Supporting Statement

Family Planning Annual Report 2.0

Submitted to

Office of Management and Budget
Office of Information and Regulatory Affairs

Submitted by

Department of Health and Human Services
Office of the Assistant Secretary for Health
Office of Population Affairs
POC: Jamie Kim

Jamie.Kim@hhs.gov

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A. JUSTIFICATION

This is a request for Office of Management and Budget (OMB) approval for a new encounter level data collection for the Family Planning Annual Report (FPAR). This builds on the existing OMB approved FPAR collection (OMB No. 0990-0221, expiration January 31, 2023), but with a higher level of detail and information. 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" (Public Law 91-572)], which was enacted in 1970 as Title X of the Public Health Service Act (Section 1001 of Title X of the Public Health Service Act, 42 United States Code [USC] 300).[1]

The HHS Office of Population Affairs' Title X Family Planning Program is the only federal grant program dedicated solely to providing individuals with comprehensive family planning and related preventive health services. The program's purpose is to assist individuals in determining the number and spacing of their children, thereby contributing to positive birth outcomes and healthy families. The program is designed to provide access to contraceptive services, supplies, and information to all who want and need them. By law, priority is given to persons from low-income families (Section 1006[c] of Title X of the Public Health Service Act, 42 USC 300). [2]

In fiscal year 2019, the Title X program received approximately $286.5 million in federal Title X funding. In accordance with the statute and regulations (42 Code of Federal Regulations [CFR] Part 59), [3] at least 90% of the appropriation is used for clinical family planning services. [2] Annually, the Title X program helps women and couples to avoid one million unintended pregnancies that would otherwise result in an estimated? 501,000 unplanned births and 345,000 abortions.[4] In 2019, Title X-funded providers served approximately 3.1 million family planning users (i.e. clients) through 4.7 million family planning encounters. There is at least one clinic that receives Title X funds and provides services as required under the Title X statute in 64% of U.S. counties.[5]

Attachment A to this statement contains a copy of the authorizing Title X program regulations that necessitate the collection of the information; **Attachment B** is a copy of the current version of the *Title X Family Planning Annual Report 2.0 Encounter Data Elements.* **Attachment C** is a copy of the *60-Day Federal Register Notice;* **Attachment D** is a copy of the *2019 Family Planning Annual Report National Summary.*

1.   Circumstances Making the Collection of Information Necessary
Annual submission of the FPAR is required of all Title X Family Planning Services grantees for purposes of monitoring and reporting program performance (45 CFR Part 74 and 45 CFR Part 92).[6-8] OPA is transitioning to a new data collection and reporting system for the Title X program, called FPAR 2.0. The FPAR 2.0 data collection builds on data already reported in FPAR 1.0 and adds additional detail that will allow OPA to report to HHS leadership and Congress more completely on the services provided by Title X grantees in their communities. Currently, aggregate level data collection in FPAR 1.0 limits analyses primarily to descriptive

analytics that are of limited utility. Encounter level data collection will allow for richer and more detailed analysis. Several of the new data elements are related to clinical quality measures only recently developed and endorsed (in 2016) or OPA/CDC developed Quality Family Planning guidelines (first released in 2014). Under FPAR 2.0, grantees will report fine-grained information on individual encounters between a client and a Title X provider. This detailed information will enable OPA to more closely monitor grantees' performance, service provision, and compliance with legislative mandates.

2.   Purpose and Use of Information Collection

The FPAR is the only source of annual, uniform reporting by all grantees ("Title X services grantees") funded under Section 1001 of the Title X Public Health Service Act.[1] The new FPAR 2.0 system will provide consistent, national-level data on the Title X Family Planning program and its users. OPA will be able to assemble and analyze comparable and relevant program data to answer questions about the characteristics of the population served, the provision and use of services, and the impact of the program on certain family planning outcomes. FPAR 2.0 will collect a standard set of data elements pertaining to users and encounters, such as user demographics, service delivery, family planning intentions and methods, and other indicators. Under the previous FPAR, aggregate measures resulted in valid and reliable estimates of key indicators that allowed for comparisons over time at multiple levels of the program (e.g., national, regional, state, and grantee). Encounter level data collected through FPAR 2.0 will ultimately improve the quality of data reported to OPA and reduce reporting burden for grantees. The new system will automate procedures currently done manually, such as tabulating and checking basic counts of clients served and types of services provided. Additionally, the more granular data collected with FPAR 2.0 will help contribute to a learning healthcare environment by greatly expanding the options for data analysis and reporting—for example, through interactive data dashboards and visualizations, customized tabulations and reports, and application of analytics and statistical analyses on the encounter-level data files.

Information from FPAR 2.0 is important to OPA for several reasons. First, OPA will use FPAR 2.0 data to monitor program compliance with statutory requirements, regulations, and operational guidance set forth in the Title X Family Planning Guidelines, consisting of the *Program Requirements for Title X Funded Family Planning Projects (Title X Requirements)* and the clinical recommendations as outlined in *Providing Quality Family Planning* Services *(QFP)*,[9,10] which include the following:

- Monitoring compliance with legislative mandates, such as giving priority in the provision of services to low-income persons (Section 1006[c] of Title X of the Public Health Service Act, 42 USC 300)[2]

- Ensuring that Title X services grantees and their subcontractors provide a broad range of family planning methods and services (Section 1001[a] of Title X of the Public Health Service Act, 42 USC 300)[1]

Second, OPA will use FPAR 2.0 data to meet accountability and federal performance requirements for Title X family planning funds as required by the 1993 Government Performance and Results Act. Performance goals for the Title X Family Planning program (see **Exhibit 1**) include giving priority in the provision of family planning services to low-income individuals, reducing invasive cervical cancer through Pap testing, reducing infertility

through chlamydia screening, and increasing program efficiency by monitoring the cost of care.

Exhibit 1–Goals for the Title X Family Planning Program

Goal II.A.1 — Decrease the total number of unduplicated clients served in Title X clinics. (Outcome)
Goal II.A.2 — Maintain the proportion of clients served who are at or below 200% of the federal poverty level at 90% of total unduplicated family planning users. (Outcome)
Goal II.A.3 — Increase the number of unintended pregnancies averted by providing Title X family planning services, with priority for services to low-income individuals. (Outcome)
Goal II.B.1 — Reduce infertility among women attending Title X family planning clinics by identifying chlamydia infection through screening of females ages 15 to 24 years. (Outcome)
Goal II.C.3 — Increase the proportion of females ages 15 to 24 attending Title X family planning clinics screened for chlamydia infection.
Efficiency — Maintain the actual cost per Title X client below the medical care inflation rate.

Third, OPA will rely on FPAR 2.0 data to guide strategic and financial planning, respond to inquiries from policymakers and Congress about the program, and estimate program impact. FPAR 2.0 data will also provide needed context for objective grant reviews, comprehensive program reviews and evaluation, and assessment of program technical needs. Ultimately, the data will be used for continuous quality improvement at both the program and grantee level to ensure the best quality care is delivered to clients.

FPAR Structure and Content

FPAR 2.0 data will include: 1) encounter data, 2) a grantee profile cover sheet, 3) a project revenue report, and 4) utilization of family planning clinical services providers report. These will provide OPA with information on the characteristics of the Title X service network and the individuals (family planning "users" or "clients") who receive Title X services, including information on clients' contraceptive use and receipt of related preventive health services. Below, we describe each FPAR 2.0 component and present OPA's justification for collecting the data. In addition, we explain how OPA will use the data and present illustrative questions, including those that also address HP2030 health objectives, which OPA can answer with the data.

Encounter-level Data

In this section, we describe the data elements reflected in the user encounter data (Attachment B).

- User demographic data, including age, sex, ethnicity, and race, allows OPA to monitor access to and use of Title X services among the diverse populations these projects serve.

- In order to better measure and assess care delivered to lesbian, gay, bisexual, and transgender (LGBT) clients, OPA is adding the collection of sexual orientation or gender identity (SO/GI) data elements to FPAR 2.0. Including the collection of this information is essential to providing high-quality, patient centered care and is recommended by the National Academy of Medicine, the Joint Commission[19], and is included in other federal data collections including the Health Resources and Services Administration's Uniform Data System (OMB 0915-0193; expiration date 02/28/2023).

These data permit OPA to answer such questions as:

- How does the age composition of users compare across regions, states, and grantees?

- What is the ethnic or racial composition of female and male clients served by Title X-funded service sites?

- What is the ethnic or racial composition of Title X clients who do not self-identify with one or more of the five minimum OMB race categories? [1]

- How do user ethnic and racial composition compare across regions, states, and grantees?

- Are we providing client-centered care?

User economic and social data will allow OPA to monitor the Title X program's role in supporting the health care safety net for vulnerable individuals who confront financial, social, or cultural barriers to care due to low income, lack of health insurance, or limited English proficiency (LEP). The data that will be collected to monitor these barriers are:

User Income reported by grantees allow OPA to monitor use of services by low-income individuals, assess compliance with the statutory requirements and regulations regarding priority in the provision of care to low-income persons, and guide funding allocation across regions and grantees. By federal statute (Section 1006[c] of Title X of the Public Health Service Act, 42 USC 300),[2] programs that receive Title X funding are required to give priority to persons from low-income families, defined as individuals with family incomes of 100% or less of the HHS poverty guidelines ("poverty level"). Program regulations (42 CFR Part 59)[3] further specify that persons from low-income families must receive services at no charge, unless a third-party source (e.g., Medicaid, other public or private health insurance) is authorized or obligated to pay the charge, and that Title X service providers must develop and apply a schedule of discounts based on ability to pay for persons with family incomes between 101% and 250% of the poverty level. In 2017, 90% (3.6 million) of users had family incomes that qualified them for either subsidized or no-charge services. The data collected will permit OPA to answer such questions as:

- What percentage of Title X clients has family incomes at or below 200% of the poverty level?

- What percentage of Title X clients has family incomes at or below 100% the poverty level, thereby qualifying them for services at no charge?

- What percentage of Title X clients has family incomes between 101% and 250% of the poverty level, thereby qualifying them for services on a sliding fee scale?

User's Principal Health Insurance Coverage Status is a key indicator of health care access. Insured individuals are more likely than those without insurance to have a usual source of medical care and to receive timely, recommended, and needed health care. [12,13] Uninsured individuals who are also low income are even more vulnerable to experiencing health care access barriers and are especially dependent on safety net providers like Title X-funded sites. In 2019, 58% (1.8 million) of family planning users had either public (38%, 1.2 million) or private (20%, 607,961) insurance covering broad primary medical care benefits; 41% (1.3 million) were uninsured. Health insurance coverage status was unknown or not reported for 1% (45,684) of users. In addition to serving as an indicator of health care access, health insurance status has important implications for project financing and sustainability. Coupled with reductions in funding, Title X-funded service providers continue to experience the financial strain of providing a broad range of family planning services to a predominantly low-income and uninsured client base. Identifying clients with health insurance allows providers to seek third-party payment for the full cost of care in accordance with program regulations. The demand for free and subsidized Title X-funded services persists among individuals who remain uninsured after Patient Protection and Affordable Care Act (ACA) implementation because they are exempt, not eligible, view coverage as unaffordable, or live in a state that has chosen not to expand Medicaid. [14,15] OPA and service providers will collect data to assess patterns and trends in clients' health insurance status, monitor the impact of ACA implementation on Title X providers at the state and national levels, and identify opportunities and technical assistance needs among grantees and subrecipients. The data collected will permit OPA to answer such questions as:

- What percentage of family planning users is insured (i.e., has public or private health insurance covering broad primary medical care)?

- What percentage of family planning users is uninsured (i.e., has no public or private health insurance covering broad primary medical care) (HP2030 AHS–1)?

Limited English Proficiency (LEP) of the client is reported by grantees in compliance with Title VI of the 1964 Civil Rights Act and Title VI regulations[16] that require Title X service providers to ensure meaningful access to LEP clients who seek Title X-funded services. In the Title X setting, LEP users are those clients who do not speak English as their primary language and who have a limited ability to read, write, speak, or understand English. Because of their limited English proficiency, LEP users derive little benefit from Title X family planning services and information provided in English. The federal guidance[16] in addressing the needs of LEP individuals who seek HHS-funded services lists four factors that are the basis for evaluating compliance: (1) the number or proportion of LEP persons eligible to be served or likely to be encountered by the program or grantee, (2) the frequency with which LEP individuals come in contact with the program, (3) the nature and importance of the recipient program activity or service, and (4) the resources available to the recipient and the cost of implementing language assistance measures. The LEP reporting requirement requires that Title X–funded agencies establish mechanisms for identifying and counting LEP individuals, thereby generating the data needed to assess language assistance needs and the adequacy of language assistance plans. OPA uses LEP data to assess the program's compliance with regulations related to ensuring meaningful access to clients who have limited English proficiency and identify grantee technical

assistance needs in the area of language assistance. The data collected will permit OPA to answer the question:

- What percentage of Title X users report LEP and are best served in a language other than English?

Family planning method use (by sex and age) reported by grantees allow OPA to assess patterns and trends in female and male contraceptive method use over time, monitor the program's contribution to Healthy People objectives for family planning and disease prevention, monitor the availability and use of newer FDA–approved contraceptive technologies, and compare the program's contraceptive method-mix with nationally representative data sources (e.g., National Survey of Family Growth). The types of contraceptive methods (i.e., most effective) that providers offer may vary in terms of supply costs and service delivery requirements, thereby affecting overall project costs. Title X projects are required to provide a broad range of acceptable and effective, medically approved family planning methods (Section 1001[a] of Title X of the Public Health Service Act, 42 USC 300 and 42 CFR Part 59).[1,3] The data collected permit OPA to monitor project financial concerns that may result from contraceptive supply issues and permit OPA to answer questions such as:

- What are the patterns of contraceptive use (i.e., "method mix") by method type or age group for female and male users?

- What percentage of female clients use contraception? What percentage of female clients rely on moderately and highly effective family planning methods?

- What percentage of female clients are pregnant or seeking pregnancy?

- What percentage of female and male clients aged 15 to 19 use condoms as their primary contraceptive method (HP2030 FP–05 and FP–06)?

Use of related preventive health services data are reported by grantees as required by Title X regulation [42 CFR 59].[3] This includes the number of cervical cancer screenings, and referrals (female users only), tests for STDs—for example, chlamydia, gonorrhea, syphilis, and HIV. OPA monitors these data for the program's implementation of early detection and prevention of cancers, efforts to reduce infertility through chlamydia screening, adoption and adherence to changing screening guidelines, and contribution to Healthy People 2030 objectives for cancer detection and STD prevention, as well as delivery of the number of positive STD tests. The data collected permit OPA to answer such questions as:

- How many female users received a Pap test (HP2030 C–09)?

- Of the total number of Pap tests performed, what percentage were abnormal and requires further follow-up?

- What percentage of female users less than 25 years of age were tested for chlamydia (HP2030 STD–01 and STD–07)?

- How many gonorrhea and syphilis tests were performed?

- How many anonymous HIV tests were performed?

- How many confidential HIV tests were positive?

Number of family planning encounters by provider type (i.e., physicians, physician assistants, nurse practitioners, certified nurse midwives, and registered nurses with an expanded scope of practice) are reported by grantees to help OPA monitor patterns and trends in service utilization and to respond to frequently asked questions about the types of clinical services providers (CSPs) that deliver Title X-funded care. The data collected permit OPA to answer such questions as:

- What percentage of family planning encounters do CSPs deliver? What percentage of encounters do other service providers deliver?

Grantee Profile Cover Sheet

The Grantee Profile Cover Sheet identifies the grantee organization, person(s) responsible for overseeing the Title X grant and preparation of the report, and the time period covered by the report. The cover sheet also collects information on the number of Title X subrecipients and service delivery sites supported by the grant. This information will be automatically populated in the Grantee Profile Cover Sheet based on previous information provided by the grantee to OPA. If there is an error in the pre-populated fields, the grantee may enter the corrected information in the Grantee Profile Cover Sheet "Note" field and notify the program officer (PO) that key grant information has changed.

Project Revenue

Project revenue (i.e., actual cash receipts or drawdown amounts) is reported by grantees during the reporting period from each funding source to support activities within the scope of the grantee's approved Title X services grant, even if the funds are not expended during the reporting period. Title X Family Planning Services grantees are required to maintain a financial management system that meets the standards for administering grants, as specified in 45 CFR Part 74[6] and 45 CFR Part 92,[7] as well as document and keep records of all income and expenditures. OPA will use the revenue data to monitor patterns and trends in the amount of Title X project revenue from all sources and at all program levels. OPA is requesting no changes to the project revenue report. The data collected will permit OPA to answer such questions as the following:

- What is the composition of revenue, by source, reported by Title X family planning projects (e.g., Title X, Medicaid, private third-party, state or local government, state block grants, or patient payments)?

- What percentage of total project revenue is from public or private third-party sources?

Utilization of Family Planning Clinical Services Providers

Grantees report data on the composition (full-time equivalents [FTEs]) of clinical provider staffing (i.e., physicians, physician assistants, nurse practitioners, certified nurse midwives, and registered nurses with an expanded scope of practice). In conjunction with information about family planning encounters by provider type collected in the encounter data, OPA will be able to monitor patterns and trends in the number and composition of clinical services provider staffing and provider efficiency. OPA is no longer requesting data on number of family planning encounters by type of program staff in this section, since it would duplicate information provided in the encounter data. The data collected permit OPA to answer such questions as:

- What is the composition of CSP staff?
- What is the ratio of mid-level CSP FTEs to physician FTEs?
- How many family planning encounters with a CSP are there per CSP FTE?

3.   Use of Improved Information Technology (IT) and Burden Reduction

To minimize reporting burden, OPA collects only the minimum information needed to monitor compliance with statutory and regulatory requirements and to manage the Title X program. In addition, OPA encourages and supports several efforts to improve the efficiency and ease with which grantees compile, tabulate, and report FPAR data.

One such effort is OPA's support of a standalone website to replace the existing FPAR reporting module website. In late 2020, OPA awarded a 5-year contract for the design and operation of the new website. The new *FPAR 2.0 Data System* (URL TBD) dedicated solely to collecting and managing FPAR data, will open in January 2023 to HHS/OPA staff and grantees for submission of 2022 FPAR data. Similar to the current *FPAR Data System, FPAR 2.0* will have several features to ease FPAR reporting, including a user-friendly interface; streamlined navigation; forms that pre-populate with grant identifying information to reduce data input and increase accuracy; a Helpdesk accessed by toll-free phone or e-mail; online reference materials for grantees; and extensive technical assistance to help grantees transition to the new system (e.g., training webinars, frequently asked questions [FAQ] briefs, and video-based trainings).

Reporting encounter-level data will reduce administrative burden on OPA and Title X grantees and enable them to automate procedures currently done manually, such as tabulating and checking basic counts of clients served and types of services provided. It also expands the options for data analysis and reporting—for example, through interactive data dashboards and visualizations, customized tabulations and reports, and application of analytics and statistical analyses on the encounter-level data files.

Furthermore, the *FPAR 2.0 Data System* will allow grantees to validate their encounter-level data using a range of automated validation checks. The *FPAR* 2.0 *Data System* will also prevent grantees from submitting a final report that includes tables with unresolved validation issues. The electronic validation feature and the system's rules regarding submission of a final FPAR reduce the time burden for grantees, HHS/OPA staff, and the FPAR contractor associated with identifying and resolving inconsistencies in the reported data.

For HHS/OPA staff that review and approve each FPAR, the *FPAR 2.0 Data System* will offer automated features to streamline FPAR review and approval, including automated e-mails to inform the grantee or OPA about specific actions taken on an FPAR (e.g., submission, acceptance/approval, request for revision) and an *FPAR Submission Status Report* that shows total and region-specific information on the submission status of all FPARs on any selected day. In addition, the *FPAR 2.0 Data System will* provide a user administration page where HHS/OPA staff manage (i.e., register, approve, and disable) all system user accounts.

4.   Efforts to Identify Duplication and Use of Similar Information

As noted in Section A.2, FPAR 2.0 will be the only source of annual, uniform reporting by all Title X Family Planning Services grantees. The information requested in FPAR 2.0 is unique to the Title X Family Planning program and is unavailable from other sources. Furthermore,

FPAR 2.0 does not duplicate items from other OPA data collection efforts for this program. In the absence of FPAR 2.0 data, there is no other source or mechanism for collecting timely and uniform data that OPA relies on to guide program policies, priorities, decisions, and strategies.

While the federally-funded National Survey of Family Growth (NSFG) is an important source of detailed information about family planning and reproductive health knowledge, attitudes, and behaviors among reproductive-aged individuals in the United States, the survey is designed to be representative of the reproductive-aged population (15 to 44 years) nationally and is not representative of Title X clients. Due to the survey's design, the NSFG is an inappropriate data source for monitoring and managing the Title X Family Planning program because NSFG data cannot be used to generate reliable estimates of Title X service utilization patterns, client demographic characteristics, or client contraceptive behaviors.

5.   Impact on Small Businesses or Other Small Entities

No small business will be impacted in this study.

6.   Consequences of Not Collecting the Information or Less Frequent Collection

Title X services grantees are required to complete and submit the FPAR on an annual basis. OPA uses FPAR data for key management tasks such as monitoring compliance with statutory requirements, allocating funds among grantees, determining grantee eligibility for continued funding, and strategic program and financial planning. Less frequent collection of FPAR data would severely hamper OPA's ability to manage the Title X Family Planning grant program and adjust changes in funding or other factors in a timely manner.

7.   Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

The proposed data collection is consistent with guidelines set forth in 5 CFR 1320.5.

8.   Comments in Response to the Federal Register Notice/Outside Consultation

Comments in Response to the Federal Register Notice.

A 60-day Federal Register Notice was published in the *Federal Register* on 2/11/2021 and closed on 4/12/2021(86 FR 9077). 25 organizations and individuals submitted comments. Submitters included current Title X grantees, former grantees, and other interested parties. The majority of comments submitted followed a template and were organized around the following themes:

Data collection/elements that are inappropriate or in excess of what is needed to manage the Title X grant program, data privacy, implementation burden, resource constraints, and outdated burden estimate.

OPA appreciates the interest and concern of all submissions. In response, OPA has communicated and clarified the following in grantee webinars (3/16/21 and 5/27/21), grantee listserv messages (5/7/21 and 5/11/21) and will continue to communicate with grantees through listserv messages, website updates, and webinars.

- Regarding data collection/elements in excess of what is needed to manage the Title X grant program:

- FPAR 2.0 data collection will not drive the clinical encounter, i.e. not all elements are required to be collected at every encounter. Only those elements needed for the encounter should be recorded.
- FPAR 2.0 builds on the FPAR 1.0 data elements and include elements related to the Quality Family Planning Guidance (OPA/CDC 2014, 2015, 2017) and modified versions of the National Quality Forum endorsed contraceptive care measures.
- Sexual history questions were deleted as they are no longer needed for the developmental contraceptive care electronic clinical quality measure specifications.
- Alternative reporting guidance for lab values is being developed
- Regarding data privacy:
  - OPA has consulted the HHS Privacy Officer and a SORN will not be required. During the EPLC/ATO process, OPA will complete necessary documentation and follow all applicable HHS and federal regulations.
- Regarding implementation burden/resource constraints:
  - OPA is providing a three-year alternate reporting pathway for grantees
    - With OPA approval, grantees can continue reporting FPAR 1.0, at the site level in the first year.
    - Additional details will be provided for the second and third years, but will provide a stepwise process to full implementation
    - OPA will work with those grantees who continue to have technical challenges through technical assistance providers
  - A non-competitive grant supplement of $160,000 was awarded to all grantees early 2021 to assist with implementation burden
  - It was announced on the 5/27/21 grantee webinar that an additional amount worth an estimated 6-7% of total grant funding will be awarded to all grantees by the end of FY21 to further assist with implementation
  - TA documentation is being developed in response to OMB comments and grantee feedback.
  - The FPAR 2.0 data system is being developed through a human-centered design approach incorporating feedback from federal staff and grantees.
- Regarding outdated burden estimate:
  - OPA revised the burden estimate based on comments received from the National Family Planning and Reproductive Health Association. They report estimates based on a NFPRHA administered survey of 40 Title X respondents. Revisions were made to section 12.

Outside Consultation. Outside consultation was conducted from 2011 – 2020 in preparation for the 2021 FPAR 2.0 OMB change request.

Exhibit 2–List of Individuals that Provided Extensive Review and Feedback on FPAR 2.0

Year	Name/Title/Affiliation
2020 - 2021	Mathematica – contracted to OPA
2020 - 2021	Family Planning National Training Center (run by JSI, INC) – grantee of OPA
2012 - 2021	HHS Office of Population Affairs
2016 - 2021	American College of Obstetricians and Gynecologists – contracted to OPA
2012 - 2021	Title X Grantees – expert work groups and surveys

In addition, OPA asked regional HHS staff that oversees grantee Title X projects and interacts with grantees on FPAR reporting issues, to share any known problems and issues with the current forms and instructions, as well as suggest ways to resolve any unclear wording that might reduce data quality or add burden.

9. Explanation of Any Payment/Gift to Respondents

No payments or gifts will be provided to respondents.

10. Assurance of Confidentiality Provided to Respondents

Per 42 CFR Part 593, while personally identifiable information (PII) will be collected about clients, the PII will not include client names or other direct personal identifiers; consequently, the data will not constitute Privacy Act records. FPAR 2.0 will not be used to attempt to identify particular clients, but only to study clients' characteristics at an aggregate level. The PII about a particular client will include a unique identifying number for data integrity purposes to ensure the system does not double-count individuals when compiling aggregate data covering more than one encounter. The unique identifying number will not be a direct personal identifier and cannot be used to retrieve data for study. Currently data is reported annually in 15 aggregate tables, and that will continue. Additional analyses will not include small cell sizes.

The FPAR 2.0 data system will be hosted in the contractor's Amazon Web Services (AWS) FedRAMP-compliant cloud environment and comply with HHS Enterprise Performance Life Cycle including requirements for Authority to Operate, Privacy, etc.

11. Justification for Sensitive Questions

The FPAR 2.0 collects several items of a sensitive nature in the encounter data (e.g., user income and insurance status, user race and ethnicity, type of contraceptive method used or adopted, STD tests performed, and Pap and HIV test results). These sensitive data are required to monitor compliance with statutory requirements, program regulations and guidelines, performance reporting, and ongoing program management.

12.   Estimates of Annualized Burden Hours (Total Hours and Wages)

12A. Estimated Annualized Burden Hours

OPA has revised burden estimates based on comments received by the National Family Planning and Reproductive Health Association (NFPRHA) during the 60-day comment period. According to a member survey of 40 members, NFPRHA reports an average one-time implementation burden of 183 hours per grantee. This member survey was based on outdated information, specifically the number of data elements, several of which have been deleted or made optional, so the estimate below should represent a higher estimate.

Additionally, recognizing the challenges in implementing FPAR 2.0, OPA is offering a 3-year optional reporting pathway for those grantees who cannot meet the existing FPAR 2.0 implementation timeline. As currently planned, in year 1, a grantee would report FPAR 1.0 at the site level; in year two, FPAR 2.0 elements in aggregate; and in year 3, FPAR 2.0 by encounter at the site level. Based on previous feedback and research, OPA assumes that governmental agencies will have the largest implementation burden and will choose the optional reporting pathway.

For non-governmental agencies, OPA assumes that they will incur the 183 implementation hours as reported by NFPHRA to meet the FPAR 2.0 timeline in year one. In the next two years of the OMB clearance, reporting burden would be less. OPA assumes twice as much hourly burden as the FPAR 1.0 clearance, for 72 hours.

For governmental agencies, OPA assumes that they will report FPAR 1.0 in the first year and incur the same hourly burden (36 hours), spend 183 one-time implementation hours in year two, and incur 72 hours of reporting burden in year three.

Of current grantees, there are 29 non-governmental agencies and 41 governmental agencies. Using the above methodology, OPA expects a total of hourly burden of 21,414 hours over 3 years, an average of 7138 hours per year, and an **average of 102 hours per respondent** per year.

The estimated annualized hour burden of responding to this information collection is **7,140 hours** (see **Exhibit 3**). The hour-burden estimates include the time spent by grantee staff to retrieve, compile, verify, and report the FPAR data using the *FPAR 2.0 Data System*, and exclude any hour burden associated with customary and usual practices that the grantee would carry out in the absence of the FPAR reporting requirement.

Exhibit 3–Estimated Hour Burden

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average Annualized Burden per Response (Hours)	Annualized Total Burden (Hours)
Grantees	FPAR	70	1	102	7,140

The majority of Title X service grantees have some type of electronic reporting system, although not all. The annual reporting burden will vary greatly depending on available technology and available resources.

12. B. Estimated Annualized Respondent Cost Burden

The estimated total annualized labor cost to respond to the FPAR is **$286,457** or an average of **$4,092.24** per respondent (see **Exhibit 4**). The estimated hourly wage rate ($40.12) is a weighted average based on the distribution of the hour burden across four different categories of grantee labor (i.e., clerical/unskilled, skilled/technical, managerial or professional, and executive). This hour burden across labor categories is based on findings from the *2009 FPAR Burden Study*. [17] The average wage rate for each labor category was obtained from the U.S. Bureau of Labor Statistics 2019 wage rates for the health care and social assistance sector. [18]

Exhibit 4–Estimated Annualized Cost to Respondents for Information Collection

Type of Respondent	Total Burden Hours	Average (Weighted) Hourly Wage Rate	Total Respondent Cost
Grantees	7,140	$40.12	**$286,457**

13.   Estimates of other Total Annual Cost Burden to Respondents or Recordkeepers/Capital Costs

NFPRHA reports an average estimated one-time non-labor cost of $65,000 per grantee, annualized to $21,667. The non-labor costs are expenses, excluding labor, incurred by grantees to generate, maintain, and disclose FPAR 2.0 information, and exclude expenses associated with customary and usual practices. This may include computer and software upgrades and testing.

14.   Annualized Cost to Federal Government

The estimated annualized cost to the federal government for collecting FPAR data is **$643,466**. **Exhibit 5** presents a breakdown of this total. The estimate includes costs by federal staff at the regional and central levels and by the FPAR contractor for the following activities:

- **OPA Staff and FPAR Data Coordinator–**To review, correct, and approve FPAR submissions, oversee and coordinate the work of the FPAR data contractor, review and approve validation procedures performed by contractor and addressed by the FPAR Review Checklist, and review contractor prepared reports about data quality and data submission; and

- **FPAR 2.0 Contractor**–To validate FPAR data, including review and update SAS programs, preparation and dissemination of the validation results report, and work with the FPAR Data Coordinator and regional staff to resolve issues; develop/update FPAR Review Checklist for use by OPA staff in their review of FPARs; prepare of initial tabulations of national and regional data; prepare the FPAR Data Validation/Quality/Transition Report and the FPAR Submission Reports; operate and maintain the FPAR Data System website, staff Helpdesk, resolve system issues/bugs, prepare and deliver grantee and OPA training webinars, review and update system documentation, and update system security documents and interact with HHS/OIT and ASPA on issues related to website compliance with HHS requirements.

Exhibit 5–Annualized Cost of FPAR Reporting to Federal Government

Source	Amount ($)
FPAR review/approval and validation resolution, seed data review by OPA Office Staff (400 hours x $40/hour)	$16,000
FPAR review/approval, validation resolution, seed data request, FPAR contractor oversight/management (350 hours x $40/hour)	$14,000
FPAR 2.0 project management	$52,956
System development and maintenance	$358,228
Technical assistance to grantees and electronic health record vendors	$202,282
Total Annualized Cost	**$643,466**

15. Explanation for Program Changes or Adjustments

Estimated Annualized Burden Hours. The requested annualized burden of 7,140 hours is 213% higher than the current estimate of 3,348 hours. This adjustment is the result of a more complicated data collection

Estimated Annualized Labor and Non-labor Costs. As a result of the decrease in total requested hour burden, the annualized labor cost and non-labor costs have also increased.

16. Plans for Tabulation and Publication and Project Time Schedule

Annually, the FPAR 2.0 contractor will validate, tabulate, analyze, and disseminate the FPAR data in the form of a national summary and a regional summary for each HHS region. If possible, with the more granular data, OPA will produce more summaries based on geographic data. For the reporting period (calendar year), the national summary presents national and regional (aggregate) data for each of the components described in the FPAR 2.0 encounter data and project revenues, user income level and age group by state, and trend data (from 1999 to the current reporting year) for selected FPAR data items. The national summary also presents a description of the procedures used to compile and validate the data, as well as definitions of all key FPAR 2.0 terms and definitions. The appendix to the national summary contains detailed, table-specific notes on any discrepancies between OPA-requested data and what individual grantees were able to provide, how those data inconsistencies were resolved, and the effect, if any, on the data presented in the report. OPA posts a 508-compliant PDF version of the national summary on the OPA website, where the public has full access, and distributes a hard copy to OPA staff who manage the Title X Family Planning program. **Attachment D** includes a copy of the *2019 Family Planning Annual Report (FPAR) National Summary*.

The region-specific summaries present national, regional, and grantee-specific data for each of the components described in the FPAR 2.0 encounter data and project revenues, and the appendix in each regional summary contains detailed, table-specific notes about the reported data from the grantees, OPA, and the data contractor. OPA distributes the regional summaries

internally to OPA staff and posts the national summaries online for access by grantees and the general public. HHS/OPA staff also receives the data tables in MS Excel format.

This request is for changes from the current (2019) FPAR data system. Data collection under the current system is ongoing by Title X services grantees and is expected to end with the 2021 calendar year. By February 15 of each year, the grantees compile and submit data for the recently completed calendar year. **Exhibit 6** presents the timetable for key activities following OMB approval. The timetable assumes an OMB approval date in early December 2021.

Exhibit 6–Timetable for Data Collection, Analysis, and Publication

Activity	Expected Date of Completion
Data collection	Commences one month following OMB approval for the 2022 calendar year
End of reporting period	12 months following OMB approval
Resolve validation issues	13 months following OMB approval
Export initial FPAR data file to contractor for validation and preliminary tabulation	14 months following OMB approval
Resolve validation issues	15-16 months following OMB approval
Export final FPAR data file to contractor for validation and preliminary tabulation	16 months following OMB approval
Prepare draft national/regional summaries for OPA review	18 months following OMB approval
Submit final national/regional summaries for OPA approval	19 months following OMB approval
Print and distribute copies of the reports	21 months following OMB approval
Post 508-compliant version of national summary to OPA Web site	21 months following OMB approval

17. Reason(s) Display of OMB Expiration Date Is Inappropriate

The 3-year expiration date for OMB approval will be displayed on all versions of the form (i.e., electronic, Web-based).

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

B. DATA COLLECTION PROCEDURES: FPAR DATA SYSTEM

The FPAR reporting requirement does not use statistical methods. In accordance with federal regulations, annual FPAR submission is required of all Title X Family Planning Services

grantees for purposes of monitoring and reporting program performance (45 CFR Part 74 and 45 CFR Part 92).[6-8] The Family Planning Annual Report 2.0 (FPAR 2.0) Data System is dedicated to collecting and managing Title X FPAR data. The System's purpose is to facilitate user-friendly submission of annual FPAR data by Title X service grantees and to provide a central location for review, approval, storage, and management of FPAR data by HHS/OPA staff. The website's target audiences include authorized staff of Title X service grantees and HHS/OPA staff responsible for administering grants and monitoring performance. The general public is not an intended audience.

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