Supporting Statement:
Privacy and Security Capacity Assessment of the Title X Network

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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A. BACKGROUND

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).[1] The Office of Population Affairs (OPA) within the Office of the Assistant Secretary for Health administers the Title X program.

In fiscal year 2015, Congress appropriated approximately $286.4 million for Title X family planning activities. In accordance with the statute and regulations (42 Code of Federal Regulations [CFR] Part 59),[2] at least 90% of the appropriation is used for clinical family planning services.[3] In 2013, 95 Title X grantees provided family planning services to nearly five million women and men through a network of approximately 4,200 community-based clinics that include state and local health departments, tribal organizations, and other public and private nonprofit agencies. 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.[4]

All Title X service grantees are required to collect and report data for the Family Planning Annual Report (FPAR), the program's only source of annual, uniform data. 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).[5] FPAR provides information on program users, service providers, utilization of family planning and related preventive health services, and sources of Title X and other program revenue. The data

[1] 42 USC 300 Section 1006 [300a-4], Regulations and Payments. Retrieved March 1, 2013, from http://www.hhs.gov/opa/pdfs/title-x-statute-attachment-a.pdf; 1970.

[2] 42 Code of Federal Regulations (CFR) Part 59, Grants for Family Planning Services (October 1, 2000). Retrieved March 1, 2013, from http://www.hhs.gov/opa/pdfs/42-cfr-59-b.pdf.

[3] 42 USC 300 Section 1006 [300a-4], Regulations and Payments. Retrieved March 1, 2013, from http://www.hhs.gov/opa/pdfs/title-x-statute-attachment-a.pdf; 1970.

[4] 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.

[5] 45 CFR Part 74, Uniform Administrative Requirements for Awards and Subawards to Institutions of Higher Education, Hospitals, Other Nonprofit Organizations, and Certain Grants and Agreements with States, Local Governments and Indian Tribal Governments. Retrieved March 1, 2013, from http://www.hhs.gov/opa/grants-and-funding/grant-forms-and-references/45-cfr-74.html. 45 CFR Part 92, Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments. Retrieved March 1, 2013, from http://www.hhs.gov/opa/pdfs/45-cfr-92.pdf. FY13 Announcement of Anticipated Availability of Funds for Family Planning Services Grants (CFDA: 93.217). 2013. Retrieved March 27, 2013, from https://www.grantsolutions.gov/gs/preaward/previewPublicAnnouncement.do?id=15585.)

are aggregated at the grantee level through the web-based FPAR Data System, and national and regional reports are generated annually for the previous year. Specifically, OPA and Title X-funded agencies use FPAR data to:

- monitor program performance and compliance with statutory requirements;
- comply with accountability and federal performance requirements for Title X family planning funds;
- guide strategic and financial planning and respond to inquiries from policy makers and Congress about the program; and
- estimate the impact of Title X-funded activities on key reproductive health outcomes, including prevention of unintended pregnancy, infertility, and invasive cervical cancer.

It has been 10 years since the last major overhaul of FPAR. Since then, technology has changed, OPA has adopted new quality-based clinical guidelines[6], and both internal and external studies, such as the Title X Performance Information & Monitoring System Project and the Institute of Medicine's Comprehensive Review of the Title X Program[7], have demonstrated the need and potential for a more robust data system. The health care landscape has also dramatically changed. The Affordable Care Act has placed an increased emphasis on clinical outcomes and performance measurement. Meaningful data will be essential for Title X-funded agencies to prove their value in the new health care environment, adapt to new models of care, seek new health insurance contracts, and partner with primary care providers.

In 2012, OPA engaged an FPAR Expert Work Group consisting of Regional Program Consultants, grantee representatives, and other federal and federally-funded stakeholders to assess the feasibility of revising the data elements and transitioning FPAR reporting to an enhanced encounter-level system. This next generation of FPAR, or FPAR 2.0, will have a range of benefits at the service delivery level. Grantees will be able to more accurately measure their performance and compare themselves to each other and industry standards or benchmarks. At the national level, the revised system will contribute to the growing culture of quality improvement, allowing the program to capitalize on high performers' practices and more accurately target training and technical assistance to agencies most in need. An enhanced encounter-level system would also bolster OPA's efforts to monitor Title X funding and to report on the use and impact of this funding to Congress and other national stakeholders and show the program's progress on national health objectives.

A critical component of moving to an encounter-level system is ensuring that the privacy, security and confidentiality of Title X patients and their data will be maintained throughout (and beyond) the FPAR 2.0 data-collection process. To that end, OPA has been working with an SDO (Standards Development Organization) as well as a private contractor to develop a Privacy and Security Roadmap for the network. The Roadmap details how to uphold privacy and security standards throughout the transition to the new, interoperable method of FPAR 2.0 data collection.

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[6] Gavin L, Moskosky S, Carter M, et al. Providing Quality Family Planning Services: Recommendations from Centers for Disease Control and Prevention and the US Office of Population Affairs. *Morbidity and Mortality Weekly Report*, 63 (4), April 25, 2014. http://www.cdc.gov/mmwr/pdf/rr/rr6304.pdf

[7] Institute of Medicine. *A Review of the HHS Family Planning Program: Mission, Management, and Measurement of Results*. Washington, DC: The National Academies Press, 2009.

The creation of this Roadmap has highlighted opportunities for capacity building at all levels of the network independent of any reporting needs by OPA.

JUSTIFICATION

This is a request to the Office of Management and Budget (OMB) for approval of a new data collection form (Privacy and Security Capacity Assessment) to collect feedback from the Title X network regarding Title X grantees' and service sites' current privacy and security capabilities. This voluntary form will be administered at most annually and enable the Title X network to share important information to critically inform OPA's development of FPAR 2.0, as well as identify any training assistance and inform guidance that OPA may offer in the future. OPA will solicit feedback from Title X agencies to advise our work on privacy and security, and proposes to make this data collection form available for up to 3 years so that OPA can accept feedback from the network regarding any changes or trends that might alter our approach to privacy and security as we proceed through the design and build process for the planned FPAR 2.0 data repository.

1. Circumstances Making the Collection of Information Necessary

As OPA plans for the FPAR 2.0 build, the office wishes to provide Title X grantees and stakeholders with an opportunity to inform OPA on the current state of sophistication within the Title X network in regard to the privacy and security safeguards that may already be in place. It is also an opportunity for these stakeholders to provide feedback on the proposed privacy and security workflow suggestions, since they will likely need to alter their current data collection processes to best comply with the proposed FPAR 2.0 Privacy and Security guidance. Collecting feedback via this Capacity Assessment will allow OPA to gauge what privacy and security concerns will need to be taken into consideration moving forward, which will lead to a better and more secure final FPAR 2.0 repository.

2. Purpose and Use of Information Collection

The assessment will focus on infrastructure and workflow practices currently in place at Title X sites, and assess their ability to enact and maintain critical privacy and security standards. Specifically, it will assess the sites' ability to comply with the fundamental elements of the Privacy and Security Roadmap.

The assessment will use SurveyMonkey. It will primarily consist of multiple choice questions, but will also include some open text fields for further clarification so respondents can provide detailed comments and explanations, if necessary. This rich, qualitative data will help to contextualize and compliment the quantitative findings.

This information collection provides Title X grantees and other stakeholders an opportunity to inform the FPAR 2.0 design and build. It will allow OPA to assess the state of privacy and security policies and practices in the network thereby enabling OPA to take into account any concerns held by clinical, administrative or other relevant staff in Title X-funded settings. Further, this collection facilitates OPA's efforts to be both inclusive and transparent in the FPAR revision process.

The data will be used to identify a "baseline" of privacy and security capabilities throughout the network. This baseline will guide OPA's strategy in the larger FPAR 2.0 build, and will inform the office regarding the direction of any future technical assistance funds.

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

To minimize reporting burden, OPA will collect the data at most annually.

4. Efforts to Identify Duplication and Use of Similar Information

This is a new initiative therefore there is no risk of duplication.

5. Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this collection.

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

It is essential for OPA to include its stakeholders in the FPAR 2.0 revision process. Forcing a "top-down" approach, especially into a clinical setting, can have unintended negative consequences in terms of workflow disruption and other burdens. Title X grantees have expressed a desire to be involved in the process, which OPA finds to be reasonable and necessary. A one-time collection of their current practices is necessary, at minimum. However, annual collection for up to 3 years would be even more informative, as we expect sites' practices and capabilities to change over time.

Implementation of FPAR 2.0 introduces Privacy and Security implications for OPA and its' grantees and sub-recipients that must be taken into account when designing the privacy and security strategy and how to roll it out across the FPAR 2.0 community. An understanding of the current state of HIPAA compliance and the privacy and security process and technology capacity across stakeholders is a critical component of ensuring a realistic approach.

Additionally, similar implementations have shown increased stakeholder engagement when making efforts to build privacy and security capacity across the community by first identifying common challenges in HIPAA compliance and providing support to address those challenges as part of a broader privacy and security effort.

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 will be consistent with guidelines set forth in 5 CFR 1320.5.

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

In response to the 60-day Federal Register Notice will be published on March 12, 2015, OS/OPA received the following summarized comments from Planned Parenthood Federation of America on May 11, 2015 and provided the summarized responses that also follow on October 6, 2015:

1. *We encourage the Department to request information from Title X agencies regarding their capacity to capture, exchange, and incorporate patient health information and patient-generated health data as part of its proposed information collection request… the Department should assess Title X providers' systems and readiness for bidirectional data exchange, their ability to incorporate patient-generated health data into CEHRT, and their ability to produce streamlined privacy and security policies to ensure the confidentiality of patient driven data.*

   Response: Patient-generated health data is out of scope for this particular information collection request and for the current plans for the FPAR 2.0 system, but we will take this recommendation under advisement for future architecture plans and enhancements as we further develop the forms-based RFD mechanism and plan future technology assessments of the Title X network.

2. *We urge the Department to consider ways to minimize the burden of information collection on respondents in order to optimize the number and quality of voluntary submissions while accommodating the needs of Title X providers.*

   Response: With regard to your concern to minimize the burden of information collection, we agree that this is a priority. The Privacy and Security Survey that we are planning to administer has been designed as a qualitative information gathering tool, geared toward helping OPA understand where Title X grantees and their subrecipients would need the most support from OPA in terms of privacy and security training, tools, and templates. Comprehensive responses to this particular survey are not required. We expect that the survey will be successful in providing sufficient guidance to OPA with as few as 10% of the Title X grantees, subrecipients, and service sites participating. While it would be informative to garner participation from the service sites given that they are normally responsible for implementing privacy and security protocols at the local level, we are not aiming for participation from the universe of sites for this particular collection as we understand the burden of participating in federally-sponsored surveys is not insignificant and takes staff away from patient care. Therefore, we are intentionally reserving requests for network-wide participation only for the most critical information collections for this project in order to best protect the time of service site staff to deliver family planning services to clients in need.

   To provide some assurance that this collection should not be burdensome for those who do decide to take part, we piloted the current survey tool with a Title X clinician and asked that individual to provide information on the number of hours it took to complete the survey. The response was that the survey took approximately 10 minutes to complete, which was our target duration for the survey.

9. Explanation of Any Payment/Gift to Respondents

No payments or gifts will be provided to respondents.

10. Assurance of Confidentiality Provided to Respondents

No protected health information (PHI) will be collected with this assessment as it focuses on organizational practices. It will be configured to protect the anonymity of respondents. Should a grantee accidentally disclose any PHI, it will not be used or analyzed. No individual identifiers will be collected on the survey, and no person can be identified based on the aggregate totals.

11. Justification for Sensitive Questions

There are no sensitive questions on the assessment.

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 **409 hours,** or a weighted average of **0.4 hours per respondent** (see **Exhibit 1**). The hour-burden estimates include the time spent by staff to retrieve, compile, verify, and report the data and exclude any hour burden associated with customary and usual practices that the grantee would carry out in the absence of the reporting requirement (for example regular communications with service sites).

Exhibit 1–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, Subrecipients, and Service Sites		818	1	0.4	327

Note: These burden estimates are based on the clinic census contained within the OPA Family Planning database (https://opa-fpclinicsdb.icfwebservices.com/) as of November 2013 and the response rates from the Family Planning National Training Centers 2013 Training Needs Assessment sent to these clinics. The proposed assessment will be distributed to all grantees, subrecipients, and service sites.

12B. Estimated Annualized Respondent Cost Burden

The estimated total annualized labor cost to respond to the assessment is **$13,119** or an average of **$40.12** an hour per respondent (see **Exhibit 2**). 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*[8] which was conducted for a larger data collection effort by an OPA contractor. 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.[9]

Exhibit 2–Estimated Annualized Cost to Respondents for Information Collection

Type of Respondent	Total Burden Hours	Average (Weighted)	Total Respondent Cost

[8] RTI International. Family Planning Annual Report Burden Study. Research Triangle Park, NC: RTI; 2009.

[9] Bureau of Labor Statistics. May 2011 National Industry-Specific Occupational Employment and Wage Estimates: Sector 62-Health Care and Social Assistance; March 2012.

		Hourly Wage Rate	
Grantees, Subrecipients, and Service Sites	327	$40.12	**$13,119**

13. Estimated Annualized Respondent Nonlabor Cost Burden

The estimated total annualized non-labor cost of this reporting is negligible because grantees are already expected to collect data for reporting to the Family Planning Annual Report (FPAR) (OMB No. 0990-0221, expiration Sept 30, 2016) and have the infrastructure (computers, phone lines etc.) to do so.

14. Annualized Cost to Federal Government

The estimated annualized cost to the federal government for performing this data collection is **$14,100**. **Exhibit 3** presents a breakdown of this total. The estimate includes costs by federal staff at central office and by a contractor for the following activities:

- **OPA Staff (1.5 FTEs) –** To review and finalize OMB submissions, oversee and coordinate the work of the contractor, develop a web-based assessment for data entry; provide TA for participants; extract, clean, and analyze data; and compile results.
- **Privacy & Security Contractor (0.3 FTE)** – To develop the assessment and assist with analyzing the results.

Exhibit 3–Annualized Cost of Privacy & Security Assessment Reporting to Federal Government

Staff	Amount ($)
Assessment development, administration, data cleaning and analysis by OPA Staff (165 hours x $40/hour)	$6,600
Assessment development and analysis by contractor (50 hours x $150/hour)	$7,500
Total Annualized Cost	**$14,100**

15. Explanation for Program Changes or Adjustments

This is a new data collection.

16. Plans for Tabulation and Publication and Project Time Schedule

Tabulation will occur after the assessment is closed, and results will not be published.

This request is for a three-year clearance, which is needed to further revise the assessment and solicit ongoing input from the Title X network as FPAR 2.0 is being tested and built.

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

Activity	Expected Date of Completion
Program assessment in online form software, and test assessment	1 month following OMB approval
Data collection period	1-3 months following OMB approval

Clean and analyze data	3-4 months following OMB approval
Develop recommendations	4-5 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 assessment (i.e., electronic, Web-based, and hard-copy).