

Supporting Statement
for the Title X Family Planning Annual Report

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Office of Information and Regulatory Affairs

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Office of the Assistant Secretary for Health
Office of Population Affairs
Office of Family Planning

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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, 2010). 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

More specifically, OPA is requesting (1) extension of the 2011 version of the FPAR form—*Family Planning Annual Report: Forms and Instructions (Reissued January 2011)*—for a 3-year period and (2) approval to use the current ("2007 version") FPAR form—*Family Planning Annual Report: Forms and Instructions (Reissued October 2007)*—through February 2011. The 2011 FPAR is a slightly modified version of the 2007 form. Due to a 3-month delay in awarding a contract to build and operate a new Web-based FPAR data system to collect FPAR data for 2011 to 2013, OPA must request an extension of the 2007 form so that grantees are able to submit the 2010 data in the current FPAR data system (GrantSolutions.gov), using reporting templates and instructions based on the 2007 FPAR form. The new FPAR Website will base reporting templates and instructions on the 2011 FPAR form and will be operational by January 2012, in time to receive 2011 FPAR data. The modifications reflected in the 2011 FPAR, which are described in greater detail in this statement, are not substantive and aim to simplify and clarify the instructions, frequently asked questions (FAQs), and structure of row headings for selected FPAR reporting tables. These revisions have not increased burden, but instead have made the form more user-friendly. The increase in the reporting burden from 20 hours (2007 version, see *Section A.15*) to 40 hours (2011 version) is based on findings from a 2009 study² of FPAR reporting burden and is unrelated to the modifications to the 2007 form.

The 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 (e.g., screening for breast and cervical cancer, sexually transmitted diseases (STDs), and human immunodeficiency virus [HIV]). The program's purpose is to help couples space births and plan intended pregnancies, which are important elements in ensuring a positive birth outcome and a healthy start for infants. 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).³ The Office of Family Planning (OFP), within the Office of the Assistant Secretary for Health (ASH), OPA, administers the program. In fiscal year 2010, Congress appropriated over \$317 million for family planning activities supported under Title X. At least 90 percent of the appropriation is used for clinical family planning services as described in the statute and regulations (42 Code of Federal Regulations [CFR] Part 59).⁴ In calendar year 2009, 89 Title X grantees provided family planning services to approximately 5 million women and men through a network of more than 4,500 community-based clinics (e.g., State and local health departments, independent clinics, community health centers, and other public and private nonprofit agencies). Approximately 73 percent of U.S. counties have at least one clinic that receives Title X funds and provides services as required under the Title X statute.⁵ Annually, the Title X program prevents an estimated

970,000 unintended pregnancies that would likely result in 430,000 unintended births and 410,000 abortions.⁶

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 2007 version of the *Family Planning Annual Report: Forms and Instructions (Reissued October 2007)*, **Attachment C** is a copy of the 2011 version *Family Planning Annual Report: Forms and Instructions (Reissued January 2011)*, **Attachment D** is a copy of the 60-day *Federal Register Notice*, **Attachment E** is the *83-I form and the Certification for Paperwork Reduction Act Submission*, **Attachment F** is the *Family Planning Annual Report: 2008 National Summary*, and **Attachment G** is the *OMB Notice of Action* for the current (2007 version) FPAR.

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).⁷⁻⁸

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 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—for example, 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 *Program Guidelines for Project Grants for Family Planning Services (“Program Guidelines”)*,⁹ 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)³
- 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)¹⁰

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. Current performance goals for the Title X Family Planning program include giving priority in the provision of family planning services to low-income individuals, increasing access to and utilization of cervical cancer screening as a means of reducing invasive cervical cancer, reducing infertility by screening for Chlamydia, and ensuring program efficiency as measured by the cost per user served. **Exhibit 1** lists the goals for the Title X Family Planning program.

Exhibit 1—Goals for the Title X Family Planning Program

Goal II.A.1 — Increase the total number of unduplicated clients served in Title X clinics by 5 percent over 5 years. (Outcome)
Goal II.A.2 — Maintain the proportion of clients served who are at or below 200 percent of the federal poverty level at 90 percent 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.1 — Increase the number of unduplicated female clients who receive a Pap test.
Goal II.C.2 — Reduce invasive cervical cancer among women attending Title X family planning clinics by providing Pap tests. (Outcome)
Efficiency — 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 OPA staff use 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 2010 (HP2010) and Healthy People 2020 (HP2020) national objectives, OPA is responsible for monitoring the progress of the Title X program in family planning and related focus areas (e.g., health access, cancer, HIV, STDs, and adolescent health). The FPAR tables that provide data to measure current HP2010 objectives are highlighted in the next section.

FPAR Structure and Content

The FPAR consists of a grantee profile form and 14 tables in which grantees report data on user demographic characteristics, user social and economic characteristics, primary contraceptive use, utilization of related preventive health services, staffing and efficiency, and project revenues. The Grantee Profile Cover Sheet and each reporting table are described below.

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 total number of Title X subcontractors 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 through 3)

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

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*

Tables 1 through 3 provide data on the demographic characteristics of family planning users or clients, including their distribution by age, sex, ethnicity, and race. The terms “user” and “client” are used synonymously throughout this statement. These data allow OPA to monitor access to and use of Title X services among the diverse populations these projects serve. OPA is requesting no changes to Tables 1 through 3.

The categories for ethnicity and race in Tables 2 and 3 conform to the *OMB 1997 Revisions to the Standards for the Classification of Federal Data on Race and Ethnicity*,¹¹ and age, race, and ethnicity categories are similar to those used by compilers of such national data sets as the National Survey of Family Growth (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. The data collected in Tables 1 through 3 permit OPA to answer such questions as the following:

- How many female and male users are served by Title X clinics (HP2010 Ref 9-6)?
- What is the age, ethnic, or racial group distribution of female and male clients served by Title X clinics?
- 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 demographic characteristics compare with national or state data?

User Economic and Social Profile (FPAR Tables 4 through 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 individuals who confront financial or sociocultural barriers to care due to low income, lack of health insurance, or limited English proficiency (LEP). In addition, OPA uses these data to assess the program’s compliance with legislative or regulatory mandates, including giving priority care in the provision of services to individuals who are low income,³ and ensuring meaningful access to clients who are LEP.¹²

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

By federal statute (Section 1006[c] of Title X of the Public Health Service Act, 42 USC 300),³ 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 percent of the poverty level or less. Program regulations (42 CFR Part 59)⁴ further specify that individuals with family incomes at or below 250 percent of the poverty level qualify to receive services at no charge (\leq 100 percent of poverty) or on a sliding fee scale (101 percent to 250 percent of poverty). OPA uses Table 4 data to monitor compliance with the statutory requirements and regulations and to assess the number of users that qualify for free or subsidized care. In addition, the proportion of clients that is low-income is part of OPA’s criteria for allocating funding across regions and grantees. OPA is not

requesting any changes to Table 4. Questions that can be answered using Table 4 data include the following:

- What proportion of clients served in Title X clinics is from families with an income at or below 100 percent of poverty or between 101 and 250 percent of poverty?

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

According to the most current national estimates (2007), 20 percent of reproductive-age women (15 to 44 years) are uninsured, and 37 percent of reproductive-age women who are poor (incomes <100 percent of poverty) are uninsured.¹³ Health insurance coverage is a key indicator of an individual's access to health care and is associated with having a usual source of care and receiving timely family planning and related preventive health care. For many clients, especially those who are low income and uninsured, Title X clinics provide the only continuing source of preventive health care and health education. OPA uses data from Table 5 to monitor and describe the proportion of Title X clients that is uninsured, as well as those with coverage for broad primary care services through private and public third-party sources (e.g., Medicaid or other public health insurance plans). Additionally, the number of uninsured clients receiving care in Title X-funded programs has important financing implications. Title X-funded service providers are experiencing the financial strain of providing a broad range of family planning services to an increasing uninsured client base. The data collected in Table 5 permit OPA to answer questions such as the following:

- What proportion of family planning users is insured or is uninsured (i.e., have no insurance covering primary medical care) (HP2010 Ref 1-1)?

In the 2011 version of the FPAR, OPA is requesting a minor modification to simplify Table 5. Specifically, OPA is eliminating three rows (2a, 2b, and 2c) where grantees report, on an optional basis, the number of privately insured users with coverage for all or some (row 2a), none (row 2b), or unknown (row 2c) contraceptive and related services. OPA has decided to eliminate these three rows of Table 5 because they do not provide an accurate estimate of underinsurance among the privately insured, and the burden associated with validating these data outweighs the benefits of the information reported to date. The original purpose for collecting data on the level of private coverage for contraceptive and related health services was to address grantee concerns about underinsurance for contraceptive and related services among those with private coverage. This data item was optional to eliminate the burden associated with having to verify coverage levels for users who did not plan to use their private plan to pay for care. Since 2005, when OPA began collecting data on user health insurance status, most grantees have opted to not report levels of private coverage for contraceptive and related care, unless the private plan was to be billed for care. In 2008, 72 percent of privately insured users had an unknown level of coverage for contraceptive and related services.¹⁴

Table 6—Unduplicated Number of Family Planning Users with LEP

As recipients of U.S. Department of Health and Human Services (HHS) funding, Title X services grantees and their subcontractors are responsible for complying with Title VI of the 1964 Civil Rights Act and Title VI regulations,¹² which require Title X service providers to ensure meaningful access to LEP clients who seek Title X-supported services. In the Title X setting, LEP clients are those 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 services and information provided in English. The

federal guidance for assisting fund recipients in addressing the needs of LEP individuals who seek HHS-funded services is the 2003 *Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons*¹² (“*LEP Guidance*”). The guidance lists four factors that are the basis for evaluating recipient compliance, including (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. Table 6 data require that Title X–funded agencies establish mechanisms for identifying and counting LEP individuals who need language assistance (Factor #2). These data, combined with data on language characteristics of the community served (Factor #1), form the basis for developing and assessing the adequacy of grantee language assistance plans and services and for identifying grantee technical assistance needs in the area of language assistance. The data obtained from Table 6 allow OPA to answer the following question:

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

In the 2011 version of the FPAR, OPA is requesting a minor change that simplifies the definition of LEP user. This revised LEP user definition is easier to understand, consistent with the federal *LEP Guidance*,¹² and does not differ substantively from the definition in the 2007 FPAR form. Use of the simplified LEP definition has also allowed OPA to delete definitions for terms incorporated into the previous LEP definition, which themselves required explanation (e.g., English proficiency, native language, dominant language, and interpreter competence).

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).^{4, 10} Tables 7 and 8 provide age-specific information on the types of family planning methods that female (Table 7) or male (Table 8) clients continue or adopt at exit from the family planning encounter to prevent unintended pregnancy. The method use data by age and sex allow OPA to compare the data from Title X clinics with other sources of information, including the NSFG. These data also permit OPA to track patterns in method use over time at the state, regional, and national levels; to examine the extent to which Title X service providers contribute to increased access to and use of newer, U.S. Food and Drug Administration–approved contraceptive technologies; and to assess the program’s contribution to the Healthy People objectives for family planning and disease prevention. Furthermore, the types of contraceptive methods that are offered and adopted have implications for overall project costs because of method-specific variations in supply costs and service delivery requirements.

Primary method use data for male clients (Table 8), which OPA added to the FPAR in 2005, allow OPA to monitor the extent to which males utilize the contraceptive services (e.g., method provision, information, and counseling) offered through Title X clinics. While research shows that men recognize unintended pregnancy, STDs, and HIV/acquired immune deficiency syndrome (AIDS) as serious problems, and acknowledge that prevention is a joint responsibility, experience has shown that drawing men into service programs that offer family planning and reproductive health services and information requires approaches that focus on their needs. Over the past 10 years, OPA has responded to public health concerns regarding continued high levels of

unintended pregnancy and increasing STD rates by increasing funding and attention to programs that improve the delivery of contraceptive and related preventive health services to male clients. While males comprised just 6 percent (327,843) of total Title X clients in 2008, the number of male family planning users more than doubled between 1999 and 2008. The data collected from Tables 7 and 8 permit OPA to answer such questions as the following:

- What are the patterns of contraceptive use (i.e., “method mix”) overall and by age group for female and male users?
- What proportion of female clients uses contraception (HP2010 9-3)?
- What proportion of female clients relies on long-acting reversible methods, hormonal methods, less effective methods, or no method?
- What proportion of clients overall and what proportion of clients less than 18 years of age use condoms as their primary method (HP2010 Refs 13-6, 9-10, and 25-11)?

In the 2011 version of the FPAR, OPA has made several minor edits to the definition of contraceptive methods, row headings, and row order of Tables 7 and 8. These modifications include updating the list of Fertility Awareness Methods, removing the word “hormonal” from the row heading “hormonal contraceptive patch,” including the Lactational Amenorrhea Method under the category “rely on female method(s)” in Table 8, adding the word “withdrawal” to the row heading “withdrawal and other methods,” and clarifying the definition of “method unknown or not reported.” Finally, the rows in both tables have been reordered so that the row for reporting users with an “unknown or not reported” primary method appears last in each table. With these minor changes, OPA aims to ease reporting by ensuring that the method categories and their definitions are clear, comprehensive, mutually exclusive, and reflect the contraceptive methods that are available or in use. Furthermore, OPA expects these changes to reduce reporting burden associated with correcting or addressing post-submission validation flags related to errors in primary method reporting.

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

Table 9—*Cervical Cancer Screening Activities*

Table 10—*Clinical Breast Exams and Referral*

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

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

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].⁴ 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. Furthermore, data from these tables permit OPA to monitor achievement of performance objectives related to the prevention of invasive cervical cancer (Table 9) and infertility (Table 11), as well as the program’s contribution to achievement of Healthy People objectives related to cancer detection, disease prevention (e.g., STDs and HIV), and health promotion. OPA is requesting no changes to Tables 9 through 12. However, OPA updated the references and corrected an omission in the instructions for reporting abnormal Pap test results in Table 9. Data from these tables permit OPA to answer such questions as the following:

- How many female users have a Pap test (HP2010 Ref 3-11)?

- How many Pap tests are performed, and of those, what proportion is abnormal and requires further follow-up or management?
- How many users have a clinical breast exam?
- What proportion of female users less than 25 years of age is tested for Chlamydia (HP2010 Refs 25-1a and 25-16)?
- How many gonorrhea, syphilis, and confidential HIV tests are performed overall and by sex of user (HP2010 Refs 25-2 and 25-3)?
- What proportion of confidential HIV tests is positive (HP2010 Ref 13-7)?

Family Planning Encounters and Utilization of Family Planning Clinical Services Providers

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

Data from Table 13 provide OPA with information on the staffing composition (full-time equivalents [FTEs]), service utilization (family planning encounters), and efficiency of clinical services providers (e.g., number of family planning encounters per clinical services FTE). OPA uses the data collected in Table 13 to respond to frequently asked questions (FAQ) about the types of health personnel (e.g., physicians, nurse practitioners, certified nurse midwives, physician assistants, or other personnel) that provide clinical family planning services at Title X service sites. The data collected in Table 13 permit answers to such questions as the following:

- What is the composition of clinical services provider (CSP) FTEs?
- What is the ratio of mid-level CSP FTEs to physician FTEs?
- What is the ratio of FTEs for registered nurses with an expanded scope of practice to mid-level provider FTEs?
- What proportion of family planning encounters is attended by a clinical services provider? What proportion is attended by other services providers?
- How many family planning encounters with a CSP are there per CSP FTE?

In the 2011 version of the FPAR, OPA is requesting a minor change to Table 13. Specifically, OPA is requesting that the row heading for row 1c be changed from “other clinical services providers” to “registered nurses with an expanded scope of practice who are trained and permitted by state-specific regulations to perform all aspects of the user physical assessment.” OPA expects that increasing the specificity of the row heading will reduce the likelihood that on row 1c grantees include FTEs for registered nurses who *do not have* an expanded scope of practice or other nursing staff (e.g., licensed practical/vocational nurses, public health nurses). The service provider and family planning encounter definitions have been clarified to make them consistent with the row heading. This change is expected to reduce reporting burden associated with correcting or addressing post-submission validation flags.

Title X Project Revenue

Table 14—*Revenue Report*

Title X services grantees must maintain a financial management system that meets the standards for administering grants, as specified in 45 CFR Part 74⁷ and 45 CFR Part 92,⁸ and document and keep records of all income and expenditures. Table 14 identifies the sources and amounts of financial support for a grantee’s Title X project, including revenue collected from appropriate

third parties and individuals. 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)?

In the 2011 version of the FPAR, OPA is requesting minor modifications to the table and instructions that are designed to simplify revenue reporting, clarify the revenue that should be reported on each row, and reduce post-submission validation issues. Specifically, OPA has changed the category heading “federal grants” to “Title X grant,” and moved the non-Title X sources of federal grant revenue (e.g., Bureau of Primary Health Care) to the “other revenue” category. OPA has also clarified the instructions for reporting revenue from Medicaid and Medicaid expansions (e.g., family planning expansion waivers and the State Children’s Health Insurance Program). The instructions have been changed to reflect the modifications to the table. Additionally, OPA has made minor edits to the terms and definitions section to ensure consistency in the language used to refer to each revenue source, and the FAQ section has been updated to include a question about changes to the table and several questions about commonly occurring reporting questions and validation issues.

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

To minimize reporting burden, OPA supports region- and grantee-based efforts to improve the quality of FPAR data and the efficiency of data collection and tabulation. As demonstrated in the review of the FPAR tables, OPA collects only the minimum information required to monitor compliance with statutory and regulatory requirements and to manage the Title X program. The Web-based system used by grantees to submit the FPAR data has reduced burden for grantees, OPA staff, and the FPAR data contractor. Since the 2005 FPAR, a majority of Title X services grantees (93 percent [n=82] in 2009) have submitted the FPAR data using the FPAR module of OPA’s Web-based grants management system (GrantSolutions.gov). For reports submitted as hardcopy or e-mail attachment (n=6 in 2009), regional office staff enter the grantees’ FPAR data into the system so that all FPAR data are in an electronic form. The FPAR reporting module of the Web-based system pre-populates identifying and contact information for each FPAR, automatically calculates row and column totals, and interactively validates each FPAR table by checking for cross-table consistency and out-of-range values. The system will not accept a report with unresolved validation issues, forcing grantees to identify and correct the error(s) before they can submit their reports. The interactive validation feature reduces the amount of time spent by the grantee, OPA staff that review and approve the report, and the FPAR data contractor to identify and resolve data errors post-submission. The new FPAR Website, which will be operational by January 2012 to receive the 2011 FPAR data, will incorporate key design features and functionality of the GrantSolutions.gov site. However, these features and functions will be enhanced on the new Website to ease data entry, validation, and correction. The new FPAR Website will also expand and enhance the interactive validation function using the grantees’ previous year’s data.

Furthermore, once OPA exports the FPAR data (comma-delimited ASCII file) to the contractor for further validation, tabulation, and analysis, the contractor uses electronic procedures and systems to validate (SAS) and track (Microsoft [MS] Access) the validation status of each FPAR. SAS is used to tabulate each table in the FPAR national and regional summaries. SAS outputs the data to MS Excel templates, which mirror the final templates in MS Word. Finally, each year the

contractor updates the previous year's SAS, MS Excel, and MS Access programs and systems, thereby maximizing existing systems to further reduce burden.

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 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. FPAR data are used 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.

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 notice was published in the Federal Register on August 16, 2010, Vol. 75, No. 157; pp. 49936-7 (see **Attachment D**). There was one public response to the notice, dated October 13, 2010, from the Arizona Family Planning Council (AFPC). The letter from AFPC expressed support for the proposed changes to FPAR tables 5, 6, 7, 8, 13, and 14, and used such terms as "clarifying," "logical," and "appropriate" to characterize them. The AFPC did not oppose any specific change(s) to the FPAR instrument. However, AFPC noted that although the "proposed revisions were relatively minor," resources would be required to implement the changes in data collection systems and procedures, including staff training.

OPA recognizes that the proposed changes may impose some burden in terms of minor edits to data collection forms or instructions and reviewing these changes with staff. However, the proposed modifications are not substantive ones requiring major modifications (i.e., addition of new fields or re-definition of existing fields) to agency data management systems. OPA reviewed the FPAR data validation history to identify the FPAR data items that would benefit most from minor, non-substantive adjustments to row headings, instructions, or definitions, and the addition or clarification of FAQs. These minor revisions to the FPAR form will provide an opportunity for

grantees to refresh and improve their understanding of the FPAR reporting requirements, ease reporting, and reduce post-submission validation queries and corrections. Overall, OPA expects that the proposed FPAR changes will lower total reporting burden while improving the quality of FPAR data.

Outside Consultation. In preparing for renewal of the current FPAR, OPA consulted with RTI International* (RTI), the current contractor responsible for validating, tabulating, analyzing, and disseminating FPAR data; HHS/OPA Regional Program Consultants (RPCs) who administer Title X service grants in each Public Health Service (PHS) region; and grantees that participated in the *2009 FPAR Burden Study*.² **Exhibit 2** presents a list of individuals consulted regarding the FPAR reporting requirement.

Exhibit 2–Consultations Regarding the FPAR Reporting Requirements

Year	Name/Title/Affiliation	Phone/e-mail
RTI International		
2006-2010	Christina Fowler, PhD, Health Research Analyst RTI International	919-316-3447 cfowler@rti.org
2006-2010	Julia Gable, MS, Statistician RTI International	770-234-5018 jgable@rti.org
2009	Brienne Lyda-McDonald, MSPH, Analyst RTI International	919-541-6695 blmcdonald@rti.org
OPA		
2010	Marjie Witman, Regional Program Consultant HHS/OPA, PHS Region X	206-615-2501 marjie.witman@hhs.gov
2010	Kathy Desilets, Regional Program Consultant HHS/OPA, PHS Region I	617-565-1062 Kathleen.desilets@hhs.gov
Title X Grantees–FPAR Burden Study		
2009	Joan Whitaker, Director ABCD/Boston Family Planning	617-348-6260 whitaker@bostonabcd.org
2009	Joseph Alifante, Executive Director New Jersey Family Planning League, Inc.	973-622-2425 jalifante@njfpl.org
2009	Bonnie Birkel, Director Maryland Department of Health and Mental Hygiene	410-767-6717 birkelb@dhmh.state.md.us
2009	Sydney Atkinson, Project Director, North Carolina Statewide Family Planning Program	919-707-5693 Sydney.Atkinson@ncmail.net
2009	Thad Burk, MCH Assessment Oklahoma State Department of Health	405-271-9444 thadb@health.ok.gov
2009	Charlene Rohrich-Reiswig, Title X Project Director North Dakota State Department of Health	701-328-4535 creiswig@nd.gov
2009	Diane Chamberlain California Family Health Council, Inc.	213-386-5614 chamberlaind@cfhc.org
2009	Maryjane Puffer, CCHP Division Director, California Family Health Council, Inc.	213-386-5614 pufferm@cfhc.org
2009	Ricardo Alvarado, Area Manager California Family Health Council, Inc.	213-386-5614 alvarador@cfhc.org
2009	Sharon McAllister, Manager State of Washington Department of Health	360-236-3403 sharon.mcallister@doh.wa.gov

* RTI International is a trade name of Research Triangle Institute.

Consultation with RTI on issues affecting data quality and validation is ongoing and includes an annual OPA-RTI review of the *Family Planning Annual Report: Data Validation, Quality, and Transition Report*,¹⁵ which RTI prepares and submits to OPA after the final FPAR reports have been approved and distributed. The report provides detailed documentation on data validation and quality issues and is the key resource for identifying the FPAR tables with persistent validation or quality issues, as well as the exact nature of these issues. The report provides detailed information and analysis on the following: submission statistics, issues associated with data export, and table-by-table review of data validation and quality issues that were identified during the electronic and manual review (table-specific “notes” field) of the exported data file.

The report for the 2008 FPAR¹⁵ presents FPAR submission and validation results for the 2005 to 2008 FPAR data, including information on the number of and trends in validation and quality flags and the types or sources of the validation or quality issues.

RPCs play a major role in administering the Title X Family Planning program in each PHS region, including collection and reporting of FPAR data. RPCs provide ongoing technical support for FPAR data issues, approve FPAR submissions for their regions, and work with the grantee to resolve outstanding validation issues. In preparation for the OMB renewal, OPA solicited feedback from all RPCs and sent each of them a copy of the FPAR validation report. Two RPCs responded to OPA’s request.

Finally, eight grantees were asked to prepare detailed estimates of the burden associated with their FPAR reporting requirement. The 2009 study of the FPAR reporting burden (*Family Planning Annual Report Burden Study*)² was conducted by RTI under their previous FPAR contract. OPA has used the findings of this study to assist in preparing estimates of hour and nonlabor reporting burden (See sections A.12.A and A.12.B).

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).⁴ 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, type of contraceptive method used or adopted, STD tests performed, and Pap and HIV test results), individuals cannot be identified because federal regulation (42 CFR Part 59)⁴ requires that grantees report only aggregate user totals. 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)

12.A. Estimated Annualized Burden Hours

The estimated annualized hour burden of responding to this information collection is **3,520 hours**, or an average of **40 hours per respondent** (see **Exhibit 3**). The hour-burden estimates include the time spent by grantee staff to retrieve, compile, record, and verify the FPAR data, 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. The hour-burden estimate is a weighted average estimate based on applying the hour-burden findings from the *2009 FPAR Burden Study*² to the population of grantees, and making minor downward adjustments to the average hour burden to reflect the expected effects of the proposed modifications to the 2011 version of the FPAR, as well as successful adoption and implementation of improved health IT.

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	88	1	40	3,520

Based on findings of the *2009 FPAR Burden Study*,² the FPAR hour burden varies by type of grantee (e.g., state health department, Planned Parenthood or other reproductive health–focused provider, or primary health agency) and the methods and systems used by grantees to compile the FPAR-related data. For example, among grantees that are state health departments, the hour burden ranges from 8 to 137 hours (mean=58; median=46), and from 31 to 50 hours (mean=41) for grantees that are private agencies (reproductive health–focused and others). Additionally, grantees that compile the FPAR data internally report an average hour burden of 27 hours (range=8 to 46 hours) compared to almost 94 hours (range=50 to 137) reported by grantees that use the services of an external data contractor. In general, state health departments and other grantees that focus on the delivery of reproductive health services 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 reproductive health–focused grantees are also more likely than smaller and primary health–focused grantees to attribute a greater portion of time spent compiling, retrieving, and verifying FPAR data to their 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 family planning encounter or data that are typically used for reporting (e.g., user demographic and service use and procedure/test data) or billing purposes (e.g., service use and procedure/test data) are generally less burdensome than FPAR tables (e.g., 10, 12, 13, and 14), which rely on data that are available after the family planning encounter (e.g., Pap or HIV test results) or are not stored with client-level data in electronic practice or other data management systems (e.g., staffing and revenue data). Though OPA has made efforts to minimize collection of data items that are not readily available at the time of the family planning encounter or are stored apart from client-level data, these data are needed for Title X performance 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 **\$136,541** or an average of **\$1,552** per respondent (see **Exhibit 4**). The estimated hourly wage rate 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 distribution is based on findings from the *2009 FPAR Burden Study*.² The average wage rate for each labor category used in the calculation was obtained from the U.S. Bureau of Labor Statistics 2009 wage rates for the health care and social assistance sector.¹⁶

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	3,520	\$38.79	\$136,541

13. Estimated Annualized Respondent Nonlabor Cost Burden

The estimated total annualized nonlabor cost of FPAR reporting is **\$200,200** or an average of **\$2,275 per respondent**. The average nonlabor cost estimate includes \$1,215 in capital and start-up costs (assume a 5-year useful life) and \$1,060 in operations, maintenance, and purchased services costs. This estimate is a weighted average estimate based on applying the nonlabor cost findings (by agency type and region) from the *2009 FPAR Burden Study*² to the population of grantees. The nonlabor costs are expenses, excluding labor, incurred by grantees to generate, maintain, and disclose FPAR information. The capital and start-up costs include the costs of computer and software upgrades, monitoring and testing new software, modifying administrative and electronic data entry forms, and training staff in the use of new forms or procedures. Operation, maintenance, and purchased service costs 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. These estimates exclude nonlabor expenses associated with customary and usual practices.

According to findings of the *2009 FPAR Burden Study*,² the average annualized nonlabor costs varied between \$0 and \$10,200 (mean=\$1,642 and median=\$0), with state health department participants reporting a mean of \$2,298 and private agency participants reporting zero nonlabor costs (one agency participated in an OPA-funded regional data system and the other considered nonlabor costs to be part of their usual and customary practice).

14. Annualized Cost to Federal Government

The estimated annualized cost to the federal government for collecting FPAR data is **\$235,443**. A breakdown of this total is presented in **Exhibit 5**.

Exhibit 5—Annualized Cost of FPAR Reporting to Federal Government

Source	Amount (\$)
Region I Title X Data System	\$26,667
Region X Title X Data System	\$25,750
Verification/problem resolution by Regional Office Staff (400 hours x \$35/hour)	\$14,000
Review by Central Office Staff, including FPAR Coordinator and FPAR Data Systems staff (400 hours x \$40/hour)	\$16,000
Validation, tabulation, analysis, and dissemination of national/regional data reports by Contractor	\$153,026
Total Annualized Cost	\$235,443

These figures take into account OPA’s recent experience of processing FPAR data and disseminating findings. The estimate includes the cost of the FPAR-related portions of the Title X-funded data systems in Regions I and X; federal (OPA) staff labor (i.e., regional offices, central office, and FPAR Data Coordinator) to review, verify, correct, and approve FPAR submissions, oversee and coordinate the work of the FPAR data contractor, and review and approve final reports; labor for FPAR data system staff to provide technical assistance to OPA in managing and retrieving the FPAR data; and the contractor for validating, tabulating, analyzing, and disseminating the national and regional reports.

15. Explanation for Program Changes or Adjustments

Estimated Annualized Burden Hours. The estimated average FPAR hour burden of 40 hours (2011 version) is 20 hours more than the 2007 estimate of 20 hours and 7 hours more than the 2003 estimate of 33 hours. The 40-hour estimated average FPAR hour burden is based on the results of the *2009 FPAR Burden Study* and is adjusted for burden-reducing changes to selected tables. The 2009 study is the most current hour-burden estimate available. OPA assumes that the proposed hour-burden estimate is more accurate than the 2007 and 2003 estimates because it is based on grantee experience with a version of the FPAR form for which clearance is currently being sought. The 2003 estimate was based on an early version of the FPAR form, and both the 2003 and 2007 estimates were based on assumptions that grantees would adopt health IT (e.g., practice management systems and electronic health records) and that increased use of health IT would reduce the FPAR reporting burden. The gains in IT-related efficiency envisioned in 2003 and 2007 have not been realized because of limited funding or continued use of less-efficient manual systems to track FPAR data items that are available after the family planning encounter or are not client based.

Estimated Annualized Labor Costs. The estimated average labor cost of \$1,552 is higher than the 2007 (\$600) and 2003 (\$990) estimates due to a higher hour burden, a higher average hourly wage rate, and use of a different hour-burden distribution across the four labor categories.

Estimated Annualized Nonlabor Costs. The estimated average nonlabor cost of \$2,275 is higher than the 2007 estimate of \$0 and considerably lower than the 2003 estimate of \$11,650. The 2003 estimate was much higher because (1) the estimate did not account for grantees with zero nonlabor costs because of participation in region-based data systems funded by Title X, and (2) OPA overestimated the cost to modify or upgrade data systems to account for new data items collected in the 2005 revision of the FPAR. The 2007 estimate of \$0 was based on the assumption that any investments by the grantees in health IT had been made. However, it failed to account for ongoing costs.

16. Plans for Tabulation and Publication and Project Time Schedule

Annually, a contractor validates, tabulates, analyzes, and disseminates the FPAR data in the form of a national summary and a regional summary for each PHS 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 (1999 to FPAR 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. The national summary is distributed in hard copy to each grantee and OPA central and regional staff who manage the Title X Family Planning program. The national summary is posted on the OPA Web site (PDF and Section 508-compliant HTML versions) where the public has full access. A copy of the *Family Planning Annual Report (FPAR): 2008 National Summary* is presented in **Attachment F**.

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 (i.e., RPCs and FPAR Data Coordinator), and the data contractor. The regional summaries are distributed internally to OPA central and regional

staff and grantees. OPA staff at central and regional levels receive electronic copies of the reports (MS Word and PDF) and the data tables (MS Excel).

This request is for a 3-year extension of the 2011 FPAR version and for approval to use the 2007 FPAR version through February 2011. Data collection is ongoing by Title X services grantees. Calendar year data are compiled and submitted by grantees on February 15 of the following year. **Exhibit 6** presents the timetable for key activities following OMB approval. The timetable assumes an OMB approval date in early January 2011.

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

Activity	Expected Date of Completion
End of reporting period	0 months following OMB approval
Due date for FPAR submissions	1.5 months following OMB approval
Export initial FPAR data file to contractor for validation and preliminary tabulation	4 months following OMB approval
Resolve validation issues	5–7 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	8–9 months following OMB approval
Submit final national/regional summaries for OPA approval	10 months following OMB approval
Print and distribute copies of the reports	11 months following OMB approval
Post 508-compliant version to OPA Web site	11 months following OMB approval
Submit validation, quality, transition report	12 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). A copy of the Notice of OMB action for the current (2007) FPAR is contained in **Attachment G**.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

B. STATISTICAL METHODS

Statistical methods are not used in this activity.

C. REFERENCES

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5. Frost JJ, Frohwirth L, Purcell A. The Availability and Use of Publicly Funded Family Planning Clinics: U.S. Trends, 1994–2001. *Perspectives on Sexual and Reproductive Health* 2004;36:206-15.
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