

ingredients under section 904(a)(1) as most of these submissions are expected to be for products subject to the deeming compliance period.

Based on FDA's experience and the actual number of product ingredient listings submitted over the past 3 years, FDA estimates that 35 establishments will each submit 2 reports (1 every 6 months). FDA also estimates that the confirmation or updating of product (ingredient) listing information required by section 904(c) of the FD&C Act is expected to take 0.40 hour (24 minutes) and will take 48 minutes annually for two confirmations or updates per establishment, for a total 28 burden hours. FDA estimates that obtaining a DUNS (data universal numbering system) number will take 30 minutes. FDA assumes that all new establishment facilities that will be required to initially register under section 905 of the FD&C Act would obtain a DUNS number. FDA estimates that up to 100 establishments would need to obtain this number each year. The total industry burden to obtain a DUNS number is 50 hours.

FDA estimates the total burden for this collection to be 830 hours. We have adjusted our burden estimate, which has resulted in a decrease of 93,086 hours to the currently approved burden. Based on data we reviewed from the past 3 years and projecting the number of remaining establishments that have not registered and submitted product ingredient listings, we revised the number of respondents and burden hours in this information collection.

Dated: May 9, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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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: HRSA Ryan White HIV/AIDS Program AIDS Education and Training Centers Evaluation Activities, OMB No. 0915-0281—Revision

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.

DATES: Comments on this ICR should be received no later than June 14, 2019.

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.

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: HRSA Ryan White HIV/AIDS Program AIDS Education and Training Centers Evaluation Activities: (OMB No. 0915-0281) Revision.

Abstract: The RWHAP AETC program, authorized by Title XXVI of the Public Health Service Act, supports a network of regional and national centers that conduct targeted, multidisciplinary education and training programs for health care providers serving people living with HIV (PLWH). The purpose of the RWHAP AETC program is to increase the size and strengthen the skills of the current and novice HIV clinical workforce in the United States and to develop and disseminate information on treatment and prevention of HIV to at-risk populations. Through the provision of specialized professional education and training, the RWHAP Regional AETCs aim to improve outcomes along the HIV care continuum including diagnosis, linkage, retention, and viral suppression and to reduce HIV incidence by improving the achievement and maintenance of viral load suppression of PLWH. In addition, the RWHAP AETC program includes the National Coordinating Resource Center (NCRC), which offers a virtual library of online training resources for adaptation by HIV care providers and other healthcare professionals to meet local training needs. The RWHAP AETC NCRC works closely with the HRSA HIV/AIDS Bureau (HAB) to coordinate cross-regional collaborative efforts, manage the NCRC website, plan and execute the national RWHAP Clinical

Conference, and develop an online curriculum for clinical learners.

The RWHAP AETC proposes several revisions to the Event Records (ER) and the Participant Information Form (PIF). The ER will have 11 new data elements; however, only 7 data elements will require responses from all respondents. The option to respond to the other four data elements will depend on how participants respond to previous questions. There are four data element deletions to the ER.

The PIF will have one new data element that asks whether respondents prescribe antiretroviral therapy to their patients. Two data elements were deleted. These revisions reflect changes in the National AETC program guidance on reporting sources of funding and multi-session events.

Despite a net increase of eight data elements across both the ER and PIF instruments, pilot respondents reported a decrease in burden. HRSA HAB modified the data instruments to help inform the evaluation of AETC outcomes, improve the logical flow of questions within each instrument and to improve the overall clarity of each of the questions being asked.

A 60-day **Federal Register** Notice was published in the **Federal Register** on December 18, 2018, vol. 83, No. 242; pp. 64845-47. There were no public comments.

Need and Proposed Use of the Information: As part of an ongoing effort to evaluate RWHAP AETC activities, information is needed on AETC training sessions, clinical consultations, and technical assistance activities. Each regional center collects information on RWHAP AETC training events and is required to report aggregate data on their activities to HRSA's HAB. The goal of national data collection efforts is to create a uniform set of data elements that will produce an accurate summary of the national scope of RWHAP AETC professional training, consultation, and events. The elements included in the national database have been selected for their relevance in demonstrating the RWHAP AETCs' efforts in achieving the program's stated goals: To improve care for PLWH by providing education, training, and clinical consultation; and to provide support to clinicians and other providers. HRSA HAB uses the data collected when conducting programmatic assessments and to determine future program needs. The national data elements are intended to be a meaningful core set of elements that individual RWHAP AETCs can use in programmatic and strategic planning. HRSA HAB also uses this information to

respond to requests from HHS, Congress, and others.

Likely Respondents: RWHAP AETC trainees are asked to complete the PIF either at the start or at conclusion of an event. Trainers are asked to complete an ER for each training event they conduct during the year. In addition, each regional RWHAP AETC (eight total) and the RWHAP AETC National Coordinating Resource Center will compile these data into a data set and submit to HRSA HAB once a year.

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.

The estimated annual response burden to trainers, as well as trainees of training programs is follows:

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Participant Information Form (PIF)	61,288	1	61,288	0.05	3,064
Event Record (ER)	10,522	1	10,522	0.13	1,368
Total	71,810		71,810		4,432

The estimated annual burden to RWHAP AETCs is as follows:

	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Aggregate Data Set	9	1	9	10	90

Amy P. McNulty,

Acting Director, Division of the Executive Secretariat.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria

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

ACTION: Notice.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) is hereby giving notice that a meeting is scheduled to be held for the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (Advisory Council). The meeting will be open to the public; a public comment session will be held during the meeting. Pre-registration is required for members of the public who wish to attend the meeting and who wish to participate in the public comment session. Individuals who wish to attend the meeting and/or send in their public comment via email

should send an email to CARB@hhs.gov. Registration information is available on the website <http://www.hhs.gov/ash/carb/> and must be completed by July 2, 2019; all in-person attendees must pre-register by this date. Additional information about registering for the meeting and providing public comment can be obtained at <http://www.hhs.gov/ash/carb/> on the Meetings page.

DATES: The meeting is scheduled to be held on July 10, 2019, from 9:00 a.m. to 5:00 p.m. and July 11, 2019, from 9:00 a.m. to 5:00 p.m. ET (times are tentative and subject to change). The confirmed times and agenda items for the meeting will be posted on the website for the Advisory Council at <http://www.hhs.gov/ash/carb/> when this information becomes available. Pre-registration for attending the meeting in person is required to be completed no later than July 2, 2019; public attendance at the meeting is limited to the available space.

ADDRESSES: Hilton McLean Tysons Corner, International Ballroom C, 7920 Jones Branch Dr., McLean, VA 22102.

The meeting can also be accessed through a live webcast and via teleconference on the day of the meeting. For more information, visit <http://www.hhs.gov/ash/carb/>.

FOR FURTHER INFORMATION CONTACT:

Jomana Musmar, Designated Federal Officer, Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria, Office of the Assistant Secretary for Health, U.S. Department of Health and Human Services, Room L133, Switzer Building, 330 C St. SW, Washington, DC 20201. Phone Number: (202) 795-7678. Email: CARB@hhs.gov.

SUPPLEMENTARY INFORMATION: Under Executive Order 13676, dated September 18, 2014, authority was given to the Secretary of HHS to establish the Advisory Council, in consultation with the Secretaries of Defense and Agriculture. Activities of the Advisory Council are governed by the provisions of Public Law 92-463, as amended (5 U.S.C. App.), which sets forth standards for the formation and use of federal advisory committees.

The Advisory Council will provide advice, information, and recommendations to the Secretary of HHS regarding programs and policies intended to support and evaluate the implementation of Executive Order 13676, including the National Strategy for Combating Antibiotic-Resistant Bacteria and the National Action Plan for Combating Antibiotic-Resistant Bacteria. The Advisory Council shall function solely for advisory purposes.