Essential Access Health Response to 30-Day Public Comment Request: Family Planning Annual Report 2.0

INTRODUCTION

Essential Access Health welcomes the opportunity to submit comments in response to the Department of Health and Human Services' (HHS) Agency Information Collection Request 0990-New-30D on Family Planning Annual Report 2.0, issued on June 10, 2021.

We write to express our serious concerns with the Office of Population Affairs' (OPA) proposal for new encounter-level data collection for the Title X Family Planning Program ["Population Research and Voluntary Family Planning Programs" (Public Law 91-572)] Family Planning Annual Report (FPAR):

- **The burden estimate provided by OPA is badly out of date and inaccurate, and severely underestimates the time and financial requirements for grantees and subrecipients.**
- **The proposed new data elements would offer limited or no utility for monitoring the program in meaningful ways.**
- **It is unclear how OPA plans to protect the confidentiality of sensitive data, and to what extent OPA will allow grantees to de-identify data before it is submitted.**
- **The current timeline is unworkable, particularly given that grantees have not yet received final specifications and other details needed for implementation, and will likely not receive this information until much later in 2021.**

Currently collected in aggregate under OMB No. 0990-0221, this new data collection, "FPAR 2.0", proposes to collect visit information at the encounter level and build on the existing data collection and reporting system by adding 23 new data elements to FPAR's standard set of data elements (for a total of 45 data elements to be collected at every visit).

Under the best of circumstances, OPA's proposal for FPAR 2.0 is flawed. Not only does FPAR 2.0, as proposed, require cost and time (i.e., burden hour) investments that are exponentially higher than the outdated estimates published in the Federal Register (86 FR 9077); it also puts forward data collection requirements that far exceed the minimum amount of data needed to monitor compliance with statutory and regulatory requirements and to manage the Title X program.

While Essential Access appreciates the need for a more robust data system for monitoring and improving program performance and is committed to implementing such a system, the current FPAR 2.0 project must be paused. At the same time, OPA must plan and initiate a new process for transitioning to a new data collection and reporting system with continued stakeholder involvement.

BACKGROUND AND CONTEXT

As California's leading Title X grantee for nearly 50 years, Essential Access Health has built the largest and most comprehensive Title X network in the country to support the delivery of quality family planning and related services for low-income and uninsured patients throughout the state. Our 47 subrecipient organizations represent 242 health center sites, and include Federally Qualified Health Centers and city and county health departments. Eight different electronic health record systems are in use across the network.

At this time – against the backdrop of a year-long public health emergency that resulted in an unprecedented drop in patient census and following a 46% decline in the network's capacity after an estimated one in four service sites left the Title X program in response to the 2019 Title X Rule[1] – implementation of FPAR 2.0 simply is not feasible. We are working hard to hold on, rebuild, and continue providing critical services to patients.

Before the 2019 Title X Rule took effect, California's statewide Title X provider network included 63 health centers collectively operating 366 service sites in 38 California counties. After the regulations were fully implemented, providers across the state were forced to make the difficult decision to exit the program and leave behind critical resources. As a result, the state's Title X provider network was drastically reduced to 242 clinic sites in 20 counties and the number of patients served by the program in the state has been reduced by more than 80%.

In addition, the COVID-19 pandemic has brought on its own challenges to all subrecipients across the network. These organizations have faced decreased patient numbers, Title X and IT staff being diverted to the COVID-19 response, budget shortfalls amidst the need to purchase PPE and provide vital COVID-19-related services, staff resigning or going on extended leave for personal or health-related reasons, implementation of telehealth services, and temporary health center closures. All of these additional burdens have challenged the network to provide low-income individuals with family planning and related preventive health services.

Any attempt to implement FPAR 2.0 in accordance with current timelines will severely disrupt and undermine their ability to continue to respond to and recover from the pandemic and our ability to re-build our network once the 2019 Title X Rule is reversed.

[1] Mia R Zolna, Sean Finn, and Jennifer J Frost, *Estimating the Impact of Changes in the Title X Network on Patient Capacity* (New York: Guttmacher Institute, 2020).

ACCURACY OF ESTIMATED BURDEN

Essential Access requests that OPA complete an up-to-date burden study to provide a complete and accurate estimate of the burden associated with implementing FPAR 2.0. Cost burden estimates in the Public Comment Request are extremely low and based on an inappropriate and incredibly outdated source. The source for estimates, the Family Planning Annual Report (FPAR) Burden Study[2], was published in 2009 using data collected from Title X grantees more than twelve years ago. Since this time, several developments have taken place that make the data collected no longer relevant.

Firstly, OPA has not collated recent feedback from the Title X network regarding costs associated with encounter-level data collection and the proposed new FPAR 2.0 data elements. Estimates in the FPAR Burden Study, where gross non-labor costs were estimated to be $163,300 (or $2,207 per respondent) and annualized labor costs were estimated at $106,880 (or $1,444 per respondent)[3], are based on the cost and time burdens of implementing a new FPAR system that reports data aggregately (as opposed to encounter-level data reporting and collection). **It is inappropriate for OPA to use data collected from the 2009 FPAR Burden Study to quantify costs for implementing the encounter-level data reporting system currently proposed**, as these estimates relate to a completely different iteration of the proposed overhaul of FPAR that would have been substantially less burdensome on grantees and subrecipients.

Secondly, due to challenges with interoperability (i.e., electronic sharing of data between systems), there is no "one size fits all" approach for implementing FPAR 2.0 electronic reporting from Title X service sites to grantees, necessitating that each grantee-subrecipient dyad invest in upgrades to electronic systems and establishing interoperability between their respective systems. In addition, each sub-recipient utilizes its electronic health record system differently, including in how and where in the system data elements are collected, resulting in each organization needing to develop their own custom reporting solution.

In its response to comments from the initial 60-Day Comment Period, OPA noted that, "Proposed EHR changes will use standardized code systems to increase ease of adoption. OPA is also working to add equivalent code sets to further increase ease of adoption," and "Once implemented, a standards-based data collection should reduce reporting burden." In theory, a standards-based approach to data collection would reduce burden and contribute to improved data quality. However, this approach fails to take into account the lengthy timeline of multiple years- if not decades- before all EHR's fully embed such standards in a way that would allow for standards-based reporting. Currently, every subrecipient collects data in unique ways that suit their patients, their workflows, and the limitations of their EHR system. **OPA should delay**

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[2] RTI International, *Family Planning Annual Report Burden Study* (Research Triangle Park, NC: RTI, 2009).
[3] *Supporting Statement for the Title X Family Planning Annual Report 2.0, Submitted to Office of Management and Budget, Office of Information and Regulatory Affairs* (Washington, DC: Department of Health and Human Services, Office of the Assistant Secretary for Health, Office of Population Affairs; February 5, 2021).

implementation of FPAR 2.0 until such a time as a standards-based approach is actually feasible.

For Essential Access as a grantee, we estimate that implementing FPAR 2.0 will amount to approximately $225,000 in one-time labor costs. This estimate is based on the cost of four staff persons working a combined 2400 hours on tasks related to implementation, including implementing an upgraded data management system that can accommodate the additional data, updating and testing subrecipient configurations in the new data system, updating a secondary aggregate data system to accommodate the additional data elements, training subrecipient staff on how to collect new data elements and how to use the new system, working with subrecipient staff and their third party vendors to make updates to EHR systems including new fields and report modifications, and performing quality assurance of preliminary data collected.

We also estimate that each of our subrecipients, whose number we expect to increase to approximately 60 organizations, will spend an average of 80 hours implementing FPAR 2.0, plus 4 hours of training per service site at an estimated 300 services sites, for an estimated total of 6000 hours in one-time labor costs of approximately $385,000 across this single Title X grantee network. Again, OPA is proposing this time commitment take place when we are continuing to respond to – and facing burnout from – the COVID-19 public health emergency. Costs for ongoing operations and maintenance are not included in these estimates. They also do not include the additional time it will take health care providers and staff at Title X service sites to document more than 20 additional data elements as part of every single Title X visit.

Essential Access estimates that implementing FPAR 2.0 as proposed at the grantee level will amount to $480,000 in one-time non-labor costs to purchase the upgraded data management system. Furthermore, we estimate that each of our estimated 60 subrecipients will outlay an average of $2000 in non-labor costs to implement FPAR 2.0, for an estimated total of $120,000 in non-labor costs across this single Title X grantee network. This comes during the same fiscal year(s) as the COVID-19 public health emergency when resources have been redirected to emergency response and revenue has dwindled due to decreases in patient census. These cost estimates do not include ongoing expenses such as computer and software upgrades.

In its response to comments from the initial 60-Day Comment Period, OPA noted that, "…for the purpose of assessing burden, we are focused on the estimated time to collect and report the required data elements, not any capital investments needed for system development and enhancements." But OPA's burden analysis only accounts for grantee time and cites 102 hours per grantee. **We would estimate an annual burden of 500 hours and $20,000 for Essential Access Health to maintain the constantly changing mapping for all new fields for all sub-recipients, and to engage in data quality efforts to improve the quality and completeness of collected data for the new fields.** OPA's failure to include sub-recipient burden is puzzling, as each organization will need to maintain constantly changing mapping, engage in additional data quality efforts to try to improve the quality and completeness of collected data for the new

fields, and engage in ongoing staff training on data collection instructions given the constant turnover in staffing. **We would estimate an annual burden of 3660 additional hours across our sub-recipient network, at a cost of $147,000, to collect and report on new FPAR 2.0 fields.**

BURDEN, NECESSITY AND UTILITY OF FPAR 2.0 DATA

The 23 additional data elements go beyond what is necessary for quality improvement and what is required by statutory requirements, regulations, and operational guidance. We ask for additional opportunities to provide feedback on what additional data elements are feasible to add to the current FPAR clinic visit record and would be most helpful to us for program management and quality improvement.

Management of the Title X program entails monitoring progress towards performance goals required by the 1993 Government Performance and Results Act (Pub. L. 103-62), which 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. However, with the addition of 23 new data elements – many of which are irrelevant to monitoring Title X program compliance and accountability to the above performance goals – **FPAR 2.0 represents an effort that has no intention of being minimally burdensome**.

Furthermore, some proposed data elements pertain to services that are outside of the core family planning services in the *Recommendations for Providing Quality Family Planning Services* (QFP), including elements related to cardiovascular disease risk factors.[4] While, as OPA has affirmed, these "related preventive health services… are appropriate to deliver in the context of a family planning visit even though they do not contribute directly to achieving or preventing pregnancy,"[5] they certainly should not be monitored at the encounter level to monitor accountability to program goals. We request additional justification for collecting these new data elements beyond the rationale provided by the Healthy People 2030 health objectives.

The following data elements are of particular concern:

New Data Elements: Sexual Activity

OPA has proposed that Title X service sites report the following three data fields for patients at every visit: Ever had sex, Sex in the last 3 months, and Sex in the last year. Asking these three data points at every visit is burdensome and threatens the patient-provider relationship. It also is inconsistent with current best practice guidelines, which recommend assessing whether an adult

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[4] L Gavin L and K Pazol, "Update: Providing Quality Family Planning Services — Recommendations from CDC and the U.S. Office of Population Affairs, 2015," *MMWR Morb Mortal Wkly Rep* 65 (2016): 231-234, DOI: http://dx.doi.org/10.15585/mmwr.mm6509a3external icon.

[5] Office of Population Affairs, "Family Planning Services," accessed March 19, 2021, https://opa.hhs.gov/guidelines/clinical-guidelines/quality-family-planning/qfp-services/family-planning-services-text-only/index.

or adolescent patient is sexually active only annually [unless the patient is at increased risk for infection or is seeking evaluation and treatment for sexually transmitted infections (STIs)].[6] These sexual activity-related data fields also are not needed to monitor our Title X network's accountability to program goals.

Data Elements: Cervical Cancer Screening

FPAR 2.0 requires that Title X service sites collect and report five different data elements related to cervical cancer screening: Pap test at this visit, Last Pap result, All Pap test in the last five years, HPV test performed at this visit, and HPV test result. The collection of information on a patient's Pap (at current and previous visit) and HPV tests performed may be helpful as quantitative measures; for instance, to compute the number of tests provided during a specified period, the distribution of abnormal cytology results, or use of different cervical cancer screening technologies (cytology-alone, hrHPV-alone, co-testing) during a specified period. However, the utility of collecting of Pap test in the last five years and HPV test results are questionable, as no national guideline recommends cervical cytology alone at a five-year interval and there is no national benchmark pertaining to the rate of tests that should come back as positive.[7] Furthermore, there is no way to differentiate in the FPAR data whether an HPV test was done as part of routine screening or as a follow up after an abnormal screening test or for post-treatment surveillance.

It is critical to underscore that ASCCP Risk-Based Management Consensus Guidelines for abnormal cervical cancer screening tests and cancer precursors are dependent on patient age and other risk factors that support screening.[8] As a result, none of these cervical cancer screening-related data elements can be used to monitor adoption and adherence to screening guidelines or track progress towards Healthy People 2030 goals (i.e., increase the proportion of females who receive a cervical cancer screening based on the most recent guidelines), as described in the Supporting Statement for the Title X FPAR 2.0.[9] [10] When extracting data to calculate measures, there is no way to qualify whether an appropriate screening interval was applied.

New Data Elements: Cardiovascular Risk Factors

FPAR 2.0 suggests that Title X service sites collect and report on five different data elements related to cardiovascular health: Systolic blood pressure, Diastolic blood pressure, Height, Weight, and Smoking status.

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[6] AH Krist, KW Davidson, and CM Mangione, et al., "US Preventive Services Task Force. Behavioral counseling interventions to prevent sexually transmitted infections: US Preventive Services Task Force recommendation statement." *JAMA* 324, no. 7 (2020):674-681, doi:10.1001/jama.2020.13095.

[7] Rebecca B Perkins, et al., "2019 ASCCP Risk-Based Management Consensus Guidelines for Abnormal Cervical Cancer Screening Tests and Cancer Precursors," *Journal of Lower Genital Tract Disease* 24, no. 2 (2020):102-131, doi: 10.1097/LGT.0000000000000525.

[8] Ibid.

[9] Office of Disease Prevention and Health Promotion, "Increase the proportion of females who get screened for cervical cancer -- C-09," accessed March 22, 2021, https://health.gov/healthypeople/objectives-and-data/browse-objectives/cancer/increase-proportion-females-who-get-screened-cervical-cancer-c-09.

[10] *Supporting Statement for the Title X Family Planning Annual Report 2.0, Submitted to Office of Management and Budget, Office of Information and Regulatory Affairs*, 2021.

Separate reporting of systolic and diastolic blood pressure measurements does not make sense clinically, as the interpretation of a single measurement at a point in time must be tempered by the age of the patient, anxiety level when blood pressure is measured (i.e., "white coat" hypertension), and other factors. Unless the systolic and diastolic pressures are quite elevated, the diagnosis of hypertension cannot be made without multiple measurements on several separate occasions. If increasing control of high blood pressure is a priority for OPA, this data element should be reconfigured to identify whether diagnosis of hypertension has been made or if screening for elevated blood pressure has been performed consistent with nationally recognized guidelines.

Self-reported smoking status also is not helpful as a quality metric. If this topic is a priority for OPA, this data element should be reconfigured to report the intervention(s) offered to tobacco smokers, using those listed by the US Preventive Services Task Force.[11]

The collection of height and weight data, presumably to calculate body mass index (BMI), is problematic. Such measurements are not reliable for identifying whether that patient is overweight or obese – and, in turn, at risk for cardiovascular disease. Developed for and tested on a sample of predominantly white European men, BMI is not a useful indicator of health, especially for women of color, because it fails to account for differences in body composition, fitness levels, and nutritional differences.[12]

New Data Element: National Provider Identifier (NPI)

While most advanced practice clinicians have a NPI number, they are not required for those providers who do not transmit Health Information Portability and Accountability Act- (HIPAA) covered data or those who provide services "incident to" another provider. Furthermore, only advanced practice clinicians may obtain an NPI; however, in 2019, 7.4% of all Title X family planning encounters in the Essential Access network were performed by other services providers, including registered nurses, licensed practical nurses, health educators, and social workers. As such, many of our providers delivering Title X services do not have individual NPI to report for FPAR 2.0.

CONFIDENTIALITY OF SENSITIVE PERSONAL HEALTH INFORMATION

Essential Access requests clarification on the steps OPA will take to maintain the confidentiality of the sensitive personal health information collected by FPAR 2.0.

Confidentiality is a hallmark of the Title X program, and all patients, including adolescents, are guaranteed confidential services. Such protections are grounded in the statute, regulations, and

[11] US Preventive Services Task Force, "Interventions for Tobacco Smoking Cessation in Adults, Including Pregnant Persons: US Preventive Services Task Force Recommendation Statement," *JAMA* 325, no. 3 (2021): 265-279, doi:10.1001/jama.2020.25019.

[12] Mahbubur Rahman and Abbey B Berenson, "Accuracy of current body mass index obesity classification for white, black, and Hispanic reproductive-age women," *Obstetrics and Gynecology* 115, no. 5 (2010): 982-988, doi:10.1097/AOG.0b013e3181da9423.

case law. Further, they are grounded in medical and ethical standards and reflect research demonstrating that, without access to confidential care, some patients would not seek needed health services.[13] Despite this assurance, the Supporting Statement for the Title X FPAR 2.0 fails to address how OPA will maintain the confidentiality of the sensitive personal health information it wants to collect through FPAR 2.0.[14] Despite a range of opinions about what qualifies as sensitive health information, it generally is considered to be information that carries with it unusually high risks in the event of disclosure. Several data elements within FPAR are sensitive in nature, as they relate to sexual behaviors and other deeply personal topics.

While encounter-level data will be de-identified, OPA has not released specifications for how the patient identifier data element will be used in a way that ensures that patient confidentiality is preserved. Furthermore, OPA has not provided information on the HIPAA Security Rule Standards it will adopt to ensure the appropriate consent and safeguarding of this encounter-level data at the federal, grantee, and subrecipient levels; for example, specifying encryption standards for data at rest and in motion. Given the cybersecurity issues that all organizations currently are facing, **it is imprudent to move forward with FPAR 2.0 without releasing more information about – and seeking stakeholder feedback on – the steps that OPA will take to protect FPAR 2.0's encounter-level data from unauthorized access, use, and disclosure, as well as what steps we will be required to take.**

PROPOSED TIMELINE

Essential Access requests that OPA establish a new timeline for FPAR 2.0 planning and implementation given the challenges all Title X grantees and service sites currently are facing. Even in the absence of the above challenges, the current timeline for FPAR 2.0 data collection to begin on January 1, 2022 is unworkable. To implement FPAR 2.0, Essential Access would need to upgrade to its information technology (IT) infrastructure, as would its projected 60 subrecipients. However, as of April 12, 2021, OPA has not released final specifications for (i.e., instructions for how to collect) FPAR 2.0's data elements, including how to map each data element and response options to standardized value sets. In the absence of these specifications, we are in the difficult position of having to wait while the time window needed to implement systems changes narrows.

Currently, we estimate it will take approximately 12 months to provide technical assistance to 60 subrecipients to add new fields to their systems, and another 12 months of technical assistance to help subrecipients update their data reports. In addition, concurrently it will take us an estimated 18 months to make all necessary upgrades to our data system and agency configurations inside that system. Extending this timeline is the limited availability of subrecipient IT staff to complete upgrades due to competing projects such as telehealth implementation, and because of understaffing due to the pandemic.

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[13] Liza Fuentes, Meghan Ingerick, Rachel Jones, and Laura Lindberg, "Adolescents' and Young Adults' Reports of Barriers to Confidential Health Care and Receipt of Contraceptive Services," *Journal of Adolescent Health* 62, no. 1 (2018): 36-43, https://doi.org/10.1016/j.jadohealth.2017.10.011.

[14] Ibid.

After making system upgrades, Essential Access and its subrecipients (which will operate approximately 300 service sites) will require 4 hours per service site to train health care providers and staff on how to collect new data elements, conduct preliminary data collection, run reports to ensure data mapping is correct, and perform quality assurance of preliminary data collected, as needed, for a total of 1200 hours**. Initiating upgrades before final specifications are available would be wasteful, as inconsistencies would require revisions that would carry additional costs and burden hours spent.**

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The current FPAR 2.0 project stands to severely disrupt operations during already uncertain times. Essential Access, like many Title X grantees, will have a harder time recruiting additional safety net providers to join its network, an ongoing effort since the 2019 Title X Rule took effect and Essential Access lost 16 subrecipients, departures that resulted in 80% fewer Title X patients served in 2020. **We are also concerned about losing existing subrecipients and service sites that cannot absorb this data collection burden.**

We are striving to see more patients after unprecedented declines in patient census. While we agree that the Title X program needs a more contemporary data system for monitoring and improving program performance, such an endeavor cannot come at the expense of serving those in need of services, specifically patients who are low-income, uninsured, and under-insured. Such an effort also cannot come at the expense of Title X patients receiving the same standard of care as their counterparts who receive care in non-Title X settings, which is just what FPAR 2.0 - with burdensome and unnecessary data elements that are required for every visit – would do. Accordingly, Essential Access urges OPA to pause and re-evaluate FPAR 2.0.

If you require additional information about the issues raised in this letter, please contact Karen Peacock, Associate Vice President of Research + Evaluation, at kpeacock@essentialaccess.org.

Sincerely,

Julie Rabinovitz
President + CEO
Essential Access Health

Karen Peacock
Associate Vice President, Research + Evaluation
Essential Access Health