's understanding of service provision.

*Likely Respondents:* RWHAP Part A and Part B Recipients and Subrecipients funded by the EHE Initiative.

*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 |
|---|---|---|---|---|---|
| EHE Triannual Module | 47 | 3 | 141 | 1 | 141 |
| Total | 47 | | 141 | | 141 |

**Maria G. Button,**

*Director, Executive Secretariat.*

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**BILLING CODE 4165–15–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

### Notice of Establishment and Solicitation of Nominations for Tribal Advisory Council

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

**ACTION:** Establishment of HRSA Tribal Advisory Council and Request for Tribal Delegate Member Nominations.

**SUMMARY:** HRSA is soliciting comments and recommendations regarding HRSA's intent to establish the HRSA Tribal Advisory Council (TAC) and is seeking nominations of qualified tribal officials as candidates for consideration for appointment as voluntary delegate members of the HRSA TAC. The HRSA TAC will engage in regular and meaningful collaboration and consultation with tribal officials on policies that have tribal implications and a substantial direct effect on Indian tribes. The HRSA TAC will be the vehicle for acquiring a broad range of tribal views, determining the impact of HRSA programs on the American Indian/Alaska Native (AI/AN) health systems and population, developing innovative approaches to deliver health care and assisting with effective tribal consultations. HRSA is also seeking nominations of qualified candidates to fill up to 12 positions on the HRSA TAC; one authorized tribal representative (and one designated alternate) from each of the 12 Indian Health Service geographic areas.

**DATES:** Nominations for membership on the HRSA TAC must be received on or before May 7, 2020.

**ADDRESSES:** Written comments on the described intent to establish the HRSA TAC and nomination packages must be submitted to:

1. *Submission of comments on the intent to establish the HRSA TAC.* CAPT Elijah K. Martin, Jr., EdD, MPH, Manager, Tribal Health Affairs, Office of Health Equity (OHE), HRSA, 5600 Fishers Lane, Room 13N44, Rockville, Maryland 20857, ATTN: HRSA TAC Establishment.

2. *Submission of HRSA TAC nomination packages.* CAPT Elijah K. Martin, Jr., EdD, MPH, Manager, Tribal Health Affairs, OHE, HRSA, 5600 Fishers Lane, Room 13N44, Rockville, Maryland 20857, ATTN: HRSA TAC Nomination Package.

3. *Electronic submission of comments on the intent to establish the HRSA TAC: aianhealth@hrsa.gov,* SUBJECT: HRSA TAC Establishment.

4. *Electronic submission of HRSA TAC Nomination Packages: aianhealth@hrsa.gov,* SUBJECT: HRSA TAC Nomination Package.

**FOR FURTHER INFORMATION CONTACT:** CAPT Elijah K. Marin, Jr., EdD, MPH, Manager, using the contact information provided above, or Michelle Allender, RN, BSN, MS, Director, OHE, HRSA, 5600 Fishers Lane, Room 13N09, Rockville, Maryland 20857, or 301–443–7526.

A copy of the HRSA TAC charter and list of the membership, once established, may be obtained by submitting a written request to: *aianhealth@hrsa.gov.*

**SUPPLEMENTARY INFORMATION:** The HRSA TAC will be established to engage in regular and meaningful collaboration and consultation with tribal officials on policies that have tribal implications