COLORADO
Department of Public Health & Environment

Public Comment
Project Title: Family Planning Annual Report 2.0
Document Identifier: 0990-New-60D

Office of the Secretary

Health and Human Services

Attn.: Sherrette Funn, Reports Clearance Officer

Dear Sherrette Funn, March 15, 2021

The Colorado Department of Public Health and Environment's (CDPHE) Family Planning Program (FPP) is a Title X grantee. We have significant concerns regarding Family Planning Annual Report (FPAR) 2.0 data elements and systems changes proposed in this rule (project title: Family Planning Annual Report 2.0; document identifier: 0990-New-60D).

Specific concerns include:

- The overall purpose and intention behind collecting additional and encounter-level data elements is unclear. Significantly more meaningful research into the overall magnitude and consequences of proposed FPAR 2.0 changes (particularly on providers, clinics, and patients), and whether the changes will ultimately improve the Title X program, is needed.

- Many of the proposed FPAR 2.0 data elements do not adhere to modern sexual and reproductive health clinical guidelines and are concerning from the perspective of establishing and maintaining trust with diverse Title X patient populations over time.

- Many of the proposed FPAR 2.0 data elements risk breaching patient trust, confidentiality, and privacy, particularly for minors and individuals who are undocumented. Data "masking" will likely not lessen these concerns because of continued sensitivity and trust concerns when sharing data with the federal government.

- Many of the proposed FPAR 2.0 data elements, particularly those inquiring as to a patient's sexual activity, administrative sex, and/or intention to become pregnant, are repetitive, intrusive, and unnecessary. There is significant potential the proposed elements will hinder and/or harm trusted provider-patient relationships, especially given the sensitive nature of sexual and reproductive health. Many of the proposed elements should not be collected at the federal or state level, and some could be considered as protected health information.

- Many of the proposed FPAR 2.0 data elements, which are medically unnecessary, will also hinder the ability to provide effective and quality family planning services, including comprehensive contraceptive and/or preconception counseling, during a telehealth visit, which typically lasts only 20 minutes.

- It is unclear which proposed FPAR 2.0 data elements will be required or optional. This makes preparing for a FPAR 2.0 launch (both at the grantee and service site level) difficult.

- Collecting itemized data for sexually-transmitted infection testing and other procedures will require significant changes to clinical workflows, which will add considerable additional burden to clinics already operating with high turnover, limited numbers of providers, and limited budgets.

- Many providers will need to make cumbersome and complex changes to their electronic health record (EHR) systems, which can be expensive and place a high cost burden on clinics already providing critical family planning services under a limited budget to communities in need.

- The proposed FPAR 2.0 data elements will overburden providers with reporting requirements, as Title X is not the only federal program that requires significant data submission and reporting. Many Title X providers receive funding from other such federal programs/providers. Many providers may consider leaving the Title X program due to the considerable level of time, effort, and funding needed to comply with proposed FPAR 2.0 changes.

Please take these comments into consideration before finalizing this rule. They represent a summary of the serious concerns CDPHE, Colorado Title X providers, and Title X grantees and providers in many other states have regarding proposed FPAR 2.0 changes. Additionally, we request this rule be postponed until additional research into the overall magnitude and consequences of FPAR 2.0 can be conducted and/or additional support for Title X grantees and service sites can be provided.

If additional information is helpful, please let me know.

Sincerely,

Benjamin Cajarty

Benjamin Cajarty, Esq.

FPP Manager

NFPRHA Response to 60-Day Public Comment Request:
Family Planning Annual Report 2.0

I. Introduction

Converge welcomes the opportunity to submit comments in response to the Department of Health and Human Services' (HHS) Agency Information Collection Request 0990-New-60D on Family Planning Annual Report 2.0, issued on February 11, 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). 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). While Converge 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.

Converge was founded in October 2018. Converge collaborates with health care providers, insurance companies, and community partners to build a health care system that places people at the center of family planning care. Our vision is that all people have access to quality, affordable family planning care. As part of this vision, Converge collaborates with the current Title X Grantee in Mississippi to ensure quality data reporting and quality care is provided to all clients. In 2020, Converge began implementing a data dashboard for all community health clinic members of the Mississippi Title X network. This marked the first time the clinics were providing regular data updates to the grantee.

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. 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.

Timeline

Converge 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.

Accuracy of Estimated Burden

Converge 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 translate to the data collected no longer being 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 be 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 each grantee-subrecipient dyad to invest in upgrading to electronic systems (as applicable) and establishing interoperability between their respective systems

Burden, Necessity and Utility of FPAR 2.0 Data

Converge believes the 23 additional 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. It corresponds to the deliberate transition of FPAR from a program monitoring tool to a research dataset, requiring Title X service sites to collect excessive information from patients at every single visit, even though such information is not necessitated by clinical practice guidelines or other evidence-based standards.

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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).

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 include screening for breast and cervical cancer,"[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 (or lack of) are of particular concern to Converge:

New Data Elements: Future Pregnancy Intention Reported

The inclusion of reported pregnancy intention as a reportable data measure fails to address the well documented reality of pregnancy ambivalence. Very few people conceive of pregnancy decision making in the very formal time limited way that One Key Question and other intention assessments frame this. In addition to the unacceptable focus on intention, collecting data on how people state their desire for a pregnancy does not speak to their contraceptive decision making as often these elements are not directly related. [6] As the Title X program continues to address the need for noncoercive and equitable care, it is critical to properly address contraceptive decision making as person-centered and driven by preferences stated by the client. Patients themselves have stated a preference for shared decision making that is guided by their preferences and the medical input of their provider [7] A continued focus on "pregnancy intention" leads can lead to a focus on method effectiveness to prevent pregnancy that may not be at all guided by patient preference for contraceptive methods. Thus, collecting intention around pregnancy both generates data that does not actually mean very much with relation to patient decision making and it may have the unintended consequence of encouraging non-equitable and even coercive counseling practices.

Lack of Data: No Patient Reported Measures

FPAR 2.0, like previous FPAR data and many other large efforts to generate data on healthcare utilization fails to collect any data from patients themselves. This lack of patient input speaks to a very narrow focus on clinical outcomes and practices while failing to properly address the critical element of how patients experience this federally funded health care program. In particular on the topic of family planning and reproductive healthcare, there is a lengthy history as well a contemporary reality of coercion and abuse. Failing to value the reported experiences of patients equally with medical health record data does nothing to protect against the possibility of care that is harmful. Converge would propose the uniform usage of a patient reported measure that speaks to the patient-centeredness of care provided. The Patient-Centered

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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.

[6] Borrero S, Nikolajski C, Steinberg JR, Freedman L, Akers AY, Ibrahim S, Schwarz EB. "It just happens": a qualitative study exploring low-income women's perspectives on pregnancy intention and planning. Contraception. 2015 Feb

[7] Christine Dehlendorf, Kira Levy, Allison Kelley, Kevin Grumbach, Jody Steinauer, Women's preferences for contraceptive counseling and decision making, Contraception, Volume 88, Issue 2, 2013

Contraceptive Counseling measure[8] is one such tool that could be used throughout the Title X program to ensure patient input is being collected and valued. The measure is validated by the National Quality Forum.

New Data Elements: Sexual Activity

The Supporting Statement for the Title X FPAR 2.0 describes how FPAR 2.0 will supplement the federally funded National Survey for Family Growth (NSFG), a population-level, nationally representative dataset that gathers information on pregnancy and births, infertility, use of contraception, and general and reproductive health.[9] However, while NSFG surveys a representative sample of respondents and allows them to *voluntarily* respond, the data elements that will be collected and reported through FPAR 2.0 will be required for every patient visit. More specifically, 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 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)].[10] These sexual activity-related data fields also are not needed to monitor our Title X network's accountability to program goals.

It is important to emphasize that patients accessing services in non-Title X settings would not be asked to provide responses to these personal, guideline-unconcordant questions at every visit, nor would their responses be reported at the encounter level to the federal government. When the federal government begins collecting research data for its benefit and requires those accessing services through the safety net to provide such information as a precursor to receive care, it exacerbates medical mistrust, potentially dissuading patients from coming to us for needed services.

Data Elements: Cervical Cancer Screening

FPAR 2.0 suggests the Title X service sites collect and report five different data elements related to cervical cancer screening: Pap test at this visit, Last Pap result, Pap test in the last five years, HPV test performed at this visit, and HPV test result. Collecting and reporting all five data elements for every Title X visit would carry substantial burden with minimal benefit.

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

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8 Dehlendorf C, Fox E, Silverstein IA, Hoffman A, Campora Pérez MP, Holt K, Reed R, Hessler D. Development of the Person-Centered Contraceptive Counseling scale (PCCC), a short form of the Interpersonal Quality of Family Planning care scale. Contraception. 2021 Jan

9 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.

10 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.

at a five-year interval and there is no national benchmark pertaining to the rate of tests that should come back as positive.[11]

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.[12] 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.[13] [14] 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 (detailed as ever smoker, ex-smoker, smokes daily, occasional smoker, smoker, status unknown, heavy smoker, light smoker).

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 determine to report the intervention(s) offered to tobacco smokers, using those listed by the US Preventive Services Task Force.[15]

Converge believes the collection of height and weight data, presumably to calculate body mass index (BMI), is problematic. From a clinical perspective, there is no logical rationale to record and report body weight *at every visit*, and OPA does not state why it is necessary to collect this information and how it will be used in the Supporting Statement for the Title X FPAR 2.0.[16] Even

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11 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.

[12] Ibid.

[13] 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.

[14] *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.

[15] 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.

[16] *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.

when collecting a patient's height and weight data is clinically indicated, 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 because it fails to account for differences in body composition, fitness levels, and nutritional differences.[17] Furthermore, the practice of weighing clients at every visit – even health education sessions or when not clinically indicated – may deter clients from accessing services due to experiences of body shame and weight discrimination.[18]

Patients accessing health services in non-Title X settings are not weighed at every visit unless clinically indicated. Title X patients should receive the same standard of care and should not be subject to weight stigmatization at every visit. Weight stigma invokes psychological stress and emerging research suggests that this stress leads can exacerbate poor physical health outcomes for obese individuals[19], with the potential to perpetuate racial/ethnic and socioeconomic health disparities in overweight and obesity. It is time to move away from this measure and focus on measures of health that are scientifically valid and designed for diverse patient populations.

Screening for cardiovascular risk factors is indicated to support contraceptive decision-making (i.e., to ensure a patient does not have contraindications to combined oral contraceptives and other hormonal contraception) and pre-pregnancy health. While it may be desirable to capture these measures for additional patients, there is no explicit expectation or requirement for Title X providers to obtain information beyond that which is clinically necessary. Accordingly, we should not be required to document and report these measurements for every visit.

Confidentiality of Sensitive Personal Health Information

Converge requests further 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 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.[20] 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.[21] 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

[17] 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.
[18] Janell L Mensinger, Tracy L Tylka, and Margaret E Calamari, "Mechanisms underlying weight status and healthcare avoidance in women: A study of weight stigma, body-related shame and guilt, and healthcare stress," *Body Image* 25 (2018):139-147. doi.org/10.1016/j.bodyim.2018.03.001.
[19] Rebecca M Puhl and Chelsea A Heuer, "Obesity stigma: important considerations for public health," *American Journal of Public Health* 100, no. 6 (2010):1019-28. doi:10.2105/AJPH.2009.159491.
[20] 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.
[21] Ibid.

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 seems 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.

Despite a range of opinions about what qualifies as sensitive health information, it generally is 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.

Converge urges OPA to pause and re-evaluate FPAR 2.0.

If you require additional information about the issues raised in this letter, please contact Danielle Lampton at DLampton@Convergems.org

Sincerely,

Danielle Lampton and Jamie Bardwell
Co-Founders, Converge
Jackson, MS

Denver Health Response to 60-Day Public Comment Request:
Family Planning Annual Report 2.0

I. Introduction

Denver Health welcomes the opportunity to submit comments in response to the Department of Health and Human Services' (HHS) Agency Information Collection Request 0990-New-60D on Family Planning Annual Report 2.0, issued on February 11, 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). 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). While Denver Health 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.

Denver Health (DH) is Colorado's primary integrated safety-net health system and has been serving the community since 1860. Clinical care, health education and research are at the core of Denver Health's mission. DH provides access to the highest quality health care, whether for prevention, or acute and chronic diseases, regardless of a patient's ability to pay and serve as a model for other safety net institutions across the nation. DH cares for 33% of Denver's population annually and special populations such as the poor, uninsured, pregnant teens, persons with substance use disorders, victims of violence and the homeless.

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 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. At this time, implementation of FPAR 2.0 simply is not feasible. Like all safety net providers, Denver Health has experienced challenges related to the COVID-19 public health emergency, including prioritizing testing and treatment; implementing telehealth services; cost of personal protective equipment (PPE); and vaccine distribution for communities. Any attempt to implement FPAR 2.0 in accordance with current timelines will disrupt our ability to respond to these top priorities.

Timeline

Denver Health 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, Denver Health would need to make upgrades to its information technology (IT) infrastructure, However, as of 3/27/2021 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 option 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. After making system upgrades, Denver Health will require several months 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. Initiating upgrades before final specifications are available would be wasteful, as inconsistencies would require revisions that would carry additional costs and burden hours spent.

Accuracy of Estimated Burden

Denver Health 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[1], 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 translate to the data collected no longer being relevant.

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)[2], 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 be substantially less burdensome on grantees and subrecipients.

Burden, Necessity and Utility of FPAR 2.0 Data

Denver Health believes the 23 additional 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. It corresponds to the deliberate transition of FPAR from a program monitoring tool to a research dataset, requiring Title X service sites to collect excessive information from patients at every single visit, even though such information is not necessitated by clinical practice guidelines or other evidence-based standards.

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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.[3] 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 include screening for breast and cervical cancer,"[4] 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 to Denver Health:

New Data Elements: Sexual Activity

The Supporting Statement for the Title X FPAR 2.0 describes how FPAR 2.0 will supplement the federally funded National Survey for Family Growth (NSFG), a population-level, nationally representative dataset that gathers information on pregnancy and births, infertility, use of contraception, and general and reproductive health.[5] However, while NSFG surveys a representative sample of respondents and allows them to *voluntarily* respond, the data elements that will be collected and reported through FPAR 2.0 will be required for every patient visit. More specifically, 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 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.

It is important to emphasize that patients accessing services in non-Title X settings would not be asked to provide responses to these personal, guideline-unconcordant questions at every visit, nor would their responses be reported at the encounter level to the federal government. When the federal government begins collecting research data for its benefit and requires those accessing services through the safety net to provide such information as a precursor to receive care, it exacerbates medical mistrust, potentially dissuading patients from coming to us for needed services.

Data Elements: Cervical Cancer Screening

FPAR 2.0 suggests the Title X service sites collect and report five different data elements related to cervical cancer screening: Pap test at this visit, Last Pap result, Pap test in the last five years, HPV test performed at this visit, and HPV test result. Collecting and reporting all five data elements for every Title X visit would carry substantial burden with minimal benefit.

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[3] 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.

[4] 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.

[5] *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.

[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.

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 for Denver Health to differentiate 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 (detailed as ever smoker, ex-smoker, smokes daily, occasional smoker, smoker, status unknown, heavy smoker, light smoker).

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 determine to report the intervention(s) offered to tobacco smokers, using those listed by the US Preventive Services Task Force.[11]

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[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.

[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.

Denver Health believes the collection of height and weight data, presumably to calculate body mass index (BMI), is problematic. From a clinical perspective, there is no logical rationale to record and report body weight *at every visit*, and OPA does not state why it is necessary to collect this information and how it will be used in the Supporting Statement for the Title X FPAR 2.0.[12] Even when collecting a patient's height and weight data is clinically indicated, 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 because it fails to account for differences in body composition, fitness levels, and nutritional differences.[13] Furthermore, the practice of weighing clients at every visit – even health education sessions or when not clinically indicated – may deter clients from accessing services due to experiences of body shame and weight discrimination.[14]

Patients accessing health services in non-Title X settings are not weighed at every visit unless clinically indicated. Title X patients should receive the same standard of care and should not be subject to weight stigmatization at every visit. Weight stigma invokes psychological stress and emerging research suggests that this stress leads can exacerbate poor physical health outcomes for obese individuals[15], with the potential to perpetuate racial/ethnic and socioeconomic health disparities in overweight and obesity. It is time to move away from this measure and focus on measures of health that are scientifically valid and designed for diverse patient populations.

Screening for cardiovascular risk factors is indicated to support contraceptive decision-making (i.e., to ensure a patient does not have contraindications to combined oral contraceptives and other hormonal contraception) and pre-pregnancy health. While it may be desirable to capture these measures for additional patients, there is no explicit expectation or requirement for Title X providers to obtain information beyond that which is clinically necessary. Accordingly, we should not be required to document and report these measurements for every visit.

New Data Element: National Provider Identifier (NPI)

While most advanced practice clinicians have an 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. Title X family planning encounters at Denver Health are routinely performed by other providers, including registered nurses and health educators. 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

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[12] *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.

[13] 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.

[14] Janell L Mensinger, Tracy L Tylka, and Margaret E Calamari, "Mechanisms underlying weight status and healthcare avoidance in women: A study of weight stigma, body-related shame and guilt, and healthcare stress," *Body Image* 25 (2018):139-147. doi.org/10.1016/j.bodyim.2018.03.001.

[15] Rebecca M Puhl and Chelsea A Heuer, "Obesity stigma: important considerations for public health," *American Journal of Public Health* 100, no. 6 (2010):1019-28. doi:10.2105/AJPH.2009.159491.

Denver Health requests further 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 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.[16] 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.[17] 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 seems 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.

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 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 providing Title X patients with 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, Denver Health urges OPA to pause and re-evaluate FPAR 2.0.

Sincerely,

Simon Hambidge, MD, PhD
CEO Denver Community Health Services
Chief Ambulatory Officer
Denver Health
simon.hambidge@dhha.org

[16] 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.
[17] Ibid.

April 9, 2021

Regarding: **0990-New-60D Family Planning Annual Report 2.0**
Wyoming Health Council Response to 60-Day Public Comment Request

Sherrette Funn
Sherrette.funn@hhs.gov
Reports Clearance Officer
Office of Secretary, HHS

Dear Ms. Funn,

The purpose of this letter from Wyoming Health Council (WHC) is to request that the implementation of FPAR 2.0 be put on hold. 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). While the WHC 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.

We have identified below our areas of concern with what is being proposed:

- FPAR 2.0 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.
- 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 – implementation of FPAR 2.0 simply is not feasible at this time. We are working hard to hold on, rebuild, and continue providing critical services to patients.
- Like all safety net providers, WHC has experienced several challenges since 2019. The Wyoming Title X network saw one service site withdrawal which resulted in a loss of over 800 being served in one community over the restrictions related to abortion services. Our eight (8) subrecipients experienced a 24% decrease in unduplicated clients and a 23% decrease in total encounters as a result of COVID-19.
- WHC 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.

- Currently, we estimate it will take 12-18 months to implement and test the systems upgrades needed to collect and report encounter-level data through FPAR 2.0. This includes required steps to upgrade systems, which may include processes related to vendor procurement, adopting and implementing a new electronic health record (EHR) or electronic data collection system to report encounter-level data, customizing existing systems so the FPAR 2.0 data elements map to existing standardized value sets, data validation efforts, etc.

- Extending this timeline is the limited availability of IT staff or external consultants/vendors to complete upgrades due to competing projects and existing engagements (e.g., developing vaccine appointment scheduling systems and registries).

- After making system upgrades, WHC and its subrecipients (which operate eleven (11) service sites) will require a minimum of six to eight (6-8) months 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. Initiating upgrades before final specifications are available would be wasteful, as inconsistencies would require revisions that would carry additional costs and burden hours spent.

- Current OPA timelines also assume a level of baseline technology at both the Title X grantee and subrecipient levels. However, 2 of our subrecipients have not yet adopted EHR systems and one of these subrecipients has only 1 administrative/financial and 1 clinical staff. Instead, these organizations use paper forms to collect FPAR data for aggregate submission. Those service sites without EHRs will not be able to begin reporting FPAR 2.0 data electronically on January 1, 2022, as EHR implementation typically takes 9 to 11 months, with three months for planning and six to eight months for implementation. Instead, if FPAR 2.0 goes into effect on that date, they will need to collect and perform manual data entry of FPAR 2.0's 45 proposed data elements for every visit, and then determine how to de-identify line-item records so that they can be transmitted securely. This cumbersome process not only raises concerns about the effective use of Title X resources, but also about the security and confidentiality of clients' sensitive health information.

- WHC 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.

- In WHC's Title X network, there are 8 subrecipients using 2 EHR platforms.

- WHC estimates that implementing FPAR 2.0 as proposed at the grantee-level will amount to over $75,000.00 in one-time non-labor costs. This estimate is based on initial estimates for program data assessment, data program installation, and training. Furthermore, WHC estimates that each of its eight (8) subrecipients will outlay an average of $7,036.00 in non-labor costs to implement FPAR 2.0, for an estimated total of $56,288.00 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 and purchased service costs.

- All of our programs rely on some state funding to support various program activities. This year, all state programs were required to cut 20% of their budgets. The result may be that local, county and state governments will have less dollars at their disposal to support Title X program.

- WHC has been unable to realistically assess one-time labor costs to implement FPAR 2.0. The reality is that the Grantee has 2 full time staff (Executive Director and Clinical Director) and two part-time staff whose responsibilities do not include FPAR data. This estimate is based on the cost of the Executive and Clinical Directors working a combined 200 hours on tasks related to implementation, which may include: selecting and/or creating a contract with a vendor, working (with vendors) to perform necessary system upgrades and map out FPAR 2.0's data elements to existing standardized value sets, training health care providers and staff on how to collect new data elements, conducting preliminary data collection, running reports to ensure data mapping is correct, and performing quality assurance of preliminary data collected]. For grantees: We also estimate that each of our eight (8) subrecipients will spend an average of eighty (80) hours implementing FPAR 2.0, for an estimated total of 840 hours in one-time labor costs across this single Title X grantee network.

- 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.

- WHC believes the 23 additional 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.

- The following data elements are of particular concern to WHC:
    - 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 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)]. These sexual activity-related data fields also are not needed to monitor our Title X network's accountability to program goals.
    - When the federal government begins collecting research data for its benefit and requires those accessing services through the safety net to provide such information as a precursor to receive care, it exacerbates medical mistrust, potentially dissuading patients from coming to us for needed services.
    - FPAR 2.0 suggests the Title X service sites collect and report five different data elements related to cervical cancer screening: Pap test at this visit, Last Pap result, Pap test in the last five years, HPV test performed at this visit, and HPV test result. Collecting and reporting all five data elements for every Title X visit would carry substantial burden with minimal benefit.
    - Furthermore, there is no way for WHC to differentiate 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. 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. When extracting data to calculate measures, there is no way to qualify whether an appropriate screening interval was applied.

- 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 (detailed as ever smoker, ex-smoker, smokes daily, occasional smoker, smoker, status unknown, heavy smoker, light smoker).

- 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.

- WHC believes the collection of height and weight data, presumably to calculate body mass index (BMI), is problematic. From a clinical perspective, there is no logical rationale to record and report body weight *at every visit*, and OPA does not state why it is necessary to collect this information and how it will be used in the Supporting Statement for the Title X FPAR 2.0.

- 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. Furthermore, the practice of weighing clients at every visit – even health education sessions or when not clinically indicated – may deter clients from accessing services due to experiences of body shame and weight discrimination.

- WHC requests further 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 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.

    - Given the cybersecurity issues that all organizations currently are facing, it seems 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.

- 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.

The current FPAR 2.0 project stands to severely disrupt WHC's operations during already uncertain times. WHC, 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 WHC lost one subrecipient, a departure that resulted in approximately 800 fewer Title X patients served in 2020. WHC also is concerned of losing existing subrecipients and service sites that cannot absorb this data collection burden.

We are striving to see more patients. 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 providing Title X patients with 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, WHC urges OPA to pause and re-evaluate FPAR 2.0.

If you require additional information about the issues raised in this letter, please contact Rob Johnston (rjohnston@wyhc.org) or Gail Wilson (gwilson@wyhc.org).

Sincerely,

Robert Johnston

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National
Family Planning
& Reproductive Health Association

April 9, 2021

Sherrette Funn
Reports Clearance Officer
U.S. Department of Health and Human Services
200 Independence Avenue SW, Room 713F
Washington, DC 20201

RE: Comments on 0990-New-60D; 60-Day Public Comment Request on Family Planning Annual Report 2.0 (86 FR 9077)

Dear Sherrette Funn:

The National Family Planning and Reproductive Health Association (NFPRHA) welcomes the opportunity to submit comments in response to the Department of Health and Human Services' (HHS) Agency Information Collection Request 0990-New-60D on Family Planning Annual Report 2.0, issued on February 11, 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). Currently collected in aggregate under OMB No. 0990-0221, this new data collection system, "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). While NFPRHA appreciates the need for a modern data system for monitoring and improving program performance, the current FPAR 2.0 project must be paused. The 23 additional elements go beyond what is necessary for quality improvement and what is required by statutory requirements, regulations, and operational guidance. Accordingly, NFPRHA requests that OPA plan and initiate a different process for transitioning to a new data collection and reporting system with continued stakeholder involvement.

NFPRHA is a national, nonprofit membership organization that advances and elevates the importance of family planning in the nation's health care system and promotes and supports the work of family planning providers and administrators, especially those in the safety net. NFPRHA envisions a nation where all people can access high-quality, culturally responsive family planning and sexual health services; and where people who rely on safety net settings for services, including those funded by the Title X program, receive the same respectful, patient-centered, and evidence-based care as those individuals accessing services outside of the safety net. NFPRHA represents more than 977 health care organizations and individuals in all 50 states, the District of Columbia, and the territories. NFPRHA's organizational members include state, county, and local health departments; private, nonprofit family planning organizations; family planning councils; Planned Parenthood affiliates, hospital-based clinics; and federally qualified health centers. These organizational members include 53 of the 72 grantee organizations currently funded by OPA through the Title X program, as well as 15 of the

17 grantee organizations that withdrew in response to the 2019 Title X Rule. In fact, in 2019, more than 3,500 of the 3,895 Title X service sites reported by OPA in the 2019 FPAR were operated by NFPRHA's network of members.[1] Accordingly, NFPRHA is uniquely positioned to respond to OPA's Public Comment Request.

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. 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[2] – implementation of FPAR 2.0 simply is not feasible for Title X grantees and subrecipients. These organizations are working hard to rebuild and continue providing critical services to patients.

Timeline

NFPRHA requests that OPA establish a new timeline for FPAR 2.0 planning and implementation given the challenges all Title X grantees and service sites 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, Title X grantees and subrecipients must upgrade existing information technology (IT) infrastructure. However, as of April 9, 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 option to standardized value sets; nor has it published the anticipated data elements on its website. In the absence of these specifications, grantees are in the difficult position of having to wait while the time window needed to implement systems changes narrows. Initiating upgrades before final specifications are available would be wasteful, as inconsistencies would require revisions that carry additional costs and burden hours spent.

NFPRHA estimates that it will take 12-18 months to initiate encounter-level data collection and reporting through FPAR 2.0, which includes the following steps:

- **Implementing necessary system upgrades:** To implement FPAR 2.0, grantees must implement IT system upgrades that involve building or modifying an existing data warehouse and setting up secure file transfer with subrecipients using secure file transfer protocol (SFTP). On the subrecipient level, organizations must engage in system upgrades that may involve adopting and implementing new electronic health record (EHR) or electronic data collection systems to report encounter-level data or customizing existing systems so the FPAR 2.0 data elements map to existing standardized value sets. Most grantees and subrecipients must manage vendor acquisition and procurement processes as part of this phase, a process that can be particularly slow in the public sector. Of note, 40 Title X service grants are administered by state and local health departments.
- **Data validation:** Grantees must work with each of their subrecipients to electronically validate data. Data validation is an involved process that entails ensuring that all data

[1] C Fowler, J Gable, B Lasater, and K Asman, *Family Planning Annual Report: 2019 National Summary* (Washington, DC: Office of Population Affairs, 2020).
[2] 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).

are present and, from there, conducting quality assurance to ensure there are no incongruent or incomplete counts, duplicate data, incorrect formats, and null field values.
- **Training:** After making all necessary system upgrades, grantees must train staff at their organizations and at the subrecipient level on how to collect new data elements. From there, to ensure full and accurate data collection when systems "go live," grantees will conduct preliminary data collection, perform quality assurance of preliminary data collected, and offer technical assistance and retrain as needed.

The limited availability of IT staff or vendors/external consultants to complete upgrades due to competing projects and existing engagements (e.g., developing vaccine appointment scheduling systems and registries, integrating telehealth platforms with EHRs, providing day-to-day IT support to remote staff) also will extend the standard timeline for such changes.

Current OPA timelines also assume a level of baseline technology at both the Title X grantee and subrecipient levels. However, many Title X grantees and subrecipients have not yet adopted EHR systems; as of 2016, 31% of Title X service sites had not adopted EHR systems.[3] Instead, these organizations use paper forms and/or homegrown legacy systems (e.g., billing systems, Department of Social Services Medicaid portals) to collect FPAR data for aggregate submission. Those service sites without EHRs will not be able to begin reporting FPAR 2.0 data electronically on January 1, 2022, as EHR implementation typically takes 9 to 11 months, with three months for planning and six to eight months for implementation.[4] Instead, if FPAR 2.0 goes into effect on that date, they will need to collect and perform manual data entry of FPAR 2.0's 45 proposed data elements for every visit, and then determine how to deidentify line-item records so that they can be transmitted securely. This cumbersome process not only raises concerns about the effective use of Title X resources, but also about the security and confidentiality of clients' sensitive health information.

Accuracy of Estimated Burden

NFPRHA requests that OPA complete an up-to-date burden study to provide a complete and accurate estimate of the burden associated with implementing encounter-level data collection and reporting through 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[5], was published in 2009 using data collected from Title X grantees about the cost and time burdens of implementing a new FPAR system that reports data aggregately (as opposed to encounter-level data reporting and collection). OPA has not collected more recent feedback from the Title X network regarding burden and costs associated with encounter-level data collection and the proposed new FPAR 2.0 data elements.

The FPAR Burden Study estimated gross non-labor costs to be $163,300 (or $2,207 per respondent) and annualized labor costs to be $106,880 (or $1,444 per respondent).[6] It is inappropriate for OPA to use data collected from the 2009 FPAR Burden Study to quantify costs

[3] Office of Population Affairs, "Service Delivery Improvement Projects," accessed March 19, 2021, https://opa.hhs.gov/research-evaluation/title-x-services-research/service-delivery-improvement-projects.
[4] Roboam R Aguirre, et al., "Electronic Health Record Implementation: A Review of Resources and Tools," *Cureus* 11, no. 9 (2019): e5649, doi:10.7759/cureus.5649.
[5] RTI International, *Family Planning Annual Report Burden Study* (Research Triangle Park, NC: RTI, 2009).
[6] *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).

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 be substantially less burdensome on grantees and subrecipients. Indeed, it was not until 2012 that 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.[7] In 2014, OPA requested Office of Management and Budget (OMB) approval to begin assessing the feasibility of encounter-level data collection and the proposed new FPAR 2.0 data elements,[8] but that assessment was not completed.

Another factor that has changed in the last decade is the cost of technology for use in health care. The Health Information Technology for Economic and Clinical Health (HITECH) Act, enacted in 2009, led to changes in the health IT industry that increased costs for these proposed changes. As part of the American Recovery and Reinvestment Act (ARRA), the HITECH Act allocated $19.2 billion to promote the adoption of use of health IT by providers who serve patients with Medicare and Medicaid. While HITECH Act funds supported some, but not all, Title X service sites to adopt and implement electronic health records (EHRs), the infusion of funds into the health IT industry gave rise to a multitude of EHR vendors and platforms and, in turn, challenges with interoperability (i.e., electronic sharing of data between systems). Health data exchange and interoperability solutions are available to streamline data exchange and electronic reporting, but this additional technology carries time (burden hours) and costs for customizations. In addition, HITECH funds were one-time investments, so funding to support upgrades and changing technology is not available. Consequently, there is no “one size fits all” approach for implementing FPAR 2.0 electronic reporting from Title X service sites to grantees, necessitating each grantee-subrecipient dyad to invest in upgrading to electronic systems (as applicable) and establishing interoperability between their respective systems.

Of note, though local and state health departments were eligible to receive HITECH Act funds and understood that IT investments were imperative, most lacked the necessary staff expertise, time, and resources to meet the timelines mandated by HITECH.[9] Based on NFPRHA’s estimates, almost half (47%) of Title X service sites currently are operated by local and state health departments. Because many of these service sites did not benefit from HITECH funds and may continue to use paper forms or homegrown legacy systems, they lack the IT infrastructures needed to implement FPAR 2.0 in accordance with OPA’s project schedule. And, for the same reasons that many local and statement health departments could not meet the timelines mandated by HITECH, they also cannot implement FPAR 2.0 in accordance with OPA’s project schedule.

In 2020, NFPRHA began conversations with various grantees and health information system subject matter experts about the burden and cost of implementing FPAR 2.0. Based on information collected, NFPRHA estimates that implementing FPAR 2.0 as proposed will amount to $65,000 in average one-time non-labor costs per grantee, or an average of $4,680,000 across all 72 service grantees.[10] Spending will be on engaging EHR vendors or other external contractors to build or modify existing data warehouses and perform system upgrades, as well

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[7] *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; November 19, 2014).
[8] Ibid.
[9] Adil Moiduddin and Michael Millman, *Assessing the status and prospects of state and local health department information technology infrastructure* (Washington, DC: Assistant Secretary for Planning and Evaluation, 2013).
[10] $65,000 x 72 grantees = $4,680,000

as purchasing or subscribing to a SFTP server. These cost estimates do not include ongoing expenses such as computer and software upgrades and purchased service costs.

Labor costs also will be high. In March 2021, 40 grantee organizations provided NFPRHA with estimates for the number of hours they will need to spend implementing FPAR 2.0 as currently planned. Based on this data, NFPRHA estimates grantee organizations each will spend 183 hours implementing FPAR 2.0. These estimates are based on the cost of working on tasks related to implementation, including selecting and/or creating a contract with a vendor, working with vendors to perform necessary system upgrades and map out FPAR 2.0's data elements to existing standardized value sets, training health care providers and staff on how to collect new data elements, conducting preliminary data collection, running reports to ensure data mapping is correct, and performing quality assurance of preliminary data collected. Based on average (weighted) hourly wage estimates published in the Supporting Statement for the Title X FPAR 2.0 ($40.12), these burden hours will amount to $7,342 in one-time labor costs per grantee, or $528,621 across all 72 current grantees.[11]

Another striking limitation of the 2009 Burden Study is its failure to include estimates for the burden that must be undertaken by the Title X network's 1,060 subrecipients and 3,825 service sites.[12] Based on information submitted by 36 grantees in March 2021, NFPRHA estimates that each subrecipient will spend an average of 85 hours implementing FPAR 2.0 as currently planned in 2021. Based on average (weighted) hourly wage estimates published in the Supporting Statement for the Title X FPAR 2.0 ($40.12), these burden hours will amount to $3,410 in one-time labor costs per subrecipient, or $3,614,812 across all 1,060 current subrecipients.[13] Furthermore, NFPRHA estimates that current subrecipients will spend an average of $18,000 in one-time non-labor costs, primarily paid to EHR vendors and/or external contractors, to make changes to their EHRs or practice management systems (e.g., build new or update existing templates, code new data elements' value sets). Across all 1,060 current subrecipients these one-time non-labor costs amount to $19,080,000.[14] To reiterate, subrecipients will incur these capital costs during the same fiscal year(s) as the COVID-19 public health emergency – a time when resources have been redirected to emergency response and revenue has dwindled due to decreases in patient census.

Based on the above estimates, the cost of implementing FPAR 2.0 as currently planned across the Title network is **$27,903,433**.[15] NFPRHA can provide additional information to substantiate this estimate upon request.

Again, OPA is proposing this time commitment take place when grantees and subrecipients 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.

Burden, Necessity and Utility of FPAR 2.0 Data

NFPRHA believes the 23 additional elements go beyond what is necessary for quality improvement and what is required by statutory requirements, regulations, and operational guidance. NFPRHA asks for additional opportunities for grantees and other

[11] $40.12 x 183 hours = $7,341.96; $7,341.96 x 72 grantees = $528,621.12
[12] C Fowler, et al., *Family Planning Annual Report: 2019 National Summary*, 2020.
[13] $40.12 x 85 hours = $3,410.20; $3,410.20 x 1,060 subrecipients = $3,614,812
[14] $18,000 x 1,060 subrecipients = $19,080,000
[15] $4,680,000 + $528,621 + $3,614,812 + $19,080,000 = $27,903,433

stakeholders to provide feedback on what additional data elements are feasible to add to the current FPAR clinic visit record and would be most helpful 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 These data elements seem to map more to the elements in a research database than in a program monitoring tool, requiring Title X service sites to collect excessive information from patients at every single visit, even though such information is not necessitated by clinical practice guidelines or other evidence-based standards.

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.[16] 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 include screening for breast and cervical cancer,"[17] they certainly should not be monitored at the encounter level to monitor accountability to program goals. NFPRHA requests 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 to NFPRHA and its members:

New Data Elements: Sexual Activity

The Supporting Statement for the Title X FPAR 2.0 describes how FPAR 2.0 will supplement the federally funded National Survey for Family Growth (NSFG), a population-level, nationally representative dataset that gathers information on pregnancy and births, infertility, use of contraception, and general and reproductive health.[18] However, while NSFG surveys a representative sample of respondents and allows them to *voluntarily* respond, the data elements that will be collected and reported through FPAR 2.0 will be required for every patient visit. More specifically, 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 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

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[16] 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.

[17] 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.

[18] *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.

transmitted infections (STIs)].[19] These sexual activity-related data fields also are not needed to monitor Title X grantees' accountability to program goals.

It is important to emphasize that patients accessing services in non-Title X settings would not be asked to provide responses to these personal, guideline-unconcordant questions at every visit, nor would their responses be reported at the encounter level to the federal government. When the federal government begins collecting research data for its benefit and requires those accessing services through the safety net to provide such information as a precursor to receive care, it exacerbates medical mistrust, potentially dissuading patients from accessing needed services.

New Data Element: Future Pregnancy Intention Reported

Another example of a proposed data element that is inconsistent with current research on the provision of patient-centered contraceptive care is the FPAR 2.0 data element tracking patients' intention to either become pregnant or prevent a pregnancy in the next year. Research suggests that many patients cannot articulate their pregnancy intentions over the next year; doing so is inconsistent with how they think about and approach their reproductive lives.[20] [21] Indeed, not all individuals overtly plan to have children or not have children, suggesting that asking about reproductive "intentions" or "plans" may be problematic.[22] Asking patients this kind of a question at every visit, regardless of the reason for the visit, could compromise the patient-provider relationship by breaking rapport and shifting the visit away from what the patient wants.

Reflecting current research that patients prefer to be asked about their service needs than about pregnancy intentions or desires[23], NFPRHA recommends that FPAR 2.0 use a more patient-centered approach to measurement. An example of an alternative measure that assesses patients' desire for contraceptive services is the Self-Identified Need for Contraception (SINC)[24] question developed by the University of California, San Francisco (UCSF) Person-Centered Reproductive Health Program in consultation with Reproductive Justice advocates. Of note, UCSF has an award from OPA to develop a new electronic Clinical Quality Measures (eCQMs) of contraceptive provision using the SINC question to define the denominator. As such, use of

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[19] 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.

[20] Abigail RA Aiken, Sonya Borrero, Lisa Callegari, and Christine Dehlendorf, "Rethinking the Pregnancy Planning Paradigm: Unintended Conceptions or Unrepresentative Concepts?," *Perspectives on Sexual and Reproductive Health* 48, no. 3 (2016):147-151, https://doi.org/10.1363/48e10316.

[21] Lisa S Callegari, Abigail RA Aiken, Christine Dehlendorf, Patty Cason, and Sonya Borrero, "Addressing potential pitfalls of reproductive life planning with patient-centered counseling," *American Journal of Obstetrics and Gynecology* 216, no. 2 (2017):129-134, https://doi.org/10.1016/j.ajog.2016.10.004.

[22] Lisa S Callegari, et al., "Addressing potential pitfalls of reproductive life planning with patient-centered counseling," 2017.

[23] Heidi E Jones, Cynthia Calixte, Meredith Manze, Michele Perlman, Susan Rubin, Lynn Roberts, and Diana Romero, "Primary care patients' preferences for reproductive health service needs assessment and service availability in New York Federally Qualified Health Centers," *Contraception* 101, no. 4 (2020): 226-230.

[24] "Do you want to talk about contraception or pregnancy prevention during your visit today?"

- If yes: Mark "yes" and ensure appropriate counseling is provided
- If no: "There are a lot of reasons why a person wouldn't want to talk about this, and you don't have to share anything you don't want to. Do any of these apply to you?" (mark all that apply):
    - I'm here for something else
    - This question does not apply to me
    - I prefer not to answer
    - I am already using contraception (and what)
    - I am unsure or don't want to use contraception
    - I am hoping to become pregnant in the near future

the SINC question in FPAR 2.0 would be consistent with other initiatives underway at OPA. Use of this type of measure also would facilitate the removal of problematic data elements related to sexual activity, which have been included to identify whether a patient is perceived as "at risk" for pregnancy.

Data Elements: Cervical Cancer Screening

FPAR 2.0 suggests the Title X service sites collect and report five different data elements related to cervical cancer screening: Pap test at this visit, Last Pap result, Pap test in the last five years, HPV test performed at this visit, and HPV test result. Collecting and reporting all five data elements for every Title X visit would carry substantial burden with minimal benefit. 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.[25] Furthermore, there is no way for grantees and subrecipients to differentiate 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.[26] 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.[27] [28] Therefore, the time and resource investments that grantees and subrecipients must make to collect and report these additional data elements will produce data with little – if not no – value for monitoring and improving program performance.

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 (detailed as never smoker, ex-smoker, smokes daily, occasional smoker, smoker, status unknown, heavy smoker, light smoker).

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,

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[25] 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.

[26] Ibid.

[27] 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.

[28] *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.

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.[29]

NFPRHA believes the collection of height and weight data, presumably to calculate body mass index (BMI), is problematic. From a clinical perspective, there is no logical rationale to record and report body weight *at every visit*, and OPA does not state why it is necessary to collect this information, and how it will be used, in the Supporting Statement for the Title X FPAR 2.0.[30] Even when collecting a patient's height and weight data is clinically indicated, 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.[31] Furthermore, the practice of weighing clients at every visit – even health education sessions or when not clinically indicated – may deter clients from accessing services due to experiences of body shame and weight discrimination.[32]

Patients accessing health services in non-Title X settings typically are weighed (or asked to self-report their weight) only when clinically indicated. Title X patients should receive the same standard of care and should not be subject to weight stigmatization at every visit. Weight stigma invokes psychological stress and emerging research suggests that this stress can exacerbate poor physical health outcomes for obese individuals[33], with the potential to perpetuate racial/ethnic and socioeconomic health disparities in overweight and obesity. It would be more appropriate to focus on measures of health that are scientifically valid and designed for diverse patient populations.

Screening for cardiovascular risk factors is indicated to support contraceptive decision-making (i.e., to ensure a patient does not have contraindications to combined oral contraceptives and other hormonal contraception) and pre-pregnancy health. While it may be desirable to capture these measures for all patients, there is no explicit expectation or requirement for Title X providers to obtain information beyond that which is clinically necessary. Accordingly, service sites should not be required to document and report these measurements for every visit.

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[29] 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.

[30] *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.

[31] 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.

[32] Janell L Mensinger, Tracy L Tylka, and Margaret E Calamari, "Mechanisms underlying weight status and healthcare avoidance in women: A study of weight stigma, body-related shame and guilt, and healthcare stress," *Body Image* 25 (2018):139-147. doi.org/10.1016/j.bodyim.2018.03.001.

[33] Rebecca M Puhl and Chelsea A Heuer, "Obesity stigma: important considerations for public health," *American Journal of Public Health* 100, no. 6 (2010):1019-28. doi:10.2105/AJPH.2009.159491.

New Data Element: National Provider Identifier (NPI)
NPI is yet another proposed data element in FPAR 2.0 that has little or no value to grantees and subrecipients. 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, 32% percent of all Title X family planning encounters were performed by other types of providers, including registered nurses, registered nurses with an expanded scope of practice, licensed practical nurses, health educators, and social workers.[34] As such, many providers delivering Title X services do not have individual NPI to report for FPAR 2.0.

Confidentiality of Sensitive Personal Health Information
NFPRHA requests further 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 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.[35] 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.[36] 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 seems 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 grantees will be required to take.

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.

OPA has historically interpreted 42 CFR Part 59 as precluding the collection of identifying information in connection with sensitive services. For example, in Supporting Statements for the Title X FPAR that were submitted to OMB (dated June 29, 2010 and October 15, 2010), OPA states in its "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),

[34] C Fowler, et al., *Family Planning Annual Report: 2019 National Summary*, 2020.
[35] 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.
[36] Ibid.

> individuals cannot be identified because federal regulation (42 CFR Part 59) 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."[37] [38]

However, in the February 5, 2021 Supporting Statement for the Title X FPAR 2.0, OPA describes the need to collect encounter-level data of a sensitive nature, stating that the collection of such data "are required to monitor compliance with statutory requirements, program regulations and guidelines, performance reporting, and ongoing program management."[39]

Given this shift in OPA's justifications to OMB, OPA needs to provide clarification on the permissibility of submitting encounter-level data through FPAR 2.0.

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The current FPAR 2.0 project stands to severely disrupt Title X providers' operations during already uncertain times. NFPRHA's members are striving to see more patients after unprecedented declines in patient census. NFPRHA supports investments in Title X program infrastructure, including investment in a more contemporary data system for monitoring and improving program performance; however, such a venture 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 providing Title X patients with 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, NFPRHA urges OPA to pause and re-evaluate FPAR 2.0.

If you require additional information about the issues raised in this letter, please contact Elizabeth Jones, Director, Service Delivery Improvement at ejones@nfprha.org.

Sincerely,

Clare Coleman
President & CEO
National Family Planning & Reproductive Health Association

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[37] *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; June 29, 2010).
[38] *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; October 15, 2010).
[39] *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.

Children's Hospital Colorado
Here, it's different.

April 9, 2021

Office of the Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201
Attn: Sherrette Funn, Reports Clearance Officer

Re: 0990-New-60D Comments on Family Planning Annual Report 2.0

Dear Sherette Funn:

Children's Hospital Colorado welcomes the opportunity to submit comments in response to the Department of Health and Human Services' Agency Information Collection Request 0990-New-60D on Family Planning Annual Report 2.0, issued on February 11, 2021. We write to express our serious concerns with the Office of Population Affairs' proposal for new encounter-level data collection for the Title X Family Planning Program. Currently collected in aggregate under OMB No. 0990-0221, this new data collection, Family Planning Annual Report, "(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).

Children's Hospital Colorado's BC4U Clinic provides reproductive health services and educational resources to over 5,000 people under the age of 25 in Colorado. The BC4U Clinic supports Colorado's continued success in improving the health and well-being of Colorado's children and families through access to effective and affordable family planning services and reducing unintended pregnancies. As a Title X sub-recipient, the BC4U Clinic would be directly impacted by these proposed changes.

We write today with significant concerns about the proposed changes in this rule and the impact they will have on patients, providers and clinics in our state. These changes would jeopardize patient and provider relationships, interfere with evidence-based practice, and threaten patient confidentiality. A patient's sexual and reproductive health are sensitive. The proposed FPAR 2.0 data elements risk the trust, confidentiality and privacy that's essential in providing quality patient care, especially among the young people we see in our clinic.

Patient-provider relationships will be harmed by inquiring about the invasive and unnecessary specifics in many of the proposed FPAR 2.0 data elements, which include details on a patient's sexual activity, intention to become pregnant, sexually transmitted infection testing and more. The proposed data elements do not adhere to modern sexual and reproductive health clinical guidelines and have the potential to harm a provider's ability to build and maintain trust with diverse Title X patient populations. These data elements are irrelevant to monitoring the Title X program for compliance and accountability to performance goals and will not ultimately improve the Title X program.

Collection of this data would weaken clinics' and providers' ability to serve patients effectively with quality family planning services. Many of these encounters are short, especially telehealth visits, and collecting itemized data and additional personal information from patients would interfere with providing comprehensive contraceptive and/or preconception counseling during these appointments.

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The proposed FPAR 2.0 data elements would also burden providers as they would require significant changes to clinical workflow and complex changes to electronic health record systems. Many Title X providers already spend a considerable amount of time on data submission and reporting to other federal programs and providers. These proposed data elements will overburden providers with reporting requirements.

It is unclear what the patient identifier will be under FPAR 2.0, but even if data is de-identified, there will still be sensitivity and patient trust concerns as this patient-level data will be shared with the federal government. Many of the proposed elements should not be collected at the federal or state level, and some could be considered as protected health information.

We strongly encourage you to take these concerns into consideration before finalizing this rule. Thank you for the opportunity to provide comments and we are happy to answer additional questions.

Sincerely,

Liz Romer DNP, FNP-C
Section of Adolescent Medicine, Children's Hospital Colorado
Executive Director, BC4U Clinic

Essential Access Health Response to 60-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-60D on Family Planning Annual Report 2.0, issued on February 11, 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 237 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 237 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 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.

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.

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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).

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.

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. It corresponds to the deliberate transition of FPAR from a program monitoring tool to a research dataset**, requiring Title X service sites to collect excessive information from patients at every single visit, even though such information is not necessitated by clinical practice guidelines or other evidence-based standards.

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

The Supporting Statement for the Title X FPAR 2.0 describes how FPAR 2.0 will supplement the federally funded National Survey for Family Growth (NSFG), a population-level, nationally representative dataset that gathers information on pregnancy and births, infertility, use of contraception, and general and reproductive health.[6] However, while NSFG surveys a representative sample of respondents and allows them to *voluntarily* respond, the data elements that will be collected and reported through FPAR 2.0 will be required for every patient visit. More specifically, 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 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)].[7] These sexual activity-related data fields also are not needed to monitor our Title X network's accountability to program goals.

It is important to emphasize that patients accessing services in non-Title X settings would not be asked to provide responses to these personal, guideline-unconcordant questions at every visit, nor would their responses be reported at the encounter level to the federal government. **When the federal government begins collecting research data for its benefit and requires those accessing services through the safety net to provide such information as a precursor to receive care, it exacerbates medical mistrust, potentially dissuading patients from coming to us for needed services.**

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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.

[6] *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.

[7] 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.

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. Collecting and reporting all five data elements for every Title X visit would carry substantial burden with minimal benefit.
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.[8] 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.[9] 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.[10] [11] 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.

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

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[8] 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.
[9] Ibid.
[10] 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.
[11] *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.

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.[12]

The collection of height and weight data, presumably to calculate body mass index (BMI), is problematic. From a clinical perspective, there is no logical rationale to record and report body weight *at every visit*, and OPA does not state why it is necessary to collect this information and how it will be used in the Supporting Statement for the Title X FPAR 2.0.[13] Even when collecting a patient's height and weight data is clinically indicated, 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.[14] Furthermore, the practice of weighing clients at every visit – even health education sessions or when not clinically indicated – may deter clients from accessing services due to experiences of body shame and weight discrimination.[15]

Patients accessing health services in non-Title X settings are not weighed at every visit unless clinically indicated. Title X patients should receive the same standard of care and should not be subject to weight stigmatization at every visit. Weight stigma invokes psychological stress and emerging research suggests that this stress can exacerbate poor physical health outcomes for obese individuals[16], with the potential to perpetuate racial/ethnic and socioeconomic health disparities in overweight and obesity. It is time to move away from this measure and focus on measures of health that are scientifically valid and designed for diverse patient populations.

Screening for cardiovascular risk factors is indicated to support contraceptive decision-making (i.e., to ensure a patient does not have contraindications to combined oral contraceptives and other hormonal contraception) and pre-pregnancy health. While it may be desirable to capture these measures for additional patients, there is no explicit expectation or requirement for Title X

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[12] 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.

[13] *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.

[14] 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.

[15] Janell L Mensinger, Tracy L Tylka, and Margaret E Calamari, "Mechanisms underlying weight status and healthcare avoidance in women: A study of weight stigma, body-related shame and guilt, and healthcare stress," *Body Image* 25 (2018):139-147. doi.org/10.1016/j.bodyim.2018.03.001.

[16] Rebecca M Puhl and Chelsea A Heuer, "Obesity stigma: important considerations for public health," *American Journal of Public Health* 100, no. 6 (2010):1019-28. doi:10.2105/AJPH.2009.159491.

providers to obtain information beyond that which is clinically necessary. Accordingly, we should not be required to document and report these measurements for every visit.

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 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.[17] 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.[18] 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.**

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[17] 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.
[18] Ibid.

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.

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

April 12, 2021

Office of the Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201
Attn: Sherrette Funn, Reports Clearance Officer
Submitted via email to: Sherrette.Funn@hhs.gov

Re: 0990-New-60D Comments on Family Planning Annual Report 2.0

Dear Sherette Funn:

The LARC4CO Coalition welcomes the opportunity to submit comments in response to the Department of Health and Human Services' Agency Information Collection Request 0990-New-60D on Family Planning Annual Report 2.0, issued on February 11, 2021. We write to express our serious concerns with the Office of Population Affairs' proposal for new encounter-level data collection for the Title X Family Planning Program. Currently collected in aggregate under OMB No. 0990-0221, this new data collection, Family Planning Annual Report, "(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).

LARC4CO is a broad coalition of over 60 organizations and groups in the state of Colorado who support Colorado's continued success in improving the health and well-being of Colorado's children and families through access to effective and affordable family planning services and reducing unintended pregnancies. Our coalition includes consumer advocacy organizations, reproductive rights and justice organizations, health care provider associations, public health organizations and a number of Title X grantees who would be directly impacted by these proposed changes.

We write today with significant concerns about the proposed changes in this rule and the impact they will have on patients, providers and clinics in our state. These changes would jeopardize patient and provider relationships, interfere with evidence-based practice, and threaten patient confidentiality. A patient's sexual and reproductive health are sensitive. The proposed FPAR 2.0 data elements risk the trust, confidentiality and privacy that's essential in providing quality patient care, especially among young people and individuals who are undocumented.

Patient-provider relationships will be harmed by inquiring about the invasive and unnecessary specifics in many of the proposed FPAR 2.0 data elements, which include details on a patient's sexual activity, intention to become pregnant, sexually transmitted infection testing and more. The proposed data elements do not adhere to modern sexual and reproductive health clinical guidelines and have the potential to harm a provider's ability to build and maintain trust with diverse Title X patient populations.

These data elements are irrelevant to monitoring the Title X program for compliance and accountability to performance goals and will not ultimately improve the Title X program.

Collection of this data would weaken clinics' and providers' ability to serve patients effectively with quality family planning services. Many of these encounters are short, especially telehealth visits, and collecting itemized data and additional personal information from patients would interfere with providing comprehensive contraceptive and/or preconception counseling during these appointments.

The proposed FPAR 2.0 data elements would also burden providers as they would require significant changes to clinical workflow and complex changes to electronic health record systems. Many Title X providers already spend a considerable amount of time on data submission and reporting to other federal programs and providers. These proposed data elements will overburden providers with reporting requirements.

It is unclear what the patient identifier will be under FPAR 2.0, but even if data is de-identified, there will still be sensitivity and patient trust concerns as this patient-level data will be shared with the federal government. Many of the proposed elements should not be collected at the federal or state level, and some could be considered as protected health information.

We strongly encourage you to take these concerns into consideration before finalizing this rule. Thank you for the opportunity to provide comments and we are happy to answer additional questions.

Sincerely,

Erin Miller
Vice President, Health Initiatives
Colorado Children's Campaign
Convener of the LARC4CO Coalition

From:	Llew Brown
To:	Ruth Hsu; Michael Kerachsky; Annu van Bodegom
Subject:	FW: 0990-New-60D Comments on Family Planning Annual Report 2.0
Date:	Tuesday, April 13, 2021 10:05:36 AM

From: Kim, Jamie (HHS/OASH) <Jamie.Kim@hhs.gov>
Sent: Tuesday, April 13, 2021 9:27 AM
To: Llew Brown <LOBrown@mathematica-mpr.com>
Cc: Daniel Shapiro <DShapiro@mathematica-mpr.com>; Nora Paxton <NPaxton@mathematica-mpr.com>; Menon, Roshni (HHS/OASH) <Roshni.Menon@hhs.gov>
Subject: FW: 0990-New-60D Comments on Family Planning Annual Report 2.0

From: Funn, Sherrette (OS/OCIO/CDO) <Sherrette.Funn@hhs.gov>
Sent: Tuesday, April 13, 2021 9:26 AM
To: Kim, Jamie (HHS/OASH) <Jamie.Kim@hhs.gov>; Farb, Amy (HHS/OASH) <Amy.Farb@hhs.gov>
Subject: FW: 0990-New-60D Comments on Family Planning Annual Report 2.0

Hi Jamie,
Another public comment in the email below.

Sherrette Funn
Office of the Secretary Report Clearance Officer
Department of Health and Human Services
200 Independence, S.W. suite 345F
Work cell# 202-264-0041

From: Yeatman, Sara <Sara.Yeatman@ucdenver.edu>
Sent: Monday, April 12, 2021 8:24 AM
To: Funn, Sherrette (OS/OCIO/CDO) <Sherrette.Funn@hhs.gov>
Subject: 0990-New-60D Comments on Family Planning Annual Report 2.0

To Whom It May Concern:

I am writing to express concern about the new requirements for encounter-level data for the Family Planning Annual Report (FPAR) 2.0 in document 099-New-60D. I am a family planning researcher who has used FPAR data and studies the reach and efficacy of Title X clinics. Thus,

as much as I value quality data, I have serious concerns about the proposed requirements which I anticipate will weaken Title X overall. Specifically, my concerns are three-fold:

1. The requirements are onerous and will discourage small clinics from continuing to participate in Title X.
2. The requirements will substantially alter the patient-provider interaction and foster distrust among patients due to the many, invasive questions required.
3. Marginalized populations most in need of the reproductive healthcare only available to them through Title X will be the most affected.

For the reasons outlined above, I strongly encourage you to take these concerns into consideration before finalizing this rule.

Sincerely,
Sara Yeatman, PhD

--
Sara Yeatman, PhD
Associate Professor and Department Chair
Department of Health and Behavioral Sciences
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t: +1 303 315 7180
pronouns: she/her/hers

Introduction

The Family Planning Council of Iowa (FPCI) is grateful for the opportunity to submit comments in response to the Department of Health and Human Services' (HHS) Agency Information Collection Request 0990-New-60D on Family Planning Annual Report 2.0, issued on February 11, 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). 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). While the Family Planning Council of Iowa 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.

Since 1980, the goal of the Family Planning Council of Iowa (FPCI) has been to provide quality reproductive health care and family planning services to all people in Iowa who desire it. Our organization has been a Title X grantee for nearly 40 years. At FPCI we advocate for our patients first, and feel it is necessary to provide comment on FPAR 2.0 on behalf of not only our organization, but more important, for what is in the best interest of our patients.

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. 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.

Like all safety net providers, the Family Planning Council of Iowa has experienced several challenges since 2019. As a direct result in the change of the Title X rules in 2019 over 55% of the Family Planning Council of Iowa's (FPCI's) network of clinics was forced to withdraw from the program. FPCI has spent roughly the last 18 months desperately trying to recruit and onboard new clinics and providers to serve more low-income patients while managing through a global pandemic, COVID-19. FPCI had begun preparations to implement a centralized data system but the project was paused for over 12 months due to COVID-19 because many of the agencies we partner with to provide Title X services are Federally Qualified Health Centers and small, localized public health departments where IT staff were diverted to adjust systems at these facilities to manage disaster response. The pandemic is not over and any attempt to implement FPAR 2.0 in accordance with current timelines will severely disrupt and undermine our ability to respond to these top priorities of stabilizing and growing our network.

[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).

Timeline

The Family Planning Council of Iowa respectfully 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, FPCI would need to upgrade to its information technology (IT) infrastructure, as would its 13 subrecipients. However, as of 4/12/21, 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 option 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, FPCI would need to implement a Centralized Data System with all subrecipients which we do not even have as we have always collected aggregate data through the use of excel spreadsheets.

Current OPA timelines also assume a level of baseline technology at both the Title X grantee and subrecipient levels which FPCI does not have. as previously mentioned, we use paper systems to collect FPAR data for aggregate submission. As data system and EHR enhancements typically takes 9 to 11 months, with three months for planning and six to eight months for implementation.[2] Instead, if FPAR 2.0 goes into effect on that date, we will need to collect and perform manual data entry of FPAR 2.0's 45 proposed data elements for every visit, and then determine how to deidentify line-item records so that they can be transmitted securely. This cumbersome process not only raises concerns about the effective use of Title X resources, but also about the security and confidentiality of clients' sensitive health information.

Burden, Necessity and Utility of FPAR 2.0 Data

FPCI believes the 23 additional 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. It corresponds to the deliberate transition of FPAR from a program monitoring tool to a research dataset, requiring Title X service sites to collect excessive information from patients at every single visit, even though such information is not necessitated by clinical practice guidelines or other evidence-based standards.

The following data elements are of particular concern to FPCI:

[2] Roboam R Aguirre, et al., "Electronic Health Record Implementation: A Review of Resources and Tools," *Cureus* 11, no. 9 (2019): e5649, doi:10.7759/cureus.5649.

New Data Elements: Sexual Activity

The Supporting Statement for the Title X FPAR 2.0 describes how FPAR 2.0 will supplement the federally funded National Survey for Family Growth (NSFG), a population-level, nationally representative dataset that gathers information on pregnancy and births, infertility, use of contraception, and general and reproductive health.[3] However, while NSFG surveys a representative sample of respondents and allows them to *voluntarily* respond, the data elements that will be collected and reported through FPAR 2.0 will be required for every patient visit. More specifically, 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 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)].[4] These sexual activity-related data fields also are not needed to monitor our Title X network's accountability to program goals.

It is important to emphasize that patients accessing services in non-Title X settings would not be asked to provide responses to these personal, guideline-unconcordant questions at every visit, nor would their responses be reported at the encounter level to the federal government. When the federal government begins collecting research data for its benefit and requires those accessing services through the safety net to provide such information as a precursor to receive care, it exacerbates medical mistrust, potentially dissuading patients from coming to us for needed services.

described in the Supporting Statement for the Title X FPAR 2.0.[5] [6] 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 (detailed as ever smoker, ex-smoker, smokes daily, occasional smoker, smoker, status unknown, heavy smoker, light smoker).

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

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[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*, 2021.

[4] 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.

[5] 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.

[6] *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.

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 determine to report the intervention(s) offered to tobacco smokers, using those listed by the US Preventive Services Task Force.[7]

FPCI believes the collection of height and weight data, presumably to calculate body mass index (BMI), is problematic. From a clinical perspective, there is no logical rationale to record and report body weight *at every visit*, and OPA does not state why it is necessary to collect this information and how it will be used in the Supporting Statement for the Title X FPAR 2.0.[8] Even when collecting a patient's height and weight data is clinically indicated, 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 because it fails to account for differences in body composition, fitness levels, and nutritional differences.[9] Furthermore, the practice of weighing clients at every visit – even health education sessions or when not clinically indicated – may deter clients from accessing services due to experiences of body shame and weight discrimination.[10]

Patients accessing health services in non-Title X settings are not weighed at every visit unless clinically indicated. Title X patients should receive the same standard of care and should not be subject to weight stigmatization at every visit. Weight stigma invokes psychological stress and emerging research suggests that this stress leads can exacerbate poor physical health outcomes for obese individuals[11], with the potential to perpetuate racial/ethnic and socioeconomic health disparities in overweight and obesity. It is time to move away from this measure and focus on measures of health that are scientifically valid and designed for diverse patient populations.

Screening for cardiovascular risk factors is indicated to support contraceptive decision-making (i.e., to ensure a patient does not have contraindications to combined oral contraceptives and other hormonal contraception) and pre-pregnancy health. While it may be desirable to capture these measures for additional patients, there is no explicit expectation or requirement for Title X providers to obtain information beyond that which is clinically necessary. Accordingly, we should not be required to document and report these measurements for every visit.

Confidentiality of Sensitive Personal Health Information

The Family Planning Council of Iowa requests further clarification on the steps OPA will take to maintain the confidentiality of the sensitive personal health information collected by FPAR 2.0.

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[7] 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.

[8] *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.

[9] 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.

[10] Janell L Mensinger, Tracy L Tylka, and Margaret E Calamari, "Mechanisms underlying weight status and healthcare avoidance in women: A study of weight stigma, body-related shame and guilt, and healthcare stress," *Body Image* 25 (2018):139-147. doi.org/10.1016/j.bodyim.2018.03.001.

[11] Rebecca M Puhl and Chelsea A Heuer, "Obesity stigma: important considerations for public health," *American Journal of Public Health* 100, no. 6 (2010):1019-28. doi:10.2105/AJPH.2009.159491.

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 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.[12] 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.[13] 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 seems 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.

Despite a range of opinions about what qualifies as sensitive health information, it generally is 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.

We are striving to see more patients after a 60% decline in our 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 providing Title X patients with 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, the Family Planning Council of Iowa urges OPA to pause and re-evaluate FPAR 2.0.

If you require additional information about the issues raised in this letter, please contact me at rgoss@fpcouncil.com

Respectfully,

Rachel Goss, Executive Director
Family Planning Council of Iowa

[12] 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.
[13] Ibid.

From:	Llew Brown
To:	Ruth Hsu; Michael Kerachsky; Annu van Bodegom
Subject:	FW: 0990-New-60D Comments on Family Planning Annual Report 2.0
Date:	Tuesday, April 13, 2021 10:18:33 AM

From: Kim, Jamie (HHS/OASH) <Jamie.Kim@hhs.gov>
Sent: Tuesday, April 13, 2021 10:14 AM
To: Llew Brown <LOBrown@mathematica-mpr.com>
Cc: Daniel Shapiro <DShapiro@mathematica-mpr.com>; Nora Paxton <NPaxton@mathematica-mpr.com>; Menon, Roshni (HHS/OASH) <Roshni.Menon@hhs.gov>
Subject: FW: 0990-New-60D Comments on Family Planning Annual Report 2.0

From: Funn, Sherrette (OS/OCIO/CDO) <Sherrette.Funn@hhs.gov>
Sent: Tuesday, April 13, 2021 10:13 AM
To: Kim, Jamie (HHS/OASH) <Jamie.Kim@hhs.gov>; Farb, Amy (HHS/OASH) <Amy.Farb@hhs.gov>
Subject: FW: 0990-New-60D Comments on Family Planning Annual Report 2.0

Hi Jamie and Amy,
Please see more comments from the public below. Thanks

Sherrette Funn
Office of the Secretary Report Clearance Officer
Department of Health and Human Services
200 Independence, S.W. suite 345F
Work cell# 202-264-0041

From: smollborn@gmail.com <smollborn@gmail.com>
Sent: Monday, April 12, 2021 5:05 PM
To: Funn, Sherrette (OS/OCIO/CDO) <Sherrette.Funn@hhs.gov>
Subject: 0990-New-60D Comments on Family Planning Annual Report 2.0

To Whom It May Concern:

I am writing to share comments regarding the Agency Information Collection Request in document 099-New-60D regarding the Office of Population Affairs' (OPA) new request for encounter-level data collection for the Family Planning

Annual Report (FPAR). I have many concerns about the proposed changes to the FPAR.

I am a sociologist who is working on a large-scale research team at the University of Colorado Boulder to evaluate the long-term impacts of Colorado's Title X program. I am employed as a Professor of Sociology at the University of Colorado Boulder.

My concerns, which reflect those articulated by others, include the following:

- The new FPAR data collection system is likely to reduce providers' willingness to participate in Title X, which would have dire consequences for family planning provision in the US.
- Marginalized populations would likely hesitate to seek services from Title X providers because there would be risks to patient privacy in the new system.
- The data provided by the new system are likely to be biased because of difficulties for smaller Title X providers with providing the requested data.

Other proposals should be sought to improve FPAR data collection, as the current one is fundamentally flawed.

Respectfully,
Stefanie Mollborn

Family Planning Annual Report 2.0 [Document Identifier: 0990-New-60D]
Public Comment – Public Health Solutions
April 12, 2021

I. Introduction

Public Health Solutions (PHS) welcomes the opportunity to submit comments in response to the Department of Health and Human Services' (HHS) Agency Information Collection Request 0990-New-60D on Family Planning Annual Report 2.0, issued on February 11, 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). 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). While PHS 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.

PHS is the largest public health non-profit serving New York City. For over 60 years, PHS has been a leader in addressing critical public health issues, including food and nutrition, health insurance access, maternal and child health, sexual and reproductive health (SRH), HIV/AIDS prevention, and more. PHS served as the non-governmental Title X grantee in New York State from 1982 to 2019, when it voluntarily relinquished our grant because of our opposition to the newly implemented Title X rule. Our six subrecipients included PHS' own Sexual and Reproductive Health (SRH) Centers, as well as Charles B. Wang Community Health Center (CBWCHC), Community Healthcare Network (CHN), The Door – A Center of Alternatives' Adolescent Health Center (The Door), Planned Parenthood of New York City (PPNYC), and Ryan Health.

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. 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.

Like all safety net providers, PHS has experienced several challenges since 2019, including the loss of Title X, which comprised one-third of PHS' SRH Centers' budget. This funding loss resulted in the departure of key clinical staff and required the Centers to drastically reduce their operating hours, which limited our ability to see patients for several months. This loss, combined with the onset of COVID-19, has been devastating for PHS' SRH Centers. From 2019 to 2020, the Centers' patient census decreased by 43%. Already reeling from staffing and operational challenges related to relinquishing Title X, clinical and operations staff were diverted to responding to COVID-19 and the rapid implementation of telemedicine services. These

[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).

challenges, combined with critical patient and staff health and safety concerns, reduced patient volume and correspondingly reduced patient revenue, which has created stress and uncertainty for PHS' SRH Centers. Similarly, since losing Title X funding in 2019, nearly all of PHS' former Title X subrecipients have been forced to prioritize which services to subsidize with the limited available funds and all but one subrecipient have seen fewer patients compared to their last full year as a Title X subrecipient. Any attempt to implement FPAR 2.0 in accordance with current timelines will severely disrupt and undermine our ability to respond to these top priorities.

Timeline

PHS 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, PHS would need to upgrade to its information technology (IT) infrastructure, as would our five former 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 option 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 3 months to implement and test the systems upgrades needed to collect and report encounter-level data through FPAR 2.0. PHS would need to create new clinical workflows to align with the new FPAR 2.0 framework and modify existing EMR systems to capture new data elements. Staff would need to be trained on new workflows and where to code the new fields. IT technical staff and EMR vendors would also need to work collaboratively to build out a new reporting framework that would allow for the submission and validation of these new data elements. Importantly, providers would be spending additional clinical time filling out the new data elements, which takes time away from providing patient care. Extending this timeline is the limited availability of the operations management team to complete upgrades due to competing projects and existing engagements related to stabilizing and recovering patient volume following the impact of COVID-19. After making system upgrades, PHS will require 3 months 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. Initiating upgrades before final specifications are available would be wasteful, as inconsistencies would require revisions that would carry additional costs and burden hours spent.

Accuracy of Estimated Burden

PHS 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 translate to the data collected no longer being 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

[2] RTI International, *Family Planning Annual Report Burden Study* (Research Triangle Park, NC: RTI, 2009).

(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 be 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 each grantee-subrecipient dyad to invest in upgrading to electronic systems (as applicable) and establishing interoperability between their respective systems.

In addition, we estimate that implementing FPAR 2.0 at PHS' SRH Centers will amount to $17,700 in one-time labor costs. This estimate is based on the cost of 8 staff persons working a combined 441 hours on tasks related to implementation, including working to perform necessary system upgrades and map out FPAR 2.0's data elements to existing standardized value sets, training health care providers and staff on how to collect new data elements, conducting preliminary data collection, running reports to ensure data mapping is correct, and performing quality assurance of preliminary data collected. We also estimate that each of our five former subrecipients will spend a similar number of hours implementing FPAR 2.0, for an estimated total of 2,646 hours in one-time labor costs 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.

Burden, Necessity and Utility of FPAR 2.0 Data

PHS believes the 23 additional 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. It corresponds to the deliberate transition of FPAR from a program monitoring tool to a research dataset, requiring Title X service sites to collect excessive information from patients at every single visit, even though such information is not necessitated by clinical practice guidelines or other evidence-based standards.

[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).

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 include screening for breast and cervical cancer,"[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 to PHS:

New Data Elements: Sexual Activity

The Supporting Statement for the Title X FPAR 2.0 describes how FPAR 2.0 will supplement the federally funded National Survey for Family Growth (NSFG), a population-level, nationally representative dataset that gathers information on pregnancy and births, infertility, use of contraception, and general and reproductive health.[6] However, while NSFG surveys a representative sample of respondents and allows them to *voluntarily* respond, the data elements that will be collected and reported through FPAR 2.0 will be required for every patient visit. More specifically, 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 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)).[7] These sexual activity-related data fields also are not needed to monitor our Title X network's accountability to program goals.

It is important to emphasize that patients accessing services in non-Title X settings would not be asked to provide responses to these personal, guideline-unconcordant questions at every visit, nor would their responses be reported at the encounter level to the federal government. When the federal government begins collecting research data for its benefit and requires those accessing services through the safety net to provide such information as a precursor to receive care, it exacerbates medical mistrust, potentially dissuading patients from coming to us for needed services.

Data Elements: Cervical Cancer Screening

FPAR 2.0 suggests the Title X service sites collect and report five different data elements related to cervical cancer screening: Pap test at this visit, Last Pap result, Pap test in the last five years, HPV test performed at this visit, and HPV test result. Collecting and reporting all five data elements for every Title X visit would carry substantial burden with minimal benefit.

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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.

[6] *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.

[7] 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.

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.[8] Furthermore, there is no way for PHS to differentiate 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.[9] 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.[10] [11] 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 (detailed as ever smoker, ex-smoker, smokes daily, occasional smoker, smoker, status unknown, heavy smoker, light smoker).

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 determine to report the intervention(s) offered to tobacco smokers, using those listed by the US Preventive Services Task Force.[12]

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[8] 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.

[9] Ibid.

[10] 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.

[11] *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.

[12] 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.

PHS believes the collection of height and weight data, presumably to calculate body mass index (BMI), is problematic. From a clinical perspective, there is no logical rationale to record and report body weight *at every visit*, and OPA does not state why it is necessary to collect this information and how it will be used in the Supporting Statement for the Title X FPAR 2.0.[13] Even when collecting a patient's height and weight data is clinically indicated, 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 because it fails to account for differences in body composition, fitness levels, and nutritional differences.[14] Furthermore, the practice of weighing clients at every visit – even health education sessions or when not clinically indicated – may deter clients from accessing services due to experiences of body shame and weight discrimination.[15]

Patients accessing health services in non-Title X settings are not weighed at every visit unless clinically indicated. Title X patients should receive the same standard of care and should not be subject to weight stigmatization at every visit. Weight stigma invokes psychological stress and emerging research suggests that this stress leads can exacerbate poor physical health outcomes for obese individuals[16], with the potential to perpetuate racial/ethnic and socioeconomic health disparities in overweight and obesity. It is time to move away from this measure and focus on measures of health that are scientifically valid and designed for diverse patient populations.

Screening for cardiovascular risk factors is indicated to support contraceptive decision-making (i.e., to ensure a patient does not have contraindications to combined oral contraceptives and other hormonal contraception) and pre-pregnancy health. While it may be desirable to capture these measures for additional patients, there is no explicit expectation or requirement for Title X providers to obtain information beyond that which is clinically necessary. Accordingly, we should not be required to document and report these measurements for every visit.

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, 15 percent of all Title X family planning encounters at PHS' SRH Centers 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.

<u>Confidentiality of Sensitive Personal Health Information</u>

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

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[13] *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.

[14] 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.

[15] Janell L Mensinger, Tracy L Tylka, and Margaret E Calamari, "Mechanisms underlying weight status and healthcare avoidance in women: A study of weight stigma, body-related shame and guilt, and healthcare stress," *Body Image* 25 (2018):139-147. doi.org/10.1016/j.bodyim.2018.03.001.

[16] Rebecca M Puhl and Chelsea A Heuer, "Obesity stigma: important considerations for public health," *American Journal of Public Health* 100, no. 6 (2010):1019-28. doi:10.2105/AJPH.2009.159491.

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 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.[17] 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.[18] 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 seems 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.

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.

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The current FPAR 2.0 project stands to severely disrupt PHS' operations during already uncertain times. We are striving to see more patients after an unprecedented 43% decline in patient census from 2019 to 2020. 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 providing Title X patients with 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, PHS urges OPA to pause and re-evaluate FPAR 2.0.

If you require additional information about the issues raised in this letter, please contact Natalie Tobier at ntobier@healthsolutions.org.

Sincerely,

Natalie Tobier
Public Health Solutions

[17] 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.
[18] Ibid.

April 12, 2021

Iowa Department of Public Health Response to 60-Day Public Comment Request:
Family Planning Annual Report 2.0

I. Introduction

The Iowa Department of Public Health (IDPH) welcomes the opportunity to submit comments in response to the Department of Health and Human Services' (HHS) Agency Information Collection Request 0990-New-60D on Family Planning Annual Report 2.0, issued on February 11, 2021. We write to express our 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). 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). While IDPH appreciates the need for a more robust data system for monitoring and improving program performance and is committed to implementing such a system, the department would like to request that the current FPAR 2.0 project be paused.

IDPH has been awarded and administered Title X Family Planning funds since 1971. The Title X program is located within the Bureau of Family Health in the Division of Health Promotion and Chronic Disease Prevention at IDPH, Iowa's statewide public health agency. The location within IDPH provides opportunities to enhance Title X services through linkages with other state public health and human service programs to enhance the quality, scope and reach of services. IDPH serves as an umbrella agency for seven contracted subrecipients (SRs). All SRs are required to provide the core family planning services in addition to other reproductive health services. The network of SRs consists of one local health jurisdiction, one large health system, two Community Action Organizations and three Federally Qualified Health Centers.

FPAR 2.0, as proposed, requires cost and time (i.e., staff time for data entry) 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.

Timeline

IDPH requests that OPA establish a new timeline for FPAR 2.0 planning and implementation given the challenges Title X grantees and service sites currently are facing. The current timeline for FPAR 2.0 data collection to begin on January 1, 2022 is not feasible. As of April 1, 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 option 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 six months at the IDPH level, along with six to 12 months at the SR level to implement and test the systems upgrades needed to collect and report encounter-level data through FPAR 2.0. This includes steps to upgrade the current Title X data system at IDPH, including processes related to SRs modifying their current electronic health record (EHR) or electronic data collection system to report specific data elements and customizing the existing IDPH data system so FPAR 2.0 data elements map to existing standardized value sets, and data validation efforts. After making system upgrades, IDPH and its SRs (which operate 19 service sites) will require three months 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. Initiating upgrades before final specifications are available would be wasteful, as inconsistencies would require revisions that would carry additional costs and burden hours spent.

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. 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 requiring Title X service sites to collect excessive information from patients at every single visit, even though such information is not necessitated by clinical practice guidelines or other evidence-based standards can be burdensome.

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.[1] 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 include screening for breast and cervical cancer,"[2] 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.

Confidentiality of Sensitive Personal Health Information

IDPH requests further 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 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.[3] 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.[4] 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. 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.

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.

The current FPAR 2.0 project stands to severely disrupt IDPH's Title X operations during already uncertain times. IDPH also is concerned of losing existing subrecipients and service sites that cannot absorb this data collection burden.

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[1] 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.
[2] 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.
[3] 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.
[4] Ibid.

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 providing Title X patients with 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, IDPH urges OPA to pause and re-evaluate FPAR 2.0.

If you require additional information about the issues raised in this letter, please contact me at lindsey.jones@idph.iowa.gov or 515-321-8159. Thank you for your time.

Sincerely,

Lindsey M. Jones

Lindsey Jones
Title X Family Planning Director
Iowa Department of Public Health

April 12, 2021

Sherrette Funn, Reports Clearance Officer
Office of Population Affairs
US Department of Health and Human Services
Re: Family Planning Annual Report 2.0
Document identifier 0990-New-60D

To whom it may concern,

We represent Upstream USA, a nonprofit that partners with states to provide training and technical assistance to health centers to improve women's health, increase access to contraception, and address disparities and biases in contraceptive care. Our transformative approach empowers patients to decide if and when they want to become pregnant, a critical step towards improving maternal health, as well as positive outcomes for parents and children.

We welcome the opportunity to submit public comments in response to the Department of Health and Human Services' invitation for input on the proposed Family Planning Annual Report 2.0 (FPAR 2.0) specifications.

Upstream relies on data from Title X FPAR reporting to inform our work and to understand the landscape of contraceptive care in the United States. Besides FPAR, no other annual, census-style data system collects information on what methods of contraception patients are using. While there has been some helpful progress in measuring the use of most and moderately effective methods, and LARC methods, via NQF measures #2902, #2903, and#2904, FPAR is still the only consistently-published, method-specific data source, and is invaluable for understanding patients' access to family planning services. Upstream used publicly-available data from FPAR in Delaware, where we conducted our first state project, to model a 24% decline in the unplanned pregnancy rate among Title X patients. This data was later matched by a PRAMS analysis showing a 25% decline in unplanned pregnancy statewide. Data from FPAR is critical to our ability to show our impact in helping to reduce unplanned pregnancy, and understanding which methods are more and less accessible.

Upstream has extensive experience in facilitating encounter-level data collection from our health agencies partners in Washington, Massachusetts, North Carolina, and Rhode Island, and we would like to share some of our experiences as they relate to planned FPAR 2.0 activities. First, many electronic health record (EHR) systems continue to lack data elements that are part of both FPAR 1.0 and FPAR 2.0 and it takes a substantial amount of staff time and technical assistance to build out those missing data elements. In particular, the lack of standard fields for pregnancy intention screening, contraceptive counseling, and the contraceptive method a patient is using as of the end of their visit have presented serious barriers to Upstream's ability to do our work, and also likely presents barriers to the implementation of FPAR 2.0. Needs

assessments should be conducted to ensure that the data elements are placed in EHR templates that fit the contraceptive care workflow at the particular agency. The Title X network will need technical support and resources to recommend workflow options within different EHR systems.

We would welcome OPA's advocacy with government offices like ONC and with EHR vendors around including family planning data elements to ensure that contraceptive care and other aspects of reproductive healthcare are appropriately standardized within these new systems.

We also recommend limiting the number of data elements that must be newly incorporated into grantee EHR systems for reporting purposes. While there is utility in having three measures of sexual activity for research purposes, it is likely too burdensome to build out and to require clinicians to provide that level of documentation. Likewise, it seems that the two "reason for no contraceptive method" data elements are redundant because some of the response options will not change from the beginning to end of an encounter (i.e., sterility status).

In our work with health centers, we have found that requiring some data be collected every 12 months (instead of every visit) is more reasonable and is aligned with best practice. Will the FPAR 2.0 data system be able to do patient matching (at the health facility level) to see whether a patient was screened for pregnancy intention, cervical cancer, CT/GC, and syphilis according to clinical guidelines?

We are happy to share more about our experiences trying to capture and standardize data across EHRs if it would be of service to OPA. We appreciate the work of OPA and the Title X grantee network in providing essential preventive care to patients across the country, and gathering data about Title X patient care.

Sincerely,

Lise LeRoy
Director of Measurement, Evaluation and Learning
Upstream USA

April 12, 2021

Sherrette Funn
Reports Clearance Officer
U.S. Department of Health and Human Services
Via email: sherrette.funn@hhs.gov

RE: Comments on Proposed Data Collection for Family Planning Annual Report 2.0 (0990-New-60D)

Dear Ms. Funn:

Every Body Texas welcomes the opportunity to submit comments in response to the Department of Health and Human Services' (HHS) Agency Information Collection Request 0990-New-60D on Family Planning Annual Report 2.0, issued on February 11, 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). 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). While Every Body Texas 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 + COVID-19 Impacts

Every Body Texas is a non-profit organization dedicated to ensuring that every person in Texas can access safe, unbiased, high-quality sexual and reproductive healthcare. As the statewide Title X Family Planning Program grantee for Texas, Every Body Texas funds a diverse network of 37 providers—including federally qualified health centers (FQHCs), public health departments, hospital-based clinics, and free-standing family planning clinics—that operates more than 170 service sites throughout Texas.

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. 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—implementation of FPAR 2.0 simply is not feasible. We are working hard to hold on, rebuild, and continue providing critical services to patients.

Like all safety net providers, Every Body Texas has experienced several challenges since 2019. Every Body Texas moved quickly at the start of the 2020-2021 budget period to support its sub-recipients in responding to the COVID-19 pandemic. The impacts of COVID-19 on Every Body Texas's Title X Project are not unique. Like other safety net healthcare providers, sub-recipients have experienced temporary closures and reduced availability of in-person services—and have reported serving fewer clients, even as they worked tirelessly to maintain access to Title X services by incorporating no-contact methods, including teleservices.

Most pressing for sub-recipients is the reality that reduced client volume has translated into reduced revenue. Over the last decade, sub-recipients have repeatedly navigated state-level funding and policy changes that threatened the sustainability of the family planning safety net. COVID-19 now presents another threat to critical funding. Sub-recipients are concerned that women's health funding appropriated by the Texas Legislature and administered by the Texas Health and Human Services Commission (HHSC) will not adequately address the increased rates of uninsured and unemployed Texans seeking safety net healthcare services. Because Every Body Texas's sub-recipients rely on HHSC's women's health funding to support their overall family planning projects, depending upon the severity of the funding impacts, there could be adverse impacts on Every Body Texas's Title X Project—including but not limited to reduced client volume, reduced program income, and service site closures.

At the grantee level, Every Body Texas transitioned to remote work on March 16, 2020 and paused all work-related travel. A COVID-19 return-to-work playbook was finalized in October 2020, supporting the optional use of Every Body Texas's office space—which has been outfitted with sneeze guards and social distance markers and is subject to occupancy limits; however, plans to return to the office full time or to resume work-related travel have not been established.

Throughout the COVID-19 pandemic Every Body Texas has worked to ensure that staff and sub-recipients felt supported to continue advancing the Title X Project and that funders, including the Office of Population Affairs, were kept current on any changes to Title X service delivery. Every Body Texas anticipates lasting changes to the healthcare landscape and stands ready to adapt the Title X Project as needed to ensure that sub-recipients have the support needed to provide these critical services to clients and communities across Texas.

As a result of COVID-19, Every Body Texas made changes to its Title X Project workplan activities and outcomes. Every Body Texas originally planned to increase the percentage of clients served by 17% across the project period. Although Every Body Texas was able to make progress toward this goal during the 2019-2020 budget period, serving 182,461 unduplicated clients, COVID-19 swiftly eliminated these gains. Every Body Texas's sub-recipients are reporting that the need for and complexity of services are increasing as a result of COVID-19 and its impacts.

Throughout the COVID-19 pandemic Every Body Texas has worked to ensure that staff and sub-recipients felt supported to continue advancing the Title X Project and that funders, including the Office of Population Affairs, were kept current on any changes to Title X service delivery. Texas anticipates lasting changes to the healthcare landscape and any attempt to implement FPAR 2.0 in accordance with current timelines will severely disrupt and undermine our ability to respond to these top priorities.

Timeline

Every Body Texas 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, the data warehouse for Every Body Texas, Ahlers & Associates, has estimated that it will need 520 hours to upgrade its information technology (IT) infrastructure. Twenty of Every Body Texas's 37 subrecipients that do not use Ahlers & Associates software or web-based applications to enter and transmit Title X data would have to add fields to their EMRs for the new data elements and update extraction methods and tools—in addition to conducting all testing and validation for these changes.

All 37 subrecipients would require training and operational changes to ensure the new data elements are populated consistently. However, at present, 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 option 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. These technical unknowns on the OPA side, coupled with the diversity of our sub-recipients in terms of size and IT capacity, complicate time burden estimates for FPAR 2.0 implementation. With that in mind, and assuming that funding and staff for these new activities is available, **we estimate it will take at least 18 months to coordinate our efforts with our data warehouse and subrecipients to implement and test technologies, train staff and conduct basic monitoring.**

These activities by entity include:

Every Body Texas

- Internal review and customization of OPA technical specifications, messaging and instructions for our subrecipient network
- Validate changes made by Ahlers & Associates for all new data elements
- Review sub-recipient test datasets and provide feedback for initial submission of new data elements
- Create and conduct trainings for sub-recipients on integrating new data elements into clinical practice
- Conduct technical assistance to 20 sub-recipients
- Reprogram existing data collection system to add new data fields
- Modify all internal reports and dashboards
- Modify all onboarding materials and internal documents
- Work with vendor to modify internal data warehouse for new data elements
- Monitoring and validation of new data elements for 12 months

Every Body Texas time estimate: 18 months

Ahlers & Associates

- Modify existing data file format to accommodate FPAR 2.0 changes.
- Create and publish the new data file format, field values, and edit list for agencies not using Ahlers software to submit their family planning encounters to give to their system vendors for reprogramming of their clinical systems.
- Reprogram existing data collection system to accommodate new data fields, edits, and field values associated with FPAR 2.0. This includes transmission import programs and web site functions (Raw Data Download, Build A Report, etc.)
- Reprogram Ahlers WinCVR module and WebCVR to accommodate new data fields, edits, and field values associated with FPAR 2.0.
- Create data export program and code conversions from existing database to FPAR 2.0 specifications to enable data uploads to OPA data collection contractor.

Ahlers & Associates time estimate: 3 months (520 hours)

Sub-recipients

- Review technical requirements and prepare implementation plans with analytics and clinical staff
- Procure EMR vendor or other consultants to add fields for new data elements
- Modify reporting tool formatting & map new fields
- Test and validate data mapping procedures
- Revise policies for Title X documentation in EMR

- Modify workflows to ensure new data elements are populated
- Train and retrain staff to document new data elements in EMR
- Conduct preliminary data collection and perform quality assurance
- Send test files to Every Body Texas and correct errors
- Conduct quality assurance activities

Sub-recipient time estimate: 12 months

Extending this timeline is the limited availability of IT staff or external consultants/vendors to complete upgrades due to competing projects and existing engagements (e.g., EMR changes and upgrades, telehealth upgrades, etc.). After making system upgrades, Every Body Texas and its subrecipients (which operate more than 170 service sites) will require time 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. Initiating upgrades before final specifications are available would be wasteful, as inconsistencies would require revisions that would carry additional costs and burden hours spent.

Accuracy of Estimated Burden

Every Body Texas 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, 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 translate to the data collected no longer being 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), 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 be substantially less burdensome on grantees and subrecipients.

Every Body Texas estimates that implementing FPAR 2.0 as proposed at the grantee-level will amount to $82,000 in one-time non-labor costs. This estimate is based on quotes received from existing vendors, including Ahlers & Associates.

Every Body Texas' Title X network is extremely diverse and ranges from rural practices with a single provider to large hospitals systems in urban areas. Our network includes 20 subrecipients without the Ahlers & Associates Title X CVR module that would require EMR upgrades and changes to extraction processes and reporting tools. Any one-time labor and cost estimates for our subrecipients would be based on stacked assumptions, which is something we actively oppose. Instead, we request that a thorough labor and cost assessment be performed so we can accurately understand the impact of FPAR 2.0 to our 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 and purchased service costs.

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.

Burden, Necessity and Utility of FPAR 2.0 Data

Every Body Texas believes the 23 additional 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. It corresponds to the deliberate transition of FPAR from a program monitoring tool to a research dataset, requiring Title X service sites to collect excessive information from patients at every single visit, even though such information is not necessitated by clinical practice guidelines or other evidence-based standards.

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. 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 include screening for breast and cervical cancer," 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 to Every Body Texas:

Sexual Activity

The Supporting Statement for the Title X FPAR 2.0 describes how FPAR 2.0 will supplement the federally funded National Survey for Family Growth (NSFG), a population-level, nationally representative dataset that gathers information on pregnancy and births, infertility, use of contraception, and general and reproductive health. However, while NSFG surveys a representative sample of respondents and allows them to voluntarily respond, the data elements that will be collected and reported through FPAR 2.0 will be required for every patient visit. More specifically, 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 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)]. These sexual activity-related data fields also are not needed to monitor our Title X network's accountability to program goals.

It is important to emphasize that patients accessing services in non-Title X settings would not be asked to provide responses to these personal, guideline-unconcordant questions at every visit, nor would their responses be reported at the encounter level to the federal government. When the federal government begins collecting research data for its benefit and requires those accessing services through the safety net to provide such information as a precursor to receive care, it exacerbates medical mistrust, potentially dissuading patients from coming to us for needed services.

Cervical Cancer Screening

FPAR 2.0 suggests the Title X service sites collect and report five different data elements related to cervical cancer screening: Pap test at this visit, Last Pap result, Pap test in the last five years,

HPV test performed at this visit, and HPV test result. Collecting and reporting all five data elements for every Title X visit would carry substantial burden with minimal benefit.

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. Furthermore, there is no way for Every Body Texas to differentiate 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. 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. When extracting data to calculate measures, there is no way to qualify whether an appropriate screening interval was applied.

CT test result, GC test result, HIV Rapid test result, HIV Supplemental Test results, syphilis test result

Linking test results to test encounters is already a challenge for FPAR 1.0 data elements for pap smears/abnormal results and HIV tests/HIV+ results due to the segregation of data collection systems for most of our sub-recipients. While connecting tests to results is a worthwhile endeavor, the accelerated FPAR 2.0 timeline may lead to short-term solutions that serve Title X reporting only, as opposed to care improvements.

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 (detailed as ever smoker, ex-smoker, smokes daily, occasional smoker, smoker, status unknown, heavy smoker, light smoker).

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 determine to report the intervention(s) offered to tobacco smokers, using those listed by the US Preventive Services Task Force.

Every Body Texas believes the collection of height and weight data, presumably to calculate body mass index (BMI), is problematic. From a clinical perspective, there is no logical rationale to record and report body weight at every visit, and OPA does not state why it is necessary to collect this information and how it will be used in the Supporting Statement for the Title X FPAR 2.0. Even when collecting a patient's height and weight data is clinically indicated, 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 because it fails to account for differences in body composition, fitness levels, and nutritional differences. Furthermore, the practice of weighing clients at every visit – even health education sessions or when not clinically indicated – may deter clients from accessing services due to experiences of body shame and weight discrimination.

Patients accessing health services in non-Title X settings are not weighed at every visit unless clinically indicated. Title X patients should receive the same standard of care and should not be subject to weight stigmatization at every visit. Weight stigma invokes psychological stress and emerging research suggests that this stress leads can exacerbate poor physical health outcomes for obese individuals , with the potential to perpetuate racial/ethnic and socioeconomic health disparities in overweight and obesity. It is time to move away from this measure and focus on measures of health that are scientifically valid and designed for diverse patient populations.

Screening for cardiovascular risk factors is indicated to support contraceptive decision-making (i.e., to ensure a patient does not have contraindications to combined oral contraceptives and other hormonal contraception) and pre-pregnancy health. While it may be desirable to capture these measures for additional patients, there is no explicit expectation or requirement for Title X providers to obtain information beyond that which is clinically necessary. Accordingly, we should not be required to document and report these measurements for every visit.

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, 43% percent of all Title X family planning encounters in Every Body Texas' 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

Every Body Texas requests further 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 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. 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. 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 seems 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.

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.

Closing Thoughts

The current FPAR 2.0 project stands to severely disrupt Every Body Texas's operations during already uncertain times. Every Body Texas, 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 Every Body Texas lost two subrecipients. Every Body Texas also is concerned of losing existing subrecipients and service sites that cannot absorb this data collection

burden. When onboarding new Title X subrecipients, Every Body Texas staff conduct an assessment of their IT and analytics resources and capacity to prepare a timeline to start Title X encounter submission. In some cases, we have provided funding for EMR upgrades and in all cases, these new subrecipients receive considerable technical assistance from us. In that ideal scenario, it takes most new subrecipients 12 months to fully onboard and submit valid and reliable encounter data, just for FPAR 1.0 data elements.

We are striving to see more patients after unprecedented declines in patient census. Every Body Texas experienced a 13% loss of unduplicated clients in the past two FPARs; from 175,799 in 2019 to 152,168 in 2020. 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 providing Title X patients with 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, Every Body Texas urges OPA to pause and re-evaluate FPAR 2.0.**

Every Body Texas appreciates the opportunity to provide these comments. If you require additional information about the issues raised in this letter, please contact me at kami.geoffray@everybodytexas.org or (512) 448-4857.

Sincerely,

Kami Geoffray
Chief Executive Officer

NEW YORK STATE OF OPPORTUNITY. Department of Health

ANDREW M. CUOMO
Governor

HOWARD A. ZUCKER, M.D., J.D.
Commissioner

LISA J. PINO, M.A., J.D.
Executive Deputy Commissioner

April 12, 2021

Sherrette Funn
Reports Clearance Officer
U.S. Department of Health & Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Sherrette Funn:

Please see the attached Comments in Response to Department of Health and Human Services' (HHS) Agency Information Collection Request 0990-New-60D on Family Planning Annual Report 2.0.

If you require additional information, please contact Eileen Shields at 518-474-0535 or eileen.shields@health.ny.gov. Thank you.

Sincerely,

Rae Ann Augliera
Assistant Bureau Director
Bureau of Women, Infant & Adolescent Health

Attachment

cc: Ms. Shields

New York State Department of Health
Comprehensive Family Planning and Reproductive Health Program

Comments in Response to Department of Health and Human Services' (HHS) Agency Information Collection Request 0990-New-60D on Family Planning Annual Report 2.0

The New York State Department of Health (NYSDOH) welcomes the opportunity to submit comments in response to the Department of Health and Human Services' (HHS) Agency Information Collection Request 0990-New-60D on Family Planning Annual Report 2.0, issued on February 11, 2021.

The NYSDOH has had a long history of supporting comprehensive family planning and reproductive health services for low-income, uninsured and underinsured people of reproductive age, in high-need communities through the New York State Comprehensive Family Planning and Reproductive Health Program (FPP). The NYSDOH provides funding in support of the FPP through a statewide provider network of more than 40 agencies with about one hundred fifty clinic sites. All FPP agencies are required by contract to submit electronic Clinic Visit Records (CVRs) that document services provided to clients during the family planning visit. Agencies are allowed to use proprietary electronic health record systems of their choice to collect data, but are required to submit CVRs in the NYSDOH prescribed format to a centralized data system managed by Ahlers and Associates, a national family planning data processing and management vendor. The FPP's data system has been automated since 1983 and became an all-electronic reporting system in 2003. The NYSDOH had been a Title X grantee throughout this lengthy period, until withdrawing from the program in September 2019 in response to the 2019 Title X Rule.

In anticipation of forthcoming changes to the Title X regulations and the opportunity to reapply for grantee status, NYSDOH is anxious to express its serious concerns with the proposed changes to 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).

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). While the NYSDOH appreciates that there may be a need for a more robust data system for monitoring and improving program performance, the NYSDOH is concerned that implementation of the FPAR 2.0 data collection and reporting system as defined is not feasible and must be paused.

Our main concerns to be detailed below include the following:

- Confidentiality of sensitive personal health information
- Necessity and burden of data elements
- Prohibitive cost of changes to software and systems
- Timing of changes and technical/training burden to providers

Confidentiality of Sensitive Personal Health Information

First and foremost, NYSDOH requests clarification on the steps that the Office of Population Affairs (OPA) will take to maintain the confidentiality of the sensitive personal health information proposed to be 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 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.[1]

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.[2] While encounter-level data will be partially de-identified, OPA has not released specifications for how the patient identifier data element alone, and more particularly in combination with the National Provider ID (NPI), and full birth and visit dates, will be used in a way that ensures that patient confidentiality is preserved.

Furthermore, OPA has not provided information on the Health Information Portability and Accountability Act- (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 face, OPA should engage with the network to seek 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.

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. While some of the data elements in the current version of the FPAR are concerning, several of the new data elements within FPAR 2.0 are *extremely* sensitive in nature, as they relate to sexual behaviors and other deeply personal topics.

Adding this sensitive health information to supplement public use data files such as the National Survey for Family Growth requires a higher level of scrutiny and protection for these data.

Necessity and Burden of FPAR 2.0 Data Elements

NYSDOH believes the 23 additional elements go beyond what is required by statutory requirements, regulations, and operational guidance or should be made required to support quality improvement. We ask for additional opportunities to provide feedback on what additional

[1] [1] 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.
[2] Ibid.

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, 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 – in FPAR 2.0 is burdensome. These additional data elements signal a potential transition of FPAR from a program monitoring tool to a research dataset, requiring Title X service sites to collect information from patients at every single visit, which may have consequences to the core mission to serve patients in an inclusive way and without stigma.

Furthermore, proposed data elements have been included that pertain to services outside of the core family planning services in the Recommendations for Providing Quality Family Planning Services (QFP). These data elements include sexual activity and cardiovascular disease risk factors.[3] 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 including screening for breast and cervical cancer,"[4] NYSDOH does not support requiring collection of these data at the encounter level and would argue that the burden of doing so would be excessive.

New Data Elements of Particular Concern

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. In addition to the forementioned extreme sensitivity of this information, 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 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)].[5] These sexual activity-related data fields also are not needed to monitor Title X grantee and subrecipient accountability to program goals.

[3] 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.

[4] 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.

[5] 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.

It is important to emphasize that patients accessing services in non-Title X settings would not be asked to provide responses to this level of personal questioning at every visit, nor would their responses be reported at the encounter level to the federal government.

Requiring the collecting of this level of sensitive information as part of the process of accessing services through the safety net may exacerbate medical mistrust, potentially dissuading patients from seeking needed services.

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 (detailed as ever smoker, ex-smoker, daily smoker, occasional smoker, smoker, status unknown, heavy smoker, light smoker).

The NYSDOH believes there is no logical rationale to record and report these data; there is no explicit expectation or requirement for Title X providers to obtain information beyond that which is clinically necessary. Accordingly, we should not be required to document and report these measurements for every visit.

Patients accessing health services in non-Title X settings are not weighed at every visit unless clinically indicated. Title X patients should receive the same standard of care and should not be subject to weight stigmatization at every visit. Weight stigma invokes psychological stress and emerging research suggests that this stress can exacerbate poor physical health outcomes for obese individuals,[6] with the potential to perpetuate racial/ethnic and socioeconomic health disparities in overweight and obesity.

Cervical Cancer, HPV and Sexually Transmitted Infection (STI) Testing and Results

FPAR 2.0 suggests the Title X service sites collect and report five different data elements related to cervical cancer screening: Pap test at this visit, Last Pap result, Pap test in the last five years, HPV test performed at this visit, and HPV test result. Collecting and reporting all five data elements for every Title X visit would carry substantial burden with minimal benefit.

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

[6] Rebecca M Puhl and Chelsea A Heuer, "Obesity stigma: important considerations for public health," *American Journal of Public Health* 100, no. 6 (2010):1019-28. doi:10.2105/AJPH.2009.159491.

should come back as positive.[7] Furthermore, there is no way for the NYSDOH FPP to differentiate 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 American Society of Colposcopy and Cervical Pathology (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., i**ncrease 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.

FPAR 2.0 further suggests that Title X service sites collect and report on a number of different data elements related to STI screening at each client visit, including screening at current visit and multiple results for Chlamydia, gonorrhea, and syphilis, as well testing at current visit, and rapid and supplemental results for HIV. Results, such as those for gonorrhea, may include as many as twenty different selections.

The NYSDOH believes there is no logical rationale to record and report these data at every visit and report them in such detail. Capturing such detailed information in its existing status would be excessively burdensome and would require significant adjustment as laboratory testing technology evolves over time. Accordingly, we feel strongly that we should not be required to document and report these measurements for every visit.

National Provider Identification Number (NPI)

While most advanced practice clinicians have a NPI number, they are not required for those providers who do not transmit HIPAA covered data or those who provide services "incidental to" another provider. Furthermore, only advanced practice clinicians may obtain an NPI; however, in 2019, 6.4 percent of all encounters in the NYSDOH FPP were performed by other services providers, including registered nurses, licensed practical nurses, health educators, and social workers. As such, many of our providers do not have individual NPI to report for FPAR 2.0.

Further, in those instances where the NPI is available, the NYSDOH is concerned about the increased identifiability risk to sensitive confidential personal health information, as described in an earlier section herein.

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[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.

Cost Burden of FPAR 2.0 Changes

FPAR 2.0, as proposed, requires cost and time (i.e., burden hour) investments that are exponentially higher than the outdated estimates published in the Federal Register (86 FR 9077).

The implementation of FPAR 2.0 would have burdensome economic consequences both for the NYSDOH and for the agencies participating in the FPP. As noted above, NYS contracts with Ahlers and Associates to manage its centralized data system. Compliance with FPAR 2.0 reporting requirements would necessitate an extensive overhaul of the current system's complex information technology infrastructure, which would incur substantial expense at a time when NYS's budget is already overburdened. In the absence of complete specifications, it is difficult to accurately estimate the additional revenue required, but based on the information at hand, we estimate a cost of at least $250,000 but it could cost more.

Additional costs would be incurred by each of the agencies participating in the FPP to cover the expense of changes to their respective software systems. Based on past experience, we have found that the cost of adding two simple selection options to an existing data element, can cost nearly $1,000 for each agency. With 23 additional elements, and their myriad selection options, we anticipate that electronic health record (EHR) vendors might impose charges that will run well into the tens of thousands of dollars per agency during a time when resources are already severely stretched. With upwards of 40 agencies in the FPP, we estimate that this would total as much as $500,000, if not more. While the added cost would be burdensome in general, it would be particularly onerous for the small single-clinic and rural organizations, but also for the larger urban organizations that have struggled to maintain access and service during the COVID-19 crisis.

Further, neither of these costs includes the inestimable additional expense required for NYSDOH FPP staff and agencies' and clinics' health care providers and staff to allot and coordinate their time and efforts on training and implementing the FPAR 2.0 changes.

Burden of Timeline for FPAR 2.0 Changes

The implementation timeline for FPAR 2.0 to begin on January 1, 2022 is not feasible. OPA has yet to release final specifications for collecting and reporting FPAR 2.0's data elements, including how to map each data element and response option to standardized value sets. If NYSDOH were required to implement FPAR 2.0, we would need to:

- Work with our current data vendor to customize its information technology infrastructure, including mapping each new data element and response option; importing, processing and ensuring data quality; integrating into our quarterly standardized and ad hoc reporting functionality; modifying our data extraction functionality;
- Explain the data collection and workflow changes to 40+ agencies and approximately 150 clinics and their 10 collective EHR vendors to customize their data systems to implement those changes and submit their data to our vendor in an accurate and timely manner; and

- Train health care providers and staff to accurately record these new data elements.

In addition, agencies also would be required to train their staff on the changes to their EHR systems, along with the time-consuming new requirements for data collection each visit. Additional time would be required to conduct preliminary data collection, run reports to ensure data mapping is correct, and perform quality assurance of preliminary data collected, as needed.

We estimate that these processes would take at least 12 months of time once specifications are known, but probably longer.

Title X safety net providers and the NYSDOH have experienced several challenges since 2019. The impact of COVID-19 has been particularly severe in New York State, resulting in closure of a number of the FPP clinics, both temporarily and permanently; implementing and diverting care to telehealth visits; and maintaining management of the program under the strain of staff redeployed to pandemic response service. Any attempt to implement FPAR 2.0 in accordance with current timelines would severely disrupt and undermine our ability to respond to these top priorities.

In Summary, the FPAR 2.0, as proposed, will require cost and time (i.e., burden hour) investments that are higher than the estimates published in the Federal Register (86 FR 9077); it also puts forward data collection requirements that exceed the amount of data needed to monitor compliance with statutory and regulatory requirements and to manage the Title X program. At this time – against the backdrop of a year-long public health emergency and on the heels of the anticipated reapplication process for Title X grantee status, implementation of FPAR 2.0 is not feasible. We are working hard to hold on, rebuild, and continue providing critical reproductive health services to NYS's underserved people of reproductive age.

Accordingly, the NYSDOH urges OPA to pause and re-evaluate FPAR 2.0.

Sherrette Funn
Reports Clearance Officer
U.S. Department of Health and Human Services
200 Independence Avenue SW, Room 713F
Washington, DC 20201

Sent via email at sherrette.funn@hhs.gov

RE: Agency Information Collection Request 0990-New-60D, Family Planning Annual Report 2.0

I. Introduction

Missouri Family Health Council, Inc. welcomes the opportunity to submit comments in response to the Department of Health and Human Services' (HHS) Agency Information Collection Request 0990-New-60D on Family Planning Annual Report 2.0, issued on February 11, 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). 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). While MFHC appreciates the need for a more modern 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.

MFHC is a private nonprofit organization based in Jefferson City, MO. For the last forty years MFHC has received and administered the Title X funding for Missouri. Currently, our network consists of 15 subrecipient agencies that operate a total of 63 clinic sites. Our diverse network consists of health departments, federally qualified health centers, community action agencies, hospitals, and other stand-alone family planning providers. In total, the network serves approximately 40,000 Title X clients per year.

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. 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.

Timeline

MFHC requests that OPA establish a new timeline for FPAR 2.0 planning and implementation given the challenges all Title X grantees and service sites 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, MFHC would need to upgrade to its information technology (IT) infrastructure, as would its 15 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 option 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 18-24 months to implement and test the systems upgrades needed to collect and report encounter-level data through FPAR 2.0. This includes upgrades to MFHC's centralized database, customizing reporting and mapping, working with 8 different EHR vendors on integration of new data elements, mapping, and reporting, data validation and testing, etc. After making system upgrades, MFHC and its subrecipients (which operate 63 service sites) will require 6-12 months 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. Initiating upgrades before final specifications are available would be wasteful, as inconsistencies would require revisions that would carry additional costs and burden hours spent.

Accuracy of Estimated Burden

MFHC 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 translate to the data collected no longer being relevant.

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[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).

[2] RTI International, *Family Planning Annual Report Burden Study* (Research Triangle Park, NC: RTI, 2009).

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 be 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 each grantee-subrecipient dyad to invest in upgrading to electronic systems (as applicable) and establishing interoperability between their respective systems. In MFHC's Title X network, there are 15 subrecipients using 8 EHR platforms.

MFHC estimates that implementing FPAR 2.0 as proposed at the grantee-level will amount to $150,000 in one-time non-labor costs. This estimate is based on contracting for upgrades/mapping of MFHC's centralized database. Furthermore, MFHC estimates that each of its 15 subrecipients will outlay an average of $14,000 in non-labor costs to implement FPAR 2.0, for an estimated total of $210,000 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 and purchased service costs.

In addition, we estimate that implementing FPAR 2.0 will amount to $44,000 in one-time labor costs. This estimate is based on the cost of 5 staff persons working a combined 440 hours on tasks related to implementation, including selecting and/or creating a contract with a vendor, working (with vendors) to perform necessary system upgrades and map out FPAR 2.0's data elements to existing standardized value sets, training health care providers and staff on how to collect new data elements, conducting preliminary data collection, running reports to ensure data mapping is correct, and performing quality assurance of preliminary data collected. We also estimate that each of our 15 subrecipients will spend an average of 40 hours implementing FPAR 2.0, for an estimated total of $60,000 in one-time labor costs 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.

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[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).

Missouri's total estimated cost is $464,000, drastically far above the current estimated cost burden.

Burden, Necessity and Utility of FPAR 2.0 Data

MFHC believes the 23 additional 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. These data elements seem to map more to the elements in a research database than in a program monitoring tool, requiring Title X service sites to collect excessive information from patients at every single visit, even though such information is not necessitated by clinical practice guidelines or other evidence-based standards.

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 include screening for breast and cervical cancer,"[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 to MFHC:

New Data Elements: Sexual Activity

The Supporting Statement for the Title X FPAR 2.0 describes how FPAR 2.0 will supplement the federally funded National Survey for Family Growth (NSFG), a population-level, nationally representative dataset that gathers information on pregnancy and births, infertility, use of

[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.

contraception, and general and reproductive health.[6] However, while NSFG surveys a representative sample of respondents and allows them to *voluntarily* respond, the data elements that will be collected and reported through FPAR 2.0 will be required for every patient visit. More specifically, 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 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)].[7] These sexual activity-related data fields also are not needed to monitor our Title X network's accountability to program goals.

It is important to emphasize that patients accessing services in non-Title X settings would not be asked to provide responses to these personal, guideline-unconcordant questions at every visit, nor would their responses be reported at the encounter level to the federal government. When the federal government begins collecting research data for its benefit and requires those accessing services through the safety net to provide such information as a precursor to receive care, it exacerbates medical mistrust, potentially dissuading patients from coming to us for needed services.

New Data Element: Future Pregnancy Intention Reported

Another example of a proposed data element that is inconsistent with current research on the provision of patient-centered contraceptive care is the FPAR 2.0 data element tracking patients' intention to either become pregnant or prevent a pregnancy in the next year. Research suggests that many patients cannot articulate their pregnancy intentions over the next year; doing so is inconsistent with how they think about and approach their reproductive lives.[8] [9] This is particularly true for low-income populations.[10] Indeed, not all individuals overtly plan to have children or not have children, suggesting that asking about reproductive "intentions" or "plans" may be problematic.[11] Asking patients this kind of a question at every visit, regardless of the reason for the visit, could compromise the patient-provider relationship by breaking rapport and shifting the visit away from what the patient wants.

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[6] *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.

[7] 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.

[8] Abigail RA Aiken, Sonya Borrero, Lisa Callegari, and Christine Dehlendorf, "Rethinking the Pregnancy Planning Paradigm: Unintended Conceptions or Unrepresentative Concepts?," *Perspectives on Sexual and Reproductive Health* 48, no. 3 (2016):147-151, https://doi.org/10.1363/48e10316

[9] Lisa S Callegari, Abigail RA Aiken, Christine Dehlendorf, Patty Cason, and Sonya Borrero, "Addressing potential pitfalls of reproductive life planning with patient-centered counseling," *American Journal of Obstetrics and Gynecology* 216, no. 2 (2017):129-134, https://doi.org/10.1016/j.ajog.2016.10.004.

[10] Sonya Borrero, et al., "It just happens": a qualitative study exploring low-income women's perspectives on pregnancy intention and planning," *Contraception* 91, no. 2 (2015):150-6. doi: 10.1016/j.contraception.2014.09.014.

[11] Lisa S Callegari, et al., "Addressing potential pitfalls of reproductive life planning with patient-centered counseling," 2017.

Reflecting current research that patients prefer to be asked about their service needs than about pregnancy intentions or desires[12], NFPRHA recommends that FPAR 2.0 use a more patient-centered approach to measurement. An example of an alternative measure that assesses patients' desire for contraceptive services is the Self-Identified Need for Contraception (SINC)[13] question developed by the University of California, San Francisco (UCSF) Person-Centered Reproductive Health Program in consultation with Reproductive Justice advocates. Of note, UCSF has an award from OPA to develop a new electronic Clinical Quality Measures (eCQMs) of contraceptive provision using the SINC question to define the denominator. As such, use of the SINC question in FPAR 2.0 would be consistent with other initiatives underway at OPA. Use of this type of measure also would facilitate the removal of problematic data elements related to sexual activity, which have been included to identify whether a patient is perceived as "at risk" for pregnancy.

Data Elements: Cervical Cancer Screening

FPAR 2.0 suggests the Title X service sites collect and report five different data elements related to cervical cancer screening: Pap test at this visit, Last Pap result, Pap test in the last five years, HPV test performed at this visit, and HPV test result. Collecting and reporting all five data elements for every Title X visit would carry substantial burden with minimal benefit.

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.[14] Furthermore, there is no way for MFHC to differentiate 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.[15] As a result, none of these cervical cancer screening-related data

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[12] Heidi E Jones, Cynthia Calixte, Meredith Manze, Michele Perlman, Susan Rubin, Lynn Roberts, and Diana Romero, "Primary care patients' preferences for reproductive health service needs assessment and service availability in New York Federally Qualified Health Centers," *Contraception* 101, no. 4 (2020):226-230.

[13] "Do you want to talk about contraception or pregnancy prevention during your visit today?"

- If yes: Mark "yes" and ensure appropriate counseling is provided
- If no: "There are a lot of reasons why a person wouldn't want to talk about this, and you don't have to share anything you don't want to. Do any of these apply to you?" (mark all that apply):
    - I'm here for something else
    - This question does not apply to me
    - I prefer not to answer
    - I am already using contraception (and what)
    - I am unsure or don't want to use contraception
    - I am hoping to become pregnant in the near future

[14] 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.

[15] Ibid.

elements can be used to monitor adoption and adherence to screening guidelines or track progress towards Healthy People 2030 goals (i.e., i**ncrease 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**.**[16] [17] 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 (detailed as never smoker, ex-smoker, smokes daily, occasional smoker, smoker, status unknown, heavy smoker, light smoker).

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 determine to report the intervention(s) offered to tobacco smokers, using those listed by the US Preventive Services Task Force.[18]

MFHC believes the collection of height and weight data, presumably to calculate body mass index (BMI), is problematic. From a clinical perspective, there is no logical rationale to record and report body weight *at every visit*, and OPA does not state why it is necessary to collect this information and how it will be used in the Supporting Statement for the Title X FPAR 2.0.[19] Even when collecting a patient's height and weight data is clinically indicated, 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 because it

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[16] 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.

[17] *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.

[18] 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.

[19] *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.

fails to account for differences in body composition, fitness levels, and nutritional differences.[20] Furthermore, the practice of weighing clients at every visit – even health education sessions or when not clinically indicated – may deter clients from accessing services due to experiences of body shame and weight discrimination.[21]

Patients accessing health services in non-Title X settings typically are weighed (or asked to self-report their weight) only when clinically indicated. Title X patients should receive the same standard of care and should not be subject to weight stigmatization at every visit. Weight stigma invokes psychological stress and emerging research suggests that this stress leads can exacerbate poor physical health outcomes for obese individuals[22], with the potential to perpetuate racial/ethnic and socioeconomic health disparities in overweight and obesity. It would be more appropriate to focus on measures of health that are scientifically valid and designed for diverse patient populations.

Screening for cardiovascular risk factors is indicated to support contraceptive decision-making (i.e., to ensure a patient does not have contraindications to combined oral contraceptives and other hormonal contraception) and pre-pregnancy health. While it may be desirable to capture these measures for additional patients, there is no explicit expectation or requirement for Title X providers to obtain information beyond that which is clinically necessary. Accordingly, we should not be required to document and report these measurements for every visit.

Confidentiality of Sensitive Personal Health Information

MFHC requests further 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 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.[23] 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.[24] 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

[20] 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.
[21] Janell L Mensinger, Tracy L Tylka, and Margaret E Calamari, "Mechanisms underlying weight status and healthcare avoidance in women: A study of weight stigma, body-related shame and guilt, and healthcare stress," *Body Image* 25 (2018):139-147. doi.org/10.1016/j.bodyim.2018.03.001.
[22] Rebecca M Puhl and Chelsea A Heuer, "Obesity stigma: important considerations for public health," *American Journal of Public Health* 100, no. 6 (2010):1019-28. doi:10.2105/AJPH.2009.159491.
[23] 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.
[24] Ibid.

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 seems 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.

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.

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The current FPAR 2.0 project stands to severely disrupt MFHC's operations during already uncertain times. MFHC, 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 MFHC lost three subrecipients, departures that resulted in almost 10,000 fewer Title X patients served in 2020. MFHC is also is concerned of losing existing subrecipients and service sites that cannot absorb this data collection burden.

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 providing Title X patients with 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, MFHC urges OPA to pause and re-evaluate FPAR 2.0.

If you require additional information about the issues raised in this letter, please contact Michelle Trupiano at mtrupiano@mfhc.org.

Sincerely,

Michelle Trupiano

Michelle Trupiano
Executive Director
Missouri Family Health Council, Inc.

April 12, 2021

Xavier Becerra
Secretary
Office of the Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Becerra:

AccessMatters welcomes the opportunity to submit comments in response to the Department of Health and Human Services' (HHS) Agency Information Collection Request 0990-New-60D on Family Planning Annual Report 2.0, issued on February 11, 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). 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). While AccessMatters 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.

AccessMatters' mission is to protect, expand, and enhance equitable access to sexual and reproductive health care and information for all people. As a public health non-profit organization our vision is that every person has the health care and information they seek. We focus on serving people and families with low incomes, and people from historically oppressed and marginalized communities.

AccessMatters' work reaches more than 100,000 people each year - across the Greater Philadelphia region, the Commonwealth of Pennsylvania, and throughout the nation - positively impacting people's health and wellness. AccessMatters fulfills its mission by providing services and information directly to people; by supporting a large network of healthcare provider organizations; and through research, training, and advocacy.

As the steward of several federal and state-funded programs related to sexual and reproductive health, pregnant/birthing people and child wellness, breast and cervical cancer screening, and STDs/HIV, AccessMatters is a critical part of the region's healthcare safety net. We also provide training and capacity-building services to health

and human service professionals nationwide on topics related to sexual health and health equity, including the impact of racism on health outcomes.

AccessMatters' Network of Title X Family Planning providers includes 18 subrecipient agencies operating 70 family planning service sites throughout Southeastern Pennsylvania. This large and diverse Network's service sites include federally-qualified health centers, hospital-based sites, freestanding family planning centers, public health centers, community-based agencies, school-based sites, university health centers, and more.

In 2020, AccessMatters' Title X Network, like programs across the nation and the world, was impacted by the COVID-19 Pandemic. This impact was compounded by the loss of Planned Parenthood in our network due to the Trump-era Title X rule. Both factors combined led to an average percentage drop of 60% in clients during 2020. In spite of these severe challenges, our Network served 33,551 family planning patients, of whom 85% were female and 15% were male. More than 74% of patients served reported incomes at or below 100% of the federal poverty line (FPL), and almost 82% reported incomes at or below 200% FPL. In 2020, the Network served 9,718 youth aged 19 or younger, including 1,010 youth under the age of 15.

Knowing the challenges our Network, its providers, and our public health workforce are facing as the COVID-19 pandemic rages on, AccessMatters is deeply concerned about OPA's proposal for FPAR 2.0.

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. 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 nationwide 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.

Like all safety net providers, AccessMatters has experienced several challenges since 2019. Changes to the Title X Program resulted in changes to our network of partner organizations. In our region, we lost two major health care providers who dropped out due to the Trump-era rule, accounting for between 40-50% of the clients usually seen in our network. Since these changes, we've remained focused on mitigating the impact

[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).

of the rule on providers and patients as much as possible. In addition to the impacts of the 2019 Title X rulemaking, Title X providers in our network have reported to us that they have experienced significant impact as a result of the COVID-19 pandemic. Specifically, they described considerable challenges around logistical changes (e.g., managing waiting room limits, implementing telehealth services), staffing (e.g., staff medical leave, staff being shifted to other teams to cover COVID-19 needs, increased turnover), and increased patient need (e.g., patients experiencing additional burden due to COVID-19, patients with more severe conditions due to delaying medical care during COVID-19). Despite COVID-19 vaccination efforts currently underway, COVID-19 cases continue to rise in our region and state, and the impact on our health care provider network continues with its full impact still unknown. Any attempt to implement FPAR 2.0 in accordance with planned timelines will severely disrupt and undermine our ability to respond to these top priorities.

Timeline

AccessMatters 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 face. 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, AccessMatters would need to upgrade its information technology (IT) infrastructure, as would its 18 subrecipients.

Despite discussions of FPAR 2.0 dating back several years, as of April 12, 2021, OPA has still 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 option 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 18 months to implement and test the systems upgrades needed to collect and report encounter-level data through FPAR 2.0.

This timeline reflects subrecipients' EHR or electronic data collection system procurement process and entire development lifecycle, which provides for research, wireframing, technical feasibility assessment, prototyping, design, development, testing, and deployment. Some subrecipients will modify their existing systems/software features, requiring custom coding and/or some form of implementation. The implementation may include gathering information, procuring consultants, planning, design, content writing and assembly, coding, testing and review, launch, monitoring, and regular updating.

Subrecipients will have to provide updated data files to AccessMatters for testing according to the new FPAR 2.0 elements and AccessMatters' data file manual requirements, which will also have to undergo an internal development lifecycle.

AccessMatters' development lifecycle includes a re-evaluation of its internal data systems and any necessary customizations to allow AccessMatters and subrecipients to adjust to FPAR 2.0 requirements. This internal process consists of the following:

- Working with subrecipients to identify and document their challenges with their EHR system (there are seven different EHR systems). This will aid with the internal process change assessment.
- Adding FPAR 2.0 data elements to the AccessMatters Data Warehouse Relational Database Management system.
- Updating Web Application Patient Visit Abstract Web forms and their underlying database system to include new FPAR 2.0 elements.
- Revising existing data migration packages programmatically after all databases have been updated and subrecipients start to provide AccessMatters with new test data files to facilitate new FPAR 2.0 data elements derived from the data files or Web Applications databases.
- Redeveloping the FPAR 2.0 annual report and other related reports according to the new requirements.

Extending this timeline is needed due to the limited availability of internal IT staff or external consultants/vendors to complete upgrades due to competing projects and existing engagements. After making system upgrades, AccessMatters and its subrecipients (which operate 70 service sites) will require three months to train healthcare 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. Initiating upgrades before final specifications are available would be wasteful, as inconsistencies would require revisions that would carry additional costs and burden hours spent.

Current OPA timelines also assume a level of baseline technology at both the Title X grantee and subrecipient levels. However, five of our subrecipients still use paper forms to collect FPAR data and an additional six use legacy systems that will need to be redeveloped for FPAR 2.0. If FPAR 2.0 goes into effect on January 1, 2022, these sites will need to collect and perform manual data entry of FPAR 2.0's 45 proposed data elements for every visit. This cumbersome process raises significant concerns about the effective use of Title X resources and the possibility of subrecipients opting to leave AccessMatters' Network and the Title X program, which has occurred in previous years due to the burden of data entry.

Accuracy of Estimated Burden

AccessMatters 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 render that assessment obsolete.

First, 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 are not only significantly outdated but also relate to a completely different iteration of the proposed overhaul of FPAR that would be substantially less burdensome on grantees and subrecipients.

Second, 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 each grantee-subrecipient dyad to invest in upgrading to electronic systems (as applicable) and establishing interoperability between their respective systems. In AccessMatters' Title X Network there are 18 subrecipients using at least seven different EHR platforms.

AccessMatters estimates that implementing FPAR 2.0 will exceed $1 million in one-time labor and non-labor costs combined for AccessMatters' Title X Network. This estimate is based on the cost of an internal team at AccessMatters of five staff persons working at least 200 hours to get systems and processes ready for implementation by January 2022. The tasks related to implementation include: selecting and creating contracts with vendors, working with vendors to perform necessary system upgrades and map out FPAR 2.0's data elements to existing standardized value sets, creating external-facing materials for subrecipients (e.g., cross-walk of FPAR 1.0 to 2.0 elements), training health care providers and staff on how to collect new data elements, providing tailored one-on-one technical assistance to subrecipients, conducting preliminary data collection, running reports to ensure data mapping is correct, and performing quality assurance of preliminary data collected. Our estimate also includes approximately $180,000 in funds already spent by AccessMatters on contractors to upgrade our systems to accommodate FPAR 2.0 implementation. Costs and time investment will be comparable for each subrecipient, bringing the total amount needed for

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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).

AccessMatters' Title X Network well over $1 million. OPA is proposing this massive time commitment and expenditure take place at a time when we, and every part of the Title X system nationwide, are continuing to respond – and facing burnout from – the COVID-19 public health emergency, which has required resources to be necessarily redirected to emergency response, and when revenue has dwindled due to fluctuations in patient census. It is important to note that our estimate is an underrepresentation of total cost to our Network, as these cost estimates do not include (1) ongoing expenses such as ongoing operations and maintenance in addition to computer and software upgrades and purchased service costs, or (2) 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.

Burden, Necessity and Utility of FPAR 2.0 Data

AccessMatters believes the 23 additional 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. It corresponds to the deliberate transition of FPAR from a program monitoring tool to a research dataset, requiring Title X service sites to collect excessive information from patients at every single visit, even though such information is not necessitated by clinical practice guidelines or other evidence-based standards. While AccessMatters already collects data from subrecipients at the encounter level, sending encounter level data to OPA is new and raises concerns from subrecipients about sharing protected health information (PHI) with another entity outside of their organization.

AccessMatters also has concerns about the invasive nature of the data collection and the questions these additional data sets will require providers to ask in a clinical setting. Healthcare providers need training in trauma-informed care and motivational interviewing to implement best practices around asking these more detailed questions of patients. As a grantee with a nationally-recognized training team that has experience providing healthcare providers with training and professional development around motivational interviewing and delivering trauma-informed care, AccessMatters

recommends that OPA outline a detailed plan to position providers as best as possible to deliver trauma-informed, comprehensive counseling and care. This is a critical element that must be addressed before implementation given the sensitive nature of the data elements required by FPAR 2.0.

AccessMatters also understands that the sensitive nature of additional data elements could be of great concern to some patients. This may lead to patients electing not to receive services through the Title X program because they have concerns about the amount and type of sensitive information being collected and do not want their information shared with the federal government.

AccessMatters believes it is important to recognize the history of discrimination against Black and Brown people by government entities and healthcare systems, and the distrust that is present in many communities nationwide, including immigrant communities. The distrust exacerbates concerns about sharing sensitive information with entities that have historically oppressed marginalized communities. The assumption should not be made that all patients are willing to provide sensitive information they know would be shared with government entities.

Due to these concerns, AccessMatters recommends that OPA specify how providers should capture such patient encounters.

AccessMatters also strongly encourages OPA to consider adjustments to how demographic data are currently collected in FPAR and preparing and disseminating guidance to providers about how they can collect current required demographic data elements using a trauma-informed approach. Specifically, AccessMatters encourages OPA to adjust the options for data collection around gender identity to include:

Which of the following best describes your gender identity?

- *I identify as a woman.*
- *I identify as a man.*
- *I identify as non-binary or genderqueer (neither man nor woman).*
- *I identify as something else (please specify): -_____*
- *I prefer not to answer.*

Please see the attachment *AccessMatters' Standard Demographic Language* for additional detail and recommendations on collecting demographic data, including sex assigned at birth.

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 include screening for breast and cervical cancer,"[5] they certainly do not need to be captured at every encounter 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.

In addition, AccessMatters shares the concerns offered by the National Family Planning Reproductive Health Association (NFPRHA) around the specific data elements below.

New Data Elements: Sexual Activity

The Supporting Statement for the Title X FPAR 2.0 describes how FPAR 2.0 will supplement the federally funded National Survey for Family Growth (NSFG), a population-level, nationally representative dataset that gathers information on pregnancy and births, infertility, use of contraception, and general and reproductive health.[6] However, while NSFG surveys a representative sample of respondents and allows them to *voluntarily* respond, the data elements that will be collected and reported through FPAR 2.0 will be required for every patient visit. More specifically, OPA has proposed that Title X providers inquire about oral, vaginal, and anal intercourse and complete 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 intrusive, burdensome and threatens the patient-provider relationship. It also is inconsistent with current best practice guidelines, which recommend assessing whether an adult 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)].[7] These sexual activity-related data fields also are not needed to monitor our Title X Network's accountability to program goals.

It is important to emphasize that patients accessing services in non-Title X settings would not be asked to provide responses to these personal, guideline-discordant questions at every visit, nor would their responses be reported at the encounter level

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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.

[6] *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.

[7] 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.

to the federal government. When the federal government begins collecting research data for its benefit and requires those accessing services through the safety net to provide such information as a precursor to receive care, it feels like behavior surveillance and exacerbates medical mistrust, potentially dissuading patients from coming to us for needed services.

Data Elements: Cervical Cancer Screening

FPAR 2.0 suggests the Title X service sites collect and report five different data elements related to cervical cancer screening: Pap test at this visit, Last Pap result, Pap test in the last five years, HPV test performed at this visit, and HPV test result. Collecting and reporting all five data elements for every Title X visit would carry substantial burden with minimal benefit. 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.[8] Furthermore, there is no way for AccessMatters to differentiate 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.[9] 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.[10] [11] When extracting data to calculate measures, there is no way to qualify whether an appropriate screening interval was applied.

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[8] 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.

[9] Ibid.

[10] 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.

[11] *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.

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 (detailed as ever smoker, ex-smoker, smokes daily, occasional smoker, smoker, status unknown, heavy smoker, light smoker).

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.[12]

AccessMatters believes the collection of height and weight data, presumably to calculate body mass index (BMI), is problematic. From a clinical perspective, there is no logical rationale to record and report body weight *at every visit*, and OPA does not state why it is necessary to collect this information and how it will be used in the Supporting Statement for the Title X FPAR 2.0.[13] Even when collecting a patient's height and weight data is clinically indicated, 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 because it fails to account for differences in body composition, fitness levels, and nutritional differences.[14] Furthermore, the practice of weighing clients at every visit – even health education sessions or when not clinically indicated – may deter

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[12] 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.

[13] *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.

[14] 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.

clients from accessing services due to experiences of body shaming, body size stigma, and weight discrimination.[15]

Patients accessing health services in non-Title X settings are not weighed at every visit unless clinically indicated. Title X patients should receive the same standard of care and should not be subject to weight stigmatization at every visit. Weight stigma invokes psychological stress and emerging research suggests that this stress can exacerbate poor physical health outcomes for obese individuals[16], with the potential to perpetuate racial/ethnic and socioeconomic health disparities. It is time to move away from this measure and focus on measures of health that are scientifically valid and designed for diverse patient populations.

Screening for cardiovascular risk factors is indicated to support contraceptive decision-making (i.e., to ensure a patient does not have contraindications to combined oral contraceptives and other hormonal contraception) and pre-pregnancy health. While it may be desirable to capture these measures for additional patients, there is no explicit expectation or requirement for Title X providers to obtain information beyond that which is clinically necessary. Accordingly, we should not be required to document and report these measurements for every visit.

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 a NPI number. In 2019, 24 percent of all Title X family planning encounters in AccessMatters' Network were performed by other service 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 an individual NPI number to report for FPAR 2.0.

Confidentiality of Sensitive Personal Health Information

AccessMatters requests further 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 case law. Further, those services are grounded in medical

[15] Janell L Mensinger, Tracy L Tylka, and Margaret E Calamari, "Mechanisms underlying weight status and healthcare avoidance in women: A study of weight stigma, body-related shame and guilt, and healthcare stress," *Body Image* 25 (2018):139-147. doi.org/10.1016/j.bodyim.2018.03.001.
[16] Rebecca M Puhl and Chelsea A Heuer, "Obesity stigma: important considerations for public health," *American Journal of Public Health* 100, no. 6 (2010):1019-28. doi:10.2105/AJPH.2009.159491.

and ethical standards, and reflect research demonstrating that, without access to confidential care, some patients would not seek needed health services.[17] 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.[18] 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 face, it seems 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.

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.

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The current FPAR 2.0 project stands to severely disrupt AccessMatters' operations during already uncertain times. AccessMatters, 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. AccessMatters also is concerned about losing existing subrecipients and service sites that cannot absorb this data collection burden.

We are striving to see more patients after unprecedented fluctuation 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 providing Title X patients with 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. Of highest concern is the possibility that a real or perceived lack of confidentiality of highly personal and sensitive health data would lead client to walk away from Title X services

[17] 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.
[18] Ibid.

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that they otherwise would seek – adding to, rather than ameliorating –health divides in our nation. Accordingly, AccessMatters urges OPA to pause and re-evaluate FPAR 2.0.

AccessMatters appreciates the opportunity to provide comments. If you have questions or would like additional information, please contact me at 215-985-2655 or via email at: melissa.weilergerber@accessmatters.org. Thank you.

Sincerely,

Melissa Weiler Gerber
President and CEO

Attachment: *AccessMatters' Standard Demographic Language*

AccessMatters Standard Demographic Language
Updated March 2021

Variable	2017 Final	2021 Recommendation	Rationale
PARTICIPANT ID	How many letters are in your middle name (e.g. 5, 8, 10)? ___ What is the last digit of your cell phone number (e.g. 2, 4, 9)? ___ What is the first letter of the name of the city in which you were born (e.g. A, F, P)? ___ What is the last digit of the year in which you were born (e.g. 1, 6, 7)? ___ What is the last letter of your last name (e.g. D, L, Y)? ___	How many letters are in your middle name (e.g. 5, 8, 10)? ___ What is the first letter of the name of the city in which you were born (e.g. A, F, P)? ___ What is the last digit of the year in which you were born (e.g. 1, 6, 7)? ___ What is the last letter of your last name (e.g. D, L, Y)? ___	Remove prompt related to cell phone number, since client contact information often changes.
RACE	**Please mark which of the following racial categories describe you (select all that apply):**[i] A. Black and/or African-American B. Asian and/or Asian-American C. American Indian and/or Alaska Native D. Native Hawaiian and/or Other Pacific Islander E. White F. Biracial or Multiracial G. Other (please specify): _____	**Which of the following categories describe you? Select all that apply.**[ii] A. Asian, Asian-American, Pacific Islander, or Southeast Asian B. Black, African-American, Caribbean, or African Diaspora C. Indigenous, Native American, Native Alaskan, or First Nations D. Latino/a, Latinx, Latine, or Hispanic E. Southwest Asian or Northern African F. White G. Two or more races or ethnicities H. Some other race, ethnicity, or origin (please specify): _____ I. I prefer not to answer.	U.S. Census focus groups found that many Americans don't see or understand a difference between race and ethnicity, and in the past three years of data collection at AM, we have identified populations of Latinx and SWANA folks who would historically be classified as "white," but do not self-identify as white or meaningfully experience "whiteness." This question captures a more accurate picture of American identity.
ETHNICITY	**Please mark which of the follow ethnicity categories describe you:**[iii] A. Hispanic and/or Latino. B. Middle Eastern and/or Northern African. C. Both A & B. D. None of the above.		
SEXUAL ORIENTATION	**Which of the following best describes your sexual orientation?**[iv] A. I identify as straight or heterosexual. B. I identify as gay, lesbian, homosexual, or same gender loving. C. I identify as bisexual or pansexual. D. I identify as asexual. E. I identify as something else (please specify): _____ F. I prefer not to answer.	**Which of the following best describes your sexual orientation?** A. I identify as straight or heterosexual B. I identify as gay, lesbian, homosexual, or same gender loving C. I identify as bisexual or pansexual D. I identify as asexual E. I identify as something else (please specify): _____ F. I prefer not to answer	Question remains the same. Still aligned with best practices.

AccessMatters Standard Demographic Language
Updated March 2021

Variable	2017 Final	2021 Recommendation	Rationale
GENDER IDENTITY	**Which of the following best describes your gender identity?**[v] A. I identify as a woman. B. I identify as a man. C. I identify as genderqueer or non-binary (neither man nor woman). D. I identify as something else (please specify): - _____ E. I prefer not to answer.	**Which of the following best describes your gender identity?** A. I identify as a woman. B. I identify as a man. C. I identify as non-binary or genderqueer (neither man nor woman). D. I identify as something else (please specify): _____ E. I prefer not to answer. (*if working with a queer-specific sample population*) **Which of the following words describe your gender? Select all that apply.** A. Woman B. Man C. Non-binary D. Genderqueer E. Agender F. Genderfluid G. Two-Spirit or other indigenous gender H. Transgender/trans I. Cisgender/cis J. Something else (please specify): _____ K. I prefer not to answer	Question remains essentially the same. Still aligned with best practices. Added more expansive option for use with known queer populations.
TRANSGENDER STATUS	**"Transgender" describes people whose gender identity or expression is different from the sex assigned to them at birth (for example, on their original birth certificates). Do you consider yourself to be transgender?**[vi] A. Yes, I consider myself to be transgender. B. No, I do not consider myself to be transgender. C. I prefer not to answer.	**"Transgender" and "trans" are words that can describe people whose gender identity is different from the sex assigned to them at birth (for example, on their original birth certificate). Do you consider yourself to be transgender and/or trans?**[vii] A. Yes, I consider myself to be transgender/trans. B. No, I do not consider myself to be transgender/trans. C. I prefer not to answer.	Added "trans" – some people use "trans", but don't use the full word "transgender" to describe themselves.

AccessMatters Standard Demographic Language
Updated March 2021

Variable	2017 Final	2021 Recommendation	Rationale
EDUCATIONAL ATTAINMENT	**What is the highest level of education that you have completed?**[viii] A. Less than 9th grade B. 9th to 12th grade, no diploma C. High school graduate or GED D. Some college, no degree E. Associate's degree F. Bachelor's degree G. Graduate or professional degree, please specify: _____	**What is the highest level of education that you have completed?**[ix] A. 8th grade or earlier B. Some high school C. High school diploma or GED equivalent D. Vocational training E. Some college, no degree F. Associate's degree (e.g. AA, AE, AFA, AS, ASN) G. Bachelor's degree (e.g. BA, BBA, BFA, BS) H. Some post-undergraduate study I. Master's degree (e.g. MA, MBA, MFA, MS, MSW) J. Doctorate degree (e.g. PhD, MD, PsyD, EdD, JD) K. Other, please specify: _____ L. I prefer not to answer	Removed "less than" language to avoid stigmatizing. Added more examples for clarity; broke down category of graduate/professional degree for specificity; added options for "vocational training" and "some post-undergrad study" to reflect other educational pathways
EMPLOYMENT STATUS	**What is your current employment status?**[x] A. Employed full-time by an employer. B. Employed part-time by an employer. C. Self-employed. D. Unemployed and looking for work. E. Unemployed and not looking for work. F. Student. G. Homemaker or full-time parent. H. Not employed due to disability. I. Retired.	**What is your current employment status? Select all that apply.** A. Employed full-time by an employer B. Employed part-time by an employer C. Self-employed D. Unemployed and looking for work E. Unemployed and not looking for work F. Student G. Stay-at-home parent or homemaker H. Not employed due to disability I. Retired J. Other, please specify: _____ K. I prefer not to answer	Updated to add fill-in option and opt-out option. Also updated to make "select all that apply" – anecdotally, we've had a lot of clients who are both students AND employed, or both retired AND working part-time.

AccessMatters Standard Demographic Language
Updated March 2021

Variable	2017 Final	2021 Recommendation	Rationale
AGE	**Please indicate your age: _____** **What is your age?**[xi] A. Under 13 B. 13-17 C. 18-24 D. 25-34 E. 35-44 F. 45-54 G. 55-64 H. 65 or Older **What is your age?** *[youth samples only]* A. Under 13 B. 13-14 C. 15-17 D. 18-19 E. 20-24 I. 25 or Older	**What is your age, in years? _____** **What is your age?** A. Under 13 B. 13-17 C. 18-24 D. 25-34 E. 35-44 F. 45-54 G. 55-64 H. 65-74 I. 75-84 J. 85-94 K. 95 or Older **What is your age?** *[youth samples only]* A. Under 13 B. 13-14 C. 15-17 D. 18-19 E. 20-24 F. 25 or Older **What is your date of birth? _____/_____/_____**	Updated to clarify fill-in as age, in years, and to add DOB question option (which allows us to auto-calculate age at any time). Expanded age categories to respond to experiences of ageism among older adults.
LEGAL MARITAL STATUS	**What is your current legal marital status?**[xii] A. Married. B. Legally-recognized civil union. C. Registered domestic partnership. D. Widowed. E. Divorced. F. Separated. G. Single, never married. H. I prefer not to answer.	**What is your current legal marital status?** A. Married B. Legally-recognized civil union C. Registered domestic partnership D. Widowed E. Divorced F. Separated G. Single, never married H. I prefer not to answer	Question remains the same, because legal marital status categories have not changed.

AccessMatters Standard Demographic Language
Updated March 2021

Variable	2017 Final	2021 Recommendation	Rationale
RELATIONSHIP STATUS	**What is your current relationship status (select all that apply)?**[xiii] A. Partnered, living together B. Partnered, not living together C. Dating (one or more casual partners) D. Single E. Other relationship status (please specify): _____ F. I prefer not to answer	**Are you currently in an ongoing romantic and/or sexual relationship with a partner or partners?**[xiv] A. Yes, with one partner B. Yes, with multiple partners C. No **If you answered yes, what is your current relationship status? Select all that apply.** A. Partnered, living together B. Partnered, not living together C. Dating (one or more casual partners) D. Other relationship status, please specify: _____ E. I prefer not to answer	Split into two questions for greater inclusion of (and collection of data about) polyamorous/non-monogamous people.
NATIONAL ORIGIN	**Where were you born?**[xv] A. In the United States. B. In Puerto Rico, Guam, the U.S. Virgin Islands, or Northern Marianas. C. Somewhere else (please specify nation): _____	**In what country were you born?** _____	Changed to open-ended to avoid perpetuating U.S. hegemony. Also clarified that the question is asking for country of origin (not city, state, etc.).
CITIZENSHIP STATUS[xvi]	**Are you a citizen of the United States?** A. Yes, born in the United States or U.S. territories (e.g. Puerto Rico, Guam, etc.). B. Yes, born abroad to U.S. citizen parents. C. Yes, by naturalization. D. No, not a U.S. citizen. E. I prefer not to answer.	**Remove from Demographic Guidance.**	Due to increased concerns about the use and confidentiality of such data, we are removing this question.

AccessMatters Standard Demographic Language
Updated March 2021

Variable	2017 Final	2021 Recommendation	Rationale
HEALTH INSURANCE COVERAGE	**Are you currently enrolled in any form of health insurance or health coverage plan?** A. Yes B. No **What type of health insurance or health coverage plan do you have?**[xvii] A. Insurance through my current or former employer. B. Insurance through someone else's current or former employer. C. Insurance purchased through HealthCare.Gov or a Health Insurance Marketplace. D. Insurance purchased directly from an insurance company. E. Medicare. F. Medicaid/Medical Assistance. G. TRICARE or other Military insurance. H. Veterans Affairs (VA) insurance. I. Indian Health Service (IHS). J. Some other kind of health insurance (please specify): _____	**Are you currently enrolled in any form of health insurance or health coverage plan?** A. Yes B. No C. Not sure/don't know D. I prefer not to answer **What type of health insurance or health coverage plan do you have?** A. Insurance through my current or former employer B. Insurance through someone else's current or former employer C. Insurance purchased through HealthCare.Gov or a Health Insurance Marketplace D. Insurance purchased directly from an insurance company E. Medicare (coverage for people age 65+ and some people with disabilities) F. Medicaid/Medical Assistance (coverage for low-income people and families) G. TRICARE or other Military insurance H. Veterans Affairs (VA) insurance I. Indian Health Service (IHS) J. Some other kind of health insurance, please specify: _____	Updated to clarify common sense definitions for Medicare and Medicaid. Anecdotally, many Medicaid users do not use that name to describe their coverage.
LANGUAGE SPOKEN[xviii]	**What language(s) do you speak at home?** A. English only. B. English and another language (please specify): _____ C. Another language only (please specify): _____	**What language(s) do you speak at home?** A. English only B. English and another language, please specify: _____ C. Another language only, please specify: _____	Question remains the same. Still aligned with best practices.
ENGLISH PROFICIENCY	**How well do you speak English?**[xix] A. Very well. B. Well. C. Not well. D. Not at all.	**Remove from Demographic Guidance.**	Responsive to experiences of institutional racism related to English proficiency. (Also, we have not previously had a use for this question. Its inclusion was based on Census practice alone.)

AccessMatters Standard Demographic Language
Updated March 2021

Variable	2017 Final	2021 Recommendation	Rationale
INCOME[xx]	**What is your total annual household income?** A. Less than $10,000 B. $10,000 to $14,999 C. $15,000 to $24,999 D. $25,000 to $34,999 E. $35,000 to $49,999 F. $50,000 to $74,999 G. $75,000 to $99,999 H. $100,000 to $149,999 I. $150,000 to $199,999 J. $200,000 or more K. I prefer not to answer. **How many minor children (under the age of 18) reside in your household? _____** **How many adults (over the age of 18) reside in your household? _____**	**What is your total annual household income?** A. Less than $10,000 B. $10,000 to $24,999 C. $25,000 to $49,999 D. $50,000 to $74,999 E. $75,000 to $99,999 F. $100,000 to $149,999 G. $150,000 to $199,999 H. $200,000 or more I. I prefer not to answer **What is your total annual household income? _____** A. How many minor children (under the age of 18) reside in your household? _____ B. How many adults (over the age of 18) reside in your household? _____	Broke long multiple-choice question into two separate options: 1) A shorter multiple-choice question, for when we are looking to sort people by general income level 2) An open-ended specific income and household size question, for when we are looking to calculate federal poverty level
RELIGIOUS AFFILIATION	**Which of the following best describes your religious practice and/or affiliation (select all that apply)?**[xxi] A. Agnostic B. Atheist C. Protestant D. Catholic E. Orthodox Christian F. Mormon G. Jehovah's Witness H. Other Christian I. Jewish J. Muslim K. Buddhist L. Hindu M. Other religion or faith (please specify): _____ N. Not affiliated with any belief system. **O.** I prefer not to answer.	**Which of the following best describes your religious practice and/or affiliation? Select all that apply.** A. Agnostic B. Atheist C. Bahá'í D. Buddhist E. Christian – Catholic F. Christian – Protestant G. Christian – Other H. Hindu I. Jewish J. Muslim K. Sikh L. Taoist M. Other religion or faith, please specify: _____ N. Not affiliated with any belief system O. I prefer not to answer	Cut down listed options for Christian denominations to avoid perpetuation of Christian hegemony. Added other Abrahamic and non-Abrahamic religions with strong representation in the United States.

AccessMatters Standard Demographic Language
Updated March 2021

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[i] Adapted from: U.S. Census Bureau. (2015). *American Community Survey*.
[ii] Adapted from: Hughes, J.L., Camden, A.A., and Yangchen, T. (2016). "Rethinking and Updating Demographic Questions: Guidance to Improve Descriptions of Research Samples." *Psi Chi Journal of Psychological Research* 21(3): 138-151.
[iii] Adapted from: National Center for Education Statistics. (2012). "Collecting Race and Ethnicity Data from Students and Staff using the New Categories." Integrated Postsecondary Education Data System. Washington, D.C.: U.S. Department of Education, Institute of Education Sciences.
[iv] Adapted from: The Fenway Institute. (2013). *Asking Patients Questions about Sexual Orientation and Gender Identity in Clinical Settings.* Boston, MA: The Fenway Institute and Center for American Progress.
[v] Adapted from: The Fenway Institute. (2013). *Asking Patients Questions about Sexual Orientation and Gender Identity in Clinical Settings.* Boston, MA: The Fenway Institute and Center for American Progress; Harrison, J, J Grant, and JL Herman. (2012). "A Gender Not Listed Here: Genderqueers, Gender Rebels, and OtherWise in the National Transgender Discrimination Survey." *LGBTQ Policy Journal at the Harvard Kennedy School* 2: 13-24.
[vi] Adapted from: The Fenway Institute. (2013). *Asking Patients Questions about Sexual Orientation and Gender Identity in Clinical Settings.* Boston, MA: The Fenway Institute and Center for American Progress; Harrison, J, J Grant, and JL Herman. (2012). "A Gender Not Listed Here: Genderqueers, Gender Rebels, and OtherWise in the National Transgender Discrimination Survey." *LGBTQ Policy Journal at the Harvard Kennedy School* 2: 13-24.
[vii] Adapted from: The Fenway Institute. (2013). *Asking Patients Questions about Sexual Orientation and Gender Identity in Clinical Settings.* Boston, MA: The Fenway Institute and Center for American Progress; Harrison, J, J Grant, and JL Herman. (2012). "A Gender Not Listed Here: Genderqueers, Gender Rebels, and OtherWise in the National Transgender Discrimination Survey." *LGBTQ Policy Journal at the Harvard Kennedy School* 2: 13-24.
[viii] Adapted from: U.S. Census Bureau. (2015). *American Community Survey*.
[ix] Adapted from: Hughes et al 2016.
[x] Adapted from: U.S. Census Bureau. (2015). *American Community Survey*.
[xi] Adapted from: U.S. Census Bureau. (2015). *American Community Survey.*
[xii] Adapted from: National Center for Transgender Equality. (2015). *U.S. Trans Survey.* Washington, D.C.: NCTE.
[xiii] Adapted from: National Center for Transgender Equality. (2015). *U.S. Trans Survey.* Washington, D.C.: NCTE.
[xiv] Adapted from: Hughes et al 2016.
[xv] Adapted from: U.S. Census Bureau. (2015). *American Community Survey*.
[xvi] Adapted from: U.S. Census Bureau. (2015). *American Community Survey*.
[xvii] Adapted from: U.S. Census Bureau. (2015). *American Community Survey.*
[xviii] Adapted from: U.S. Census Bureau. (2015). *American Community Survey*.
[xix] Adapted from: U.S. Census Bureau. (2015). *American Community Survey*.
[xx] Adapted from: U.S. Census Bureau. (2015). *American Community Survey*.
[xxi] Adapted from: U.S. Census Bureau. (2015). *American Community Survey*.

MEMORANDUM

TO: Sherrette Funn, Reports Clearance Officer, Department of Health and Human Services
FROM: Wisconsin Title X Grantee: The Department of Health Services
SUBJECT: Comment on FPAR 2.0 [Document Identifier OS-0990-xxxx]
DATE: 04/12/2021

Summary

Encounter-level data collected by Title X Grantees and reported to the Office of Population Affairs (OPA) should minimize collecting Personal Identifiable Information (PII).[1] Currently, the Family Planning Annual Report (FPAR) [2] collects demographic information including family planning user age, sex, race, ethnicity. Requiring grantees to collect and report family planning user demographics such as date of birth or zip code of residence could compromise patient confidentiality and grantees' ability to comply with OPA reporting requirements. If OPA requires encounter-level data that could compromise patient confidentiality, OPA needs to demonstrate the necessity of collecting such information. OPA has also vastly underestimated the burden hours required for implementing and complying with any changes in data elements collected.

Protecting Personally Identifiable Information of Family Planning Users.

Changes to the FPAR data required from grantees should only collect as much family planning user information necessary to assure program adherence and analyze trends in family planning. Family planning users are individuals who have at least one family planning encounter at a Title X service site.[2] Grantees are currently reporting aggregate data of family planning users to the Office of Population Affairs (OPA) on an annual basis. To report this data, the Wisconsin Department of Health Services (DHS), a grantee of the Title X program, is collecting family planning encounter data from Title X service site subrecipients. Currently, family planning users' PII is protected by de-identifying encounter-level data before being collected by DHS. Requiring Title X grantees to collect family planning user demographic information such as date of birth or zip code would compromise patient confidentiality without enhancing the quality of data collected.

Sub Recipient Compliance

The DHS Title X subrecipients have expressed concern in changes to reporting family planning user demographics, such as date of birth and zip code, collected by the DHS and reported to OPA. The DHS Title X subrecipients have an obligation to provide high-quality, confidential family planning services and adhere to reporting requirements. This conflict of providing high quality, confidential care and the reporting requirements of the program could result in clinics omitting data reported to the DHS or making the choice to leave the Title X program.

Burden Hours Are Underestimated

The OPA has underestimated the burden hours required – 36 per grantee - to make changes to collecting and reporting data elements in a new FPAR. The DHS vendor working with subrecipients to collect encounter-level data estimates 600 hours to build the FPAR 2.0 requirements. The DHS estimates FPAR 2.0 elements will need to be approved in July 2021 to design and deploy the modifications of current modules to support the new reporting requirements.

1. U.S. Department of Health and Human Services. *Title X Family Planning Annual Report Forms and Instructions.* Reissued January 2021. Office of Population Affairs. OMB No.0990-0221
2. U.S. General Service Administration. *GSA Rules of Behavior for Handling Personally Identifiable Information (PII*). October 28, 2019.

From:	Llew Brown
To:	Ruth Hsu; Michael Kerachsky; Annu van Bodegom
Subject:	(Virginia Dept of Health) FW: Comment Submission: FPAR 2.0. (0990-New-60D)
Date:	Tuesday, April 13, 2021 11:58:21 AM

Fyi, I added this to the spreadsheet

From: Kim, Jamie (HHS/OASH) <Jamie.Kim@hhs.gov>
Sent: Friday, April 9, 2021 9:57 PM
To: Llew Brown <LOBrown@mathematica-mpr.com>
Cc: Daniel Shapiro <DShapiro@mathematica-mpr.com>; Nora Paxton <NPaxton@mathematica-mpr.com>
Subject: FW: Comment Submission: FPAR 2.0. (0990-New-60D)

From: Funn, Sherrette (OS/OCIO/CDO) <Sherrette.Funn@hhs.gov>
Sent: Friday, April 9, 2021 7:47 PM
To: Kim, Jamie (HHS/OASH) <Jamie.Kim@hhs.gov>
Cc: Farb, Amy (HHS/OASH) <Amy.Farb@hhs.gov>
Subject: FW: Comment Submission: FPAR 2.0. (0990-New-60D)

Sherrette Funn
Office of the Secretary Report Clearance Officer
Department of Health and Human Services
200 Independence, S.W. suite 345F
Work cell# 202-264-0041

From: Yeatts, Emily <emily.yeatts@vdh.virginia.gov>
Sent: Friday, April 9, 2021 7:13 PM
To: Funn, Sherrette (OS/OCIO/CDO) <Sherrette.Funn@hhs.gov>
Cc: Macdonald Jennifer oir66280 <jennifer.macdonald@vdh.virginia.gov>; Janelle Anthony <janelle.anthony@vdh.virginia.gov>; Burney, Kimani <kimani.burney@vdh.virginia.gov>
Subject: Comment Submission: FPAR 2.0. (0990-New-60D)

Ms. Funn:

The Virginia Department of Health (VDH) welcomes the opportunity to submit comments in response to the Department of Health and Human Services' (HHS) Agency Information

Collection Request 0990-New-60D on Family Planning Annual Report 2.0, issued on February 11, 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). 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). While VDH appreciates the need for a more robust data system for monitoring and improving program performance and is committed to implementing such a system, VDH also has serious concerns about the current project and timeline. We ask for OPA to consider planning and initiating a new process for transitioning to a new data collection and reporting system with continued stakeholder involvement so that the project is ultimately effective.

VDH has participated in the Title X Family Planning Program since its inception. The sole Title X grantee in Virginia, VDH maintains a robust network of approximately 135 clinical sites located across the Commonwealth. Title X clinics serve as a critical part of Virginia's safety net, working in concert with programs such as Medicaid, Plan First, FAMIS, and TANF to serve families. VDH values the Title X program's dedication to quality and access, and uses its Title X funds to remove barriers to care for patients seeking basic reproductive health services. The majority of VDH's Title X patients are low-income, live in rural areas, and would not have access to family planning services without the support of this program. While VDH has serious concerns about FPAR 2.0, in no way do these comments intend to imply a lack of dedication or appreciation for the Title X program and its positive impact on Virginians. VDH submits these comments in a sincere effort to ensure the project's success.

Like all safety net providers, VDH has experienced unprecedented challenges since 2020. As the public health agency for Virginia, VDH has been tasked with both monitoring and mitigating the COVID-19 pandemic. Staff across the agency have been directly affected by COVID-19 in both their personal and professional lives for over a year. As of April 8, 2021, Virginia has seen 631,083 cases of COVID-19, and 10,436 Virginians have died of the disease. Administrative staff have shifted to telework and been assigned additional tasks related to the pandemic. Clinical staff have been reassigned to COVID-related responsibilities such as contact tracing, public education, and vaccinations. Any staff with IT and data analysis skills have been expected to help with COVID-19 data collection, analysis, and dissemination. The VDH workforce is stretched thin as the agency attempts to maintain core services and respond to COVID-19.

The aforementioned challenges have meant that any VDH staff who would otherwise have been assigned to FPAR 2.0 preparation have been required to prioritize COVID activities. Furthermore, clinical sites have been forced to reduce their previous efforts to expand family planning services. VDH's Title X program has experienced a 42% decline in patient volume between 2019 and 2020, and numerous Title X sites across the Commonwealth were forced to adjust hours or temporarily close. When the pandemic subsides, VDH will need to invest all available resources into rebuilding the Title X program to its previous capacity.

VDH requests that OPA establish a new timeline for FPAR 2.0 planning and

implementation given the challenges Title X grantees and service sites currently are facing. Even in the absence of the aforementioned challenges, the current timeline for FPAR 2.0 data collection to begin on January 1, 2022 needs to be revised. In order to implement FPAR 2.0, VDH and its three federally qualified health center (FQHC) subrecipients would need to upgrade its IT infrastructure. However, as of April 8, 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 option to standardized value sets. In the absence of these specifications, VDH is in the difficult position of having to wait while the time window needed to implement systems changes narrows. Initiating upgrades before final specifications are available would be wasteful, as inconsistencies would require revisions that would carry additional costs and burden hours spent. Currently, VDH estimates it will take 36 months to pilot, implement, test, and revise the modifications necessary to collect and report the encounter-level data required by FPAR 2.0, as well as provide the appropriate training to staff.

Current OPA timelines assume a level of baseline technology at both the Title X grantee and subrecipient levels. However, VDH does not have an EHR system. Instead, VDH uses paper forms and WebVision, a homegrown legacy system that tracks information for billing purposes, to collect FPAR data for aggregate submission. Any Title X sites that do not have an EHR will not be able to procure and implement an EHR by January 1, 2022, as EHR implementation typically takes 9 to 11 months, with three months for planning and six to eight months for implementation. Furthermore, VDH is unable to procure an EHR until the Virginia General Assembly allocates considerable and sustained funding to the agency for this purpose. If FPAR 2.0 goes into effect on January 1, 2022, VDH will need to collect and perform manual data entry of FPAR 2.0's 45 proposed data elements for every visit, and then determine how to de-identify line-item records so that they can be transmitted securely.

In the absence of an EHR, VDH clinical sites will need to modify the WebVision system so that it can collect encounter-level data for each patient visit. WebVision was not designed to function in this capacity, and the agency would need to invest considerable time and resources to build out its infrastructure to include all of the FPAR 2.0 data elements. The final result will likely be cumbersome and difficult for clinic staff to navigate, which will not only add a significant amount of time to each visit but also require a significant amount of training and quality assurance (QA)/quality improvement (QI) work to ensure that staff are entering the data correctly. QA/QI work will be difficult to manage given the limitations of the WebVision system; again, WebVision was not designed to work in this capacity but rather to serve as a way to track basic patient and payment information for billing purposes.

The absence of an EHR has led to VDH to build out an infrastructure that will make FPAR 2.0 difficult to navigate without considerable time for planning, piloting projects, and evaluating the results. For example, VDH contracts with LabCorp, an external laboratory, for STI tests and Pap tests. VDH collects the specimen during the patient's family planning visit, and then sends the specimen to LabCorp for analysis. LabCorp then bills the patient directly for costs related to the test. While LabCorp notifies VDH of the patient's test results, VDH does not have an electronic mechanism for filing this information. This information is currently filed in the patient's paper chart and would then become part of the patient's treatment plan. VDH partners with LabCorp to collect the necessary aggregate data for FPAR, but FPAR 2.0 would require a specific test result to be electronically connected to a specific encounter, a functionality that does not exist with VDH's current IT systems. This

simple example demonstrates the considerable resources that would be required for VDH to meet FPAR 2.0's requirement for extensive encounter-level data.

VDH's Title X network includes three FQHCs that would also face challenges with implementing FPAR 2.0 under the current timeline even though they currently have EHR systems in place. FPAR 2.0 will require extensive customization as well as support from their respective EHR vendors. VDH would need to hire consultants to guide the FQHCs through this process and invest resources in upgrading their EHR systems. After making system upgrades, VDH and its three FQHC subrecipients would require at least 12 months 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.

VDH also 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, was published in 2009 using data collected from Title X grantees more than twelve years ago.

The current FPAR 2.0 project stands to disrupt VDH's operations during already uncertain times. As mentioned before, VDH anticipates needing at least 36 months to implement FPAR 2.0 once data elements are finalized. This work would include system modifications, troubleshooting, and training. That said, VDH is not confident that its current infrastructure can withstand the modifications required by FPAR 2.0 and questions whether doing so would be an appropriate use of scarce Title X resources. Given the potential burden of implementing FPAR 2.0 as currently proposed, VDH anticipates having a difficult time recruiting additional safety net providers to join its network, an ongoing effort since 2017. VDH is also concerned of losing existing subrecipients and service sites that cannot absorb this data collection burden.

VDH urges OPA to pause and re-evaluate FPAR 2.0. If you require additional information about the issues raised in these comments, please contact Emily Yeatts at Emily.yeatts@vdh.virginia.gov.

Sincerely,

Emily Yeatts
Title X Director
Virginia Department of Health

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Emily Yeatts
Title X Director | Reproductive Health Unit Supervisor
Division of Child and Family Health
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April 12, 2021

Sherrette Funn
Reports Clearance Officer
Office of the Secretary
Department of Health and Human Services

RE: Response to 60-Day Public Comment Request, Family Planning Annual Report 2.0 (0090-New-60D)

Dear Ms. Funn,

Arizona Family Health Partnership (AFHP) welcomes the opportunity to submit comments in response to the Department of Health and Human Services' (HHS) Agency Information Collection Request 0990-New-60D on Family Planning Annual Report 2.0, issued on February 11, 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). 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). While AFHP 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.

AFHP was incorporated as a private non-profit agency in 1974, serving as a training and resource agency for family planning providers in Arizona until 1983 when the Title X grant was awarded to the agency. Over the past 38 years, AFHP has successfully administered the Title X grant through innovation, outstanding compliance, experienced staff and leadership, and dedicated community partners. Currently, AFHP's network is comprised of 12 subrecipients and over 55 health centers that provide quality family planning services and comprehensive client education. AFHP's

expertise and resources include a Centralized Data System for encounter data submission and reporting, a Program Information Management System for fiscal data collection and sub-recipient applications, in-house expertise to provide trainings on all Title X related topics, and tools to monitor sub-recipient performance and services.

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. 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.

Like all safety net providers, AFHP has experienced several challenges since 2019. The implementation of the Title X 2019 Rules created an enormous burden and negatively impacted AFHP's capacity to provide low-income individuals with family planning and related preventive health services. Significant time was spent on successfully implementing the 2019 Title X Final Rule at the grantee and sub-recipient level that took time away from activities to accomplish goals and objectives in AFHP's work plan. Many hours were spent on reviewing the rules, conducting meetings and trainings with subrecipients, drafting the Compliance Monitoring Tool, reviewing sub-recipient tools and submissions, and completing action plans. Due to the withdrawal of Planned Parenthood Arizona in August 2019, AFHP spent the last two years reaching out to new partners to fill the gaps in family planning services. AFHP spent a substantial amount of time onboarding six new subrecipients including reviewing policies and procedures, providing input and technical assistance to meet Title X requirements, and providing orientation and training to staff. With new subrecipients, it has taken 4-6 months to complete the contracting process and another 4-6 months to onboard from the signing of a contract to the start of services.

In March 2020, as with the rest of the country, Arizona was impacted by COVID-19. In May 2020, the Navajo Nation had the highest COVID-19 infection rate in the country and Arizona became the new national hotspot for COVID-19 positive cases in June 2020. During the first wave of COVID-19, Arizona reached its peak of 'new daily cases' in early July, along with 24% positivity. Since the inception of COVID-19, Arizona's major and most populous county, Maricopa County, has ranked 4th for number of cases and ranked 6th for number of deaths due to COVID-19,

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[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).

according to Johns Hopkins Coronavirus Resource Center. Due to the pandemic, mobile units and school-based clinics stopped serving clients as schools closed and transitioned to virtual learning. Additionally, some subrecipients had to temporary close health centers and divert staff to the COVID-19 response. Amidst the pandemic, subrecipients found innovative ways to provide essential reproductive health services while protecting clients and staff such as implementing telehealth visits via telephone and video, mailing out birth control, and conducting drive through services.

Both the loss of Planned Parenthood Arizona in 2019 and the COVID-19 response in 2020 has significantly decreased client numbers. Over the past two years, AFHP saw 24% (n=7,941) fewer clients in 2019 and 39% (n=10,177) fewer clients in 2020. AFHP is moving closer to stabilizing our network as we continue supporting and onboarding subrecipients. Most recently, the focus for many subrecipients has shifted to administering the COVID-19 vaccine to health center staff as well as the public. Any attempt to implement FPAR 2.0 in accordance with current timelines will severely disrupt and undermine our ability to respond to these top priorities.

Timeline

AFHP 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, AFHP would need to upgrade its information technology (IT) infrastructure, as would its 12 subrecipients. However, as of April 9, 2021, OPA has not released final specifications (i.e., instructions for how to collect) for 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 at least six months to implement and test the systems upgrades needed to collect and report encounter-level data through FPAR 2.0. This includes upgrading electronic health record (EHR) systems, mapping FPAR 2.0 data elements to existing standardized value sets, validating data, and modifying clinic flow and operations to ensure new data elements are captured by clinical and non-clinical staff. Extending this timeline is needed due to the limited availability of subrecipient staff (e.g., IT and clinical staff) to complete upgrades due to competing projects and existing engagements. After making system upgrades, AFHP and its 12 subrecipients (which operate over 55 service sites) will require another six months 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. Initiating upgrades before final specifications are available would be wasteful, as inconsistencies would require revisions that would carry additional costs and burden hours spent.

Accuracy of Estimated Burden

AFHP 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 translate to the data collected no longer being 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 be 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 each grantee-subrecipient dyad to invest in upgrading to electronic systems (as applicable) and establishing interoperability between their respective systems. In AFHP's Title X network, there are 12 subrecipients using five different EHR platforms.

AFHP estimates that implementing FPAR 2.0 as proposed at the grantee-level will amount to over 200 hours and over $18,000 in one-time non-labor costs. This estimate is based on modifying AFHP's Centralized Data System to add new data fields, update standard and custom reports, and implement data validations. Furthermore, AFHP estimates that each of its 12 subrecipients will outlay an average of $5,000 in non-labor costs to implement FPAR 2.0, for an estimated total of $60,000 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 and purchased service costs.

In addition, we estimate that implementing FPAR 2.0 will amount to about $6,000 in one-time labor costs. This estimate is based on the cost of two staff persons working a combined 75 hours

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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).

on tasks related to implementation, including working with vendors to modify AFHP's Centralized Data System and testing the modifications and data validations. We also estimate that each of our 12 subrecipients will spend an average of 64 hours implementing FPAR 2.0, for an estimated total of about $38,000 in one-time labor costs across this single Title X grantee network. This estimate is based on the cost of two staff persons working with vendors to perform necessary system upgrades and map out FPAR 2.0's data elements to existing standardized value sets, training health care providers and staff on how to collect new data elements, conducting preliminary data collection, running reports to ensure data mapping is correct, and performing quality assurance of preliminary data collected. 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.

Burden, Necessity and Utility of FPAR 2.0 Data

AFHP believes the 23 additional 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. It corresponds to the deliberate transition of FPAR from a program monitoring tool to a research dataset, requiring Title X service sites to collect excessive information from patients at every single visit, even though such information is not necessitated by clinical practice guidelines or other evidence-based standards.

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

[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.

a family planning visit even though they do not contribute directly to achieving or preventing pregnancy include screening for breast and cervical cancer,"[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 to AFHP:

New Data Elements: Sexual Activity

The Supporting Statement for the Title X FPAR 2.0 describes how FPAR 2.0 will supplement the federally funded National Survey for Family Growth (NSFG), a population-level, nationally representative dataset that gathers information on pregnancy and births, infertility, use of contraception, and general and reproductive health.[6] However, while NSFG surveys a representative sample of respondents and allows them to voluntarily respond, the data elements that will be collected and reported through FPAR 2.0 will be required for every patient visit. More specifically, 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 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)].[7] These sexual activity-related data fields also are not needed to monitor our Title X network's accountability to program goals.

It is important to emphasize that patients accessing services in non-Title X settings would not be asked to provide responses to these personal, guideline-unconcordant questions at every visit, nor would their responses be reported at the encounter level to the federal government. When the federal government begins collecting research data for its benefit and requires those accessing services through the safety net to provide such information as a precursor to receive care, it exacerbates medical mistrust, potentially dissuading patients from coming to us for needed services.

New Data Elements: Cervical Cancer Screening

FPAR 2.0 suggests the Title X service sites collect and report five different data elements related to cervical cancer screening: Pap test at this visit, Last Pap result, Pap test in the last five years,

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[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.

[6] *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.

[7] 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.

HPV test performed at this visit, and HPV test result. Collecting and reporting all five data elements for every Title X visit would carry substantial burden with minimal benefit.
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.[8] Furthermore, there is no way for AFHP to differentiate 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.[9] 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.[10] [11] 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 (detailed as ever smoker, ex-smoker, smokes daily, occasional smoker, smoker, status unknown, heavy smoker, light smoker).

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,

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[8] 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.
[9] Ibid.
[10] 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.
[11] *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.

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 determine to report the intervention(s) offered to tobacco smokers, using those listed by the US Preventive Services Task Force.[12]

AFHP believes the collection of height and weight data, presumably to calculate body mass index (BMI), is problematic. From a clinical perspective, there is no logical rationale to record and report body weight at every visit, and OPA does not state why it is necessary to collect this information and how it will be used in the Supporting Statement for the Title X FPAR 2.0.[13] Even when collecting a patient's height and weight data is clinically indicated, 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 because it fails to account for differences in body composition, fitness levels, and nutritional differences.[14] Furthermore, the practice of weighing clients at every visit – even health education sessions or when not clinically indicated – may deter clients from accessing services due to experiences of body shame and weight discrimination.[15]

Patients accessing health services in non-Title X settings are not weighed at every visit unless clinically indicated. Title X patients should receive the same standard of care and should not be subject to weight stigmatization at every visit. Weight stigma invokes psychological stress and emerging research suggests that this stress leads can exacerbate poor physical health outcomes for obese individuals[16], with the potential to perpetuate racial/ethnic and socioeconomic health disparities in overweight and obesity. It is time to move away from this measure and focus on measures of health that are scientifically valid and designed for diverse patient populations.

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[12] 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.

[13] *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.

[14] 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.

[15] Janell L Mensinger, Tracy L Tylka, and Margaret E Calamari, "Mechanisms underlying weight status and healthcare avoidance in women: A study of weight stigma, body-related shame and guilt, and healthcare stress," *Body Image* 25 (2018):139-147. doi.org/10.1016/j.bodyim.2018.03.001.

[16] Rebecca M Puhl and Chelsea A Heuer, "Obesity stigma: important considerations for public health," *American Journal of Public Health* 100, no. 6 (2010):1019-28. doi:10.2105/AJPH.2009.159491.

Screening for cardiovascular risk factors is indicated to support contraceptive decision-making (i.e., to ensure a patient does not have contraindications to combined oral contraceptives and other hormonal contraception) and pre-pregnancy health. While it may be desirable to capture these measures for additional patients, there is no explicit expectation or requirement for Title X providers to obtain information beyond that which is clinically necessary. Accordingly, we should not be required to document and report these measurements for every visit.

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 2020, 33% of all Title X family planning encounters in AFHP's 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

AFHP requests further 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 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.[17] 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.[18] 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 (e.g., patient identifier, visit date, date of birth); for example, specifying encryption standards for data at rest and in motion. Given the cybersecurity issues that all organizations currently are facing, it seems 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.

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[17] 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.

[18] Ibid.

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.

The current FPAR 2.0 project stands to severely disrupt AFHP's operations during already uncertain times. AFHP 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. AFHP is also concerned of 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 as indicated in 2019 with 24% fewer clients and 39% fewer clients in 2020. 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 providing Title X patients with 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, AFHP urges OPA to pause and re-evaluate FPAR 2.0.

If you require additional information about the issues raised in this letter, please contact Jennifer Min, Vice President of Program and Evaluation, at jmin@arizonafamilyhealth.org.

Sincerely,

Jennifer Min
Vice President of Program and Evaluation

new jersey family planning league

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April 12, 2021

Sherrette Funn
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Office of the Secretary, HHS
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NJFPL Response to 60-Day Public Comment Request:
Family Planning Annual Report 2.0
Document Identifier: 0990-New-60D

Dear Ms. Funn:

The New Jersey Family Planning League (NJFPL) welcomes the opportunity to submit comments in response to the Department of Health and Human Services' (HHS) Agency Information Collection Request 0990-New-60D on Family Planning Annual Report 2.0, issued on February 11, 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). 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). While NJFPL 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.

NJFPL is committed to providing access to quality family planning and related health services for all New Jerseyans who need them, regardless of identity, income, or insurance status. As a grantee of federal Title X and state family planning and STD service funds we support a subcontracted network of 13 family planning providers, with 57 health centers across all 21 counties of NJ. Our 11 Title X providers include federally qualified health centers (FQHCs), hospital-based sites, a county health department, an academic health center, and non-profit family planning service providers. The agencies we fund offer family planning health services such as annual preventive care visits, contraception, pregnancy testing, treatment and counseling for sexually transmitted infections, HIV testing and prevention counseling, and breast and cervical cancer screening. We work together with our provider agencies to ensure that everyone

accessing publicly-funded family planning services in New Jersey receives patient-centered care that explores their needs and concerns.

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. 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.

Like all safety net providers, NJFPL has experienced several challenges since 2019. The implementation of the 2019 Title X Final Rule had a dramatic impact on NJFPL's Title X network. In addition to the requirements and administrative burden imposed by the rule, New Jersey's two Planned Parenthood affiliates withdrew from the Title X project. These providers, with their combined 22 service sites, had served more than 65% of NJFPL's Title X patients. Following the loss of these subrecipients, NJFPL prioritized increasing the number of Title X service sites throughout the state with a focus on areas of high need, maximizing access points among current providers and identifying potential new Title X providers. The Title X Final Rule has created additional challenges in this process, due to confusion for potential providers considering adding Title X services.

The COVID-19 public health emergency has also had a lasting impact on NJFPL's Title X project, as New Jerseyans followed stay at home orders and patients were reluctant to visit health centers for fear of exposure to the virus. Stay-at-home orders, lack of childcare during school closures, financial concerns due to unemployment and fear of being exposed to the virus influenced patient decisions about accessing healthcare, including family planning services. This was compounded by the challenges faced by healthcare providers with limited access to personal protective equipment (PPE), compromised staff capacity and facility adaptations necessary to support social distancing and reduce the potential for viral spread. We have been working closely with our subrecipient provider agencies to ensure they can continue to provide high-quality family planning and reproductive health services, while maintaining appropriate safety precautions. Any attempt to implement FPAR 2.0 in accordance with current timelines will severely disrupt and undermine our ability to respond to these top priorities.

Timeline

NJFPL 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

[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).

collection to begin on January 1, 2022 is unworkable. To implement FPAR 2.0, NJFPL would need to upgrade to its information technology (IT) infrastructure, as would its 11 Title X 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 option 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.

Although NJFPL's grantee data system was developed with FPAR 2.0 in mind, we anticipate that our data collection and reporting processes will require additional changes. In 2016, NJFPL received $127,300 from the Office of Population Affairs "Ensuring Access to Quality Family Planning Services" funding opportunity to assess and update its health IT infrastructure in preparation for FPAR 2.0. Under NJFPL's project "Enhancing Access to Quality Family Planning Services – Improving Health Technology Systems", NJFPL developed a new statewide central data repository, assisted sub-recipient agencies in streamlining workflows for data capture during a client visit, and worked towards transition of NJFPL's previously fragmented data collection and reporting capabilities to a fully-integrated, strategically focused IT systems capability in addition to preparing sub-recipient agencies for FPAR 2.0 data collection. While NJFPL and our subrecipient providers made significant progress towards FPAR 2.0 readiness during this yearlong project, system upgrades will be needed for both current and new providers.

Currently, we estimate it will take 3-6 months to implement and test the system upgrades needed to collect and report encounter-level data through FPAR 2.0. This includes making required changes to subrecipient electronic health record (EHR) templates, implementing these changes, testing, and training. Extending this timeline is the limited availability of IT staff or external consultants to complete upgrades due to competing projects and existing engagements, including on-boarding and training new providers. After making system upgrades, NJFPL and its subrecipients, which operate 35 service sites, will each require 4-6 weeks 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. Additionally, system upgrades and implementation timelines will vary throughout our network of providers due to the use of different EHR systems, timing, and staff capacity. Initiating upgrades before final specifications are available would be wasteful, as inconsistencies would require revisions that would carry additional costs and burden hours spent.

Accuracy of Estimated Burden

NJFPL 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 translate to the data collected no longer being relevant.

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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 be 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 each grantee-subrecipient dyad to invest in upgrading to electronic systems (as applicable) and establishing interoperability between their respective systems. In NJFPL's Title X network, there are 11 subrecipients using six EHR platforms. As NJFPL seeks to expand New Jersey's Title X family planning provider network, potential subrecipients either not using EHR platforms or transitioning from one platform to another create additional challenges for adhering to the proposed FPAR 2.0 requirements.

NJFPL estimates that implementing FPAR 2.0 as proposed at the grantee-level will amount to $25,000 in one-time non-labor costs. This estimate is based on costs associated with customizing EHR templates, implementation, and testing. Furthermore, NJFPL estimates that its 11 Title X subrecipients will incur additional non-labor costs, which will vary according to the costs associated with each of the five EHR systems used by our provider network. As the FPAR 2.0 data elements and reporting requirements are not yet finalized, it is difficult to provide a full accounting of total costs and labor required for implementation. 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 and purchased service costs.

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.

Burden, Necessity and Utility of FPAR 2.0 Data

NJFPL believes the 23 additional 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

[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).

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. It corresponds to the deliberate transition of FPAR from a program monitoring tool to a research dataset, requiring Title X service sites to collect excessive information from patients at every single visit, even though such information is not necessitated by clinical practice guidelines or other evidence-based standards.

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 include screening for breast and cervical cancer,"[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 to NJFPL:

New Data Elements: Sexual Activity

The Supporting Statement for the Title X FPAR 2.0 describes how FPAR 2.0 will supplement the federally funded National Survey for Family Growth (NSFG), a population-level, nationally representative dataset that gathers information on pregnancy and births, infertility, use of contraception, and general and reproductive health.[6] However, while NSFG surveys a representative sample of respondents and allows them to *voluntarily* respond, the data elements that will be collected and reported through FPAR 2.0 will be required for every patient visit. More specifically, 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 or adolescent patient is sexually active only annually [unless the

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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.

[6] *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.

patient is at increased risk for infection or is seeking evaluation and treatment for sexually transmitted infections (STIs)].[7] These sexual activity-related data fields also are not needed to monitor our Title X network's accountability to program goals.

It is important to emphasize that patients accessing services in non-Title X settings would not be asked to provide responses to these personal, guideline-unconcordant questions at every visit, nor would their responses be reported at the encounter level to the federal government. When the federal government begins collecting research data for its benefit and requires those accessing services through the safety net to provide such information as a precursor to receive care, it exacerbates medical mistrust, potentially dissuading patients from coming to us for needed services.

New Data Element: Future Pregnancy Intention Reported

Another example of a proposed data element that is inconsistent with current research on the provision of patient-centered contraceptive care is the FPAR 2.0 data element tracking patients' intention to either become pregnant or prevent a pregnancy in the next year. Research suggests that many patients cannot articulate their pregnancy intentions over the next year; doing so is inconsistent with how they think about and approach their reproductive lives.[8] [9] This is particularly true for low-income populations.[10] Indeed, not all individuals overtly plan to have children or not have children, suggesting that asking about reproductive "intentions" or "plans" may be problematic.[11] Asking patients this kind of a question at every visit, regardless of the reason for the visit, could compromise the patient-provider relationship by breaking rapport and shifting the visit away from what the patient wants.

Reflecting current research that patients prefer to be asked about their service needs than about pregnancy intentions or desires[12], NFPRHA recommends that FPAR 2.0 use a more patient-centered approach to measurement. An example of an alternative measure that assesses patients' desire for contraceptive services is the Self-Identified Need for Contraception (SINC)[13] question

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[7] 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.

[8] Abigail RA Aiken, Sonya Borrero, Lisa Callegari, and Christine Dehlendorf, "Rethinking the Pregnancy Planning Paradigm: Unintended Conceptions or Unrepresentative Concepts?," *Perspectives on Sexual and Reproductive Health* 48, no. 3 (2016):147-151, https://doi.org/10.1363/48e10316

[9] Lisa S Callegari, Abigail RA Aiken, Christine Dehlendorf, Patty Cason, and Sonya Borrero, "Addressing potential pitfalls of reproductive life planning with patient-centered counseling," *American Journal of Obstetrics and Gynecology* 216, no. 2 (2017):129-134, https://doi.org/10.1016/j.ajog.2016.10.004.

[10] Sonya Borrero, et al., "It just happens": a qualitative study exploring low-income women's perspectives on pregnancy intention and planning," *Contraception* 91, no. 2 (2015):150-6. doi: 10.1016/j.contraception.2014.09.014.

[11] Lisa S Callegari, et al., "Addressing potential pitfalls of reproductive life planning with patient-centered counseling," 2017.

[12] Heidi E Jones, Cynthia Calixte, Meredith Manze, Michele Perlman, Susan Rubin, Lynn Roberts, and Diana Romero, "Primary care patients' preferences for reproductive health service needs assessment and service availability in New York Federally Qualified Health Centers," *Contraception* 101, no. 4 (2020):226-230.

[13] "Do you want to talk about contraception or pregnancy prevention during your visit today?"

- If yes: Mark "yes" and ensure appropriate counseling is provided
- If no: "There are a lot of reasons why a person wouldn't want to talk about this, and you don't have to share anything you don't want to. Do any of these apply to you?" (mark all that apply):
    - I'm here for something else
    - This question does not apply to me
    - I prefer not to answer

developed by the University of California, San Francisco (UCSF) Person-Centered Reproductive Health Program in consultation with Reproductive Justice advocates. Of note, UCSF has an award from OPA to develop a new electronic Clinical Quality Measures (eCQMs) of contraceptive provision using the SINC question to define the denominator. As such, use of the SINC question in FPAR 2.0 would be consistent with other initiatives underway at OPA. Use of this type of measure also would facilitate the removal of problematic data elements related to sexual activity, which have been included to identify whether a patient is perceived as "at risk" for pregnancy.

Data Elements: Cervical Cancer Screening

FPAR 2.0 suggests the Title X service sites collect and report five different data elements related to cervical cancer screening: Pap test at this visit, Last Pap result, Pap test in the last five years, HPV test performed at this visit, and HPV test result. Collecting and reporting all five data elements for every Title X visit would carry substantial burden with minimal benefit.

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.[14] Furthermore, there is no way for NJFPL to differentiate 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.[15] 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.[16] [17] When extracting data to calculate measures, there is no way to qualify whether an appropriate screening interval was applied.

- I am already using contraception (and what)
- I am unsure or don't want to use contraception
- I am hoping to become pregnant in the near future

[14] 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.

[15] Ibid.

[16] 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.

[17] *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.

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 (detailed as ever smoker, ex-smoker, smokes daily, occasional smoker, smoker, status unknown, heavy smoker, light smoker).

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 determine to report the intervention(s) offered to tobacco smokers, using those listed by the US Preventive Services Task Force.[18]

NJFPL believes the collection of height and weight data, presumably to calculate body mass index (BMI), is problematic. From a clinical perspective, there is no logical rationale to record and report body weight *at every visit*, and OPA does not state why it is necessary to collect this information and how it will be used in the Supporting Statement for the Title X FPAR 2.0.[19] Even when collecting a patient's height and weight data is clinically indicated, 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 because it fails to account for differences in body composition, fitness levels, and nutritional differences.[20] Furthermore, the practice of weighing clients at every visit – even health education sessions or when not clinically indicated – may deter clients from accessing services due to experiences of body shame and weight discrimination.[21]

Patients accessing health services in non-Title X settings are not weighed at every visit unless clinically indicated. Title X patients should receive the same standard of care and should not be subject to weight stigmatization at every visit. Weight stigma invokes psychological stress and emerging research suggests that this stress leads can exacerbate poor physical health outcomes

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[18] 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.

[19] *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.

[20] 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.

[21] Janell L Mensinger, Tracy L Tylka, and Margaret E Calamari, "Mechanisms underlying weight status and healthcare avoidance in women: A study of weight stigma, body-related shame and guilt, and healthcare stress," *Body Image* 25 (2018):139-147. doi.org/10.1016/j.bodyim.2018.03.001.

for obese individuals[22], with the potential to perpetuate racial/ethnic and socioeconomic health disparities in overweight and obesity. It is time to move away from this measure and focus on measures of health that are scientifically valid and designed for diverse patient populations.

Screening for cardiovascular risk factors is indicated to support contraceptive decision-making (i.e., to ensure a patient does not have contraindications to combined oral contraceptives and other hormonal contraception) and pre-pregnancy health. While it may be desirable to capture these measures for additional patients, there is no explicit expectation or requirement for Title X providers to obtain information beyond that which is clinically necessary. Accordingly, we should not be required to document and report these measurements for every visit.

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 some instances, Title X family planning encounters are performed by other service providers, such as registered nurses, licensed practical nurses, health educators, and social workers.

Confidentiality of Sensitive Personal Health Information

NJFPL requests further 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 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.[23] 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.[24] 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 seems 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.

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[22] Rebecca M Puhl and Chelsea A Heuer, "Obesity stigma: important considerations for public health," *American Journal of Public Health* 100, no. 6 (2010):1019-28. doi:10.2105/AJPH.2009.159491.

[23] 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.

[24] Ibid.

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.

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The current FPAR 2.0 project stands to severely disrupt NJFPL's operations during already uncertain times. NJFPL, 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 NJFPL lost two subrecipients which operated 22 sites, departures that resulted in 63,462 fewer Title X patients served in 2020. NJFPL is also concerned with the impact of these new requirements as we seek to expand our provider network. As we work closely with new providers to align their data collection and reporting processes with those required by Title X, any changes to these requirements would create an additional burden. Furthermore, we would have to ask providers to make further changes if the final FPAR 2.0 data elements and reporting requirements differ from what had been anticipated.

We are striving to see more patients after unprecedented declines in patient census, as NJFPL's Title X program saw 28,649 patients in 2020 (compared to 82,730 in 2019). 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 providing Title X patients with 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, NJFPL urges OPA to pause and re-evaluate FPAR 2.0.

If you require additional information about the issues raised in this letter, please contact me at rachel@njpl.org.

Sincerely,

Rachel Baum
President & CEO
New Jersey Family Planning League

From:	Llew Brown
To:	Ruth Hsu; Michael Kerachsky; Annu van Bodegom
Subject:	FW: 0990-New-60D Comments on Family Planning Annual Report 2.0.
Date:	Tuesday, April 13, 2021 1:00:03 PM
Attachments:	image001.jpg

From: Kim, Jamie (HHS/OASH) <Jamie.Kim@hhs.gov>
Sent: Tuesday, April 13, 2021 12:36 PM
To: Llew Brown <LOBrown@mathematica-mpr.com>
Cc: Daniel Shapiro <DShapiro@mathematica-mpr.com>; Nora Paxton <NPaxton@mathematica-mpr.com>; Menon, Roshni (HHS/OASH) <Roshni.Menon@hhs.gov>
Subject: FW: 0990-New-60D Comments on Family Planning Annual Report 2.0.

From: Funn, Sherrette (OS/OCIO/CDO) <Sherrette.Funn@hhs.gov>
Sent: Tuesday, April 13, 2021 12:29 PM
To: Kim, Jamie (HHS/OASH) <Jamie.Kim@hhs.gov>; Farb, Amy (HHS/OASH) <Amy.Farb@hhs.gov>
Subject: FW: 0990-New-60D Comments on Family Planning Annual Report 2.0.

Sherrette Funn
Office of the Secretary Report Clearance Officer
Department of Health and Human Services
200 Independence, S.W. suite 345F
Work cell# 202-264-0041

From: Jane Menken <menken@colorado.edu>
Sent: Monday, April 12, 2021 6:41 PM
To: Funn, Sherrette (OS/OCIO/CDO) <Sherrette.Funn@hhs.gov>
Subject: 0990-New-60D Comments on Family Planning Annual Report 2.0.

Sherrette.Funn@hhs.gov

Re: 0990-New-60D Comments on Family Planning Annual Report 2.0.

To Whom It May Concern:

I am writing in response to the Agency Information Collection Request in document 099-New-60D regarding the Office of Population Affairs' (OPA) request for encounter-level data collection for the Family Planning Annual Report (FPAR).

I have two overarching concerns about the effects of the proposed changes to the FPAR (proposed FPAR 2.0):

*** The proposed changes will substantially burden Title X providers in ways not captured in the burden estimates in the document, thereby damaging the Title X program's capacity to meet its goals; and**

*** Marginalized populations may be less likely to seek services at Title X providers because of concerns about collection of identifiable data.**

The Title X clinical network as it is currently constituted is highly unlikely to be able to fulfill the reporting requirements in this document in ways such that the data would actually be useful and reliable for the research and program purposes outlined. And adding these requirements will affect healthcare providers' ability and willingness to serve clients under the Title X program. It may actually encourage providers to opt out of the program, thereby reducing its effectiveness and its service to populations most in need.

Title X is a key safety-net program serving some of the most marginalized in the US population. Substantial research indicates that marginalized populations, including young people, people without proper documentation, and others who are underserved by the health care system are particularly sensitive to privacy concerns when they seek healthcare. By introducing a new private identifiable data collection and transmittal effort for the program designed to serve these populations, FPAR 2.0 is likely to make precisely those who it is designed to serve less likely to use its services.

I am a demographer and sociologist with expertise in family planning research and program design and evaluation. I have evaluated US and international family planning programs, for over 40 years, including providing some of the earliest scientific research on contraceptive effectiveness in actual use in the U.S. and evaluating impacts of the Bangladesh Maternal and Child Health and Family Planning Program. I am participating now in a project evaluating impacts of the Colorado Title X program. I have been a professor at Princeton University, the University of Pennsylvania, and currently am Distinguished Professor and Research Professor at the University of Colorado Boulder.

I fully support OPA's intention to assure achievement of goals of program monitoring, evaluation, strategic and financial planning, responsiveness to inquiries from policymakers and Congress, and accurately estimating program impact. I also recognize the desire for identified encounter-level data.

However, Title X providers already find FPAR reporting requirements onerous. Increasing them without increasing infrastructure support to meet them will either redirect scarce resources away from clinical care or lead providers to leave Title X.

If OPA wants to collect encounter-level data as outlined in FPAR 2.0 in such a way that providers will remain in the Title X network, patients will continue to seek and trust Title X

services, and data generated meet high quality standards, **comprehensive consideration of the needed additional infrastructure support and comprehensive consideration of ways to maintain patient privacy are needed.** Neither is contained in this proposal.

Sincerely yours,

Jane Menken

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NFPRHA Response to 60-Day Public Comment Request:
Family Planning Annual Report 2.0

I. Introduction

Unity Health Care, Inc welcomes the opportunity to submit comments in response to the Department of Health and Human Services' (HHS) Agency Information Collection Request 0990-New-60D on Family Planning Annual Report 2.0, issued on February 11, 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). 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). While Unity Health Care 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.

As the largest network of community health centers in Washington, D.C., Unity Health Care provides a full-range of health and human services to meet the needs of our communities through a network of over 20 traditional and non-traditional health sites. Our team of compassionate and multicultural health professionals place Unity values into action every day to bring whole-person care and wellness to over 101,000 patients through 457,000 visits annually. Deeply rooted in the District's neighborhoods for over 35 years, Unity strives to promote healthier communities through compassion and comprehensive primary and specialty health care and wrap-around services, regardless of ability to pay.

Unity offers a comprehensive Title X program through the DC Title X Family Planning Service Project ensuring full access to Title X services for the residents of the District of Columbia To ensure full access to the Title X services to the residents of the District, we partner with other organizations that share a similar service model of providing comprehensive primary care and supportive services to individuals and families. The District Title X network current offers service in 36 locations across the District of Columbia. In addition to our 25 Unity sites we have 5 partners offering services at 11 locations throughout the city.

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. 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.

[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).

Like all safety net providers, Unity Health Care, Inc has experienced several challenges since 2019. With the impacts of the Gag rule we lost a vital partner in our service delivery network which resulted in a decrease in 10,000 patients in the subsequent reporting cycle. In addition to those impacts we have faced challenges seen across the country with the impacts of COVID-19 pandemic in day to day health center operations. Any attempt to implement FPAR 2.0 in accordance with current timelines will severely disrupt and undermine our ability to respond to these top priorities.

Timeline

Unity Health Care, Inc 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, Unity Health Care would need to upgrade to its information technology (IT) infrastructure, as would its our 3 subrecipients. However, as of 4/8/2021, 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 option 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 are unable to estimate the full impact of the modification necessary to implement and test the systems upgrades needed to collect and report encounter-level data through FPAR 2.0. This includes final ecw stakeholder review and approval, final implementation of system modifications, updated reporting methodologies and data validation processes. Extending this timeline is the limited availability of IT and informatics staff to complete upgrades and complete reporting modifications due to competing projects and existing engagements (e.g., launching pop-up vaccine clinics, mass vaccination site; covid reporting demands). After making system upgrades, Unity Health Care, Inc and its subrecipients will require ample time schedule and 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. Initiating upgrades before final specifications are available would be wasteful, as inconsistencies would require revisions that would carry additional costs and burden hours spent.

Accuracy of Estimated Burden

Unity Health Care, Inc 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 translate to the data collected no longer being 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

[2] RTI International, *Family Planning Annual Report Burden Study* (Research Triangle Park, NC: RTI, 2009).

(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 be 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 each grantee-subrecipient dyad to invest in upgrading to electronic systems (as applicable) and establishing interoperability between their respective systems. This comes during the same fiscal year(s) as the COVD-19 public health emergency when both human and financial resources have been strained by the impacts. Furthermore, these cost do not fully encompass the additional expenses that such as computer and software upgrades, impacts on workflows that may result in lost revenue caused by the more than 20 additional data elements required at every single Title X visit.

Burden, Necessity and Utility of FPAR 2.0 Data

Unity Health Care, Inc believes the 23 additional 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. It corresponds to the deliberate transition of FPAR from a program monitoring tool to a research dataset, requiring Title X service sites to collect excessive information from patients at every single visit, even though such information is not necessitated by clinical practice guidelines or other evidence-based standards.

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 include screening for breast and cervical cancer,"[5] they certainly should

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[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).

[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.

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 to Unity Health Care,Inc:

New Data Elements: Sexual Activity

The Supporting Statement for the Title X FPAR 2.0 describes how FPAR 2.0 will supplement the federally funded National Survey for Family Growth (NSFG), a population-level, nationally representative dataset that gathers information on pregnancy and births, infertility, use of contraception, and general and reproductive health.[6] However, while NSFG surveys a representative sample of respondents and allows them to *voluntarily* respond, the data elements that will be collected and reported through FPAR 2.0 will be required for every patient visit. More specifically, 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 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)].[7] These sexual activity-related data fields also are not needed to monitor our Title X network's accountability to program goals.

It is important to emphasize that patients accessing services in non-Title X settings would not be asked to provide responses to these personal, guideline-unconcordant questions at every visit, nor would their responses be reported at the encounter level to the federal government. When the federal government begins collecting research data for its benefit and requires those accessing services through the safety net to provide such information as a precursor to receive care, it exacerbates medical mistrust, potentially dissuading patients from coming to us for needed services.

Data Elements: Cervical Cancer Screening

FPAR 2.0 suggests the Title X service sites collect and report five different data elements related to cervical cancer screening: Pap test at this visit, Last Pap result, Pap test in the last five years, HPV test performed at this visit, and HPV test result. Collecting and reporting all five data elements for every Title X visit would carry substantial burden with minimal benefit.
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.[8] Furthermore, there is no way for Unity Health Care, Inc to

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[6] *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.
[7] 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.
[8] 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.

differentiate 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.[9] 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.[10] [11] 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 (detailed as ever smoker, ex-smoker, smokes daily, occasional smoker, smoker, status unknown, heavy smoker, light smoker).

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 determine to report the intervention(s) offered to tobacco smokers, using those listed by the US Preventive Services Task Force.[12]

Unity Health Care, Inc believes the collection of height and weight data, presumably to calculate body mass index (BMI), is problematic. From a clinical perspective, there is no logical rationale to record and report body weight *at every visit*, and OPA does not state why it is necessary to collect this information and how it will be used in the Supporting Statement for the Title X FPAR 2.0.[13] Even when collecting a patient's height and weight data is clinically indicated, 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

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[9] Ibid.

[10] 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.

[11] *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.

[12] 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.

[13] *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.

women of color, because it because it fails to account for differences in body composition, fitness levels, and nutritional differences.[14] Furthermore, the practice of weighing clients at every visit – even health education sessions or when not clinically indicated – may deter clients from accessing services due to experiences of body shame and weight discrimination.[15]

Patients accessing health services in non-Title X settings are not weighed at every visit unless clinically indicated. Title X patients should receive the same standard of care and should not be subject to weight stigmatization at every visit. Weight stigma invokes psychological stress and emerging research suggests that this stress leads can exacerbate poor physical health outcomes for obese individuals[16], with the potential to perpetuate racial/ethnic and socioeconomic health disparities in overweight and obesity. It is time to move away from this measure and focus on measures of health that are scientifically valid and designed for diverse patient populations.

Screening for cardiovascular risk factors is indicated to support contraceptive decision-making (i.e., to ensure a patient does not have contraindications to combined oral contraceptives and other hormonal contraception) and pre-pregnancy health. While it may be desirable to capture these measures for additional patients, there is no explicit expectation or requirement for Title X providers to obtain information beyond that which is clinically necessary. Accordingly, we should not be required to document and report these measurements for every visit.

Confidentiality of Sensitive Personal Health Information

Unity Health Care, Inc requests further 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 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.[17] 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.[18] 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 seems imprudent to move forward with FPAR 2.0 without releasing more information about – and seeking

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[14] 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.

[15] Janell L Mensinger, Tracy L Tylka, and Margaret E Calamari, "Mechanisms underlying weight status and healthcare avoidance in women: A study of weight stigma, body-related shame and guilt, and healthcare stress," *Body Image* 25 (2018):139-147. doi.org/10.1016/j.bodyim.2018.03.001.

[16] Rebecca M Puhl and Chelsea A Heuer, "Obesity stigma: important considerations for public health," *American Journal of Public Health* 100, no. 6 (2010):1019-28. doi:10.2105/AJPH.2009.159491.

[17] 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.

[18] Ibid.

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.

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.

The current FPAR 2.0 project stands to severely disrupt Unity Health Care's operations during already uncertain times. Unity Health Care, Inc, 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 Unity Health Care, inc lost 1 subrecipients, departures that resulted in 10,000 fewer Title X patients served in 2020. Unity Health Care, Inc also is concerned of losing existing subrecipients and service sites that cannot absorb this data collection burden.

Any changes to FPAR that relate to quality of care should be informed by and align with existing recommendations Title X providers are supposed to follow: QFP, USPSTF, CDC Select Practice Recommendations, CDC STI Treatment Guidelines, CDC Medical Eligibility Criteria, National Quality Forum, etc.

We strongly advocate for a coordinated and integrated quality reporting to improve patient outcomes. We recommend alignment of quality measures and programmatic performance criteria to these nationally recognized guidelines.

Furthermore expecting alignment with national recommendations would be vital to onboarding new organizations into Title X network as it reduces burden of new program and reduces impact on already strained resources.

As we continue to explore the impacts on other universally accepted standard, viewing FPAR 2.0 through the lens of the IHI Triple Aim (or Quadruple Aim, as some organizations do) raises additional concerns:

1. Improve the Health of the Population served – it makes sense to align with current nationally approved recommendations as previously mentioned rather than create a new set of reporting criteria
2. Improve patient care/improve the patient experience – Many of the data elements in FPAR 2.0 are not patient centered. Eliciting patient information on these topics as part of a nuanced counseling session is patient centered but just asking at every visit for a report is not
3. Lower cost – adding extra data fields that go beyond a standard sexual history and counseling or what a non-Title X patient would be asked will add cost in terms of building the EHR, training on the EHR and pulling and reporting the data from so many fields
4. Improve provider/staff experience - (which many organizations use as 4th aim) – adding extra data fields that dictate what needs to be completed for Title X visits but are not standard for other sexual and reproductive health visits will use extra provider/staff time and will decrease work satisfaction and many encourage organizations to leave Title X network because it is not worth it.

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 providing Title X patients with 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, Unity Health Care, Inc urges OPA to pause and re-evaluate FPAR 2.0.

If you require additional information about the issues raised in this letter, please contact Shanese Baylor, VP of Programs and Informatics at sbaylor@unityhealthcare.org or 202-715-6561.

Sincerely,

Vincent A. Keane
President and CEO
Unity Health Care, Inc

NFPRHA Response to 60-Day Public Comment Request:
Family Planning Annual Report 2.0

I. Introduction

The Washington State Department of Health Sexual and Reproductive Health Program welcomes the opportunity to submit comments in response to the Department of Health and Human Services' (HHS) Agency Information Collection Request 0990-New-60D on Family Planning Annual Report 2.0, issued on February 11, 2021. We write to express our concerns with the Office of Population Affairs' (OPA) proposal for new data collection elements for the Title X Family Planning Program ["Population Research and Voluntary Family Planning Programs" (Public Law 91-572)] Family Planning Annual Report (FPAR). Currently collected under OMB No. 0990-0221, this new data collection, "FPAR 2.0", proposes to build on the existing data collection and reporting system by adding 23 new data elements to the FPAR's standard set of data elements (for a total of 45 data elements to be collected at every visit). While the Sexual and Reproductive Health Program appreciates the need for a contemporary data system for collection, management and analysis to improve program performance and is committed to implementing such a system, the current FPAR 2.0 project should 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.

The Washington State Department of Health was forced to withdraw from the Title X Program in 2019 due to changes in Title X rules that conflicted with our state's laws. If the rule changes so that it does not conflict with our state law, we will reapply as soon as we are able.

FPAR 2.0, as proposed, requires cost and time (i.e., burden hour) investments that are significantly 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. At this time – against the backdrop of a year-long and ongoing public health emergency, implementation of FPAR 2.0 simply is not feasible. We are working hard to hold on, rebuild, and continue providing critical services to patients.

Like all safety net providers, the Sexual and Reproductive Health Program and its network of providers have experienced several challenges since 2019. The loss of Title X funding was backfilled by the legislature temporarily, but this creates vulnerability to financing the program, especially because of increased costs of COVID-19 to the state. In addition, DOH and our local health Network partners have had to divert numerous staff (including sexual and reproductive health staff) to the COVID-19 response. Our network providers are still recovering from a significant loss in patient visits and have lost staff due to pressures of COVID (health concerns or need to care for children with home learning). At the same time, they have had to bear increased costs to implement telehealth services at a reduced reimbursement rate (in our state, there is parity in reimbursement rates with Medicaid but there are some insurance plans that are excluded from the new parity requirement); provide personal protective equipment (PPE); and update clinic sites to implement COVID-19 protocols. Any attempt to implement FPAR 2.0 in accordance with current timelines will severely disrupt and undermine our ability to respond to these ongoing priorities.

Timeline

The Washington State Department of Health's Sexual and Reproductive Health Program requests that OPA establish a new timeline for FPAR 2.0 planning and implementation given the challenges all states and providers 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, in part because FPAR 2.0's data elements have not been released, including how to map each data element and response option 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 four to six months to assess what systems are needed to collect and report encounter-level data through FPAR 2.0. Our Network providers will need to work with their EMR providers to change templates to gather the data elements and 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. Initiating upgrades before final specifications are available would be inefficient, as inconsistencies would require revisions that would carry additional costs and burden hours spent.

Accuracy of Estimated Burden

The Washington State Department of Health's Sexual and Reproductive Health Program 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 significantly lower than those reported by our providers for comparable projects. The source for estimates, the Family Planning Annual Report (FPAR) Burden Study[1], 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 translate to the estimates no longer being accurate.

In addition, 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 our network of providers to the department, necessitating that our providers invest in upgrading to electronic systems (as applicable) and establishing interoperability between their respective systems. Our network of providers use several different EMR providers.

There would be additional ongoing expenses such as computer and software upgrades and purchased service costs. This increased cost would come during the same time period as costs at the clinic level have increased to meet COVID-19 protocols and clinic revenue has dwindled due to decreases in patient visits.

Burden, Necessity and Utility of FPAR 2.0 Data

The Department of Health's Sexual and Reproductive Health Program believes the 23 additional 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,

[1] RTI International, *Family Planning Annual Report Burden Study* (Research Triangle Park, NC: RTI, 2009).

reducing invasive cervical cancer through Pap testing, reducing infertility through chlamydia screening, and increasing program efficiency by monitoring the cost of care. However, it is unclear at this time how the additional of 23 new data elements are relevant to the monitoring of the Title X program compliance and accountability.

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.[2] 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 include screening for breast and cervical cancer,"[3] they should not be monitored at the encounter level to assess 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 to the Washington State Department of Health's Sexual and Reproductive Health Program:

New Data Elements: Sexual Activity

The Supporting Statement for the Title X FPAR 2.0 describes how FPAR 2.0 will supplement the federally funded National Survey for Family Growth (NSFG), a population-level, nationally representative dataset that gathers information on pregnancy and births, infertility, use of contraception, and general and reproductive health.[4] However, while NSFG surveys a representative sample of respondents and allows them to *voluntarily* respond, the data elements that will be collected and reported through FPAR 2.0 will be required for every patient visit. More specifically, 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 inconsistent with current best practice guidelines, which recommend assessing whether an adult 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)].[5] These sexual activity-related data fields are not needed to monitor our Title X network's accountability to program goals.

It is important to emphasize that patients accessing services in non-Title X settings would not be asked to provide responses to these questions at every visit, nor would their responses be reported at the encounter level to the federal government.

New Data Element: Future Pregnancy Intention Reported

The tracking of patients' intention to either become pregnant or prevent a pregnancy in the next year is discordant with the latest research. Research suggests that many patients cannot articulate their pregnancy intentions over the next year; doing so is inconsistent with how they

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[2] 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.

[3] 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.

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[5] 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.

think about and approach their reproductive lives.[6] [7] This is particularly true for low-income populations.[8] Indeed, not all individuals overtly plan to have children or not have children, suggesting that asking about reproductive "intentions" or "plans" may be problematic.[9] Asking patients this kind of a question at every visit, regardless of the reason for the visit, could compromise the patient-provider relationship by breaking rapport and shifting the visit away from what the patient wants.

Reflecting current research that patients prefer to be asked about their service needs than about pregnancy intentions or desires[10], NFPRHA recommends that FPAR 2.0 use a more patient-centered approach to measurement. An example of an alternative measure that assesses patients' desire for contraceptive services is the Self-Identified Need for Contraception (SINC)[11] question developed by the University of California, San Francisco (UCSF) Person-Centered Reproductive Health Program in consultation with Reproductive Justice advocates. Of note, UCSF has an award from OPA to develop a new electronic Clinical Quality Measures (eCQMs) of contraceptive provision using the SINC question to define the denominator. As such, use of the SINC question in FPAR 2.0 would be consistent with other initiatives underway at OPA. Use of this type of measure also would facilitate the removal of problematic data elements related to sexual activity, which have been included to identify whether a patient is perceived as "at risk" for pregnancy.

Data Elements: Cervical Cancer Screening

FPAR 2.0 suggests the Title X service sites collect and report five different data elements related to cervical cancer screening: Pap test at this visit, Last Pap result, Pap test in the last five years, HPV test performed at this visit, and HPV test result. Collecting and reporting all five data elements for every Title X visit would carry substantial burden with minimal benefit.
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

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[6] Abigail RA Aiken, Sonya Borrero, Lisa Callegari, and Christine Dehlendorf, "Rethinking the Pregnancy Planning Paradigm: Unintended Conceptions or Unrepresentative Concepts?," *Perspectives on Sexual and Reproductive Health* 48, no. 3 (2016):147-151, https://doi.org/10.1363/48e10316

[7] Lisa S Callegari, Abigail RA Aiken, Christine Dehlendorf, Patty Cason, and Sonya Borrero, "Addressing potential pitfalls of reproductive life planning with patient-centered counseling," *American Journal of Obstetrics and Gynecology* 216, no. 2 (2017):129-134, https://doi.org/10.1016/j.ajog.2016.10.004.

[8] Sonya Borrero, et al., "It just happens": a qualitative study exploring low-income women's perspectives on pregnancy intention and planning," *Contraception* 91, no. 2 (2015):150-6. doi: 10.1016/j.contraception.2014.09.014.

[9] Lisa S Callegari, et al., "Addressing potential pitfalls of reproductive life planning with patient-centered counseling," 2017.

[10] Heidi E Jones, Cynthia Calixte, Meredith Manze, Michele Perlman, Susan Rubin, Lynn Roberts, and Diana Romero, "Primary care patients' preferences for reproductive health service needs assessment and service availability in New York Federally Qualified Health Centers," *Contraception* 101, no. 4 (2020):226-230.

[11] "Do you want to talk about contraception or pregnancy prevention during your visit today?"

- If yes: Mark "yes" and ensure appropriate counseling is provided
- If no: "There are a lot of reasons why a person wouldn't want to talk about this, and you don't have to share anything you don't want to. Do any of these apply to you?" (mark all that apply):
    - I'm here for something else
    - This question does not apply to me
    - I prefer not to answer
    - I am already using contraception (and what)
    - I am unsure or don't want to use contraception
    - I am hoping to become pregnant in the near future

at a five-year interval and there is no national benchmark pertaining to the rate of tests that should come back as positive.[12]

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.[13] 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.[14] [15] When extracting data to calculate measures, there is no way to qualify whether an appropriate screening interval was applied.

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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.

It is unclear how self-reported smoking status would serve as a quality metric for program monitoring and the implementation of program stated goals. If this topic is a priority for OPA, this data element should be reconfigured to determine to report the intervention(s) offered to tobacco smokers, using those listed by the US Preventive Services Task Force.[16]

In relation to tracking BMI, from a clinical perspective, there is no benefit to recording and reporting body weight *at every visit*. OPA has not provided clarity on to the value of collecting this information or how it will be used in the Supporting Statement for the Title X FPAR 2.0.[17] Even when collecting a patient's height and weight data is clinically indicated, such

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[12] 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.

[13] Ibid.

[14] 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.

[15] *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.

[16] 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.

[17] *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.

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.[18] Furthermore, the practice of weighing clients at every visit – even health education sessions or when not clinically indicated – may deter clients from accessing services due to experiences of body shame and weight discrimination.[19]

Patients accessing health services in non-Title X settings typically are weighed (or asked to self-report their weight) only when clinically indicated[20]. Title X patients should receive the same standard of care, particularly due to concerns related to weight stigmatization. Weight stigma invokes psychological stress and emerging research suggests that this stress leads can exacerbate poor physical health outcomes for obese individuals[21] with the potential to perpetuate racial/ethnic and socioeconomic health disparities in overweight and obesity. It would be more appropriate to focus on measures of health that are scientifically valid and designed for diverse patient populations.

Screening for cardiovascular risk factors is indicated to support contraceptive decision-making (i.e., to ensure a patient does not have contraindications to combined oral contraceptives and other hormonal contraception) and pre-pregnancy health. While it may be desirable to capture these measures for additional patients, there is no explicit expectation or requirement for Title X providers to obtain information beyond that which is clinically necessary. Accordingly, we should not be required to document and report these measurements for every visit.

Confidentiality of Sensitive Personal Health Information

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 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.[22] 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.[23] 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 seems imprudent to

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[18] 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.

[19] Janell L Mensinger, Tracy L Tylka, and Margaret E Calamari, "Mechanisms underlying weight status and healthcare avoidance in women: A study of weight stigma, body-related shame and guilt, and healthcare stress," *Body Image* 25 (2018):139-147. doi.org/10.1016/j.bodyim.2018.03.001.

[20] CDC - Appendix C - US SPR - Reproductive Health

[21] Rebecca M Puhl and Chelsea A Heuer, "Obesity stigma: important considerations for public health," *American Journal of Public Health* 100, no. 6 (2010):1019-28. doi:10.2105/AJPH.2009.159491.

[22] 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.

[23] Ibid.

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.

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.

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The current FPAR 2.0 project stands to severely disrupt our operations during already uncertain times.

While we agree that the Title X program needs a more contemporary data system for monitoring and improving program performance, the process to achieve this requires more stakeholder engagement. Otherwise we risk undervaluing our patients, particularly those who are low-income, uninsured, and under-insured. Accordingly, we urge OPA to pause and re-evaluate FPAR 2.0.

Sincerely,

Cynthia Harris
Sexual and Reproductive Health Program Manager
Washington State Department of Health

NFPRHA Response to 60-Day Public Comment Request:
Family Planning Annual Report 2.0

I. Introduction

Converge welcomes the opportunity to submit comments in response to the Department of Health and Human Services' (HHS) Agency Information Collection Request 0990-New-60D on Family Planning Annual Report 2.0, issued on February 11, 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). 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). While Converge 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.

Converge was founded in October 2018. Converge collaborates with health care providers, insurance companies, and community partners to build a health care system that places people at the center of family planning care. Our vision is that all people have access to quality, affordable family planning care. As part of this vision, Converge collaborates with the current Title X Grantee in Mississippi to ensure quality data reporting and quality care is provided to all clients. In 2020, Converge began implementing a data dashboard for all community health clinic members of the Mississippi Title X network. This marked the first time the clinics were providing regular data updates to the grantee.

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. 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.

Timeline

Converge 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.

Accuracy of Estimated Burden

Converge 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 translate to the data collected no longer being 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 be 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 each grantee-subrecipient dyad to invest in upgrading to electronic systems (as applicable) and establishing interoperability between their respective systems

Burden, Necessity and Utility of FPAR 2.0 Data

Converge believes the 23 additional 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. It corresponds to the deliberate transition of FPAR from a program monitoring tool to a research dataset, requiring Title X service sites to collect excessive information from patients at every single visit, even though such information is not necessitated by clinical practice guidelines or other evidence-based standards.

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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).

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 include screening for breast and cervical cancer,"[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 (or lack of) are of particular concern to Converge:

New Data Elements: Future Pregnancy Intention Reported

The inclusion of reported pregnancy intention as a reportable data measure fails to address the well documented reality of pregnancy ambivalence. Very few people conceive of pregnancy decision making in the very formal time limited way that One Key Question and other intention assessments frame this. In addition to the unacceptable focus on intention, collecting data on how people state their desire for a pregnancy does not speak to their contraceptive decision making as often these elements are not directly related. [6] As the Title X program continues to address the need for noncoercive and equitable care, it is critical to properly address contraceptive decision making as person-centered and driven by preferences stated by the client. Patients themselves have stated a preference for shared decision making that is guided by their preferences and the medical input of their provider [7] A continued focus on "pregnancy intention" leads can lead to a focus on method effectiveness to prevent pregnancy that may not be at all guided by patient preference for contraceptive methods. Thus, collecting intention around pregnancy both generates data that does not actually mean very much with relation to patient decision making and it may have the unintended consequence of encouraging non-equitable and even coercive counseling practices.

Lack of Data: No Patient Reported Measures

FPAR 2.0, like previous FPAR data and many other large efforts to generate data on healthcare utilization fails to collect any data from patients themselves. This lack of patient input speaks to a very narrow focus on clinical outcomes and practices while failing to properly address the critical element of how patients experience this federally funded health care program. In particular on the topic of family planning and reproductive healthcare, there is a lengthy history as well a contemporary reality of coercion and abuse. Failing to value the reported experiences of patients equally with medical health record data does nothing to protect against the possibility of care that is harmful. Converge would propose the uniform usage of a patient reported measure that speaks to the patient-centeredness of care provided. The Patient-Centered

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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.

[6] Borrero S, Nikolajski C, Steinberg JR, Freedman L, Akers AY, Ibrahim S, Schwarz EB. "It just happens": a qualitative study exploring low-income women's perspectives on pregnancy intention and planning. Contraception. 2015 Feb

[7] Christine Dehlendorf, Kira Levy, Allison Kelley, Kevin Grumbach, Jody Steinauer, Women's preferences for contraceptive counseling and decision making, Contraception, Volume 88, Issue 2, 2013

Contraceptive Counseling measure[8] is one such tool that could be used throughout the Title X program to ensure patient input is being collected and valued. The measure is validated by the National Quality Forum.

New Data Elements: Sexual Activity

The Supporting Statement for the Title X FPAR 2.0 describes how FPAR 2.0 will supplement the federally funded National Survey for Family Growth (NSFG), a population-level, nationally representative dataset that gathers information on pregnancy and births, infertility, use of contraception, and general and reproductive health.[9] However, while NSFG surveys a representative sample of respondents and allows them to *voluntarily* respond, the data elements that will be collected and reported through FPAR 2.0 will be required for every patient visit. More specifically, 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 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)].[10] These sexual activity-related data fields also are not needed to monitor our Title X network's accountability to program goals.

It is important to emphasize that patients accessing services in non-Title X settings would not be asked to provide responses to these personal, guideline-unconcordant questions at every visit, nor would their responses be reported at the encounter level to the federal government. When the federal government begins collecting research data for its benefit and requires those accessing services through the safety net to provide such information as a precursor to receive care, it exacerbates medical mistrust, potentially dissuading patients from coming to us for needed services.

Data Elements: Cervical Cancer Screening

FPAR 2.0 suggests the Title X service sites collect and report five different data elements related to cervical cancer screening: Pap test at this visit, Last Pap result, Pap test in the last five years, HPV test performed at this visit, and HPV test result. Collecting and reporting all five data elements for every Title X visit would carry substantial burden with minimal benefit.

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

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8 Dehlendorf C, Fox E, Silverstein IA, Hoffman A, Campora Pérez MP, Holt K, Reed R, Hessler D. Development of the Person-Centered Contraceptive Counseling scale (PCCC), a short form of the Interpersonal Quality of Family Planning care scale. Contraception. 2021 Jan

9 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.

10 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.

at a five-year interval and there is no national benchmark pertaining to the rate of tests that should come back as positive.[11]

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.[12] 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.[13] [14] 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 (detailed as ever smoker, ex-smoker, smokes daily, occasional smoker, smoker, status unknown, heavy smoker, light smoker).

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 determine to report the intervention(s) offered to tobacco smokers, using those listed by the US Preventive Services Task Force.[15]

Converge believes the collection of height and weight data, presumably to calculate body mass index (BMI), is problematic. From a clinical perspective, there is no logical rationale to record and report body weight *at every visit*, and OPA does not state why it is necessary to collect this information and how it will be used in the Supporting Statement for the Title X FPAR 2.0.[16] Even

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11 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.

[12] Ibid.

[13] 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.

[14] *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.

[15] 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.

[16] *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.

when collecting a patient's height and weight data is clinically indicated, 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 because it fails to account for differences in body composition, fitness levels, and nutritional differences.[17] Furthermore, the practice of weighing clients at every visit – even health education sessions or when not clinically indicated – may deter clients from accessing services due to experiences of body shame and weight discrimination.[18]

Patients accessing health services in non-Title X settings are not weighed at every visit unless clinically indicated. Title X patients should receive the same standard of care and should not be subject to weight stigmatization at every visit. Weight stigma invokes psychological stress and emerging research suggests that this stress leads can exacerbate poor physical health outcomes for obese individuals[19], with the potential to perpetuate racial/ethnic and socioeconomic health disparities in overweight and obesity. It is time to move away from this measure and focus on measures of health that are scientifically valid and designed for diverse patient populations.

Screening for cardiovascular risk factors is indicated to support contraceptive decision-making (i.e., to ensure a patient does not have contraindications to combined oral contraceptives and other hormonal contraception) and pre-pregnancy health. While it may be desirable to capture these measures for additional patients, there is no explicit expectation or requirement for Title X providers to obtain information beyond that which is clinically necessary. Accordingly, we should not be required to document and report these measurements for every visit.

Confidentiality of Sensitive Personal Health Information

Converge requests further 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 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.[20] 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.[21] 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

[17] 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.
[18] Janell L Mensinger, Tracy L Tylka, and Margaret E Calamari, "Mechanisms underlying weight status and healthcare avoidance in women: A study of weight stigma, body-related shame and guilt, and healthcare stress," *Body Image* 25 (2018):139-147. doi.org/10.1016/j.bodyim.2018.03.001.
[19] Rebecca M Puhl and Chelsea A Heuer, "Obesity stigma: important considerations for public health," *American Journal of Public Health* 100, no. 6 (2010):1019-28. doi:10.2105/AJPH.2009.159491.
[20] 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.
[21] Ibid.

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 seems 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.

Despite a range of opinions about what qualifies as sensitive health information, it generally is 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.

Converge urges OPA to pause and re-evaluate FPAR 2.0.

If you require additional information about the issues raised in this letter, please contact Danielle Lampton at DLampton@Convergems.org

Sincerely,

Danielle Lampton and Jamie Bardwell
Co-Founders, Converge
Jackson, MS