

Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 809 have been approved under OMB control number 0910–0485. The collections of information in 21 CFR parts 50 and 56 have been approved under OMB control number 0910–0755. The collections of information in 21 CFR 56.115 have been approved under OMB control number 0910–0130. The collections of information in 21 CFR 50.23 have been approved under OMB control number 0910–0586. The collections of information in 21 CFR part 812 have been approved under OMB control number 0910–0078. The collections of information in 21 CFR part 820 have been approved under OMB control number 0910–0073. The collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014; and the collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001. The collections of information in the guidance document entitled “Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program” (available at <https://www.fda.gov/media/114034/download>) have been approved under OMB control number 0910–0756.

### III. Electronic Access

Persons with access to the internet may obtain the guidance at <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs>, <https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances>, <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products>, or <https://www.regulations.gov>.

Dated: October 4, 2019.

**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; Information Collection Request Title: Ryan White HIV/AIDS Program (RWHAP) Compilation of Best Practice Strategies and Interventions, OMB No. 0906–xxxx–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.

**DATES:** Comments on this ICR should be received no later than November 12, 2019.

**ADDRESSES:** Submit your comments, including the ICR Title, to the desk officer for HRSA, either by email to [OIRA\\_submission@omb.eop.gov](mailto: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 Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or call (301) 443–1984.

**SUPPLEMENTARY INFORMATION:**  
*Information Collection Request Title:* Ryan White HIV/AIDS Program (RWHAP) Compilation of Best Practice Strategies and Interventions, OMB No. 0906–xxxx–New

*Abstract:* HRSA’s 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 (PWH). 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 living with

HIV (PLWH)—more than 50 percent of all people living with diagnosed HIV in the United States. HRSA is developing a comprehensive, web-based compilation of RWHAP recipient and subrecipient best practice strategies and interventions. When completed, the online recipient compilation will be housed on TargetHIV.org (HRSA’s technical assistance site for recipients and subrecipients) and structured to allow programs to easily search and identify RWHAP best practice strategies and interventions for implementation. Recipients and subrecipients may voluntarily complete a submission form, also housed on TargetHIV.org, when they have a best practice strategy or intervention to share. Strategies and interventions that meet certain criteria will be incorporated into the online compilation.

The project team has developed a draft submission form and criteria for the types of strategies and interventions to be included in the compilation based on: (1) The quality and relevance of the approach to the RWHAP; (2) the level of feasibility, replicability, and sustainability; and (3) the quality of evidence that supports the approach’s results.

Specifically, this information collection request involves three forms of data collection as described below.

1. *Pre-Submission Screening Form:* Through extensive outreach, the project team expects up to 70 recipients and subrecipients to express interest in submission. They will be asked four screening questions to determine whether they are eligible for inclusion in the compilation.

2. *Submission Form:* Recipients and subrecipients that screen eligible will then complete a submission form describing their strategy or intervention, including service delivery model, target population, expected or achieved outcomes, and resource requirements. The project team will score the submissions based on the established criteria.

3. *Site Visit Discussion Guide:* The project team will conduct up to 30 site visits to test the criteria and gather feedback on the submission form and compilation. The half-day site visits will involve individual or small group discussions with program staff involved in implementation (e.g., program managers, direct service providers, and evaluators). The project team will then revise the submission form, criteria, and compilation template based on feedback.

A 60-day **Federal Register** Notice was published in the **Federal Register** on

June 19, 2019, vol. 84, No. 118; pp. 28561. There were no public comments.

**Need and Proposed Use of the Information:** The purpose of this data collection effort is for HRSA contractors to assess the review criteria being used to systematically identify and select RWHAP-funded best practice intervention strategies that demonstrate impact across the HIV care continuum for the online compilation.

Assessing the review criteria will allow HRSA to obtain important information from recipients and determine if the intervention strategies shared via the submission form are effective in improving outcomes across the HIV care continuum. Intervention strategies that meet the review criteria verified by HRSA contractors and approved by HRSA program staff through this data collection will be considered best practices and made available through the online

compilation for consideration, adaptation, and replication by other HIV programs. In addition, the best practices will support peer exchange to resolve problems impacting HIV care and treatment and eliminating disparities in health outcomes.

**Likely Respondents:** RWHAP recipients and subrecipients that voluntarily submit a best practice strategy or intervention will participate in the data collection. The project team expects that up to 70 recipients and subrecipients will complete the screening form and 50 will screen eligible and complete the full submission form. For the site visits, the project team will strategically select 30 sites from the universe of submitted eligible initiatives, ensuring a range of scores and representativeness of factors such as Census region, proposed strategy/intervention outcome, priority population, and the type of agency or

provider implementing the strategy or intervention.

**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
Pre-Submission Screening Form .....	70	1	70	0.08	5.60
Submission Form .....	50	1	50	3.00	150.00
Site Visit Discussion Guide .....	120	1	120	0.75	* 90.00
Program Manager Interview .....	30	1	30	1.50	45.00
Direct Service Provider Interview .....	60	1	60	0.50	30.00
Evaluator Interview .....	30	1	30	0.50	15.00
<b>Total .....</b>	<b>** 240</b>		<b>240</b>		<b>245.60</b>

\* For a total of 90 hours, each of the 30 site visits will include 1.5-hour interviews with a program manager (45 hours), up to two 0.5-hour interviews with direct service providers (30 hours), and an 0.5-hour interview with an evaluator (15 hours).\*

\*\* The total number of respondents is 240 as comprised by the number of respondents for the pre-submission screening form (70), the submission form (50), and the site visit discussion guide (120).

**Maria G. Button,**

Director, Division of the Executive Secretariat.

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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; Public Comment Request; Hospital Campaign for Organ Donation Scorecard, OMB No. 0915-0373, Revision

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

**ACTION:** Notice.

**SUMMARY:** In compliance with the Paperwork Reduction Act of 1995,

HRSA 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 November 12, 2019.

**ADDRESSES:** Submit your comments, including the ICR Title, to the desk officer for HRSA, either by email to [OIRA\\_submission@omb.eop.gov](mailto: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 Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or call (301) 443-1984.

#### SUPPLEMENTARY INFORMATION:

**Information Collection Request Title:** Hospital Campaign for Organ Donation Scorecard OMB No. 0915-0373, Revision

**Abstract:** HRSA's Hospital Campaign for Organ Donation enlists healthcare organizations nationwide to increase the number of registered organ, eye, and tissue donors by hosting education and donor registration events in their facilities and communities. A scorecard identifies activities that participants can implement and assigns points to each activity. Participants that earn a certain number of points annually are recognized by HRSA and the campaign's national partners.

For this information collection request, the proposed change to the Scorecard is the addition of the 2020 date. HRSA also intends to create a new electronic version of the Scorecard for future campaigns that will ultimately reduce the level of burden for