

is covered under already existing information collections. To avoid double counting, the agency has removed the burden which is approved under other FDA information collections. The burden for SEs are currently approved under OMB control number 0910-0673; the burden for PMTAs are currently approved under OMB control number 0910-0768; the burden for SE exemptions are currently

approved under OMB control number 0910-0684. FDA's estimates are based on actual report data from fiscal year (FY) 2015 to FY 2017, on average FDA estimated it received approximately 27 modified risk tobacco product applications (MRTPAs) from 27 respondents. Based on updated data for this collection, FDA estimates 27 EAs from 27 respondents. A total of 27 respondents will submit an average

of 1 application for environmental assessment. Based on FDA's experience, previous information provided by potential sponsors and knowledge that part of the EA information has already been produced in one of the tobacco product applications, FDA estimates that it takes approximately 80 hours to prepare an EA.

TABLE 5—ESTIMATED ANNUAL REPORTING BURDEN FOR TOBACCO PRODUCTS <sup>1</sup>

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
25.40(a) and (c) .....	27	1	27	80	2,160

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

The Estimated Annual Reporting Burden for Human Foods is no longer a part of this information collection. The burden has now been incorporated into OMB control number 0910-0541.

Our estimated burden for the information collection reflects an overall decrease of 10,566 hours (currently approved 231,224) and a corresponding decrease of 11,364 annual responses (currently approved 15,527). The new estimated totals are 220,658 hours and 4,163 annual responses. We attribute this adjustment to the removal of the majority tobacco burden from this collection, and the number of EA submissions we received since the last extension.

Dated: November 30, 2018.

**Leslie Kux,**

*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: Family-to-Family Health Information Center Feedback Surveys, OMB Number: 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 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 must be received no later than January 7, 2019.

**ADDRESSES:** Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N136B, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at (301) 443-1984.

**SUPPLEMENTARY INFORMATION:** When submitting comments or requesting information, please include the information request collection title for reference, in compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995.

*Information Collection Request Title:* Family-to-Family Health Information Center Feedback Surveys, *OMB Control Number:* 0906-xxxx-New.

*Abstract:* The Family-to-Family Health Information Center (F2F HIC) program is authorized by the Social Security Act, Title V, § 501(c) (42 U.S.C. 701(c)), as amended by § 50501 of the Bipartisan Budget Act of 2018 (Pub. L. 115-123). The goal of the F2F HIC program is to promote optimal health for children and youth with special health care needs (CYSHCN) by facilitating their access to an effective health delivery system and by meeting the health information and support needs of families of CYSHCN and the

professionals who serve them. F2F HICs are staffed by families of CYSHCN who have first-hand knowledge using health care services and programs. With this experience, these staff are uniquely positioned to provide support to other CYSHCN families and help other families like theirs navigate an often complex and confusing health care and social service system. They also serve as mentors and as a reliable source of health care information to other families.

During Fiscal Years (FY) 2003 to 2017, HRSA's Maternal and Child Health Bureau (MCHB) awarded approximately \$4.9 million per FY in grants to support 51 F2F HICs in each of the 50 states and the District of Columbia. In FY 2017, 49 centers that reported data served and trained over 184,000 families and approximately 85,500 health professionals. For FYs 2018 and 2019, HRSA MCHB will award approximately \$6 million per FY to support 59 F2F HICs: One each in the 50 states and the District of Columbia, 1 each in the 5 U.S. Territories (American Samoa, Guam, Puerto Rico, the Northern Mariana Islands and the U.S. Virgin Islands), and 3 to serve American Indians/Alaska Natives.

HRSA has developed feedback surveys to determine the extent to which F2F HICs provide service to families of CYSHCN and health professionals who serve such families. Each F2F HIC will administer the surveys and report data back to HRSA. Survey respondents will be asked to answer questions about how useful they found the information, assistance, or resources received from the F2F HICs. The purpose of this notice is to solicit comments regarding the proposed feedback surveys and the F2F HIC grant recipient activity instructions form.

**Need and Proposed Use of the Information:** Data from the feedback surveys will provide mechanisms to capture consistent performance data from F2F HIC grant recipients. The data will also allow F2F HICs to evaluate the effectiveness of their interventions and improve services provided to families and the providers who serve CYSHCN families.

**Likely Respondents:** Likely respondents are users of F2F HIC

services, which include family members of CYSHCN and health professionals who serve such families.

**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; to process and maintain information; to disclose and provide information; to train personnel 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
F2F HIC Feedback Survey .....	1,147	1	1,147	0.15	172
F2F HIC Grant Recipient Activity .....	59	1	59	89	5,251
Total .....	1,206	.....	1,206	.....	5,423

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.

**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 HIV/AIDS

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

**ACTION:** Notice.

**SUMMARY:** As stipulated by the Federal Advisory Committee Act, the U.S. Department of Health and Human Service is hereby giving notice that the Presidential Advisory Council on HIV/AIDS (PACHA or the Council) will be holding a meeting and will discuss recommendations regarding programs, policies, and research to promote effective, prevention, treatment and cure of HIV disease and AIDS. The meeting will be open to the public.

**DATES:** The Council meeting is scheduled to convene on March 14–15, 2019 from 9:00 a.m. to approximately 5:00 p.m. (ET) on March 14 and from 9:00 a.m. to 1:00 p.m. (ET) on March 15. Please note that on March 14, the meeting will include a closed session from 9:00 a.m. to 12:00 p.m. This portion of the meeting will be closed for administrative briefings to be presented to the new Council members. The meeting will be open to the public from 1:00 p.m. to 5:00 p.m. on March 14 and from 9:00 a.m.–1:00 p.m. (ET) on March 15.

**ADDRESSES:** 200 Independence Avenue SW, Washington, DC 20201 in the Penthouse (eighth floor), Room 800.

**FOR FURTHER INFORMATION CONTACT:** Ms. Caroline Talev, Public Health Analyst, Presidential Advisory Council on HIV/AIDS, 330 C Street SW, Room L106B, Washington, DC 20024; (202) 795-7622 or [Caroline.Talev@hhs.gov](mailto:Caroline.Talev@hhs.gov). More detailed information about PACHA can be obtained by accessing the Council's page on the [HIV.gov](http://www.hiv.gov) site at [www.hiv.gov/pacha](http://www.hiv.gov/pacha).

**SUPPLEMENTARY INFORMATION:** PACHA was established by Executive Order 12963, dated June 14, 1995, as amended by Executive Order 13009, dated June 14, 1996 and is currently operating under the authority given in Executive Order 13811, dated September 29, 2017. The Council was established to provide advice, information, and recommendations to the Secretary regarding programs and policies intended to promote effective prevention and care of HIV infection and AIDS. The functions of the Council are solely advisory in nature.

The Council consists of not more than 25 members. Council members are selected from prominent community leaders with particular expertise in, or knowledge of, matters concerning HIV and AIDS, public health, global health, philanthropy, marketing or business, as well as other national leaders held in high esteem from other sectors of society. Council members are appointed by the Secretary or designee, in consultation with the White House. The agenda for the upcoming meeting will be posted on the [HIV.gov](http://www.hiv.gov) website at <https://www.hiv.gov/federal-response/pacha/about-pacha>.

Public attendance at the meeting is limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify Caroline Talev at [Caroline.Talev@hhs.gov](mailto:Caroline.Talev@hhs.gov). Due to space constraints, pre-registration for public attendance is advisable and can be accomplished by contacting Caroline Talev at [Caroline.Talev@hhs.gov](mailto:Caroline.Talev@hhs.gov) by close of business on Thursday, March 7, 2019. Members of the public will have the opportunity to provide comments during the meeting. Comments will be limited to two minutes per speaker. Any individual who wishes to participate in the public comment session must register with Caroline Talev at [Caroline.Talev@hhs.gov](mailto:Caroline.Talev@hhs.gov) by close of business on Thursday, March 7, 2019; registration for public comment will not be accepted by telephone. Individuals are encouraged to provide a written statement of any public comment(s) for accurate minute taking purposes. Public comment will be limited to two minutes per speaker. Any members of the public