

The collection of information for FDA adverse event reporting and electronic submissions using the Electronic Submission Gateway and the Safety Reporting Portal has been approved under OMB control number 0910-0645.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, <https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm>, or <https://www.regulations.gov>.

Dated: October 24, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS-0990-0221]

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 November 29, 2019.

ADDRESSES: Submit your comments to OIRA_submission@omb.eop.gov or via facsimile to (202) 395-5806.

FOR FURTHER INFORMATION CONTACT: Sherrette Funn, Sherrette.Funn@hhs.gov or (202) 795-7714. When submitting comments or requesting information, please include the document identifier 0990-New-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 (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: Family Planning Annual Report (FPAR).

Type of Collection: Renewal with change.

OMB No.: 0990-0221.

Abstract: The Office of Population Affairs within the Office of the Assistant Secretary for Health is requesting an extension on a currently approved Family Planning Annual Report (FPAR) data collection and reporting tool (OMB No. 0990-0221). This annual reporting requirement is for family planning services delivery projects authorized and funded by the Title X Family Planning Program ["Population Research and Voluntary Family Planning Programs" (Pub. L. 91-572)], which was enacted in 1970 as Title X of

the Public Health Service Act (Section 1001; 42 U.S.C. 300). The FPAR data collection and reporting tool will include a new module to collect substance use disorder (SUD) screening data in this request to extend an OMB approval to collect essential, annual data from Title X grantees.

Need and Proposed Use of the Information

The Title X Family Planning Program ("Title X program" or "program") is the only Federal grant program dedicated solely to providing individuals with comprehensive family planning and related preventive health services (e.g., screening for breast and cervical cancer, sexually transmitted diseases (STDs), and human immunodeficiency virus). By law, priority is given to persons from low-income families (Section 1006(c) of Title X of the Public Health Service Act, 42 U.S.C. 300). The Office of Population Affairs (OPA) within the Office of the Assistant Secretary for Health administers the Title X program.

Likely Respondents: Respondents for this annual reporting requirement are centers that receive funding directly from OPA for family planning services authorized and funded under the Title X Family

This weighted average hour burden accounts for differences in reporting burden by type of grantee agency grantee (e.g., public health department or private agency), as found in the 2009 FPAR Burden Study. For purposes of this estimate, the average hour burden ranges between 39 hours (public health department) and 32 hours (private agency).

ANNUALIZED BURDEN HOUR TABLE

Type of respondents	Form name	Number of respondents	Number of responses per respondents	Average annualized burden per response (hours)	Annualized total burden (hours)
Grantees	FPAR	93	1	36	3,348
Total	93	1	36	3,348

Terry Clark,

Office of the Secretary, Asst Paperwork Reduction Act Reports Clearance Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as

amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material,