

**Supporting Statement  
for the Title X Family Planning Annual Report**

**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

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Supporting Statement  
for the Title X Family Planning Annual Report

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## **Supporting Statement for the Title X Family Planning Annual Report**

### **A. JUSTIFICATION**

This is a request for Office of Management and Budget (OMB) approval for extension of the Office of Population Affairs (OPA) Family Planning Annual Report (FPAR) (OMB No. 0990-0221, expiration October 31, 2019). 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).<sup>1</sup>

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 [HIV]). 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).<sup>2</sup> The Office of Population Affairs (OPA) within the Office of the Assistant Secretary for Health administers the Title X program.

In fiscal year 2017, 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),<sup>3</sup> at least 90% of the appropriation is used for clinical family planning services.<sup>2</sup> Annually, the Title X program helps women and couples to avoid one million unintended pregnancies that would otherwise result in 501,000 unplanned births and 345,000 abortions.<sup>4</sup> In 2017, Title X-funded providers served approximately 4.0 million family planning users (i.e. clients) through 6.6 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 73% of U.S. counties.<sup>5</sup>

**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: Forms and Instructions (Reissued October 2016)*; **Attachment C** is a copy of the *60-Day Federal Register Notice*; **Attachment D** is a copy of the *2017 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).<sup>6-8</sup>

#### **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.<sup>9</sup> The FPAR provides consistent, national-level data on the Title X Family Planning program and its users that allow OPA to assemble comparable and relevant program data to answer questions about the

characteristics of the population served, use of services offered, composition of revenues that complement Title X funds, and impact of the program on key health outcomes. The use of standard definitions for key FPAR data elements— family planning users and encounters, user age, and user income—have resulted in valid and reliable estimates of key indicators, which allow for comparisons over time at all levels of the program (e.g., national, regional, state, and grantee). Information from the FPAR is important to OPA for several reasons. First, OPA uses FPAR data to monitor 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)*<sup>10,11</sup>, 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)<sup>2</sup>
- 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)<sup>1</sup>

Second, OPA uses FPAR data to comply with 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**

<b>Goal II.A.1</b> — Increase the total number of unduplicated clients served in Title X clinics by 5% over 5 years. (Outcome)
<b>Goal II.A.2</b> — 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)
<b>Goal II.A.3</b> — Increase the number of unintended pregnancies averted by providing Title X family planning services, with priority for services to low-income individuals. (Outcome)
<b>Goal II.B.1</b> — Reduce Infertility among women attending Title X family planning clinics by identifying Chlamydia infection through screening of females ages 15 to 24 years. (Outcome)
<b>Goal II.C.1</b> — Increase the number of unduplicated female clients who receive a Pap test.
<b>Goal II.C.2</b> — Reduce invasive cervical cancer among women attending Title X family planning clinics by providing Pap tests. (Outcome)
<b>Efficiency</b> — Maintain the increase in the actual cost per Title X client below the medical care inflation rate.

Third, OPA relies on FPAR data to guide strategic and financial planning, to monitor performance, to respond to inquiries from policymakers and Congress about the program, and to estimate program impact. Central and regional HHS/OPA staff uses the data to set priorities for the program, to inform strategic planning and budget efforts, and to develop and justify efforts to expand and increase access to family planning and related health services. FPAR data also provide needed context for objective grant reviews, comprehensive program reviews and program evaluation, and assessment of program technical needs.

Finally, as the lead agency for coordinating the family planning focus area of the Healthy People 2020 (HP2020) national objectives, OPA is responsible for monitoring the progress of the

objectives in this topic area. In addition, in order to better assess the progress of the Title X program, OPA monitors the Healthy People 2020 objectives in related focus areas (e.g., health access, cancer, HIV, STDs, and adolescent health).

### ***FPAR Structure and Content***

The FPAR consists of 17 tables, including a grantee profile cover sheet and 16 data tables. These tables 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. In this section, we describe each FPAR table and present OPA’s justification for collecting the data. In addition, we explain how OPA uses the data and present illustrative questions, including those that also address HP2020 health objectives, which OPA can answer with the data.

### **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. OPA is requesting no change to the Grantee Profile Cover Sheet.

### **User Demographic Profile (FPAR Tables 1 to 3)**

Tables 1 through 3 provide data on the demographic characteristics of family planning users, including their number and distribution by age, sex, ethnicity, and race. These data allow OPA to monitor access to and use of Title X services among the diverse populations these projects serve.

#### **Table 1—*Unduplicated Number of Family Planning Users by Age and Sex***

In Table 1, grantees report data on the number of Title X family planning users by age group and sex. The nine age group categories are similar to those used by compilers of such national data sets as the National Survey of Family Growth (NSFG). OPA is requesting no changes to Table 1. The data collected in Table 1 permit OPA to answer such questions as:

- What is the number of female and male users served by Title X-funded service sites (HP2020 FP-7)?
- How does the age composition of users compare across regions, states, and grantees?

#### **Table 2—*Unduplicated Number of Female Family Planning Users by Ethnicity and Race***

#### **Table 3—*Unduplicated Number of Male Family Planning Users by Ethnicity and Race***

In Tables 2 and 3, grantees report data on the number of female (Table 2) and male (Table 3) Title X family planning users by race and ethnicity. The two ethnicity and six race categories conform to the *OMB 1997 Revisions to the Standards for the Classification of Federal Data on Race and Ethnicity*,<sup>12</sup> and are consistent with ethnicity and race categories used by compilers of such national data sets as the NSFG. The cross-tabulated structure of Tables 2 and 3 provide insight into the ethnic composition of users who do not self-identify with one or more of the five minimum OMB race categories. OPA is requesting no changes to Tables 2 or 3. The data collected in Tables 2 and 3 permit OPA to answer such questions as:

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

- What is the ethnic composition of Title X clients who do not self-identify with one or more of the five minimum OMB race categories?
- How do user ethnic and racial composition compare across regions, states, and grantees?

**User Economic and Social Profile (FPAR Tables 4 to 6)**

The data reported in Tables 4 through 6 provide OPA with information on key social and economic characteristics of individuals who receive family planning and related preventive health care in Title X-funded clinics. OPA uses these data 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).

**Table 4 — Unduplicated Number of Family Planning Users by Income Level**

In Table 4, grantees report data on the number of Title X family planning users according to their family income, which is measured as a percentage of the HHS poverty guidelines. OPA uses Table 4 data 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),<sup>2</sup> 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)<sup>3</sup> 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 in Table 4 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?

**Table 5 — Unduplicated Number of Family Planning Users by Principal Health Insurance Coverage Status**

In Table 5, grantees report data on the number of Title X family planning users across three categories of principal health insurance coverage for primary medical care (public, private, and uninsured). OPA is requesting no changes to Table 5.

Having health insurance 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.<sup>14,15</sup> 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 2017, 57% (2.3 million) of family planning users

had either public (38%, 1.5 million) or private (19%, 760,051) insurance covering broad primary medical care benefits; 42% (1.7 million) were uninsured. Health insurance coverage status was unknown or not reported for 1% (56,837) 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. Furthermore, with the passage of the Patient Protection and Affordable Care Act (ACA), the program and its providers will face the challenge of responding to an increased demand for care from newly insured individuals and adapting to changes in payment and service policies.<sup>17,18</sup> In addition, the demand for free and subsidized Title X-funded services will persist among individuals who remain uninsured after ACA implementation because they are exempt, not eligible, view coverage as unaffordable, or live in a state that has chosen not to expand Medicaid.<sup>17,19</sup>

Table 5 data will provide OPA and service providers with information 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. Table 5 data 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) (HP2020 AHS-1)?

**Table 6** — *Unduplicated Number of Family Planning Users with Limited English Proficiency (LEP)*

In Table 6, grantees report the number of users according to their LEP status. As recipients of U.S. Department of Health and Human Services (HHS) funding, Title X service grantees and subrecipients are responsible for complying with Title VI of the 1964 Civil Rights Act and Title VI regulations<sup>20</sup> 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<sup>20</sup> for assisting fund recipients 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 Table 6 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 obtained from Table 6 allow OPA to answer the question:

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

### **Family Planning Method Use (FPAR Tables 7 to 8)**

**Table 7**—*Unduplicated Number of Female Family Planning Users by Primary Method and Age*

**Table 8**—*Unduplicated Number of Male Family Planning Users by Primary Method and Age*

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).<sup>1,3</sup> In Tables 7 and 8, grantees report the number of female (Table 7) and male (Table 8) family planning users according to their age group and the type of primary (i.e., most effective) contraceptive method continued or adopted at exit from the encounter. OPA is requesting no changes to Tables 7 and 8.

OPA uses the data from Tables 7 and 8 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 adoption of newer FDA–approved contraceptive technologies, and compare the program’s contraceptive method-mix with nationally representative data sources (e.g., NSFG). Finally, the types of contraceptive methods that providers offer may vary in terms of supply costs and service delivery requirements, thereby affecting overall project costs. Table 7 and 8 data allow OPA to monitor project financial concerns that may result from contraceptive supply issues. Data from Tables 7 and 8 permit OPA to answer such questions 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 uses contraception? What percentage of female clients relies on moderately and highly effective family planning methods?
- What percentage of female clients is pregnant or seeking pregnancy?
- What percentage of female and male clients aged 15 to 19 uses condoms as their primary contraceptive method (HP2020 FP–10)?

## **Use of Related Preventive Health Services (FPAR Tables 9 to 12)**

As specified in the Title X program regulations, projects are required to provide (on site or through referral) a range of preventive health services related to family planning care [42 CFR 59].<sup>3</sup> Tables 9 through 12 provide OPA with information on the utilization of related preventive health services and the level of pathology among Title X family planning users.

### **Table 9—*Cervical Cancer Screening Activities***

In Table 9, grantees report the number of female users that receive a Pap test, the number of Pap tests performed, and the number of Pap tests with abnormal results (i.e., ASC or higher and HSIL or higher). OPA uses Table 9 data to monitor the program's contribution to early detection and prevention of invasive cervical cancer, the program's contribution to Healthy People objectives for cancer detection, and provider adoption and adherence to changing Pap screening guidelines. OPA requests no changes to Table 9. Data from Table 9 permit OPA to answer such questions as:

- How many female users received a Pap test (HP2020 C–15)?
- Of the total number of Pap tests performed, what percentage is abnormal and requires further follow-up?

### **Table 10—*Clinical Breast Exams and Referral***

In Table 10, grantees report the number of users that receive a clinical breast exam (CBE) and the number of users referred for follow-up based on abnormal CBE findings. OPA uses Table 10 data to monitor the program's contribution to early detection and prevention of breast cancer, the program's contribution to Healthy People objectives for cancer detection, and provider adoption and adherence to changing breast screening guidelines. In compliance with national standards of care, OPA will clarify in the Table 10 instructions that grantees should report breast screening activities (CBE exams and related referrals) for *female* users only. Data from Table 10 will permit OPA to answer such questions as:

- How many female users receive a CBE (HP2020 C–17)?
- How many female users are referred for follow-up based on an abnormal CBE finding?

### **Table 11—*Unduplicated Number of Family Planning Users Tested for Chlamydia by Age and Gender***

In Table 11, grantees report the number of users that are tested for chlamydia by sex and age group. OPA uses Table 11 data to monitor the program's effort to reduce infertility through chlamydia screening, its contribution to Healthy People objectives for STD prevention, and provider adoption of and adherence to chlamydia screening guidelines. OPA requests no changes to Table 11. Data from Table 11 permit OPA to answer the question:

- What percentage of female users less than 25 years of age is tested for Chlamydia (HP2020 STD–1 and STD–2)?

### **Table 12—*Number of Gonorrhea, Syphilis, and HIV Tests***

In Table 12, grantees report the number of gonorrhea, syphilis, and HIV tests performed by user sex, the number of confidential HIV tests that are positive, and the number of anonymous HIV tests performed. OPA uses Table 12 data to monitor the program's STD and HIV prevention efforts, its contribution to Healthy People objectives for STD prevention, and provider adoption/adherence to STD screening guidelines. No changes to Table 12.

In 2019, OPA identified as a key issue the provision of tools to ensure inclusion of substance use disorder (SUD) screening in Title-X funded family planning services. OPA added a module to collect data on substance use disorder screening performed in Title X-funded family planning services. The new module includes two data tables (Table 12B and 12C) for reporting SUD screening for female and male users. OPA will require grantees to begin collecting SUD screening data in January 2020 and to report SUD screening data for 2020 in FPARs that are due in February 2021. Data from this question will permit OPA to answer the question:

- Does the grantee provide substance use disorder screening?

### **Family Planning Encounters and Utilization of Family Planning Clinical Services Providers**

#### **Table 13—Number of Family Planning Encounters by Type of Provider**

In Table 13, 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) and the number of family planning encounters by type of program staff. OPA uses the Table 13 data to monitor patterns and trends in the number and composition of clinical services provider staffing, service utilization, and provider efficiency, and to respond to frequently asked questions about the types of clinical services providers that deliver Title X-funded care. OPA is requesting no changes to Table 13. Data from Table 13 permit OPA to answer such questions as:

- What is the composition of clinical services provider (CSP) staff?
- What is the ratio of mid-level CSP FTEs to physician FTEs?
- What percentage of family planning encounters do CSPs attend? What percentage of encounters do other service providers attend?
- How many family planning encounters with a CSP are there per CSP FTE?

### **Title X Project Revenue**

#### **Table 14 — Revenue Report**

In Table 14, grantees report the revenues (i.e., actual cash receipts or drawdown amounts) received 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 services grantees are required to maintain a financial management system that meets the standards for administering grants, as specified in 45 CFR Part 74<sup>6</sup> and 45 CFR Part 92,<sup>7</sup> and document and keep records of all income and expenditures. OPA uses Table 14 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 Table 14. The data collected from Table 14 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?

### **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 FPAR reporting module embedded within the GrantSolutions.gov website. In late 2010, OPA awarded a 4-year contract for the design and operation of the new website. The new *FPAR Data System* (<https://FPAR.opa.hhs.gov>), dedicated solely to collecting and managing FPAR data, opened in January 2012 to HHS/OPA staff and grantees for submission of 2011 FPAR data. The *Data System* has 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; FPAR reporting tables with auto-calculating rows and columns; automatic calculation and display of current and previous years STD test-to-user ratios (Table 12) and service utilization and staff efficiency ratios (Table 13); a Helpdesk accessed by toll-free phone or e-mail; an online *User Guide*; and annual training webinars. Furthermore, the *Data System* allows grantees to validate each FPAR table as they complete it by performing within and cross-table checks and confirming whether the table passed or failed the check, including identifying the cell that failed and providing a reason for the failure. The *Data System* also prevents 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 regional and central staff that reviews and approves each FPAR, the *Data System* offers 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. All action links to review, approve, and revise an FPAR are in a single location. In addition, the *Data System* provides user administration page where HHS/OPA staff manage (i.e., register, approve, and disable) all system user accounts.

Finally, the contractor managing the *Data System* makes maximum use of electronic procedures and systems to validate (SAS), track (Microsoft [MS] Access) the post-submission validation status of each FPAR, and tabulate (SAS) FPAR data.

### **4. Efforts to Identify Duplication and Use of Similar Information**

As noted in Section A.2, the FPAR is the only source of annual, uniform reporting by all Title X family planning services grantees. The information requested in the FPAR is unique to the Title X Family Planning program and is unavailable from other sources. Furthermore, the FPAR does not duplicate items from other OPA data collection efforts for this program. In the absence of FPAR 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 involved 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 such key management tasks 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 program, and to adjust in a timely way to changes in funding or other factors. There are no legal obstacles to reduce the burden.

**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 Wednesday, August 21, 2019. There were no public comments.

**Outside Consultation.** Outside consultation was conducted from 2010 – 2013 in preparation for the 2014 FPAR OMB extension request. There are no significant changes from that extension request, thus the consultation from the previous extension remains the same.

**Exhibit 2–List of Individuals that Provided Extensive Review and Feedback on the FPAR Reporting Form**

Year	Name/Title/Affiliation
2012–2013	Kathy Desilets, Former Region I Program Consultant HHS/OPA
2010–2013	Christina Fowler, PhD, Project Director FPAR Compilation Project, RTI International
2010–2013	Julia Gable, MS, Task Leader FPAR Compilation Project, RTI International
2012–2013	Lorrie Gavin, PhD, MPH, Health Scientist HHS Office of Population Affairs
2010–2013	Evelyn Glass, MSPH Former FPAR Consultant
2013	CDR Marjie Witman, Former Region X Program Consultant, HHS/OPA

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 and to suggest ways to resolve any unclear wording that might reduce data quality and add burden.

Finally, on an ongoing basis, OPA consults with the FPAR data contractor on issues affecting FPAR data quality. This consultation includes review and discussion of the annual *FPAR Data Validation, Quality, and Transition Report*<sup>21</sup> and the *FPAR Submission Report*<sup>22</sup> and regular contact by phone and e-mail to discuss data quality issues. The first report provides table-specific information on data validation and quality issues for the reporting period, and tracks validation flag statistics by table since 2005. The second report presents information on submission timing, use of electronic technology, the number of times that grantees revise a report, Helpdesk use and resolution processing statistics, and information about common Helpdesk issues. Together, these two reports provide ongoing and timely information on issues affecting FPAR submission.

**9. Explanation of Any Payment/Gift to Respondents**

No payments or gifts will be provided to respondents.

**10. Assurance of Confidentiality Provided to Respondents**

OPA provides no assurance of confidentiality of FPAR data submitted by Title X services grantees. FPAR data are presented in summary form, which protects the confidentiality of individuals who receive Title X-funded services (42 CFR Part 59).<sup>3</sup> No individual identifiers are collected on the FPAR, and no person can be identified based on the aggregate totals.

**11. Justification for Sensitive Questions**

Although the FPAR contains several data items of a sensitive nature (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), an individual cannot be identified from the aggregate data that grantees report, in accordance with federal regulations (42 CFR Part 59.11).<sup>3</sup> The FPAR collects no individual identifiers. 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**

The estimated annualized hour burden of responding to this information collection is **3,348 hours**, or a weighted average of **36 hours per respondent** (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 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	93	1	36	3,348

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*.<sup>23</sup> For purposes of this estimate, the average hour burden ranges between 39 hours (public health department) and 32 hours (private agency). The difference in hour-burden by type of grantee is not very large because public health departments and stand-alone family planning agencies, which account for a majority of Title X service grantees, are more likely to have health IT systems and resources (e.g., dedicated IT staff or tailored software) that reduce the burden of compiling, retrieving, and reporting FPAR data. Health departments and family planning–focused grantees are also more likely than smaller, primary health–focused grantees to attribute a greater portion of time spent compiling, retrieving, and verifying FPAR data to usual and customary practices.

Finally, the hour burden is not the same across FPAR tables. FPAR tables that rely on data collected at the time of the encounter (e.g., user demographic data) or used for billing (e.g., service use and procedure/test data) are less burdensome than FPAR tables (e.g., 10, 12, 13, and 14) that rely on data available after the encounter (e.g., Pap or HIV test results) or stored in a system different from the one that stores client-level demographic and encounter data (e.g., staffing and revenue data). Though OPA has made efforts to minimize collection of data items that are not available at the time of the encounter or are stored in systems apart from client-level encounter data, the data in Tables 10, 12, 13, and 14 are required for program monitoring and reporting and are not available elsewhere.

**12. B. Estimated Annualized Respondent Cost Burden**

The estimated total annualized labor cost to respond to the FPAR is **\$134,322** or an average of **\$1,444** 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*.<sup>23</sup> The average wage rate for each labor category was obtained from the U.S. Bureau of Labor Statistics 2011 wage rates for the health care and social assistance sector.<sup>24</sup>

**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	3,348	\$40.12	<b>\$134,322</b>

**13. Estimated Annualized Respondent Non-labor Cost Burden**

The estimated total annualized non-labor cost of FPAR reporting is **\$205,229** or an average of **\$2,207 per respondent**. The non-labor costs are expenses, excluding labor, incurred by grantees to generate, maintain, and disclose FPAR information, and exclude expenses associated with customary and usual practices. The capital and start-up costs (\$1,081) may include computer and software upgrades and monitoring and testing new software. Operation, maintenance, and purchased service costs (\$1,126) may include the cost of an external data or IT contractor, or providing refresher and ongoing training to existing or new staff in collecting and managing FPAR data.

The non-labor costs used in preparing the weighted estimate assume that (a) non-labor costs vary by grantee agency type and range between \$2,068 (private agency) and \$2,586 (public health department); (b) non-labor costs by agency type are 10% lower than previous estimates; (c) 10 grantees have zero non-labor cost because they assume these costs as part of usual and customary practices; and (d) the estimated non-labor cost (\$11,832) for the largest Title X grantee, a private

family planning agency, is 25% lower than a previous estimate due to their implementing a new and more streamlined electronic data system. These assumptions and adjustments are guided by findings from the *2009 FPAR Burden Study*.<sup>23</sup>

**14. Annualized Cost to Federal Government**

The estimated annualized cost to the federal government for collecting FPAR data is **\$411,600**. **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:

- **Regional Office**–To review, correct, and approve FPAR submissions, assist grantees in setting up or changing user accounts, participate in FPAR Data System training, and review of grant information uploaded into Data System;
- **Central OPA Staff and FPAR Data Coordinator**–To review 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 Data 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 regional 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 Regional 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
Website operations, system and documentation updates, grantee training, security and compliance reviews, Helpdesk operation by Contractor)	\$243,600
Data validation/resolution, data quality and submission reports, preliminary national/regional tabulations, update/distribute FPAR Quality Checklist (Contractor)	\$138,000
<b>Total Annualized Cost</b>	<b>\$411,600</b>

**15. Explanation for Program Changes or Adjustments**

**Estimated Annualized Burden Hours.** The requested annualized burden of 3,348 hours is 5% lower than the current estimate of 3,520 hours. This downward adjustment is the result of an assumed 10% decrease in hour burden per respondent (from 40 hours to 36 hours) resulting from (a) grantee adoption or enhancement of their health IT systems and capacity

and (b) grantee use of the *FPAR Data System* and its features to submit and manage FPAR submission, review, approval, and correction.

***Estimated Annualized Labor Cost.*** The requested annualized labor cost of \$134,322 is 2% lower than the current estimate of \$136,541. This downward adjustment is the result of the 5% decrease in total requested hour burden (see above). Increases in the number of respondents (from 88 to 93) and wage rates (from \$38.79 to \$40.12) were insufficient to offset the effects of a 10% decrease in per respondent hour burden.

***Estimated Annualized Non-labor Cost.*** The requested annualized non-labor cost of \$205,229 is 3% higher than the current estimate of \$200,200. This upward adjustment is the result of an increase in the number of respondents (from 88 in the current estimate to 93) and a decrease in the number of respondents assumed to have zero non-labor costs (from 17 in the current estimate to 10). On average, per respondent labor costs decreased 14% (from \$2,575 to \$2,207). This decrease was due primarily to (a) an assumption that IT upgrades and efficiencies implemented by grantees in the last three years would lower non-labor costs (25% reduction for the largest grantee and 10% for all others) and (b) that grantee systems would not need further modification because OPA was proposing no substantive changes to the FPAR form.

## **16. Plans for Tabulation and Publication and Project Time Schedule**

Annually, the FPAR contractor validates, tabulates, analyzes, and disseminates the FPAR data in the form of a national summary and a regional summary for each HHS region. For the reporting period (calendar year), the national summary presents national and regional (aggregate) data for each FPAR table, 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 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 of to each grantee and to OPA central and regional staff who manage the Title X Family Planning program. **Attachment E** includes a copy of the *2017 Family Planning Annual Report (FPAR) National Summary*.

The region-specific summaries present national, regional, and grantee-specific data for each FPAR table, 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 (hard and electronic copies of) the regional summaries internally to OPA central and regional 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 a 3-year renewal with revision of the current (2016) FPAR form. Data collection is ongoing by Title X services grantees. 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 2019.

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

<b>Activity</b>	<b>Expected Date of Completion</b>
End of reporting period	3 months following OMB approval
Due date for FPAR submissions	4.5 months following OMB approval
Export initial FPAR data file to contractor for validation and preliminary tabulation	6 months following OMB approval
Resolve validation issues	6–8 months following OMB approval
Export final FPAR data file to contractor for validation and preliminary tabulation	8 months following OMB approval
Prepare draft national/regional summaries for OPA review	9-10 months following OMB approval
Submit final national/regional summaries for OPA approval	11 months following OMB approval
Print and distribute copies of the reports	12 months following OMB approval
Post 508-compliant version of national summary to OPA Web site	12 months following OMB approval
Submit FPAR Validation and Quality Report and FPAR Submission Report	13 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, and hard-copy).

**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).<sup>6-8</sup> The Family Planning Annual Report (FPAR) Data System (<https://fpar.opa.hhs.gov>) 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 at the regional and central levels. The website’s target audiences include authorized staff of over 90 Title X service grantees and approximately 25 HHS/OPA staff that are responsible for administering grants and monitoring performance. The general public is not an intended audience.

**1. Security and Access**

**Security.** The system is designed and built according to industry and HHS standards and best practices for security (e.g., privacy and access controls, data transmission, and data storage and backup), accessibility (Section 508), usability, and look-and-feel. The FPAR Data System is a negligible risk system, as classified by the HHS Office of the Chief Information Officer following a September 2011 review of the System Security Plan and Privacy Impact Assessment. The website accommodates the following roles (levels of user access): FPAR Data Coordinator (OPA/DC), OPA Regional Office staff (OPA/RO), grantee, and System Administrator. Access to the site and to different pages, content, and features depends on the users’ role, which is controlled by a unique username (e-mail address) and strong password. Each role has a defined scope of which pages and data that role can view or edit.

The FPAR Data System is hosted on RTI servers that, for redundancy purposes, are housed in data centers in two different locations (Ragland Data Center in the Haynes Building and Herbert Building) on RTI's main campus in Research Triangle Park, North Carolina. These locations are protected by physical and environmental security controls in line with NIST 800–53. The FPAR Data System is accessible to authorized RTI project personnel and registered users using strong authentication. All data collected by the FPAR Data System are stored in password-protected Microsoft SQL Server database that resides behind a secure firewall.

**Access.** The FPAR Data System complies with federal accessibility requirements under the Section 508 Amendment to the Rehabilitation Act of 1973 and has been tested for compliance with Section 508 requirements internally at RTI and by the HHS Office of the Assistant Secretary for Public Affairs. Authorized users can access the FPAR Data System from their workstations, using several internet browsers. The system is optimized for use with either Internet Explorer (version 8 or higher) or Firefox (version 8 or higher). In addition, users must have installed on their systems Adobe Reader and Adobe Flash Player software, both of which are free, to access documents and features of the website,

## **2. Website Structure and Navigation**

**Structure.** The FPAR Data System website includes both public and private (secure) pages. All visitors to the website can view three public pages: (a) Home, (b) Reports & Forms, and (c) Training. The private pages of the FPAR Data System are accessible only to authorized users (i.e., require log in). Authorized users include HHS/OPA and grantee staff that is registered and OPA-approved to access the System. After login and prior to entering the private pages, all authorized users must accept the terms of the Privacy Statement regarding privacy expectations and the consequences of unauthorized or improper use. The six private pages are (a) MyFPAR, (b) Website Reports, (c) User Administration, (d) Contacts, (e) Links, and (f) Support. The footer on each web page includes links associated to HHS or OPA (e.g., Accessibility, Freedom of Information, and Privacy Policy) and a site map.

**Navigation.** To ease and streamline navigation, all web pages share the same layout. The title bar is at the top of the page with the horizontal tab menu underneath. Below the horizontal tab menu is the page content and a footer menu. The private pages have some additional elements, including display of the user's name and a "Logout" link above the tab menu and a "Change Password" link under the tab menu. Function buttons and links are displayed either within the rows of detail data or near the bottom of the content section. The System's web application has multiple modes of navigation to enhance the user experience, including a horizontal tab menu and breadcrumbs, intuitive flow with function buttons and links, and a site map in the footer. The horizontal tab menu allows for quick navigation across website pages. The system also uses "breadcrumbs" in the upper left corner of every web page and FPAR data entry form to help users understand their location and ease their navigation within embedded pages. Finally, action buttons or links foster an intuitive flow of actions and site navigation. When clicked, action buttons or links perform functions or take users to other web pages.

## **3. FPAR Data Collection**

The FPAR Data System provides 17 web-based data entry tables (a Grantee Profile Cover Sheet and 16 data tables), matching the content and structure of the OMB-approved (OMB No. 0990–0221) reporting tables. A grantee user must access their FPAR on the (private) MyFPAR page by clicking the "Edit" link, which directs the user to the FPAR Preparation Checklist. This Checklist displays all FPAR data tables, the status of each table (e.g., Initial, In Process, or Completed),

table-specific action links, and action buttons to submit the completed report or close and exit the report without submitting it.

The web data entry forms are intuitive and easy to use, according to internal and client acceptance testing. Under each form is a large text field where grantees can enter table-specific comments. To the extent possible, OPA provides RTI with data to pre-populate fields that contain information about the grant (number and period), the grantee (name and address), and the Title X project director (name and contact information). Where applicable, the data entry forms automatically sum rows and columns. This feature eases reporting for grantees and provides information that the system uses for cross-table validations. All data entry tables have clearly defined action buttons to execute interactive validations, save data, and exit the table.

The FPAR Data System interactively validates the FPAR data to ensure complete and consistent (within and across tables) reporting. The *FPAR Data System Interactive FPAR Validations* document describes the rules that apply for each validation check performed by the system. Within a data table, the user can execute validation checks one of two ways using the “Validate” or “Complete” action buttons. The “Complete” button will validate the data and return the user to the FPAR Preparation Checklist if the data pass all checks. The “Validate” button will check the data without closing the table if the data pass all validations. With either action button, if there are validation errors, a message (red text) will appear above the table describing each error. Additionally, a red asterisk will identify each data field that failed the validation check. Once the user has identified and corrected the errors, they can re-validate the data using either action button. A blank data entry field is a validation error. Users must enter a “0” to denote a zero value. For selected fields that lack a comparison field for validation (e.g., STD tests in Table 12 or FTEs in Table 13), the system will calculate relevant comparisons (e.g., STD test-to-user ratios) for the current year are compared with the same values from the previous year’s FPAR. The grantee can decide whether any discrepancy between years is unusual or expected based on program activities and strategies. Underneath each data entry form is a “Note” field where the user can enter table-specific comments. FPAR data entry tables are viewable and editable by grantees, HHS/OPA office staff, and the FPAR Data Coordinator. OPA office staff is able to view and edit grantee data only for grantees in the regions that they oversee. The FPAR Data Coordinator has access to all FPAR data entry tables for all grantees. Grantees can view only their own data.

Finally, FPAR data are transmitted through the Internet using 128-bit encrypted connection and Secure Sockets Layer (SSL) technology and stored in a password-protected database connected to the website through the Contractor’s secure network. A system time-out feature warns a user after 25 minutes of inactivity and automatically logs the user out after 30 minutes of inactivity.

#### **4. FPAR Review and Approval via the MyFPAR page**

HHS/OPA staff performs all FPAR review and acceptance actions by using links for each FPAR in the FPAR Tracking and Management Table (MyFPAR page). When a grantee submits a final FPAR, the system generates an automated e-mail to inform OPA regional office staff (first-level review) that the grantee’s FPAR is ready for review and acceptance. HHS/OPA staff may view the grantee’s final FPAR by clicking on the PDF action link. Once the OPA office staff has completed their review, they may either accept or allow revision of the FPAR by clicking on one of these two action links. If they accept the FPAR, the system will generate an automated e-mail to inform the FPAR Data Coordinator (second-level review) that the FPAR is ready for final review and acceptance. If the regional office staff or FPAR Data Coordinator allows a revision, the system will take two actions: (a) send an automated e-mail to the grantee or OPA office staff

that includes the revision instructions or request and (b) “open” the FPAR to editing. Once revised, the FPAR must be re-submitted and pass through all review and approval steps.

**5. Automate System E-mail Notifications**

As noted above, the FPAR Data System generates automated e-mail messages to notify the grantee, HHS/OPA office staff, and the FPAR Data Coordinators of key FPAR events—when an FPAR is submitted, accepted by OPA office, or accepted by FPAR Data Coordinator and when HHS/OPA staff request a revision—and to alert the person responsible for executing the next action in FPAR processing. In addition, the system sends e-mails to notify grantees about the FPAR submission schedule, user registration, training webinars, or system maintenance, to remind users of their user name, or to provide instructions for resetting a password.

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