

Comment Text

The overall purpose and intention behind collecting additional and encounter-level data elements is unclear. Significant magnitude and consequences of proposed FPAR 2.0 changes (particularly on providers, clinics, and patients), and what program, is needed.

Many of the proposed FPAR 2.0 data elements do not adhere to modern sexual and reproductive health clinical guidelines for 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 those with sensitive information. “masking” will likely not lessen these concerns because of continued sensitivity and trust concerns when sharing data.

Many of the proposed FPAR 2.0 data elements, particularly those inquiring as to a patient’s sexual activity, administrative burden, repetitive, intrusive, and unnecessary. There is significant potential the proposed elements will hinder and/or harm trust and the sensitive nature of sexual and reproductive health. Many of the proposed elements should not be collected at the federal level as protected health information.

Many of the proposed FPAR 2.0 data elements, which are medically unnecessary, will also hinder the ability to provide services including comprehensive contraceptive and/or preconception counseling, during a telehealth visit, which typically last less than 15 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 change and add 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 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 source of funding for submission and reporting. Many Title X providers receive funding from other such federal programs/providers. Many providers are unable due to the considerable level of time, effort, and funding needed to comply with proposed FPAR 2.0 changes.

Additionally, we request this rule be postponed until additional research into the overall magnitude and consequences of the rule and the support for Title X grantees and service sites can be provided.

Currently collected in aggregate under OMB No. 0990-0221, this new data collection, "FPAR 2.0", proposes to collect the existing data collection and reporting system by adding 23 new data elements to FPAR's standard set of data elements (collected every visit).

While Converge appreciates the need for a more robust data system for monitoring and improving program performance, 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 system with continued stakeholder involvement.

Under the best of circumstances, OPA's proposal for FPAR 2.0 is flawed. Not only does FPAR 2.0, as proposed, require resources 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 and 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 the network’s capacity after an estimated one in four service sites left the Title X program in response to the 2019 Title X funding cut – it is not feasible. We are working hard to hold on, rebuild, and continue providing critical services to patients.

Converge requests that OPA establish a new timeline for FPAR 2.0 planning and implementation given the challenges currently facing. Even in the absence of the above challenges, the current timeline for FPAR 2.0 data collection to begin on January 1, 2023, is not feasible.

Converge requests that OPA complete an up-to-date burden study to provide a complete and accurate estimate of the current burden estimates in the Public Comment Request are extremely low and based on an inappropriate and incredibly outdated study. The 2009 FPAR Burden Study, published in 2009 using data collected from Title X grantees at that time, does not reflect the developments that 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 reporting elements. Estimates in the FPAR Burden Study, where gross non-labor costs were estimated to be \$163,300 (or \$2,200 per respondent) and net costs were estimated at \$106,880 (or \$1,444 per respondent), are based on the cost and time burdens of implementing a new FPAR encounter-level data reporting and collection system. It is inappropriate for OPA to use data collected from the 2009 FPAR encounter-level data reporting system currently proposed, as these estimates relate to a completely different iteration of the system that is substantially less burdensome on grantees and subrecipients.

Due to challenges with interoperability (i.e., electronic sharing of data between systems), there is no “one size fits all” solution for reporting from Title X service sites to grantees, necessitating each grantee-subrecipient dyad to invest in upgrading their systems and interoperability between their respective systems.

Converge believes the 23 additional elements go beyond what is necessary for quality improvement and what is required for operational guidance. We ask for additional opportunities to provide feedback on what additional data elements are for which 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 Goals, which include: giving priority in the provision of family planning services to low-income individuals, reducing invasive cervical cancer and infertility through chlamydia screening, and increasing program efficiency by monitoring the cost of care. However, the proposed elements, which are irrelevant to monitoring Title X program compliance and accountability to the above performance goals – being minimally burdensome.

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

Some proposed data elements pertain to services that are outside of the core family planning services in the Recommended 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 directly to achieving or preventing pregnancy include screening for breast and cervical cancer,” they certainly should not be held accountable to program goals. We request additional justification for collecting these new data elements beyond the program objectives.

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 decision making in the very formal time limited way that One Key Question and other intention assessment questions. Collecting data on how people state their desire for a pregnancy does not speak to their contraceptive decision making related. As the Title X program continues to address the need for noncoercive and equitable care, it is critical to provide care that is patient centered and driven by preferences stated by the client. Patients themselves have stated a preference for shared decision making and medical input of their provider. A continued focus on “pregnancy intention” leads can lead to a focus on method effectiveness rather than being guided by patient preference for contraceptive methods. Thus, collecting intention around pregnancy both generates data that is not related to patient decision making and it may have the unintended consequence of encouraging non-equitable and even coercive 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 patient input speaks to a very narrow focus on clinical outcomes and practices while failing to properly address the complex needs of the federally funded health care program. In particular on the topic of family planning and reproductive healthcare, there is a long history of patient abuse. Failing to value the reported experiences of patients equally with medical health record data does nothing to protect patient autonomy. Converge would propose the uniform usage of a patient reported measure that speaks to the patient-centeredness of care. A Patient Reported Counseling measure is one such tool that could be used throughout the Title X program to ensure patient input is being valued. See 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 NSFG population-level, nationally representative dataset that gathers information on pregnancy and births, infertility, use of contraception, and sexual activity. However, while NSFG surveys a representative sample of respondents and allows them to voluntarily respond, the data collection for FPAR 2.0 will be required for every patient visit. More specifically, OPA has proposed that Title X service sites report the following data points 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 patient is in a relationship [unless the patient is at increased risk for infection or is seeking evaluation and treatment for sexually transmitted infections]. These data points 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 questions at every visit, nor would their responses be reported at the encounter level to the federal government. When we ask for its benefit and requires those accessing services through the safety net to provide such information as a precursor to receiving care, it is 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 in the last five years, HPV test performed at this visit, and HPV test result. Collecting and reporting all five data elements with minimal benefit.

The collection of information on a patient's Pap (at current and previous visit) and HPV tests performed may be helpful. The number of tests provided during a specified period, the distribution of abnormal cytology results, or use of different combinations (e.g., hrHPV-alone, co-testing) during a specified period. However, the utility of collecting of Pap test in the last five years is not clear. The guideline recommends cervical cytology alone at a five-year interval and there is no national benchmark pertaining to this. It is critical to underscore that ASCCP Risk-Based Management Consensus Guidelines for abnormal cervical cancer screening are based on patient age and other risk factors that support screening. As a result, none of these cervical cancer screening-related data elements measure adherence to screening guidelines or track progress towards Healthy People 2030 goals (i.e., increase the proportion of women on the most recent guidelines), as described in the Supporting Statement for the Title X FPAR 2.0. When extracting data, it is important to note 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 risk factors: Blood pressure, Height, Weight, and Smoking status (detailed as ever smoker, ex-smoker, smokes daily, occasional smoker, never smoker). Separate reporting of systolic and diastolic blood pressure measurements does not make sense clinically, as the interpretation of blood pressures be tempered by the age of the patient, anxiety level when blood pressure is measured (i.e., "white coat" hypertension), and whether blood pressures are quite elevated, the diagnosis of hypertension cannot be made without multiple measurements on several occasions. If blood pressure is a priority for OPA, this data element should be reconfigured to identify whether diagnosis of hypertension 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 identify intervention(s) offered to tobacco smokers, using those listed by the US Preventive Services Task Force.

Converge believes the collection of height and weight data, presumably to calculate body mass index (BMI), is problematic. There is no rationale to record and report body weight at every visit, and OPA does not state why it is necessary to collect this information. The Supporting Statement for the Title X FPAR 2.0. Even when collecting a patient's height and weight data is clinically indicated, it is not clear whether that patient is overweight or obese – and, in turn, at risk for cardiovascular disease. Developed for and tested in men, BMI is not a useful indicator of health, especially for women of color, because it fails to account for differences in body composition and differences. Furthermore, the practice of weighing clients at every visit – even health education sessions or when not seeking health 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 services should not be subject to weight stigmatization at every visit. Weight stigma invokes psychological stress and emotional distress, which exacerbate poor physical health outcomes for obese individuals, with the potential to perpetuate racial/ethnic and socioeconomic disparities. It is time to move away from this measure and focus on measures of health that are scientifically valid and designed for women. Screening for cardiovascular risk factors is indicated to support contraceptive decision-making (i.e., to ensure a patient is using contraceptives and other hormonal contraception) and pre-pregnancy health. While it may be desirable to capture the expectation or requirement for Title X providers to obtain information beyond that which is clinically necessary. Accredited Title X programs should not report these measurements for every visit.

Converge requests further clarification on the steps OPA will take to maintain the confidentiality of the sensitive personal health information. Confidentiality is a hallmark of the Title X program, and all patients, including adolescents, are guaranteed confidentiality under federal regulations, and case law. Further, they are grounded in medical and ethical standards and reflect research demonstrating that patients would not seek needed health services. Despite this assurance, the Supporting Statement for the Title X FPAR 2.0 proposal lacks confidentiality of the sensitive personal health information it wants to collect through FPAR 2.0. While encounter-level specifications for how the patient identifier data element will be used in a way that ensures that patient confidentiality is maintained, information on the HIPAA Security Rule Standards it will adopt to ensure the appropriate consent and safeguarding of data at subrecipient levels; for example, specifying encryption standards for data at rest and in motion. Given the cybersecurity risks, it seems imprudent to move forward with FPAR 2.0 without releasing more information about – and seeking stakeholder input on – 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 a risk of harm. Several data elements within FPAR are sensitive in nature, as they relate to sexual behaviors and other deeply personal information.

Currently collected in aggregate under OMB No. 0990-0221, this new data collection, “FPAR 2.0”, proposes to collect and report the existing data collection and reporting system by adding 23 new data elements to FPAR’s standard set of data elements (collected every visit).

While Denver Health appreciates the need for a more robust data system for monitoring and improving program performance, the current FPAR 2.0 project must be paused. At the same time, OPA must plan and initiate a new process for developing a data system with continued stakeholder involvement.

Under the best of circumstances, OPA’s proposal for FPAR 2.0 is flawed. Not only does FPAR 2.0, as proposed, require the collection of exponentially more data than the current system, but the cost estimates are also exponentially higher than the outdated estimates published in the Federal Register (86 FR 9077).

OPA’s proposal also puts forward data collection requirements that far exceed the minimum amount of data needed to monitor and 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 health emergency, including prioritizing testing and treatment; implementing telehealth services; cost of personal protective communities. Any attempt to implement FPAR 2.0 in accordance with current timelines will disrupt our ability to res

Denver Health requests that OPA establish a new timeline for FPAR 2.0 planning and implementation given the challenges facing. Even in the absence of the above challenges, the current timeline for FPAR 2.0 data collection to begin on Jan

To implement FPAR 2.0, Denver Health would need to make upgrades to its information technology (IT) infrastructure specifications for (i.e., instructions for how to collect) FPAR 2.0's data elements, including how to map each data element. In the absence of these specifications, we are in the difficult position of having to wait while the time window needed to

After making system upgrades, Denver Health will require several months to train health care providers and staff on data collection, run reports to ensure data mapping is correct, and perform quality assurance of preliminary data colle

Initiating upgrades before final specifications are available would be wasteful, as inconsistencies would require revisions spent.

Denver Health requests that OPA complete an up-to-date burden study to provide a complete and accurate estimate of Cost burden estimates in the Public Comment Request are extremely low and based on an inappropriate and incredible Planning Annual Report (FPAR) Burden Study, was published in 2009 using data collected from Title X grantees more than two years 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 elements. Estimates in the FPAR Burden Study, where gross non-labor costs were estimated to be \$163,300 (or \$2,200 per respondent)2, are based on the cost and time burdens of implementing a new FPAR system that reports data aggregated collection). It is inappropriate for OPA to use data collected from the 2009 FPAR Burden Study to quantify costs for implementing the proposed, as these estimates relate to a completely different iteration of the proposed overhaul of FPAR that would be substantially less

Denver Health believes the 23 additional elements go beyond what is necessary for quality improvement and what is operational guidance. We ask for additional opportunities to provide feedback on what additional data elements are for which 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 Goals, which include: giving priority in the provision of family planning services to low-income individuals, reducing invasive cervical cancer through chlamydia screening, and increasing program efficiency by monitoring the cost of care. However, with the addition of 23 new data elements for monitoring Title X program compliance and accountability to the above performance goals – FPAR 2.0 represents an additional burden.

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

Some proposed data elements pertain to services that are outside of the core family planning services in the Recommended 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 directly to achieving or preventing pregnancy include screening for breast and cervical cancer,”⁴ they certainly should not be held accountable to program goals. We request additional justification for collecting these new data elements beyond the program objectives.

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 NSFG population-level, nationally representative dataset that gathers information on pregnancy and births, infertility, use of contraception, and sexual activity. However, while NSFG surveys a representative sample of respondents and allows them to voluntarily respond, the data elements that will be collected at every patient visit. More specifically, OPA has proposed that Title X service sites report the following three data fields: 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's privacy, 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 sexually transmitted infections (STIs)].⁶ These sexual activity-related data fields also are not needed to monitor our Title X program. It is important to emphasize that patients accessing services in non-Title X settings would not be asked to provide responses at every visit, nor would their responses be reported at the encounter level to the federal government. When a patient comes to us for its benefit and requires those accessing services through the safety net to provide such information as a precursor to receive care, it exacerbates the barriers to 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: the last Pap test performed, the last HPV test performed, the last Pap test result, the last HPV test result, and the last Pap test result. Collecting and reporting all five data elements for every patient visit provides minimal benefit. The collection of information on a patient's Pap (at current and previous visit) and HPV tests performed may be helpful in determining the number of Pap tests provided during a specified period, the distribution of abnormal cytology results, or use of different cervical cancer screening methods (Pap 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 not needed for cervical cytology alone at a five-year interval and there is no national benchmark pertaining to the rate of tests that should be performed. The 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 surveillance. It is critical to underscore that ASCCP Risk-Based Management Consensus Guidelines for abnormal cervical cancer screening are based on patient age, Pap test results, and other risk factors that support screening.⁸ As a result, none of these cervical cancer screening-related data elements are needed for screening guidelines or track progress towards Healthy People 2030 goals (i.e., increase the proportion of females who receive cervical cancer screening guidelines), as described in the Supporting Statement for the Title X FPAR 2.0.⁹ ¹⁰ When extracting data to calculate measures, the five-year 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 risk factors: blood pressure, Height,

Weight, and Smoking status (detailed as ever smoker, ex-smoker, smokes daily, occasional smoker, smoker, status unknown). The collection of systolic and diastolic blood pressure measurements does not make sense clinically, as the interpretation of a single measurement is highly variable due to the age of the patient, anxiety level when blood pressure is measured (i.e., “white coat” hypertension), and other factors. If blood pressure is consistently elevated, the diagnosis of hypertension cannot be made without multiple measurements on several separate occasions. For OPA, this data element should be reconfigured to identify whether diagnosis of hypertension has been made or if a diagnosis was not 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 identify intervention(s) offered

to tobacco smokers, using those listed by the US Preventive Services Task Force.¹¹

Denver Health believes the collection of height and weight data, presumably to calculate body mass index (BMI), is not clinically indicated. The logical rationale to

record and report body weight at every visit, and OPA does not state why it is necessary to collect this information at every visit. 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 obese – and, in turn, at risk for cardiovascular disease. Developed for and tested on a sample of predominantly white European men and women of color, because it fails to account for differences in body composition, fitness levels, and nutritional status, BMI is not a valid measure for all clients at every visit – even health education sessions or when not clinically indicated – may deter clients from accessing services due to weight discrimination.¹⁴

Patients accessing health services in non-Title X settings are not weighed at every visit unless clinically indicated. Title X service sites should not be subject to weight stigmatization at every visit. Weight stigma invokes psychological stress and emotional distress, which exacerbate poor physical health outcomes for obese individuals¹⁵, with the potential to perpetuate racial/ethnic and socioeconomic disparities in obesity. It is time to move away from this measure and focus on measures of health that are scientifically valid and do not discriminate. Screening for cardiovascular risk factors is indicated to support contraceptive decision-making (i.e., to ensure a patient is using effective contraceptives and

other hormonal contraception) and pre-pregnancy health. While it may be desirable to capture these measures for additional quality improvement requirement for Title X

providers to obtain information beyond that which is clinically necessary. Accordingly, we should not be required to collect this information.

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 have an NPI number. The HIPAA Accountability Act- (HIPAA)

covered data or those who provide services “incident to” another provider. Furthermore, only advanced practice clinicians are required to report encounters at Denver

Health are routinely performed by other providers, including registered nurses and health educators. As such, many of these encounters are not reported by individual NPI

providers. Denver Health is required to report for FPAR 2.0.

Confidentiality of Sensitive Personal Health Information

Denver Health requests further clarification on the steps OPA will take to maintain the confidentiality of the sensitive information. Confidentiality is a hallmark of the Title X program, and all patients, including adolescents, are guaranteed confidentiality under federal regulations, and case law. Further, they are grounded in medical and ethical standards and reflect research demonstrating that patients would not seek needed health services.¹⁶ Despite this assurance, the Supporting Statement for the Title X FPAR 2.0 emphasizes the confidentiality of the sensitive personal health information it wants to collect through FPAR 2.0.¹⁷ While encounter-level specifications for how the patient identifier data element will be used in a way that ensures that patient confidentiality is maintained, information on the HIPAA Security Rule Standards it will adopt to ensure the appropriate consent and safeguarding of data at subrecipient levels; for example, specifying encryption standards for data at rest and in motion. Given the cybersecurity risks, it seems imprudent to move forward with FPAR 2.0 without releasing more information about – and seeking stakeholder input on – 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, in the event of disclosure,

Several data elements within FPAR are sensitive in nature, as they relate to sexual behaviors and other deeply personal

While we agree that the Title X program needs a more contemporary data system for monitoring and improving program performance at the expense of serving those in need of services, specifically patients who are low-income, uninsured, and underinsured. The current system providing Title X patients with the same standard of care as their counterparts who receive care in non-Title X settings is an unnecessary data elements that are required for every visit – would do. Accordingly, Denver Health urges OPA to pause

While the WHC appreciates the need for a more robust data system for monitoring and improving program performance, 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 system with continued stakeholder involvement.

FPAR 2.0 puts forward data collection requirements that far exceed the minimum amount of data needed to monitor 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 the network’s capacity after an estimated one in four service sites left the Title X program in response to the 2019 Title X funding cut – it 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 over 800 being served in one community over the restrictions related to abortion services. Our eight (8) subrecipients saw 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 above. Even in the absence of the above challenges, the current timeline for FPAR 2.0 data collection to begin on January 1,

Currently, we estimate it will take 12-18 months to implement and test the systems upgrades needed to collect and report data. This includes required steps to upgrade systems, which may include processes related to vendor procurement, adopting an electronic data collection system to report encounter-level data, customizing existing systems so the FPAR 2.0 data elements are collected, validation efforts, etc.

After making system upgrades, WHC and its subrecipients (which operate eleven (11) service sites) will require a multi-step process for providers and staff on how to collect new data elements, conduct preliminary data collection, run reports to ensure data is accurate, preliminary data collected, as needed. Initiating upgrades before final specifications are available would be wasteful, 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. WHC has EHR systems and one of these subrecipients has only 1 administrative/financial and 1 clinical staff. Instead, these organizations must do an aggregate submission. Those service sites without EHRs will not be able to begin reporting FPAR 2.0 data electronically. WHC typically takes 9 to 11 months, with three months for planning and six to eight months for implementation. Instead, WHC would have to collect and perform manual data entry of FPAR 2.0's 45 proposed data elements for every visit, and then determine how to transmit this sensitive health information securely. This cumbersome process not only raises concerns about the effective use of Title X resources, but also about the security of sensitive health information.

WHC requests that OPA complete an up-to-date burden study to provide a complete and accurate estimate of the burden of FPAR 2.0. The burden estimates in the Public Comment Request are extremely low and based on an inappropriate and incredibly out-

WHC estimates that implementing FPAR 2.0 as proposed at the grantee-level will amount to over \$75,000.00 in one-time estimates for program data assessment, data program installation, and training. Furthermore, WHC estimates that each grantee will incur \$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 the same fiscal year(s) as the COVID-19 public health emergency when resources have been redirected to emergency patient census. These cost estimates do not include ongoing expenses such as computer and software upgrades and purchases.

All of our programs rely on some state funding to support various program activities. This year, all state programs will experience a decrease in funding. It is anticipated 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 (the Grantee Director) and two part-time staff whose responsibilities do not include FPAR data. This estimate is based on the cost of one full-time staff member combined 200 hours on tasks related to implementation, which may include: selecting and/or creating a contract with a vendor for system upgrades and map out FPAR 2.0's data elements to existing standardized value sets, training health care providers, conducting preliminary data collection, running reports to ensure data mapping is correct, and performing quality assurance. WHC also estimate that each of our eight (8) subrecipients will spend an average of eighty (80) hours implementing FPAR 2.0. Total 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 – ongoing operations and maintenance are not included in these estimates. They also do not include the additional time spent at 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 the guidance. We ask for additional opportunities to provide feedback on what additional data elements are feasible to add and most helpful to us for program management and quality improvement.

OPA has proposed that Title X service sites report the following three data fields for patients at every visit: Ever had sex, ever had a sexually transmitted infection (STI), and ever had a partner who is sexually active. Asking these three data points at every visit is burdensome and threatens the patient-provider relationship. It also is not necessary. We recommend assessing whether an adult or adolescent patient is sexually active only annually [unless the patient is at risk for treatment for sexually transmitted infections (STIs)]. These sexual activity-related data fields also are not needed to meet program goals.

When the federal government begins collecting research data for its benefit and requires those accessing services through 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: whether a patient has been screened in the last five years, HPV test performed at this visit, and HPV test result. Collecting and reporting all five data elements is burdensome for providers and patients with minimal benefit. Furthermore, there is no way for WHC to differentiate whether an HPV test was done as part of a routine screening test or for post-treatment surveillance.

It is critical to underscore that ASCCP Risk-Based Management Consensus Guidelines for abnormal cervical cancer screening are based on patient age and other risk factors that support screening. As a result, none of these cervical cancer screening-related data elements are used to assess adherence to screening guidelines or track progress towards Healthy People 2030 goals (i.e., increase the proportion of women aged 21-65 years on the most recent guidelines), as described in the Supporting Statement for the Title X FPAR 2.0. When extracting data, it is unclear 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: Blood Pressure, Height, Weight, and Smoking status (detailed as ever smoker, ex-smoker, smokes daily, occasional smoker). Separate reporting of systolic and diastolic blood pressure measurements does not make sense clinically, as the interpretation of blood pressure should 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. There is no clinical rationale to record and report body weight at every visit, and OPA does not state why it is necessary to collect this information. See 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 and body fat distribution. Furthermore, the practice of weighing clients at every visit – even health education sessions or when not receiving 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 information collected.

Given the cybersecurity issues that all organizations currently are facing, it seems imprudent to move forward with FPAR 2.0 without seeking stakeholder feedback on – the steps that OPA will take to protect FPAR 2.0’s encounter-level data from unauthorized access. These 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 will be de-identified and how confidentiality is preserved. Furthermore, OPA has not provided information on the HIPAA Security Rule Standards for the safeguarding of this encounter-level data at the federal, grantee, and subrecipient levels; for example, specifying encryption and access controls.

The current FPAR 2.0 project stands to severely disrupt WHC's operations during already uncertain times. WHC, like many other providers, is currently recruiting additional safety net providers to join its network, an ongoing effort since the 2019 Title X Rule took effect. This effort resulted in approximately 800 fewer Title X patients served in 2020. WHC also is concerned of losing existing subrecipient data collection burden.

We are striving to see more patients. While we agree that the Title X program needs a more contemporary data system, such an endeavor cannot come at the expense of serving those in need of services, specifically patients who are low-income. A system that cannot come at the expense of providing Title X patients with the same standard of care as their counterparts who receive care through FPAR 2.0 - with burdensome and unnecessary data elements that are required for every visit - would do. Accordingly,

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

While NFPRHA appreciates the need for a modern data system for monitoring and improving program performance, the additional elements go beyond what is necessary for quality improvement and what is required by statutory requirements. NFPRHA requests that OPA plan and initiate a different process for transitioning to a new data collection and reporting system.

Under the best of circumstances, OPA's proposal for FPAR 2.0 is flawed. Not only does FPAR 2.0, as proposed, require data collection that is 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 and 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 network’s capacity after an estimated one in four service sites left the Title X program in response to the 2019 Title X funding cuts – it is not always feasible for Title X grantees and subrecipients. These organizations are working hard to rebuild and continue providing services.

NFPRHA requests that OPA establish a new timeline for FPAR 2.0 planning and implementation given the challenges outlined above. In the absence of the above challenges, the current timeline for FPAR 2.0 data collection to begin on January 1, 2022, is not realistic. Grantees and subrecipients must upgrade existing information technology (IT) infrastructure.

NFPRHA estimates that it will take 12-18 months to initiate encounter-level data collection and reporting through FPAR 2.0.

Implementing necessary system upgrades: To implement FPAR 2.0, grantees must implement IT system upgrades that include data warehouse and setting up secure file transfer with subrecipients using secure file transfer protocol (SFTP). On the subrecipient side, upgrades that may involve adopting and implementing new electronic health record (EHR) or electronic data collection systems, or upgrading existing systems so the FPAR 2.0 data elements map to existing standardized value sets. Most grantees and subrecipients are already in the process as part of this phase, a process that can be particularly slow in the public sector. Of note, 40 Title X service sites have IT departments.

Data validation: Grantees must work with each of their subrecipients to electronically validate data. Data validation is a process that is present and, from there, conducting quality assurance to ensure there are no incongruent or incomplete counts, duplicate records, etc.

Training: After making all necessary system upgrades, grantees must train staff at their organizations and at the subrecipient level. There, to ensure full and accurate data collection when systems “go live,” grantees will conduct preliminary data collection, test 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 other IT systems, such as appointment scheduling systems and registries, integrating telehealth platforms with EHRs, providing day-to-day IT support, is a significant barrier to the timeline for such changes.

Current OPA timelines also assume a level of baseline technology at both the Title X grantee and subrecipient levels. Many Title X grantees do not yet have adopted EHR systems; as of 2016, 31% of Title X service sites had not adopted EHR systems. Instead, these sites use various systems (e.g., billing systems, Department of Social Services Medicaid portals) to collect FPAR data for aggregate submission. Many are unable to begin reporting FPAR 2.0 data electronically on January 1, 2022, as EHR implementation typically takes 9 to 12 months for implementation.⁴ Instead, if FPAR 2.0 goes into effect on that date, they will need to collect and process data elements for every visit, and then determine how to deidentify line-item records so that they can be transmitted securely. This is not only about the effective use of Title X resources, but also about the security and confidentiality of clients' sensitive health information.

NFPRHA requests that OPA complete an up-to-date burden study to provide a complete and accurate estimate of the burden of 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 FPAR Burden Study. The Planning Annual Report (FPAR) Burden Study⁵, was published in 2009 using data collected from Title X grantees all using the old FPAR system that reports data aggregately (as opposed to encounter-level data reporting and collection). OPA has no current network regarding burden and costs associated with encounter-level data collection and the proposed new FPAR 2.0 system. The FPAR Burden Study estimated gross non-labor costs to be \$163,300 (or \$2,207 per respondent) and annualized labor costs to be \$1,100,000. It is inappropriate for OPA to use data collected from the 2009 FPAR Burden Study to quantify costs for implementing FPAR 2.0 as proposed, as these estimates relate to a completely different iteration of the proposed overhaul of FPAR that would be implemented at the subrecipient level. Indeed, it was not until 2012 that OPA engaged an FPAR Expert Work Group consisting of Regional FPAR grantees, federal and federally funded stakeholders to assess the feasibility of revising the data elements and transitioning FPAR to the new system. In 2014, OPA requested Office of Management and Budget (OMB) approval to begin assessing the feasibility of encountering 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. 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 and Medicaid. While HITECH Act funds supported some, but not all, Title X service sites to adopt and implement electronic reporting, the health IT industry gave rise to a multitude of EHR vendors and platforms and, in turn, challenges with interoperability. Health data exchange and interoperability solutions are available to streamline data exchange and electronic reporting (reducing staff hours) and costs for customizations. In addition, HITECH funds were one-time investments, so funding to support up-to-date systems. Consequently, there is no "one size fits all" approach for implementing FPAR 2.0 electronic reporting from Title X service sites to the subrecipient dyad to invest in upgrading to electronic systems (as applicable) and establishing interoperability between systems. Of note, though local and state health departments were eligible to receive HITECH Act funds and understood that IT systems require staff expertise, time, and resources to meet the timelines mandated by HITECH.⁹ Based on NFPRHA's estimates, all Title X service sites operated by local and state health departments. Because many of these service sites did not benefit from HITECH funding, many legacy systems, they lack the IT infrastructures needed to implement FPAR 2.0 in accordance with OPA's project schedule. If local and state health departments could not meet the timelines mandated by HITECH, they also cannot implement FPAR 2.0.

In 2020, NFPRHA began conversations with various grantees and health information system subject matter experts about the costs of implementing FPAR 2.0. Based on information collected, NFPRHA estimates that implementing FPAR 2.0 as proposed will amount to \$65,000,000, or an average of \$4,680,000 across all 72 service grantees.¹⁰ Spending will be on engaging EHR vendors or other external consultants to design and perform system upgrades, as well as purchasing or subscribing to a SFTP server. These cost estimates do not include the costs of system 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 required to implement FPAR 2.0 as currently planned. Based on this data, NFPRHA estimates grantee organizations each will spend 183 hours on the cost of working on tasks related to implementation, including selecting and/or creating a contract with a vendor, upgrading and map out FPAR 2.0's data elements to existing standardized value sets, training health care providers on the system, preliminary data collection, running reports to ensure data mapping is correct, and performing quality assurance of program data. Based on the hourly wage estimates published in the Supporting Statement for the Title X FPAR 2.0 (\$40.12), these burden hours amount to \$7,416 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 borne by the 3,825 service sites.¹² Based on information submitted by 36 grantees in March 2021, NFPRHA estimates that each grantee will spend 183 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 1,000 subrecipients. NFPRHA estimates that current subrecipients will spend an average of \$18,000 in one-time non-labor costs, primarily paid to EHR vendors for changes to their EHRs or practice management systems (e.g., build new or update existing templates, code new data elements, etc.). For all subrecipients these one-time non-labor costs amount to \$19,080,000. To reiterate, subrecipients will incur these capital costs during a public health emergency – a time when resources have been redirected to emergency response and revenue has dwindled. Based on the above estimates, the cost of implementing FPAR 2.0 as currently planned across the Title network is \$22,700,000. NFPRHA requests information to substantiate this estimate upon request.

OPA is proposing this time commitment take place when grantees and subrecipients are continuing to respond to – and manage – a public health emergency. Costs for ongoing operations and maintenance are not included in these estimates. They also do not include the cost of training and staff at Title X service sites to document more than 20 additional data elements as part of every single Title X visit.

NFPRHA believes the 23 additional elements go beyond what is necessary for quality improvement and what is required for operational guidance. NFPRHA asks for additional opportunities for grantees and other stakeholders to provide feedback on 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 Goals, which include: giving priority in the provision of family planning services to low-income individuals, reducing invasive cervical cancer and infertility through chlamydia screening, and increasing program efficiency by monitoring the cost of care. However, the current FPAR clinic visit record, which are irrelevant to monitoring Title X program compliance and accountability to the above performance goals – being minimally burdensome

These data elements seem to map more to the elements in a research database than in a program monitoring tool, requiring information from patients at every single visit, even though such information is not necessitated by clinical practice guidelines.

Some proposed data elements pertain to services that are outside of the core family planning services in the Recommended 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 visit directly to achieving or preventing pregnancy include screening for breast and cervical cancer,” they certainly should not be an accountability to program goals. We request additional justification for collecting these new data elements beyond the program objectives.

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 Longitudinal Survey of Youth (NSFG) population-level, nationally representative dataset that gathers information on pregnancy and births, infertility, use of contraception, and sexual activity. However, while NSFG surveys a representative sample of respondents and allows them to voluntarily respond, the data collection for FPAR 2.0 will be required for every patient visit. More specifically, OPA has proposed that Title X service sites report the following data points 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 patient is in a current relationship [unless the patient is at increased risk for infection or is seeking evaluation and treatment for sexually transmitted infections]. These 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 questions at every visit, nor would their responses be reported at the encounter level to the federal government. When a patient is referred to a Title X site for its benefit and requires those accessing services through the safety net to provide such information as a precursor to receiving services, it is 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 care is tracking patients' intention to either become pregnant or prevent a pregnancy in the next year. Research suggests that asking about reproductive intentions over the next year; doing so is inconsistent with how they think about and approach their reproductive lives. For patients who do not have children or not have children, suggesting that asking about reproductive "intentions" or "plans" may be problematic.²² Regardless of the reason for the visit, could compromise the patient-provider relationship by breaking rapport and shifting the focus away from the patient's needs. Reflecting current research that patients prefer to be asked about their service needs than about pregnancy intentions, a more patient-centered approach to measurement. An example of an alternative measure that assesses patients' desire for Contraception (SINC)²⁴ question developed by the University of California, San Francisco (UCSF) Person-Centered Care and Reproductive Justice advocates. Of note, UCSF has an award from OPA to develop a new electronic Clinical Quality Measure (eCQM) SINC question to define the denominator. As such, use of the SINC question in FPAR 2.0 would be consistent with current research. This measure also would facilitate the removal of problematic data elements related to sexual activity, which have been identified as a "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 in the last five years, HPV test performed at this visit, and HPV test result. Collecting and reporting all five data elements would have minimal benefit.

FPAR 2.0 suggests the Title X service sites collect and report five different data elements related to cervical cancer screening in the last five years, HPV test performed at this visit, and HPV test result. Collecting and reporting all five data elements would have minimal benefit.

The collection of information on a patient's Pap (at current and previous visit) and HPV tests performed may be helpful in understanding the number of tests provided during a specified period, the distribution of abnormal cytology results, or use of different testing methods (e.g., hrHPV-alone, co-testing) during a specified period. However, the utility of collecting of Pap test in the last five years is limited. The guideline recommends cervical cytology alone at a five-year interval and there is no national benchmark pertaining to HPV testing. Furthermore, there is no way for grantees and subrecipients to differentiate whether an HPV test was done as part of a screening test or for post-treatment surveillance.

It is critical to underscore that ASCCP Risk-Based Management Consensus Guidelines for abnormal cervical cancer screening are based on patient age and other risk factors that support screening.²⁶ As a result, none of these cervical cancer screening-related data elements will measure adherence to screening guidelines or track progress towards Healthy People 2030 goals (i.e., increase the proportion of women aged 21-65 on the most recent guidelines), as described in the Supporting Statement for the Title X FPAR 2.0.^{27 28} Therefore, the data elements that subrecipients must make to collect and report these additional data elements will produce data with little – if not no – value for performance.

New Data Elements: Cardiovascular Risk Factors

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

The collection of information on a patient's Pap (at current and previous visit) and HPV tests performed may be helpful. The number of tests provided during a specified period, the distribution of abnormal cytology results, or use of different tests (hrHPV-alone, co-testing) during a specified period. However, the utility of collecting of Pap test in the last five years is not clear. The guideline recommends cervical cytology alone at a five-year interval and there is no national benchmark pertaining to HPV testing. Furthermore, there is no way for grantees and subrecipients to differentiate whether an HPV test was done as part of a screening test or for post-treatment surveillance.

Separate reporting of systolic and diastolic blood pressure measurements does not make sense clinically, as the interpretation can be tempered by the age of the patient, anxiety level when blood pressure is measured (i.e., "white coat" hypertension), and if pressures are quite elevated, the diagnosis of hypertension cannot be made without multiple measurements on several occasions. If blood pressure is a priority for OPA, this data element should be reconfigured to identify whether diagnosis of hypertension 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 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. The rationale to record and report body weight at every visit, and OPA does not state why it is necessary to collect this information. Statement for the Title X FPAR 2.0.³⁰ Even when collecting a patient's height and weight data is clinically indicated, it is not clear whether that patient is overweight or obese – and, in turn, at risk for cardiovascular disease. Developed for and tested in clinical settings, BMI is not a useful indicator of health, especially for women of color, because it fails to account for differences in body composition and differences.³¹ Furthermore, the practice of weighing clients at every visit – even health education sessions or when receiving 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) and do not receive the same standard of care and should not be subject to weight stigmatization at every visit. Weight stigma in clinical settings suggests that this stress can exacerbate poor physical health outcomes for obese individuals³³, with the potential to perpetuate disparities in overweight and obesity. It would be more appropriate to focus on measures of health that are scientifically supported. Screening for cardiovascular risk factors is indicated to support contraceptive decision-making (i.e., to ensure a patient is using contraceptives and other hormonal contraception) and pre-pregnancy health. While it may be desirable to capture this information, the expectation or requirement for Title X providers to obtain information beyond that which is clinically necessary. Acc

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 NPIs are not required for those providers who do not transmit Health Information Portability and Accountability Act (HIPAA) information "incident to" another provider. Furthermore, only advanced practice clinicians may obtain an NPI; however, in 2019, NPIs were performed by other types of providers, including registered nurses, registered nurses with an expanded scope of practice, and social workers.³⁴ As such, many providers delivering Title X services do not have individual NPI to report for FPAR

NFPRHA requests further clarification on the steps OPA will take to maintain the confidentiality of the sensitive personal health information. Confidentiality is a hallmark of the Title X program, and all patients, including adolescents, are guaranteed confidentiality by federal regulations, and case law. Further, they are grounded in medical and ethical standards and reflect research demonstrating that patients would not seek needed health services.³⁵ Despite this assurance, the Supporting Statement for the Title X FPAR 2.0 states that the confidentiality of the sensitive personal health information it wants to collect through FPAR 2.0.³⁶ While encounter-level specifications for how the patient identifier data element will be used in a way that ensures that patient confidentiality is maintained, information on the HIPAA Security Rule Standards it will adopt to ensure the appropriate consent and safeguarding of data at subrecipient levels; for example, specifying encryption standards for data at rest and in motion. Given the cybersecurity risks, it seems imprudent to move forward with FPAR 2.0 without releasing more information about – and seeking stakeholder input on – 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, in the event of disclosure. Several data elements within FPAR are sensitive in nature, as they relate to sexual behaviors and

OPA has historically interpreted 42 CFR Part 59 as precluding the collection of identifying information in connection with the Title X FPAR. In Statements for the Title X FPAR that were submitted to OMB (dated June 29, 2010 and October 15, 2010), OPA stated:

“Although the FPAR contains several data items of a sensitive nature (e.g., user income and insurance status, user name, STD tests

performed, and Pap and HIV test results), individuals cannot be identified because federal regulation (42 CFR Part 59) prohibits the collection of such data. The FPAR

collects no individual identifiers. These sensitive data are required to monitor compliance with statutory requirements. However, in the February 5, 2021 Supporting Statement for the Title X FPAR 2.0, OPA describes the need to collect the collection of such data “are required to monitor compliance with statutory requirements, program regulations and management.”³⁹

Given this shift in OPA’s justifications to OMB, OPA needs to provide clarification on the permissibility of submitting

NFPRHA supports investments in Title X program infrastructure, including investment in a more contemporary data management system to improve performance; however, such a venture cannot come at the expense of serving those in need of services, specifically people who are uninsured. Such an effort also cannot come at the expense of providing Title X patients with the same standard of care as those in other settings, which is just what FPAR 2.0 - with burdensome and unnecessary data elements that are required for every visit - would do. We urge OPA to pause and re-evaluate FPAR 2.0.

Currently collected in aggregate under OMB No. 0990-0221, this new data collection, Family Planning Annual Report, will be collected at the encounter level and build on the existing data collection and reporting system by adding 23 new data elements to the existing 23 data elements to be collected at every visit).

We write today with significant concerns about the proposed changes in this rule and the impact they will have on patient and provider relationships, would jeopardize patient and provider relationships, interfere with evidence-based practice, and threaten patient confidentiality. The proposed FPAR 2.0 data elements risk the trust, confidentiality and privacy that’s essential in providing care to the people we see in our clinic. Patient-provider relationships will be harmed by inquiring about the invasive and unnecessary data elements, which include details on a patient’s sexual activity, intention to become pregnant, sexually transmitted infections,

The proposed data elements do not adhere to modern sexual and reproductive health clinical guidelines and have the potential to erode trust with diverse Title X patient populations. These data elements are irrelevant to monitoring the Title X program's 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, especially telehealth visits, and collecting itemized data and additional personal information from patients would interfere with preconception counseling during these appointments.

The proposed FPAR 2.0 data elements would also burden providers as they would require significant changes to clinical record systems. Many Title X providers already spend a considerable amount of time on data submission and reporting, and the 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 sensitive data that will be shared with the federal government. Many of the proposed elements should not be collected at the federal level as they constitute protected health information.

Currently collected in aggregate under OMB No. 0990-0221, this new data collection, "FPAR 2.0", proposes to collect data from the existing data collection and reporting system by adding 23 new data elements to FPAR's standard set of data elements (collected 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 data collection that is 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 and manage the Title X program.

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

At this time – against the backdrop of a year-long public health emergency that resulted in an unprecedented drop in provider network’s capacity after an estimated one in four service sites left the Title X program in response to the 2019 Title X Rule – it 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 in 20 counties. After the regulations were fully implemented, providers across the state were forced to make the difficult decision to close their doors or reduce their 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 sites 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 challenges include Title X and IT staff being diverted to the COVID-19 response, budget shortfalls amidst the need to purchase PPE and other supplies, resigning or going on extended leave for personal or health-related reasons, implementation of telehealth services, and other additional burdens have challenged the network to provide low-income individuals with family planning and related services.

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

Essential Access requests that OPA complete an up-to-date burden study to provide a complete and accurate estimate of the cost burden. Cost burden estimates in the Public Comment Request are extremely low and based on an inappropriate and incredibly outdated Planning Annual Report (FPAR) Burden Study, was published in 2009 using data collected from Title X grantees much before the developments have taken place that make the data collected no longer relevant.

OPA has not collated recent feedback from the Title X network regarding costs associated with encounter-level data elements. Estimates in the FPAR Burden Study, where gross non-labor costs were estimated to be \$163,300 (or \$2,200 per respondent) and labor costs estimated at \$106,880 (or \$1,444 per respondent)³, are based on the cost and time burdens of implementing a new FPAR encounter-level data reporting and collection system. It is inappropriate for OPA to use data collected from the 2009 FPAR encounter-level data reporting system currently proposed, as these estimates relate to a completely different iteration that is substantially less burdensome on grantees and subrecipients.

Due to challenges with interoperability (i.e., electronic sharing of data between systems), there is no “one size fits all” reporting from Title X service sites to grantees, necessitating that each grantee-subrecipient dyad invest in upgrades to their respective systems between their respective systems. In addition, each sub-recipient utilizes its electronic health record system differently, and 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 costs for four staff persons working a combined 2400 hours on tasks related to implementation, including implementing a new system to accommodate the additional data, updating and testing subrecipient configurations in the new data system, updating additional data elements, training subrecipient staff on how to collect new data elements and how to use the new system, and vendors to make updates to EHR systems including new fields and report modifications, and performing quality assurance.

We also estimate that each of our subrecipients, whose number we expect to increase to approximately 60 organizations 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 across this single Title X grantee network. Again, OPA is proposing this time commitment take place when we are confronting a COVID-19 public health emergency. Costs for ongoing operations and maintenance are not included in these estimates. We ask health care providers and staff at Title X service sites to document more than 20 additional data elements as part of FPAR 2.0. Essential Access estimates that implementing FPAR 2.0 as proposed at the grantee level will amount to \$480,000 in costs for a management system. Furthermore, we estimate that each of our estimated 60 subrecipients will outlay an average of \$2,000 in non-labor costs, for an estimated total of \$120,000 in non-labor costs across this single Title X grantee network. This comes during the same emergency when resources have been redirected to emergency response and revenue has dwindled due to decreases in ongoing expenses such as computer and software upgrades.

The 23 additional data elements go beyond what is necessary for quality improvement and what is required by statute. We ask for additional opportunities to provide feedback on what additional data elements are feasible to add to the current system that would be 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 Goals, which include: giving priority in the provision of family planning services to low-income individuals, reducing invasive cervical cancer and infertility through chlamydia screening, and increasing program efficiency by monitoring the cost of care. However, these goals, 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 research dataset, requiring Title X service sites to collect excessive information from patients at every single visit, even 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 Quality Family Planning Services (QFP), including elements related to cardiovascular disease risk factors.⁴ While, as OPA has affirmed, it is appropriate to deliver in the context of a family planning visit even though they do not contribute directly to achieving program goals, these elements should not be monitored at the encounter level to monitor accountability to program goals. We request additional justification for these elements as provided by the Healthy People 2030 health objectives.

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 of Family Growth (NSFG) population-level, nationally representative dataset that gathers information on pregnancy and births, infertility, use of contraception, and sexual activity. However, while NSFG surveys a representative sample of respondents and allows them to voluntarily respond, the data collection for FPAR 2.0 will be required for every patient visit. More specifically, OPA has proposed that Title X service sites report the following data points 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 patient is in a current relationship [unless the patient is at increased risk for infection or is seeking evaluation and treatment for sexually transmitted infections]. These data points 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 questions at every visit, nor would their responses be reported at the encounter level to the federal government. When we require such information for its benefit and requires those accessing services through the safety net to provide such information as a precursor to receiving services, it is potentially dissuading patients from coming to us for needed services.

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 in the last five years, HPV test performed at this visit, and HPV test result. Collecting and reporting all five data elements is a 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 in determining the number of tests provided during a specified period, the distribution of abnormal cytology results, or use of different testing methods (e.g., hrHPV-alone, co-testing) during a specified period. However, the utility of collecting of Pap test in the last five years is limited. The guideline recommends cervical cytology alone at a five-year interval and there is no national benchmark pertaining to HPV testing. Furthermore, there is no way to differentiate in the FPAR data whether an HPV test was done as part of routine screening or for post-treatment surveillance.

It is critical to underscore that ASCCP Risk-Based Management Consensus Guidelines for abnormal cervical cancer screening are based on patient age and other risk factors that support screening.⁹ As a result, none of these cervical cancer screening-related data elements measure adherence to screening guidelines or track progress towards Healthy People 2030 goals (i.e., increase the proportion of women aged 21-65 on the most recent guidelines), as described in the Supporting Statement for the Title X FPAR 2.0.^{10 11} When extracted, these data elements do not 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 risk factors: 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 blood pressure should be tempered by the age of the patient, anxiety level when blood pressure is measured (i.e., "white coat" hypertension), and other factors. If blood pressures are quite elevated, the diagnosis of hypertension cannot be made without multiple measurements on several occasions. If blood pressure is a priority for OPA, this data element should be reconfigured to identify whether diagnosis of hypertension 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 limited to tobacco smokers, using those listed by the US Preventive Services Task Force.

The collection of height and weight data, presumably to calculate body mass index (BMI), is problematic. From a clinical perspective, OPA should collect and report body weight at every visit, and OPA does not state why it is necessary to collect this information and how it is used. Title X FPAR 2.0. Even when collecting a patient's height and weight data is clinically indicated, such measurements are not helpful for identifying overweight or obese – and, in turn, at risk for cardiovascular disease. Developed for and tested on a sample of predominantly white individuals, BMI is an indicator of health, especially for women of color, because it fails to account for differences in body composition, fitness, and muscle mass. The practice of weighing clients at every visit – even health education sessions or when not clinically indicated – may contribute 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 service sites should not be subject to weight stigmatization at every visit. Weight stigma invokes psychological stress and emotional distress, leading to poor physical health outcomes for obese individuals¹⁶, with the potential to perpetuate racial/ethnic and socioeconomic disparities. OPA should move away from this measure and focus on measures of health that are scientifically valid and designed for diverse populations. Screening for cardiovascular risk factors is indicated to support contraceptive decision-making (i.e., to ensure a patient is using effective contraceptives and other hormonal contraception) and pre-pregnancy health. While it may be desirable to capture these data elements, OPA should not expect or requirement for Title X providers to obtain information beyond that which is clinically necessary. Access to these data elements should not 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 treat Medicare Act- (HIPAA) covered data or those who provide services “incident to” another provider. Furthermore, only advanced practice nurses, physician assistants, and other health professionals. In 2019, 7.4% of all Title X family planning encounters in the Essential Access network were performed by other service providers, including practical nurses, health educators, and social workers. As such, many of our providers delivering Title X services do not have NPI numbers.

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. Confidentiality is a hallmark of the Title X program, and all patients, including adolescents, are guaranteed confidentiality under federal regulations, and case law. Further, they are grounded in medical and ethical standards and reflect research demonstrating that patients would not seek needed health services.¹⁷ Despite this assurance, the Supporting Statement for the Title X FPAR 2.0 requests the confidentiality of the sensitive personal health information it wants to collect through FPAR 2.0.¹⁸ Despite a range of information, it generally is considered to be information that carries with it unusually high risks in the event of disclosure, 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 confidentiality is preserved. Furthermore, OPA has not provided information on the HIPAA Security Rule Standards for the safeguarding of this encounter-level data at the federal, grantee, and subrecipient levels; for example, specifying encryption and cybersecurity issues that all organizations currently are facing, it is imprudent to move forward with FPAR 2.0 without stakeholder feedback on – the steps that OPA will take to protect FPAR 2.0’s encounter-level data from unauthorized access. Additional steps will be required to take.

Essential Access requests that OPA establish a new timeline for FPAR 2.0 planning and implementation given the challenges we are facing. Even in the absence of the above challenges, the current timeline for FPAR 2.0 data collection to begin on 12/1/2020, Essential Access would need to upgrade to its information technology (IT) infrastructure, as would its projected subrecipients. OPA has not released final specifications for (i.e., instructions for how to collect) FPAR 2.0’s data elements, including how to collect standardized value sets. In the absence of these specifications, we are in the difficult position of having to wait while the infrastructure narrows.

Currently, we estimate it will take approximately 12 months to provide technical assistance to 60 subrecipients to add FPAR 2.0 data to their systems. Technical assistance to help subrecipients update their data reports. In addition, concurrently it will take us an estimated 12 months to upgrade our system and agency configurations inside that system. Extending this timeline is the limited availability of subrecipient staff and 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 need to train care providers and staff on how to collect new data elements, conduct preliminary data collection, run reports to ensure data accuracy, and assurance of preliminary data collected, as needed, for a total of 1200 hours. Initiating upgrades before final specifications would require revisions that would carry additional costs and burden hours spent.

The current FPAR 2.0 project stands to severely disrupt operations during already uncertain times. Essential Access, while recruiting additional safety net providers to join its network, an ongoing effort since the 2019 Title X Rule took effect, has seen a decline in Title X patients that resulted in 80% fewer Title X patients served in 2020. We are also concerned about losing existing subrecipients and the burden on them.

We are striving to see more patients after unprecedented declines in patient census. While we agree that the Title X program needs to be monitored and improved, such an endeavor cannot come at the expense of serving those in need, the uninsured, and under-insured. Such an effort also cannot come at the expense of Title X patients receiving the same quality of care as 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, we will evaluate FPAR 2.0.

Currently collected in aggregate under OMB No. 0990-0221, this new data collection, Family Planning Annual Report (FPAR) 2.0, will be collected at the encounter level and build on the existing data collection and reporting system by adding 23 new data elements to the existing 10 data elements to be collected at every visit).

We write today with significant concerns about the proposed changes in this rule and the impact they will have on patient-provider relationships. The proposed changes would jeopardize patient and provider relationships, interfere with evidence-based practice, and threaten patient confidentiality. The proposed FPAR 2.0 data elements risk the trust, confidentiality and privacy that's essential in providing care to patients and individuals who are undocumented.

Patient-provider relationships will be harmed by inquiring about the invasive and unnecessary specifics in many of the proposed data elements, such as details on a patient's sexual activity, intention to become pregnant, sexually transmitted infection testing and more. These data elements are irrelevant to monitoring the Title X program for compliance and accountability to performance and have the potential to harm a provider's ability to build and maintain trust with patients. These data elements are irrelevant to monitoring the Title X program for compliance and accountability to performance.

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

It is unclear what the patient identifier will be under FPAR 2.0, but even if data is de-identified, there will still be sensitive information. This data will be shared with the federal government. Many of the proposed elements should not be collected at the federal level as they constitute protected health information.

The requirements are onerous and will discourage small clinics from continuing to participate in Title X.

The requirements will substantially alter the patient-provider interaction and foster distrust among patients due to the

Marginalized populations most in need of the reproductive healthcare only available to them through Title X will be t

Not only does FPAR 2.0, as proposed, require cost and time (i.e., burden hour) investments that are exponentially higher than those required by the Federal Register (86 FR 9077); it also puts forward data collection requirements that far exceed the minimum amount of data collection required by statutory and regulatory requirements and to manage the Title X program.

Not only does FPAR 2.0, as proposed, require cost and time (i.e., burden hour) investments that are exponentially higher than those required by the Federal Register (86 FR 9077); it also puts forward data collection requirements that far exceed the minimum amount of data collection required by statutory and regulatory requirements and to manage the Title X program.

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) program**. FPCI has spent roughly the last 18 months desperately trying to recruit and onboard new clinics and providers 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 the pandemic. **Our primary partner with to provide Title X services are Federally Qualified Health Centers and small, localized public health facilities. We are currently adjusting systems at these facilities to manage disaster response.** The pandemic is not over and any attempt to implement a centralized data system severely disrupt and undermine our ability to respond to these top priorities of stabilizing and growing our network.

Even in the absence of the above challenges, **the current timeline for FPAR 2.0 data collection to begin on January 1, 2023** is unrealistic. FPCI would need to upgrade to its information technology (IT) infrastructure, as would its 13 subrecipients. However, **the current specifications** for (i.e., instructions for how to collect) FPAR 2.0's data elements, including how to map each data element to the existing data systems, in the absence of these specifications, we are in the difficult position of having to wait while the time window needed to

Current OPA timelines also assume a level of baseline technology at both the Title X grantee and subrecipient levels. **Current systems use paper systems to collect FPAR data for aggregate submission.** As data system and EHR enhancements typically take six to eight months for implementation. Instead, if FPAR 2.0 goes into effect on that date, we will need to collect and report the proposed data elements for every visit, and then determine how to deidentify line-item records so that they can be transferred to the federal government. **This raises concerns about the effective use of Title X resources, but also about the security and confidentiality of client information.**

With the addition of 23 new data elements – many of which are irrelevant to monitoring Title X program compliance goals – FPAR 2.0 represents an effort that has no intention of being minimally burdensome. It corresponds to the current monitoring tool to a research dataset, requiring Title X service sites to collect excessive information from patients at a level not necessitated by clinical practice guidelines or other evidence-based standards.

OPA has proposed that Title X service sites report the following three data fields for patients at every visit: Ever had an STI, Ever had a sexually transmitted infection, and Ever had a sexually transmitted infection. Asking these three data points at every visit is **burdensome and threatens the patient-provider relationship.** It is not reasonable to expect non-Title X settings would not be asked to provide responses to **these personal, guideline-unconcordant questions** at the encounter level to the federal government. When the federal government begins collecting research data for its benefit, it is not a safety net to provide such information as a precursor to receive care, it exacerbates medical mistrust, potentially disuading patients from seeking care.

Separate reporting of systolic and diastolic blood pressure measurements does not make sense clinically, as the must be tempered by the age of the patient, anxiety level when blood pressure is measured (i.e., “white coat” hypertension). If blood pressures are quite elevated, the diagnosis of hypertension cannot be made without multiple measurements on several occasions. **Pressure is a priority for OPA, this data element should be reconfigured to identify whether diagnosis of hypertension 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 identify whether an intervention(s) offered to tobacco smokers, using those listed by the US Preventive Services Task Force.

FPCI believes the collection of height and weight data, presumably to calculate body mass index (BMI), is problematic. **There is no rationale to record and report body weight at every visit, and OPA does not state why it is necessary to collect this data.** **Supporting Statement for the Title X FPAR 2.0.** Even when collecting a patient’s height and weight data is clinically useful for identifying whether that patient is overweight or obese – and, in turn, at risk for cardiovascular disease. Developed for European men, BMI is not a useful indicator of health, especially for women of color, because it fails to account for body composition and nutritional differences. Furthermore, the practice of weighing clients at every visit – even health education sessions – can be a barrier from accessing services due to experiences of body shame and weight discrimination.

the Supporting Statement for the Title X FPAR 2.0 fails to address how OPA will **maintain the confidentiality of the data collected through FPAR 2.0.13** While encounter-level data will be de-identified, **OPA has not released specifications on how the data will be used in a way that ensures that patient confidentiality is preserved.** Furthermore, **OPA has not provided information on how it will adopt to ensure the appropriate consent and safeguarding of this encounter-level data at the federal, grantee, and subgrantee levels.** **OPA has not provided information on the standards for data at rest and in motion.** Given the **cybersecurity issues that all organizations currently are facing** and the **need to ensure that data is protected without releasing more information about – and seeking stakeholder feedback on – the steps that OPA will take to address these issues, OPA should be required to release information on unauthorized access, use, and disclosure, as well as what steps we will be required to take.**

The new FPAR data collection system is likely to reduce providers’ willingness to participate in Title X, which would be a significant loss for the US.

Marginalized populations would likely hesitate to seek services from Title X providers because there would be risks t

The data provided by the new system are likely to be biased because of difficulties for smaller Title X providers with

Not only does FPAR 2.0, as proposed, require cost and time (i.e., burden hour) investments that are exponentially higher than those required by the Federal Register (86 FR 9077); it also puts forward data collection requirements that far exceed the minimum amount of resources required by statutory and regulatory requirements and to manage the Title X program.

Not only does FPAR 2.0, as proposed, require cost and time (i.e., burden hour) investments that are exponentially higher than those required by the Federal Register (86 FR 9077); **it also puts forward data collection requirements that far exceed the minimum amount of resources required by statutory and regulatory requirements and to manage the Title X program.**

PHS has experienced several challenges since 2019, **including the loss of Title X, which comprised one-third of PHS' revenue, and the departure of key clinical staff and required the Centers to drastically reduce their operating hours, which was a significant loss for several months.** This loss, combined with the onset of COVID-19, has been devastating for PHS' SRH Centers. From 2019 to 2020, PHS has been struggling with the implementation of telemedicine services. Already reeling from staffing and operational challenges related to relinquishing Title X, clinical and operations staff have been unable to fully implement telemedicine services.

Even in the absence of the above challenges, **the current timeline for FPAR 2.0 data collection to begin on January 1, 2020, requires that PHS would need to upgrade to its information technology (IT) infrastructure, as would our five former subrecipients. PHS has not released final specifications** for (i.e., instructions for how to collect) FPAR 2.0's data elements, including how to map data to value sets. In the absence of these specifications, we are in the difficult position of having to wait while the time window closes.

Currently, we estimate it will take 3 months to implement and test the systems upgrades needed to collect and report data. **PHS would need to create new clinical workflows to align with the new FPAR 2.0 framework and modify existing EMR systems. 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 develop a reporting framework that would allow for the submission and validation of these new data elements.**

After making system upgrades, PHS will require 3 months to train health care providers and staff on **how to collect data, how to enter data, how to collect data, how to run reports to ensure data mapping is correct, and perform quality assurance of preliminary data collection.**

Cost burden estimates in the Public Comment Request are extremely low and based on an inappropriate and outdated study. The Family Planning Annual Report (FPAR) Burden Study², was published in 2009 using data collected from Title X sites. Several developments have taken place that translate to the data collected no longer being relevant.

The addition of **23 new data elements** – many of which are irrelevant to monitoring Title X program compliance and quality – in FPAR 2.0 represents an effort that has no intention of being minimally burdensome.

Furthermore, some proposed data elements pertain to services that are outside of the core family planning services included in the Quality Family Planning Services (QFP), including elements related to cardiovascular disease risk factors. While, as OPA has affirmed, "it is appropriate to deliver in the context of a family planning visit even though they do not contribute directly to achieving the goal of reducing rates of HIV and cervical cancer," they certainly should not be monitored at the encounter level to monitor accountability to program goals. **PHS is collecting these new data elements beyond the rationale provided by the Healthy People 2030 health objectives.**

OPA has proposed that Title X service sites report the following three data fields for patients at every visit: Ever had sex, ever had a sexually transmitted infection (STI), and ever had a sexually transmitted infection (STI) in the last 12 months. **Asking these three data points at every visit is burdensome and threatens the patient-provider relationship. It is inconsistent with the CDC's 2010 STI guidelines, which recommend assessing whether an adult or adolescent patient is sexually active only annually.** OPA's proposal for reporting STI data is inconsistent with the CDC's 2010 STI guidelines, which recommend assessing whether an adult or adolescent patient is sexually active only annually seeking evaluation and treatment for sexually transmitted infections (STIs)).⁷ These sexual activity-related data fields are not necessary to monitor accountability to program goals.

FPAR 2.0 suggests the Title X service sites collect and report **five different data elements related to cervical cancer** test in the last five years, HPV test performed at this visit, and HPV test result. Collecting and reporting all five data elements is a burden with minimal benefit.

Separate reporting of systolic and diastolic blood pressure measurements does not make sense clinically, as the data must be tempered by the age of the patient, anxiety level when blood pressure is measured (i.e., “white coat” hypertension). If blood pressures are quite elevated, the diagnosis of hypertension cannot be made without multiple measurements on several occasions. If blood pressure is a priority for OPA, this data element should be reconfigured to identify whether diagnosis of hypertension 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 an intervention(s) offered to tobacco smokers, using those listed by the US Preventive Services Task Force.

PHS believes the collection of height and weight data, presumably to calculate body mass index (BMI), is probably not a rationale to record and report body weight at every visit, and **OPA does not state why it is necessary to collect this data.** **Supporting Statement for the Title X FPAR 2.0.** Even when collecting a patient’s height and weight data is clinically useful for identifying whether that patient is overweight or obese – and, in turn, at risk for cardiovascular disease. Developed for European men, BMI is not a useful indicator of health, especially for women of color, because it fails to account for body composition and nutritional differences. Furthermore, the practice of weighing clients at every visit – even health education sessions – is a barrier from accessing services due to experiences of body shame and weight discrimination.

Screening for cardiovascular risk factors is indicated to support contraceptive decision-making (i.e., to ensure appropriate use of oral contraceptives and other hormonal contraception) and pre-pregnancy health. While it may be desirable to capture information on explicit expectation or requirement for Title X providers to obtain information beyond that which is clinically necessary, **document and report these measurements for every visit.**

While most advanced practice clinicians have a NPI number, they are not required for those providers who do not treat patients. Under the HIPAA Act- (HIPAA) covered data or those who provide services “incident to” another provider. Furthermore, only advanced practice nurses, health educators, and social workers. **As such, many of our providers delivering Title X services do not have a NPI number.**

the Supporting Statement for the Title X FPAR 2.0 fails to address how OPA will maintain the confidentiality of the data collected through FPAR 2.0. While encounter-level data will be de-identified, **OPA has not released specifications on how the data will be used in a way that ensures that patient confidentiality is preserved. Furthermore, OPA has not provided information on how OPA will adopt to ensure the appropriate consent and safeguarding of this encounter-level data at the federal, grantee, and subgrantee levels.**

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 instructions for how to collect FPAR 2.0's data elements, including how to map each data element and response options to existing specifications, we are in the difficult position of having to wait while the time window needed to implement systems

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 report encounter-level data through FPAR 2.0. This includes **steps to upgrade the current Title X data system** to report their current electronic health record (EHR) or electronic data collection system to report specific data elements and map data elements 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 staff, collect data elements, conduct preliminary data collection, run reports to ensure data mapping is correct, and perform validation** needed.

With the addition of 23 new data elements, many of which are irrelevant to monitoring Title X program compliance, requiring Title X service sites to **collect excessive information from patients at every single visit, even though such information is not in 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 Recommended Family Planning Services (QFP), including elements related to cardiovascular disease risk factors. While, as OPA has affirmed, these services "deliver in the context of a family planning visit even though they do not contribute directly to achieving or preventing cancer," they certainly should not be monitored at the encounter level to monitor accountability to program goals. **We are adding new data elements beyond the rationale provided by the Healthy People 2030 health objectives.**

the Supporting Statement for the Title X FPAR 2.0 fails to address how OPA will maintain the confidentiality of data collected through FPAR 2.0. While encounter-level data will be de-identified, **OPA has not released specifications for how data will be used in a way that ensures that patient confidentiality is preserved. OPA has not provided information on the HIPAA requirements for appropriate consent and safeguarding of this encounter-level data at the federal, grantee, and subrecipient levels; for OPA and in motion.**

Despite a range of opinions about what **qualifies as sensitive health information,** it generally is considered to be information of a sensitive nature in the event of disclosure. **Several data elements within FPAR are sensitive in nature, as they relate to sexual behavior**

many **electronic health record (EHR) systems continue to lack data elements that are part of both FPAR 1.0 and 2.0, and the lack of staff time and technical assistance to build out those missing data elements.** In particular, the lack of standard fields for counseling, and the contraceptive method a patient is using as of the end of their visit have presented serious barriers to the implementation of FPAR 2.0. Needs assessments should be conducted to ensure that the data elements are consistent with the contraceptive care workflow at the particular agency. The Title X network will need technical support and resources to integrate these new systems.

We would welcome OPA's advocacy with government offices like ONC and with EHR vendors around including far more data elements so that 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.** In having **three measures of sexual activity for research purposes, it is likely too burdensome to build out and maintain the data collection and documentation.** Likewise, it seems that the **two "reason for no contraceptive method" data elements are redundant.** The 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 6 months) is not best practice.** Will the FPAR 2.0 data system be able to do patient matching (at the health facility level) to see whether patients have had cervical cancer, CT/GC, and syphilis according to clinical guidelines?

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 are far greater than the data needed to monitor compliance with statutory and regulatory requirements and to manage the Title X program.

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 are far greater than the 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 the network’s capacity after an estimated one in four service sites left the Title X program in response to the 2019 Title X funding cuts—feasible. **We are working hard to hold on, rebuild, and continue providing critical services to patients.**

Every Body Texas has experienced several challenges since 2019. Every Body Texas moved quickly at the start of the pandemic, 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 service closures—and have reported serving fewer clients, even as they worked tirelessly to maintain access to Title X services and teleservices.

Most pressing for **sub-recipients is the reality that reduced client volume has translated into reduced revenue.** Every Body Texas has navigated state-level funding and policy changes that threatened the sustainability of the family planning safety net. Continued loss of funding. Sub-recipients are concerned that women’s health funding appropriated by the Texas Legislature and administered by the Health and Human Services Commission (HHSC) will not adequately address the increased rates of uninsured and unemployed Texans seeking safety net services. Texas’s sub-recipients rely on HHSC’s women’s health funding to support their overall family planning projects, despite the fact that **continued funding cuts could be adverse impacts on Every Body Texas’s Title X Project—including but not limited to reduced client volume and service closures.**

Even in the absence of the above challenges, **the current timeline for FPAR 2.0 data collection to begin on January 1, 2023.** Ahlers & Associates, the data warehouse for Every Body Texas, has estimated that it will need 520 hours to upgrade its infrastructure.

Twenty of Every Body Texas’s 37 subrecipients that do not use Ahlers & Associates software or web-based applications will need to integrate new data fields to their EMRs for the new data elements and update extraction methods and tools—in addition to conducting additional testing. All subrecipients would require training and operational changes to ensure the new data elements are populated consistently. **Without clear specifications** for (i.e., instructions for how to collect) FPAR 2.0’s data elements, including how to map each data element to the existing data fields, **in the absence of these specifications, we are in the difficult position of having to wait while the time window needed to implement FPAR 2.0 is closing.** **unknowns on the OPA side, coupled with the diversity of our sub-recipients in terms of size and IT capacity, could impact the timeline for implementation.** With that in mind, and assuming that funding and staff for these new activities is available, **we estimate that it will take 520 hours of effort** in coordination with our data warehouse and subrecipients to implement and test technologies, train staff and conduct basic maintenance.

Every Body Texas requests that OPA complete an up-to-date burden study **to provide a complete and accurate estimate of the costs associated with FPAR 2.0.**

OPA has not collated recent feedback from the Title X network regarding costs associated with encounter-level data collection and reporting elements.

Every Body Texas estimates that **implementing FPAR 2.0 as proposed at the grantee-level will amount to \$82,000** in additional costs based on quotes received from existing vendors, including Ahlers & Associates.

Every Body Texas believes **the 23 additional elements go beyond what is necessary for quality improvement and regulations, and operational guidance.** We ask for additional opportunities to provide feedback on what additional clinic visit record and would be most helpful to us for program management and quality improvement.

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 min

Furthermore, some proposed data elements pertain to services that are outside of the core family planning services in Planning Services (QFP), including elements related to cardiovascular disease risk factors. While, as OPA has affirmed appropriate to deliver in the context of a family planning visit even though they do not contribute directly to achieving and cervical cancer,” they certainly should not be monitored at the encounter level to monitor accountability to program **collecting these new data elements beyond the rationale provided by the Healthy People 2030 health objectives**

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FPAR 2.0 suggests the Title X service sites collect and report **five different data elements related to cervical cancer** test in the last five years, HPV test performed at this visit, and HPV test result. Collecting and reporting all five data e burden with minimal benefit.

Linking test results to test encounters is already a challenge for FPAR 1.0 data elements for pap smears/abnormal res data collection systems for most of our sub-recipients. While connecting tests to results is a worthwhile endeavor, the solutions that serve Title X reporting only, as opposed to care improvements.

Separate reporting of systolic and diastolic blood pressure measurements does not make sense clinically, as the in must be tempered by the age of the patient, anxiety level when blood pressure is measured (i.e., “white coat” hyperten pressures are quite elevated, the diagnosis of hypertension cannot be made without multiple measurements on several pressure is a priority for OPA, this data element should be reconfigured to identify whether diagnosis of hypertension 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 elem 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 not a logical rationale to record and report body weight at every visit, and OPA does not state why it is necessary to do so in its Supporting Statement for the Title X FPAR 2.0. Even when collecting a patient’s height and weight data is clinically useful for identifying whether that patient is overweight or obese – and, in turn, at risk for cardiovascular disease. Developed for European men, BMI is not a useful indicator of health, especially for women of color, because it fails to account for racial and nutritional differences. Furthermore, the practice of weighing clients at every visit – even health education sessions – is a barrier from accessing services due to experiences of body shame and weight discrimination.

Screening for cardiovascular risk factors is indicated to support contraceptive decision-making (i.e., to ensure a patient is using contraceptives and other hormonal contraception) and pre-pregnancy health. While it may be desirable to capture these data, **OPA has an expectation or requirement for Title X providers to obtain information beyond that which is clinically necessary to provide care, document and report these measurements for every visit.**

While most advanced practice clinicians have a NPI number, they are not required for those providers who do not treat patients. HIPAA (Act- (HIPAA) covered data or those who provide services “incident to” another provider. Furthermore, only advanced practice nurses in 2019, 43% percent of all Title X family planning encounters in Every Body Texas’ network were performed by other staff such as practical nurses, health educators, and social workers. **As such, many of our providers delivering Title X services are not licensed healthcare providers.**

the Supporting Statement for the **Title X FPAR 2.0 fails to address how OPA will maintain the confidentiality of patient data collected through FPAR 2.0.** While encounter-level data will be de-identified, **OPA has not released specifications for how data will be stored in a way that ensures that patient confidentiality is preserved. Furthermore, OPA has not provided information on how OPA will adopt** to ensure the appropriate consent and safeguarding of this encounter-level data at the federal, grantee, and subgrantee levels. Standards for data at rest and in motion. Given the cybersecurity issues that all organizations currently are facing, it is not surprising that releasing more information about – and seeking stakeholder feedback on – the steps that OPA will take to protect FPAR 2.0 data use, and disclosure, as well as what steps we will be required to take.

“FPAR 2.0”, proposes to collect visit information at the encounter level and build on the existing data collection and reporting system. FPAR’s standard set of data elements (for a total of 45 data elements to be collected at every visit). While the NYSDOH has a robust data system for monitoring and improving program performance, **the NYSDOH is concerned that implementing the system as defined is not feasible and must be paused.**

The Supporting Statement for the Title X FPAR 2.0 fails to address how **OPA will maintain the confidentiality of the data collected through FPAR 2.0**. While encounter-level data will be partially de-identified, OPA has not released specific details and more particularly in combination with the National Provider ID (NPI), and full birth and visit dates, will be used and preserved.

Furthermore, **OPA has not provided information on the Health Information Portability and Accountability Act** to ensure the appropriate consent and safeguarding of this encounter-level data at the federal, grantee, and subrecipient levels. OPA should ensure data at rest and in motion. Given the cybersecurity issues that all organizations currently face, OPA should engage with stakeholders to ensure that OPA will take to protect FPAR 2.0's encounter-level data from unauthorized access, use, and disclosure, as well as ensure data security.

OPA has proposed that **Title X service sites report the following three data fields for patients at every visit: ever sexually transmitted infection, blood pressure, and provider relationship**. **In addition to the forementioned extreme sensitivity of this information, asking these three data points at every visit is not necessary, and asking these three data points annually** [unless the patient is at increased risk for infection or is seeking evaluation and treatment for sexually transmitted infection]. **It also is inconsistent with current best practice guidelines, which recommend assessing whether a patient has a sexually transmitted infection annually** [unless the patient is at increased risk for infection or is seeking evaluation and treatment for sexually transmitted infection]. **These three data fields also are not needed to monitor Title X grantee and subrecipient accountability to program goals.**

FPAR 2.0 suggests that Title X service sites collect and report on five different data elements related to cardiovascular health: blood pressure, height, weight, and smoking status (detailed as ever smoker, ex-smoker, daily smoker, occasional smoker, and light smoker).

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

FPAR 2.0 suggests the Title X service sites collect and report five different data elements related to cervical cancer screening: cervical cancer screening in the last five years, HPV test performed at this visit, and HPV test result. Collecting and reporting all five data elements is not necessary and has minimal benefit.

FPAR 2.0 further suggests that Title X service sites collect and report on a number of different data elements related to sexually transmitted infections: Chlamydia, gonorrhea, and syphilis, as well as testing at current visit, and rapid antigen testing 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 status at every visit. Existing status would be excessively burdensome and would require significant adjustment as laboratory testing technology advances. Accordingly, we should not be required to document and report these measurements for every visit.

While most advanced practice clinicians have a NPI number, they are not required for those providers who do not provide services "incidental to" another provider. Furthermore, only advanced practice clinicians may obtain an NPI; however, if FPP were performed by other services providers, including registered nurses, licensed practical nurses, health educators, and community health workers, **providers do not have individual NPI to report for FPAR 2.0.**

The implementation of FPAR 2.0 would have burdensome economic consequences both for the NYSDOH and for the NYS contracts with Ahlers and Associates to manage its centralized data system. **Compliance with FPAR 2.0 reporting requirements would require a major overhaul of the current system's complex information technology infrastructure, which would incur substantial costs and burdened. In the absence of complete specifications,** it is difficult to accurately estimate the additional revenue and costs. Ahlers and Associates has estimated a cost of at least \$250,000 but it could cost more.

With 23 additional elements, and their myriad selection options, we anticipate that electronic health record (EHR) vendors will charge tens of thousands of dollars per agency during a time when resources are already severely stretched. With upwards of **total as much as \$500,000, if not more**. While the added cost would be burdensome in general, it would be particularly burdensome for smaller organizations, but also for the larger urban organizations that have struggled to maintain access and service during the pandemic. Further, neither of these costs includes the **inestimable additional expense required for NYSDOH FPP staff and other agencies to allot and coordinate their time and efforts on training and implementing the 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 data elements, including how to map each data element and response option to standardized value sets.

Title X safety net providers and the NYSDOH have experienced several challenges since 2019. The impact of COVID-19 has resulted in closure of a number of the FPP clinics, both temporarily and permanently; implementing and diverting care from the program under the strain of staff redeployed to pandemic response service. Any attempt to implement FPAR 2.0 will disrupt and undermine our ability to respond to these top priorities.

Not only does FPAR 2.0, as proposed, **require cost and time (i.e., burden hour) investments that are exponential in nature, as noted in the Federal Register (86 FR 9077)**; it also puts forward data collection requirements that far exceed the minimum amount of data collection, statutory and regulatory requirements and to manage the Title X program.

Not only does FPAR 2.0, as proposed, require cost and time (i.e., burden hour) investments that are exponentially higher than what is required in the Federal Register (86 FR 9077); it also **puts forward data collection requirements that far exceed the minimum amount of data collection, 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 the network’s capacity after an estimated one in **four service sites left the Title X program in response to the 2019 Title X funding cut**, **not feasible. We are working hard to hold on, rebuild, and continue providing critical services to patients.**

Even in the absence of the above challenges, **the current timeline for FPAR 2.0 data collection to begin on January 1, 2023** is not realistic. MFHC would need to upgrade to its information technology (IT) infrastructure, as would its 15 subrecipients. However, **final specifications** for (i.e., instructions for how to collect) FPAR 2.0’s data elements, including how to map each data element to the existing data elements, are not available.

Currently, we estimate it will take **18-24 months** to implement and test the systems upgrades needed to collect and report data. This includes upgrades to MFHC’s centralized database, customizing reporting and mapping, working with 8 different EHR systems for data mapping, and reporting, data validation and testing, etc. After making system upgrades, MFHC and its subrecipients will need **6-8 months** to train health care providers and staff on how to collect new data elements, conduct preliminary data collection, and perform quality assurance of preliminary data collected, as needed. Initiating upgrades before final specifications are available will require revisions that would carry additional costs and burden hours spent.

Cost burden estimates in the Public Comment Request are extremely low and based on an inappropriate and outdated study. The Family Planning Annual Report (FPAR) Burden Study², was published in 2009 using data collected from Title X service sites. 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 elements.

Secondly, **due to challenges with interoperability** (i.e., electronic sharing of data between systems), there is no “one size fits all” for electronic reporting from Title X service sites to grantees, necessitating each grantee-subrecipient dyad to invest in up to 15 systems for establishing interoperability between their respective systems. In MFHC’s Title X network, there are 15 subrecipients.

we estimate that implementing FPAR 2.0 will amount to \$44,000 in one-time labor costs. This estimate is based on 110 hours on tasks related to implementation, including selecting and/or creating a contract with a vendor, working (with or without FPAR 2.0’s data elements) to existing standardized value sets, training health care providers and staff on how to collect data, collection, running reports to ensure data mapping is correct, and performing quality assurance of preliminary data collection. Subrecipients will spend an average of 40 hours implementing FPAR 2.0, for an estimated total of \$60,000 in one-time labor costs. Again, OPA is proposing this time commitment take place when we are continuing to respond to – and facing burnout from – Title X. Costs for ongoing operations and maintenance are not included in these estimates. They also do not include the additional time for service sites to document more than 20 additional data elements as part of every single Title X visit.

with the addition of 23 new data elements – many of which are irrelevant to monitoring Title X program compliance goals – FPAR 2.0 represents an effort that has no intention of being minimally burdensome. These data elements seem more burdensome than in a program monitoring tool, requiring Title X service sites to collect excessive information from patients at every visit, necessitated by clinical practice guidelines or other evidence-based standards.

some proposed data elements pertain to services that are outside of the core family planning services in the Recommended Quality Family Planning (QFP), including elements related to cardiovascular disease risk factors.⁴ While, as OPA has affirmed, these services “do not deliver in the context of a family planning visit even though they do not contribute directly to achieving or preventing cervical cancer,”⁵ they certainly should not be monitored at the encounter level to monitor accountability to program goals. **Why add new data elements beyond the rationale provided by the Healthy People 2030 health objectives.**

OPA has proposed that Title X service sites report the following **three data fields for patients at every visit: Ever had sex in the last year**. Asking these three data points at every visit is burdensome and threatens the patient-provider relationship. It also conflicts with research which recommend assessing whether an adult or adolescent patient is sexually active only annually [unless the patient is being evaluated and treated for sexually transmitted infections (STIs)].⁷ These sexual activity-related data fields also are inconsistent with accountability to program goals

Another example of a proposed data element that is inconsistent with current research on the provision of patient-centered care is tracking **patients’ intention to either become pregnant or prevent a pregnancy in the next year**. Research suggests that asking about intentions over the next year; doing so is inconsistent with how they think about and approach their reproductive lives and is not common in populations.¹⁰ Indeed, not all individuals overtly plan to have children or not have children, suggesting that asking about pregnancy intentions is problematic.¹¹ Asking patients this kind of a question at every visit, regardless of the reason for the visit, could compromise rapport and shifting the visit away from what the patient wants

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

Separate reporting of systolic and diastolic blood pressure measurements does not make sense clinically, as the information must be tempered by the age of the patient, anxiety level when blood pressure is measured (i.e., “white coat” hypertension). If systolic pressures are quite elevated, the diagnosis of hypertension cannot be made without multiple measurements on several occasions. If blood pressure is a priority for OPA, this data element should be reconfigured to identify whether diagnosis of hypertension 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 included in the list of intervention(s) offered to tobacco smokers, using those listed by the US Preventive Services Task Force.

MFHC believes the **collection of height and weight data, presumably to calculate body mass index (BMI), is problematic** rationale to record and report body weight at every visit, and OPA does not state why it is necessary to collect this information. The Supporting Statement for the Title X FPAR 2.0.19 Even when collecting a patient's height and weight data is clinically indicated, it is not clear whether that patient is overweight or obese – and, in turn, at risk for cardiovascular disease. Developed for and tested in men, BMI is not a useful indicator of health, especially for women of color, because it fails to account for differences in body composition.20 Furthermore, the practice of weighing clients at every visit – even health education sessions or when providing other services due to experiences of body shame and weight discrimination.21

Screening for cardiovascular risk factors is indicated to support contraceptive decision-making (i.e., to ensure a patient is using effective contraceptives and other hormonal contraception) and pre-pregnancy health. While it may be desirable to capture this information, it is not an expectation or requirement for Title X providers to obtain information beyond that which is clinically necessary. AccessMatters does not report these measurements for every visit.

the Supporting Statement for the Title X FPAR 2.0 fails to address how OPA will maintain the confidentiality of data collected through FPAR 2.0.24 While encounter-level data will be de-identified, OPA has not released specifications on how it will ensure that patient confidentiality is preserved. Furthermore, **OPA has not provided information on how it will ensure** the appropriate consent and safeguarding of this encounter-level data at the federal, grantee, and subrecipient levels. Data at rest and in motion. Given the cybersecurity issues that all organizations currently are facing, it seems imprudent to collect more information about – and seeking stakeholder feedback on – the steps that OPA will take to protect FPAR 2.0's data from disclosure, as well as what steps we will be required to take.

AccessMatters is deeply concerned about OPA's proposal for FPAR 2.0. At this time – against the backdrop of a year of unprecedented drop in patient census and following a 46% decline in the network's capacity nationwide after an estimated *response to the 2019 Title X Rule1 – implementation of FPAR 2.0 simply is not feasible.* We are working hard to hold onto our patients.

Title X providers in our network have reported to us that they have *experienced significant impact as a result of the COVID-19 pandemic*, including considerable challenges around logistical changes (e.g., managing waiting room limits, implementing telehealth services, staff shifted to other teams to cover COVID-19 needs, increased turnover), and increased patient need (e.g., patients experiencing more severe conditions due to delaying medical care during COVID-19). Despite COVID-19 vaccination efforts in our region and state, and the impact on our health care provider network continues with its full impact still unknown, our providers with planned timelines will severely disrupt and undermine our ability to respond to these top priorities.

AccessMatters requests that OPA establish a new timeline for FPAR 2.0 planning and implementation given the challenges. The current timeline for FPAR 2.0 data collection to begin on January 1, 2022 is unworkable. In the absence of having to wait while the time window needed to implement systems changes narrows. Currently, we estimate it will take several years of upgrades needed to collect and report encounter-level data through FPAR 2.0.

Despite discussions of FPAR 2.0 dating back several years, as of April 12, 2021, OPA has still not released final specifications for FPAR 2.0's data elements, including how to map each data element and response option to standardized value sets.

Current OPA timelines also assume a level of baseline technology at both the Title X grantee and subrecipient levels. AccessMatters has identified several legacy systems that will need to be redeveloped for FPAR 2.0. If FPAR 2.0 requires manual data entry of FPAR 2.0's 45 proposed data elements for every visit. This cumbersome process will impede the effective use of Title X resources and the possibility of subrecipients opting to leave AccessMatters' Network and the resulting impact due to the burden of data entry.

AccessMatters requests that OPA complete an up-to-date burden study to provide a complete and accurate estimate of the cost burden estimates in the Public Comment Request are extremely low and based on an inappropriate and incredible 2009 Planning Annual Report (FPAR) Burden Study², was published in 2009 using data collected from Title X grantees and subrecipients.

Due to challenges with interoperability (i.e., electronic sharing of data between systems), there is no "one size fits all" solution for reporting from Title X service sites to grantees, necessitating each grantee-subrecipient dyad to invest in upgrading their systems for interoperability between their respective systems. In AccessMatters' Title X Network there are 18 subrecipients using legacy systems. Our estimates that implementing FPAR 2.0 will exceed \$1 million in one-time labor and non-labor costs combined for AccessMatters, plus the cost of an internal team at AccessMatters of five staff persons working at least 200 hours to get systems and processes up and running. 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) operations and maintenance in addition to computer and software upgrades and purchased service costs, or (2) the additional cost to Title X service sites to document more than 20 additional data elements as part of every single Title X visit.

Management of the Title X program entails monitoring progress towards performance goals required by the 1993 Goals and Objectives, which include: giving priority in the provision of family planning services to low-income individuals, reducing invasive cervical cancer and infertility through chlamydia screening, and increasing program efficiency by monitoring the cost of care. However, the current data requirements, which are irrelevant to monitoring Title X program compliance and accountability to the above performance goals – being minimally burdensome.

AccessMatters also has concerns about the invasive nature of the data collection and the questions these additional data elements raise. Healthcare providers need training in trauma-informed care and motivational interviewing to implement best practices with vulnerable patients. As a grantee with a nationally-recognized training team that has experience providing healthcare providers with training in motivational interviewing and delivering trauma-informed care, AccessMatters recommends that OPA outline a detailed plan for how to deliver trauma-informed, comprehensive counseling and care. This is a critical element that must be addressed before implementation of 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 who receive services through the Title X program because they have concerns about the amount and type of sensitive information shared with the federal government.

AccessMatters also strongly encourages OPA to consider adjustments to how demographic data are currently collected from providers about how they can collect current required demographic data elements using a trauma-informed approach. We encourage OPA to explore the options for data collection around gender identity.

Please see the attachment AccessMatters' Standard Demographic Language for additional detail and recommendations for data elements assigned at birth. Pages 14 - 20.

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 Longitudinal Survey of Adolescent Health (NSFG) population-level, nationally representative dataset that gathers information on pregnancy and births, infertility, use of contraception, and sexual activity. However, while NSFG surveys a representative sample of respondents and allows them to voluntarily respond, the data collection for FPAR 2.0 will be required for every patient visit. More specifically, OPA has proposed that Title X providers inquire about 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. This data collection is intrusive, burdensome and threatens the patient-provider relationship. It also is inconsistent with current best practices for Title X programs. An adult or adolescent patient is sexually active only annually [unless the patient is at increased risk for infection or is seeking treatment for sexually transmitted infections (STIs)]. These sexual activity-related data fields also are not needed to monitor our Title X Network's access to and use of Title X 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 in the last five years, HPV test performed at this visit, and HPV test result. Collecting and reporting all five data elements with minimal benefit. The collection of information on a patient's Pap (at current and previous visit) and HPV tests provides, for instance, to compute the number of tests provided during a specified period, the distribution of abnormal cytology results, and the use of screening technologies (cytology-alone, hrHPV-alone, co-testing) during a specified period. However, the utility of collecting this information is questionable, as no national guideline recommends cervical cytology alone at a five-year interval, and there is no national guideline that requires HPV tests to come back as positive.⁸ Furthermore, there is no way for AccessMatters to differentiate whether an HPV test was done for 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 are based 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 measure adherence to screening guidelines or track progress towards Healthy People 2030 goals (i.e., "increase the proportion of women aged 21-65 years who are screened based on the most recent guidelines"), as described in the Supporting Statement for the Title X FPAR 2.0.^{10 11} When used, they should be used 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 risk factors: Blood pressure, Height, Weight, and Smoking status (detailed as ever smoker, ex-smoker, smokes daily, occasional smoker, and never smoker). Separate reporting of systolic and diastolic blood pressure measurements does not make sense clinically, as the interpretation of blood pressure should be tempered by the age of the patient, anxiety level when blood pressure is measured (i.e., "white coat" hypertension), and whether blood pressures are quite elevated, the diagnosis of hypertension cannot be made without multiple measurements on several occasions. If blood pressure is a priority for OPA, this data element should be reconfigured to identify whether diagnosis of hypertension was performed consistent with nationally recognized guidelines.

Smoking status:

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 be offered to tobacco smokers, using those listed by the US Preventive Services Task Force.¹²

Data Elements: Height, Weight, BMI

Height and weight data, presumably to calculate body mass index (BMI), is problematic. From a clinical perspective, there is no clinical indication that height and weight should be collected at every visit, and OPA does not state why it is necessary to collect this information and how it will be used in the Supportive Care program. If collecting a patient's height and weight data is clinically indicated, such measurements are not reliable for identifying patients who are at risk for cardiovascular disease. Developed for and tested on a sample of predominantly white European men, the BMI calculation is not applicable to women of color, because it fails to account for differences in body composition, fitness levels, and nutritional status. Collecting height and weight data from clients at every visit – even health education sessions or when not clinically indicated – may deter clients from accessing services due to weight stigma, and weight discrimination.

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 protected health information (PHI) under the Health Insurance Portability and Accountability Act (HIPAA) covered data or those who provide services “incident to” another provider. Furthermore, only advanced practice

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percent of all Title X family planning encounters in AccessMatters’ Network were performed by other service providers including 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. 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, as well as ethical standards, and reflect research demonstrating that, without access to confidential care, some patients would not seek care. 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* through FPAR 2.0.18 While encounter-level data will be de-identified, OPA has not released specifications for how to ensure that patient confidentiality is preserved.

OPA has not provided information on the *HIPAA Security Rule Standards* it will adopt to ensure the appropriate confidentiality protections at the federal, grantee, and subrecipient levels; for example, specifying encryption standards for data at rest and in motion. Currently, it seems imprudent to move forward with FPAR 2.0 without releasing more information about – and steps to take to protect FPAR 2.0’s encounter-level data from unauthorized access, use, and disclosure, as well as what steps

Protecting Personally Identifiable Information of Family Planning Users

Encounter-level data collected by Title X Grantees and reported to the Office of Population Affairs (OPA) should maintain confidentiality. Currently, the Family Planning Annual Report (FPAR) collects *demographic information including family planning user demographics*. Collecting and reporting family planning user demographics such as date of birth or zip code of residence could compromise confidentiality with OPA reporting requirements. If OPA requires encounter-level data that could compromise patient confidentiality, OPA should not collect such information.

Sub Recipient Compliance

The DHS Title X subrecipients have expressed concern in changes to reporting family planning user demographics, services, and reported to OPA. The DHS Title X subrecipients have an obligation to provide high-quality, confidential family planning care. This conflict of providing high quality, confidential care and the reporting requirements of the program could result in subrecipients having the choice to leave the Title X program.

Burden Hours Are Underestimated

OPA has underestimated the burden hours required – 36 per grantee - to make changes to collecting and reporting data. OPA, in consultation with subrecipients to collect encounter-level data estimates 600 hours to build the FPAR 2.0 requirements. The DHS Title X program was in July 2021 to design and deploy the modifications of current modules to support the new reporting requirements.

VDH requests that OPA establish a *new timeline* for FPAR 2.0 planning and implementation given the challenges Title X grantees and subrecipients face. VDH staff who would otherwise have been assigned to FPAR 2.0 preparation have been required to prioritize COVID-19 response efforts to reduce their previous efforts to expand family planning services. VDH's Title X program has experienced a 42% decrease in numerous Title X sites across the Commonwealth were forced to adjust hours or temporarily close. When the pandemic subsides, resources will be directed into rebuilding the Title X program to its previous capacity.

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, a health center (FQHC) subrecipients would need to upgrade its IT infrastructure.

OPA has not released final specifications for (i.e., instructions for how to collect) FPAR 2.0's data elements, including *standardized value sets*. In the absence of these specifications, VDH is in the difficult position of having to wait while OPA narrows.

Currently, VDH estimates it will take 36 months to pilot, implement, test, and revise the modifications necessary to complete 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, many sites *uses paper forms and WebVision, a homegrown legacy system that tracks information for billing purposes*, to collect data. Sites that do not have an EHR will not be able to procure and implement an EHR by January 1, 2022, as EHR implementation requires 12 to 18 months for planning and six to eight months for implementation.

VDH is unable to procure an EHR until the Virginia General Assembly allocates considerable and sustained funding. If funding takes effect on January 1, 2022, VDH will need to collect and perform manual data entry of FPAR 2.0's 45 proposed data elements and identify line-item records so that they can be transmitted securely.

VDH collects the specimen during the patient's family planning visit, and then sends the specimen to LabCorp for analysis. Test results related to the test. While LabCorp notifies VDH of the patient's test results, VDH does not have an electronic mechanism to currently file in the patient's paper chart and would then become part of the patient's treatment plan. VDH partners with LabCorp for FPAR, *but FPAR 2.0 would require a specific test result to be electronically connected to a specific encounter, a function that LabCorp does not have systems.*

VDH also requests that OPA complete an up-to-date burden study to provide a complete and accurate estimate of the burden estimates in the Public Comment Request are extremely low and based on an inappropriate and incredibly outdated *Planning Annual Report (FPAR) Burden Study, was published in 2009 using data collected from Title X grantees mo*

Currently collected in aggregate under OMB No. 0990-0221, this new data collection, “FPAR 2.0”, proposes to collect the existing data collection and reporting system by *adding 23 new data elements to FPAR’s standard set of data elements every visit*). While AFHP appreciates the need for a more robust data system for monitoring and improving program performance system, the current FPAR 2.0 project must be paused.

Under the best of circumstances, OPA’s proposal for FPAR 2.0 is flawed. Not only does FPAR 2.0, as proposed, require 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 and manage the Title X program.

The implementation of the Title X 2019 Rules created an enormous burden and negatively impacted AFHP’s capacity to plan and related preventive health services. Significant time was spent on successfully implementing the *2019 Title X* that took time away from activities to accomplish goals and objectives in AFHP’s work plan.

The COVID-19 response in 2020 has significantly decreased client numbers. Over the past two years, AFHP saw 24% fewer clients in 2020. AFHP is moving closer to stabilizing our network as we continue supporting and onboarding subrecipients has shifted to administering the COVID-19 vaccine to health center staff as well as the public. Any attempt to meet these timelines will severely disrupt and undermine our ability to respond to these top priorities.

The current timeline for FPAR 2.0 data collection to begin on January 1, 2022 is unworkable. To implement FPAR 2.0 technology (IT) infrastructure, as would its 12 subrecipients. Currently, we estimate it will take at least six months to collect and report encounter-level data through FPAR 2.0.

April 9, 2021, OPA has not released final specifications (i.e., instructions for how to collect) for FPAR 2.0's data element *response options to standardized value sets*. In the absence of these specifications, we are in the difficult position of implementing systems changes narrows.

After making system upgrades, AFHP and its 12 subrecipients (which operate over 55 service sites) will require another how to collect new data elements, conduct preliminary data collection, run reports to ensure data mapping is correct, collected, as needed.

AFHP requests that OPA complete an up-to-date burden study to provide a complete and accurate estimate of the burden <https://www.arizonafamilyhealth.org> estimates in the Public Comment Request are extremely low and based on a source for estimates, *the Family Planning Annual Report (FPAR) Burden Study 2, was published in 2009 using data 10 years ago*. Since this time, several developments have taken place that translate to the data collected no longer being relevant. The 2009 FPAR Burden Study to quantify costs for implementing the encounter-level data reporting system currently in use is a 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" electronic reporting from Title X service sites to grantees, necessitating *each grantee-subrecipient dyad to invest in unique systems and establishing interoperability between their respective systems*. In AFHP's Title X network, there are 12 subrecipients.

AFHP estimates that implementing FPAR 2.0 as proposed at the grantee-level will amount to over 200 hours and over \$38,000 in one-time labor costs. AFHP estimates that each of its 12 subrecipients will outlay an average of \$5,000 in non-labor costs to implement FPAR 2.0 across this single Title X grantee network. We estimate that implementing FPAR 2.0 will amount to about \$6,000 in non-labor costs of two staff persons working a combined 75 hours on tasks related to implementation. We also estimate that each subrecipient will spend 25 hours implementing FPAR 2.0, for an estimated total of about \$38,000 in one-time labor costs across this single Title X network. Ongoing maintenance are not included in these estimates. They also do not include the additional time it will take health care providers to enter more than 20 additional data elements as part of every single Title X visit.

With the addition of 23 new data elements – many of which are irrelevant to monitoring Title X program compliance – FPAR 2.0 represents an effort that has no intention of being minimally burdensome.

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 NSFG population-level, nationally representative dataset that gathers information on pregnancy and births, infertility, use of contraception, and sexual activity. However, while NSFG surveys a representative sample of respondents and allows them to voluntarily respond, the data for FPAR 2.0 will be required for every patient visit. More specifically, OPA has proposed that Title X service sites report the following data points 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 has a current sexual relationship. It also is inconsistent with current best practice guidelines, which recommend assessing whether an adult is at increased risk for infection or is seeking evaluation and treatment for sexually transmitted infections (STIs) [unless the patient is at increased risk for infection or is seeking evaluation and treatment for sexually transmitted infections].

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: whether a Pap test was performed in the last five years, HPV test performed at this visit, and HPV test result. Collecting and reporting all five data elements is burdensome and provides minimal benefit.

The collection of information on a patient's Pap (at current and previous visit) and HPV tests performed may be helpful in understanding the number of tests provided during a specified period, the distribution of abnormal cytology results, or use of different cytology methods (e.g., hrHPV-alone, co-testing) during a specified period. However, the utility of collecting of Pap test in the last five years is limited. The guideline recommends cervical cytology alone at a five-year interval and there is no national benchmark pertaining to the number of Pap tests performed.

New Data Elements: Cardiovascular Risk Factors - Systolic and Diastolic Blood Pressure

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

New Data Elements: Cardiovascular Risk Factors - Smoking

Reporting on whether a patient is a current or former smoker is a quality metric. If this topic is a priority for OPA, this data element should be reconfigured to determine to report the information in a way consistent with the list by the US Preventive Services Task Force.

New Data Elements: Cardiovascular Risk Factors - Height, Weight, BMI

Reporting on height and weight data, presumably to calculate body mass index (BMI), is problematic. From a clinical perspective, height and weight are not reliable measures of body composition, and OPA does not state why it is necessary to collect this information and how it will be used in clinical practice. Even when collecting a patient's height and weight data is clinically indicated, such measurements are not reliable for determining body composition – and, in turn, at risk for cardiovascular disease. Developed for and tested on a sample of predominantly white European Americans, BMI is especially for women of color, because it fails to account for differences in body composition, fitness level, and bone density.

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 treat protected health information (PHI) under the Health Insurance Portability and Accountability Act (HIPAA) - covered data or those who provide services “incident to” another provider. Furthermore, only advanced practice clinicians are required to have a NPI number. In 2020, 33% of all Title X family planning encounters in AFHP’s network were performed by other services providers, health educators, and social workers. As such, many of our providers delivering Title X services do not have individual NPI numbers.

Confidentiality is a hallmark of the Title X program, and all patients, including adolescents, are guaranteed confidentiality under federal regulations, and case law. Further, they are grounded in medical and ethical standards and reflect research demonstrating that if confidentiality is not protected, patients would not seek needed health services.¹⁷ Despite this assurance, the Supporting Statement for the Title X Final Rule expresses concern about the confidentiality of the sensitive personal health information it wants to collect through FPAR 2.0.¹⁸ While encounter-level data collection is necessary for program evaluation, the specifications for how the patient identifier data element will be used in a way that ensures that patient confidentiality is maintained are not clear.

OPA has not provided information on the *HIPAA Security Rule Standards* it will adopt to ensure the appropriate consistency of standards across federal, grantee, and subrecipient levels (e.g., patient identifier, visit date, date of birth)

Currently collected in aggregate under OMB No. 0990-0221, this new data collection, “FPAR 2.0”, proposes to collect data through a new system that will replace the existing data collection and reporting system by *adding 23 new data elements to FPAR’s standard set of data elements collected every visit*). While NJFPL appreciates the need for a more robust data system for monitoring and improving program performance, the current FPAR 2.0 project must be paused. At the same time, OPA must plan and initiate a new process for developing a new data system with continued stakeholder involvement.

The implementation of the *2019 Title X Final Rule* had a dramatic impact on NJFPL’s Title X network. 46% decline in 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.

The current timeline for FPAR 2.0 data collection to begin on January 1, 2022 is unworkable. To implement FPAR 2.0, OPA must first complete the *technology (IT) infrastructure*, as would its 11 Title X subrecipients. Currently, we estimate it will take 3-6 months to complete the infrastructure to collect and report encounter-level data through FPAR 2.0.

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* and response option to standardized value sets. In the absence of these specifications, we are in the difficult position of having to implement systems changes narrows.

NJFPL and its subrecipients, which operate 35 service sites, will each require 4-6 weeks to *train health care providers* preliminary data collection, run reports to ensure data mapping is correct, and perform quality assurance of preliminary

NJFPL requests that *OPA complete an up-to-date burden study* to provide a complete and accurate estimate of the burden estimates in the Public Comment Request are extremely low and based on an inappropriate and incredibly outdated Planning Annual Report (FPAR) Burden Study², was published in 2009 using data collected from Title X grantees m

Due to challenges with interoperability (i.e., electronic sharing of data between systems), there is no “one size fits all” reporting from Title X service sites to grantees, necessitating each grantee-subrecipient dyad to invest in *upgrading to interoperability between their respective systems*. In NJFPL’s Title X network, there are 11 subrecipients using six EHR systems. In the Title X family planning provider network, potential subrecipients either not using EHR platforms or transitioning from legacy systems for adhering to the proposed FPAR 2.0 requirements. NJFPL estimates that implementing FPAR 2.0 as proposed at the time of the labor costs.

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 NSFG population-level, nationally representative dataset that gathers information on pregnancy and births, infertility, use of contraception. However, while NSFG surveys a representative sample of respondents and allows them to voluntarily respond, the data for FPAR 2.0 will be required for every patient visit. More specifically, OPA has proposed that Title X service sites report on 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 patient is in a relationship [unless the patient is at increased risk for infection or is seeking evaluation and treatment for sexually transmitted infections]. These data points also are not needed to monitor our Title X network’s accountability to program goals.

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 care is tracking patients’ intention to either become pregnant or prevent a pregnancy in the next year. Research suggests that asking patients about their intentions over the next year; doing so is inconsistent with how they think about and approach their reproductive lives and is problematic for diverse populations.¹⁰ Indeed, not all individuals overtly plan to have children or not have children, suggesting that asking about future pregnancy intentions is problematic.¹¹ Asking patients this kind of a question at every visit, regardless of the reason for the visit, could compromise 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, a more patient-centered approach to measurement. An example of an alternative measure that assesses patients’ desire for pregnancy is the Contraception (SINC)¹³ question

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 in the last five years, HPV test performed at this visit, and HPV test result. Collecting and reporting all five data elements with minimal benefit. However, the utility of collecting of Pap test in the last five years and HPV test results are questionable. Cytology alone at a five-year interval and there is no national benchmark pertaining to the rate of tests that should be reported to NJFPL to differentiate whether an HPV test was done as part of routine screening or as a follow up after an abnormal Pap test.

New Data Elements: Cardiovascular Risk Factors - Systolic and Diastolic Blood Pressure

Collecting systolic and diastolic blood pressure measurements does not make sense clinically, as the interpretation of a single measurement at a point in time does not reflect the true level when blood pressure is measured (i.e., “white coat” hypertension), and other factors. Unless the systolic and diastolic blood pressure hypertension cannot be made without multiple measurements on several separate occasions. If increasing control of hypertension data element should be reconfigured to identify whether diagnosis of hypertension has been made or if screening for elevated blood pressure is nationally recognized guidelines.

New Data Elements: Cardiovascular Risk Factors - Smoking

Collecting smoking status as a quality metric. If this topic is a priority for OPA, this data element should be reconfigured to determine to report the information listed by the US Preventive Services Task Force.

New Data Elements: Cardiovascular Risk Factors - Height, Weight, BMI

Collecting height and weight data, presumably to calculate body mass index (BMI), is problematic. From a clinical perspective, there is no logical reason why height and weight data and OPA does not state why it is necessary to collect this information and how it will be used in the Supporting State Statement. If a patient’s height and weight data is clinically indicated, such measurements are not reliable for identifying whether there is a risk for cardiovascular disease. Developed for and tested on a sample of predominantly white European men, BMI is not a good measure of body fat, because it fails to account for differences in body composition, fitness levels, and nutritional differences. Collecting height and weight data every visit – even health education sessions or when not clinically indicated – may deter clients from accessing services due to discrimination.

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 protected health information (PHI) under the Health Insurance Portability and Accountability Act- (HIPAA) covered data or those who provide services “incident to” another provider. Furthermore, only advanced practice nurses and physician assistants are required to have an NPI. In some instances, Title X family planning encounters are performed by other service providers, such as registered nurses and community health 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. Confidentiality is a hallmark of the Title X program, and all patients, including adolescents, are guaranteed confidentiality under federal regulations, and case law. Further, they are grounded in medical and ethical standards and reflect research demonstrating that patients would not seek needed health services.²³ Despite this assurance, the Supporting Statement for the Title X Family Planning Program requests confidentiality of the sensitive personal health information it wants to collect through FPAR 2.0.²⁴ While encounter-specific specifications for how the patient identifier data element will be used in a way that ensures that patient confidentiality is maintained.

OPA has not provided information on the *HIPAA Security Rule Standards* it will adopt to ensure the appropriate controls at the federal, grantee, and subrecipient levels; for example, specifying encryption standards for data at rest and in motion. Given the challenges currently are facing, it seems imprudent to move forward with FPAR 2.0 without releasing more information about – OPA will take to protect FPAR 2.0’s encounter-level data from unauthorized access, use, and disclosure, as well as w

The proposed changes will *substantially burden Title X providers* in ways not captured in the burden estimates in the capacity to meet its goals. The Title X clinical network as it is currently constituted is highly unlikely to be able to fulfill such that the data would actually be useful and reliable for the research and program purposes outlined. And adding the ability and willingness to serve clients under the Title X program. It may actually encourage providers to opt out of the service to populations most in need.

Marginalized populations may be less likely to seek services at Title X providers because of concerns about collection and serving some of the most marginalized in the US population. Substantial research indicates that marginalized populations, undocumented, and others who are underserved by the health care system are particularly sensitive to privacy concerns. Private identifiable data collection and transmittal effort for the program designed to serve these populations, FPAR 2.0, will serve less likely to use its services.

Currently collected in aggregate under OMB No. 0990-0221, this new data collection, “FPAR 2.0”, proposes to collect the existing data collection and reporting system by adding *23 new data elements to FPAR’s standard set of data elements every visit*). While Unity Health Care appreciates the need for a more robust data system for monitoring and improving, implementing such a system, the current FPAR 2.0 project must be paused. At the same time, OPA must plan and initiate collection and reporting system with continued stakeholder involvement

As of 4/8/2021, OPA has not released final specifications for (i.e., instructions for how to collect) FPAR 2.0’s data element *response option to standardized value sets*. In the absence of these specifications, we are in the difficult position of having implement systems changes narrows. Currently, we are unable to estimate the full impact of the modification necessary to collect and report encounter-level data through FPAR 2.0.

After making system upgrades, Unity Health Care, Inc and its subrecipients will require ample time schedule and *train data elements*, conduct preliminary data collection, run reports to ensure data mapping is correct, and perform quality

Unity Health Care, Inc requests that OPA complete an up-to-date burden study to provide a complete and accurate estimate of FPAR 2.0. Cost burden estimates in the Public Comment Request are extremely low and based on an inappropriate analysis in *the Family Planning Annual Report (FPAR) Burden Study2, was published in 2009* using data collected from Title X. Several developments have taken place that translate to the data collected no longer being relevant.

Due to challenges with interoperability (i.e., electronic sharing of data between systems), there is no “one size fits all” reporting from Title X service sites to grantees, necessitating each grantee-subrecipient dyad to invest in *upgrading to interoperability between their respective systems*.

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 NSFG population-level, nationally representative dataset that gathers information on pregnancy and births, infertility, use of contraception, and sexual activity. However, while NSFG surveys a representative sample of respondents and allows them to voluntarily respond, the data for FPAR 2.0 will be required for every patient visit. More specifically, OPA has proposed that Title X service sites report three data points 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 has a current sexual relationship [unless the patient is at increased risk for infection or is seeking evaluation and treatment for sexually transmitted infections].

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: whether a Pap test was performed in the last five years, HPV test performed at this visit, and HPV test result. Collecting and reporting all five data elements is burdensome and provides minimal benefit.

The collection of information on a patient’s Pap (at current and previous visit) and HPV tests performed may be helpful in understanding the number of tests provided during a specified period, the distribution of abnormal cytology results, or use of different testing methods (e.g., hrHPV-alone, co-testing) during a specified period. However, the utility of collecting of Pap test in the last five years is limited as the guideline recommends cervical cytology alone at a five-year interval and there is no national benchmark pertaining to HPV testing.

New Data Elements: Cardiovascular Risk Factors - Systolic and Diastolic Blood Pressure

Collecting a single blood pressure measurement does not make sense clinically, as the interpretation of a single measurement at a point in time is influenced by many factors, including the level when blood pressure is measured (i.e., “white coat” hypertension), and other factors. Unless the systolic and diastolic blood pressure hypertension cannot be made without multiple measurements on several separate occasions. If increasing control of hypertension should be reconfigured to identify whether diagnosis of hypertension has been made or if screening for elevated blood pressure is consistent with nationally recognized guidelines.

New Data Elements: Cardiovascular Risk Factors - Smoking

Smoking is a key quality metric. If this topic is a priority for OPA, this data element should be reconfigured to determine to report the information listed by the US Preventive Services Task Force.

New Data Elements: Cardiovascular Risk Factors - Height, Weight, BMI

height and weight data, presumably to calculate body mass index (BMI), is problematic. From a clinical perspective, weight at every visit, and OPA does not state why it is necessary to collect this information and how it will be used in Even when collecting a patient's height and weight data is clinically indicated, such measurements are not reliable for – and, in turn, at risk for cardiovascular disease. Developed for and tested on a sample of predominantly white European especially for women of color, because it fails to account for differences in body composition, fitness level practice of weighing clients at every visit – even health education sessions or when not clinically indicated – may det body shame and weight discrimination.

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 2.0. Confidentiality is a hallmark of the Title X program, and all patients, including adolescents, are guaranteed confi statute, regulations, and case law. Further, they are grounded in medical and ethical standards and reflect research der some patients would not seek needed health services.¹⁷ Despite this assurance, the Supporting Statement for the Title the confidentiality of the sensitive personal health information it wants to collect through FPAR 2.0.¹⁸ While encour specifications for how the patient identifier data element will be used in a way that ensures that patient confidentiality

OPA has not provided information on the *HIPAA Security Rule Standards* it will adopt to ensure the appropriate cons federal, grantee, and subrecipient levels; for example, specifying encryption standards for data at rest and in motion. Currently are facing, it seems imprudent to move forward with FPAR 2.0 without releasing more information about – OPA will take to protect FPAR 2.0's encounter-level data from unauthorized access, use, and disclosure, as well as w

Currently collected under OMB No. 0990-0221, this new data collection, "FPAR 2.0", proposes to build on the existi *new data elements to the FPAR's standard set of data elements (for a total of 45 data elements to be collected at ever* Program appreciates the need for a contemporary data system for collection, management and analysis to improve pro such a system, the current FPAR 2.0 project should be paused.

The Washington State Department of Health's Sexual and Reproductive Health Program requests that OPA establish implementation given the challenges all states and providers are facing. Even in the absence of the above challenges, begin on January 1, 2022 is unworkable, in part because *FPAR 2.0's data elements have not been released, including* standardized value sets. In the absence of these specifications, we are in the difficult position of having to wait while narrows.

The Washington State Department of Health's Sexual and Reproductive Health Program requests that OPA complete accurate estimate of the burden associated with implementing FPAR 2.0. Cost burden estimates in the Public Comme our providers for comparable projects. The source for estimates, the *Family Planning Annual Report (FPAR) Burden* Title X grantees more than twelve years ago. Since this time, several developments have taken place that translate to

Due to challenges with interoperability (i.e., electronic sharing of data between systems), there is no “one size fits all” reporting from our network of providers to the department, necessitating that our providers invest in upgrading to electronic interoperability between their respective systems. Our network of providers use several different EMR providers.

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 Longitudinal Survey of Youth (NSFG), a population-level, nationally representative dataset that gathers information on pregnancy and births, infertility, use of contraception, and sexual activity. However, while NSFG surveys a representative sample of respondents and allows them to voluntarily respond, the data for FPAR 2.0 will be required for every patient visit. More specifically, OPA has proposed that Title X service sites report the following data points 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 not in line with clinical guidelines, which recommend assessing whether an adult or adolescent patient is sexually active only annually [unless the patient is seeking evaluation and treatment for sexually transmitted infections (STIs)].

New Data Elements: Cardiovascular Risk Factors - Height, Weight, BMI

Collecting height and weight data, presumably to calculate body mass index (BMI), is problematic. From a clinical perspective, there is no logical rationale for collecting this information. OPA does not state why it is necessary to collect this information and how it will be used in the Supporting Statement. If a patient's height and weight data is clinically indicated, such measurements are not reliable for identifying whether the patient has cardiovascular disease. Developed for and tested on a sample of predominantly white European men, BMI is not a useful measure because it fails to account for differences in body composition, fitness levels, and nutritional differences. Requiring this data at every visit – even health education sessions or when not clinically indicated – may deter clients from accessing services due to concerns about discrimination.

New Data Element: Future Pregnancy Intention Reported

NFPRHA recommends that FPAR 2.0 use a more patient-centered approach to measurement. An example of an alternative measure for contraceptive services is the Self-Identified Need for Contraception (SINC) question developed by the University of California, San Francisco (UCSF) Reproductive Health Program in consultation with Reproductive Justice advocates. Of note, UCSF has an award from the National Center for Quality Improvement Measures (eCQMs) of contraceptive provision using the SINC question to define the denominator. As such, use of this measure is consistent with other initiatives underway at OPA. Use of this type of measure also would facilitate the removal of problematic data points that are not 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: whether a Pap test was performed in the last five years, HPV test performed at this visit, and HPV test result. Collecting and reporting all five data elements is burdensome and provides minimal benefit.

The collection of information on a patient's Pap (at current and previous visit) and HPV tests performed may be helpful in understanding the number of tests provided during a specified period, the distribution of abnormal cytology results, or use of different testing methods (Pap alone, hrHPV-alone, co-testing) during a specified period. However, the utility of collecting of Pap test in the last five years is limited. The current guideline recommends cervical cytology alone at a five-year interval and there is no national benchmark pertaining to

New Data Elements: Cardiovascular Risk Factors - Systolic and Diastolic Blood Pressure

pressure measurements does not make sense clinically, as the interpretation of a single measurement at a point in time level when blood pressure is measured (i.e., “white coat” hypertension), and other factors. Unless the systolic and diastolic hypertension cannot be made without multiple measurements on several separate occasions. If increasing control of hypertension element should be reconfigured to identify whether diagnosis of hypertension has been made or if screening for elevated blood pressure nationally recognized guidelines.

New Data Elements: Cardiovascular Risk Factors - Smoking

quality metric. If this topic is a priority for OPA, this data element should be reconfigured to determine to report the information listed by the US Preventive Services Task Force.

New Data Elements: Cardiovascular Risk Factors - Height, Weight, BMI

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Confidentiality of Sensitive Personal Health Information

Confidentiality is a hallmark of the Title X program, and all patients, including adolescents, are guaranteed confidentiality under federal regulations, and case law. Further, they are grounded in medical and ethical standards and reflect research demonstrating that patients would not seek needed health services.¹⁷ Despite this assurance, the Supporting Statement for the Title X FPAR 2.0 does not address confidentiality of the sensitive personal health information it wants to collect through FPAR 2.0.¹⁸ While encountering difficulties with specifications for how the patient identifier data element will be used in a way that ensures that patient confidentiality

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 and response option to standardized value sets; nor has it published the anticipated data elements on its website. In this difficult position of having to wait while the time window needed to implement systems changes narrows. Initiating updates would be wasteful, as inconsistencies would require revisions that carry additional costs and burden hours spent.

Response Text

The FPAR 2.0 data collection builds on data already reported in FPAR 1.0 and adds additional detail that will allow OPA to focus completely on the services provided by Title X grantees in their communities. Currently, aggregate level data collection are of limited utility. Encounter level data collection will allow for richer and more detailed analysis. Several of the new data elements are only recently developed and endorsed (in 2016) or Quality Family Planning guidelines (first released in 2014). The FPAR 2.0 clinical encounter. If the clinical encounter includes information collected in FPAR 2.0, only then should it be recorded as an element in every single encounter. Data should only be collected if needed for the encounter. In response to this and similar comments, the following was deleted.

The FPAR 2.0 data collection builds on data already reported in FPAR 1.0 and adds additional detail that will allow OPA to focus completely on the services provided by Title X grantees in their communities. Currently, aggregate level data collection are of limited utility. Encounter level data collection will allow for richer and more detailed analysis. Several of the new data elements are only recently developed and endorsed (in 2016) or Quality Family Planning guidelines (first released in 2014). The FPAR 2.0 clinical encounter. If the clinical encounter includes information collected in FPAR 2.0, only then should it be recorded as an element in every single encounter. Data should only be collected if needed for the encounter. In response to this and similar comments, the following was deleted.

OPA is prioritizing client confidentiality. Previous consultations with the HHS Privacy Officer indicate that the level of detail in the Systems of Record Notice because OPA does not plan on using a personal identifier to retrieve individual records. OPA is working with the Enterprise Performance Life Cycle (EPLC) and Authority to Operate (ATO) process. OPA is working with the data science team on procedures using best practices and in accordance with all federal regulations.

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If indicated by the clinician, STI testing results should be ordered and recorded in the encounter record for appropriate use in the recording of such data. Acknowledging that there are sometimes technical challenges in attaching the STI lab results to the encounter record, OPA is providing alternative reporting guidance for lab values.

Proposed EHR changes will use standardized code systems to increase ease of adoption. OPA is also working to add OPA provided a non-competitive grant supplement early in 2021 to assist with FPAR 2.0 implementation and announced to be awarded in FY2021 worth 6-7% of total grant awards. OPA is also reaching out to EHR vendors to assess implementation technical assistance materials for grantees to use when discussing needed changes with EHR/IT staff.

OPA is offering a 3-year phased implementation for those grantees who cannot transition to FPAR 2.0 on the existing system. Based on grantee feedback and surveys, OPA postponed FPAR 2.0 implementation from 2020 to 2021. OPA is updating burden estimates to assess the annual burden required for data collection and reporting. To address implementation burden, OPA provided a grant supplement of \$160,000 early in 2021 to assist with FPAR 2.0 implementation and announced on 5/27/21 an additional, planned grant supplement of \$160,000, totaling 6-7% of total grant awards. Once implemented, a standards-based data collection should reduce reporting burden. OPA continues system development through regular communications and meetings. TA materials are being developed based on feedback.

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OPA is offering a 3-year phased implementation for those grantees who cannot transition to FPAR 2.0 on the existing system. Based on grantee feedback and surveys, OPA postponed FPAR 2.0 implementation from 2020 to 2021. OPA is updating burden estimates to assess the annual burden required for data collection and reporting. To address implementation burden, OPA provided a grant supplement of \$160,000 early in 2021 to assist with FPAR 2.0 implementation and announced on 5/27/21 an additional, planned grant supplement of \$160,000, totaling 6-7% of total grant awards. Once implemented, a standards-based data collection should reduce reporting burden. OPA continues system development through regular communications and meetings. TA materials are being developed based on feedback.

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OPA is offering a 3-year phased implementation for those grantees who cannot transition to FPAR 2.0 on the existing FPAR 1.0 system. Based on grantee feedback and surveys, OPA postponed FPAR 2.0 implementation from 2020 to 2021. OPA is updating its reporting burden estimates to assess the annual burden required for data collection and reporting. To address implementation burden, OPA announced in early 2021 a grant supplement of \$160,000 to assist with FPAR 2.0 implementation and announced on 5/27/21 an additional, planned grant supplement of \$160,000 of total grant awards. Once implemented, a standards-based data collection should reduce reporting burden. OPA continues to support system development through regular communications and meetings. TA materials are being developed based on feedback from grantees.

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If indicated by the clinician, STI testing results should be ordered and recorded in the encounter record for appropriate use. Sometimes technical challenges in attaching the STI lab results to the encounter record, OPA is working to develop a solution.

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OPA is prioritizing client confidentiality. Previous consultations with the HHS Privacy Officer indicate that the level of Systems of Record Notice because OPA does not plan on using a personal identifier to retrieve individual records. OPA is working with the data s Enterprise Performance Life Cycle (EPLC) and Authority to Operate (ATO) process. OPA is working with the data s procedures using best practices and in accordance with all federal regulations.

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NPI/NPI2 to be reported when available. NPI's can be held by healthcare providers other than physicians and including other types of providers (https://www.healthit.gov/cures/sites/default/files/cures/2020-08/Health_Care_Provider_Definitions_v3.pdf).

OPA is prioritizing client confidentiality. Previous consultations with the HHS Privacy Officer indicate that the level of Systems of Record Notice because OPA does not plan on using a personal identifier to retrieve individual records. OPA is working with the data s Enterprise Performance Life Cycle (EPLC) and Authority to Operate (ATO) process. OPA is working with the data s procedures using best practices and in accordance with all federal regulations.

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Proposed EHR changes will use standardized code systems to increase ease of adoption. OPA is also working to address implementation burden. OPA provided a non-competitive grant supplement early in 2021 to assist with FPAR 2.0 implementation and announced on 5/27/21 an additional, planned grant supplement to be awarded in FY2021 worth 6-7% of total grant awards. OPA is also reaching out to EHR vendors to assess implementation burden. OPA continues to incorporate working group feedback into data system development through regular communications and meetings. TA materials are being developed based on feedback.

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NPI/NPI2 to be reported when available. NPI's can be held by healthcare providers other than physicians and including other types of providers (https://www.healthit.gov/cures/sites/default/files/cures/2020-08/Health_Care_Provider_Definitions_v3.pdf).

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OPA appreciates comments expressing concern about the estimated burden of reporting FPAR 2.0 data. The department is working with subrecipients to examine changes in workflow, address challenges of interoperability across disparate EHR systems, provide training staff, and preparing workflows and systems for encounter-level reporting. However, for the purpose of assessing the burden to collect and report the required data elements, not any capital investments needed for system development and enhancement. Additionally, OPA recognizes the burdens of preparatory activities and is providing supplemental funding and technical assistance. OPA further believes that once implemented, a standards-based data collection adopted by EHR vendors and grantees should reduce the burden currently collecting input from a small sample of grantees to supplement the previous burden estimates and is reviewing similar collection and reporting activities.

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NPI/NPI2 to be reported when available. NPI's can be held by healthcare providers other than physicians and including (https://www.healthit.gov/cures/sites/default/files/cures/2020-08/Health_Care_Provider_Definitions_v3.pdf).

OPA is prioritizing client confidentiality. Previous consultations with the HHS Privacy Officer indicate that the level of Systems of Record Notice because OPA does not plan on using a personal identifier to retrieve individual records. OPA is working with the Enterprise Performance Life Cycle (EPLC) and Authority to Operate (ATO) process. OPA is working with the data management team on procedures using best practices and in accordance with all federal regulations.

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OPA has engaged grantees and EHR vendors in recent years to provide technical specifications and provide uniform data. Earlier this year, OPA began information- and requirements-gathering meetings with grantees from each Department to anticipate reporting challenges and approaches for minimizing reporting burden. OPA is also currently establishing implementation guides, options for file formats, and other guidance for IT representatives from EHR vendors to provide flexible options for acceptable file formats, including specifications for submitting flat files (that is, files that are not in a database).

The FPAR 2.0 data collection builds on data already reported in FPAR 1.0 and adds additional detail that will allow OPA to report completely on the services provided by Title X grantees in their communities. Currently, aggregate level data collection is of limited utility. Encounter level data collection will allow for richer and more detailed analysis. Several of the new data elements are only recently developed and endorsed (in 2016) or Quality Family Planning guidelines (first released in 2014). The FPAR 2.0 data collection will include information collected in FPAR 2.0, only then should it be recorded as a data element in every single encounter. Data should only be collected if needed for the encounter. In response to this and other feedback, OPA will delete unnecessary data elements.

The FPAR 2.0 data collection builds on data already reported in FPAR 1.0 and adds additional detail that will allow OPA to operate completely on the services provided by Title X grantees in their communities. Currently, aggregate level data collection is of limited utility. Encounter level data collection will allow for richer and more detailed analysis. Several of the new data elements are only recently developed and endorsed (in 2016) or Quality Family Planning guidelines (first released in 2014). The FPAR 2.0 clinical encounter. If the clinical encounter includes information collected in FPAR 2.0, only then should it be recorded as a data element in every single encounter. Data should only be collected if needed for the encounter. In response to this and similar comments, the data elements were deleted.

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If indicated by the clinician, STI testing results should be ordered and recorded in the encounter record for appropriate use. Due to sometimes technical challenges in attaching the STI lab results to the encounter record, OPA is working to develop a solution.

The FPAR 2.0 data collection builds on data already reported in FPAR 1.0 and adds additional detail that will allow for more complete reporting on the services provided by Title X grantees in their communities. Currently, aggregate level data collection is of limited utility. Encounter level data collection will allow for richer and more detailed analysis. Several of the new measures are only recently developed and endorsed (in 2016) or Quality Family Planning guidelines (first released in 2014). The FPAR 2.0 data collection is a clinical encounter. If the clinical encounter includes information collected in FPAR 2.0, only then should it be recorded as an element in every single encounter. Data should only be collected if needed for the encounter. In response to this and similar feedback, the data element was deleted.

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NPI/NPI2 to be reported when available. NPI's can be held by healthcare providers other than physicians and including (https://www.healthit.gov/cures/sites/default/files/cures/2020-08/Health_Care_Provider_Definitions_v3.pdf).

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OPA is currently developing guidance. Proposed EHR changes will use standardized code systems to increase ease of adoption and further increase ease of adoption. OPA provided a non-competitive grant supplement early in 2021 to assist with FPAR 2.0 implementation. An additional, planned grant supplement to be awarded in FY2021 worth 6-7% of total grant awards. OPA is also reaching out to grantees and is developing plain language technical assistance materials for grantees to use when discussing needed changes with vendors. OPA is also developing materials for technical and nontechnical staff to facilitate to grantees' internal training processes and promote reporting. OPA is building capacity to report encounter-level data and is working to provide alternate reporting pathways for those who cannot report. OPA requires project officer approval and a plan to ultimately transition to FPAR 2.0. OPA also notes that the transition to FPAR 2.0 grantees have been engaged in the process since that time.

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Proposed EHR changes will use standardized code systems to increase ease of adoption. OPA is also working to add additional technical assistance materials for grantees to use when discussing needed changes with EHR/IT staff. OPA provided a non-competitive grant supplement early in 2021 to assist with FPAR 2.0 implementation and announced on 5/27/21 an additional, planned \$160,000 grant supplement for 2022, totaling \$320,000 to be awarded in FY2021 worth 6-7% of total grant awards. OPA is also reaching out to EHR vendors to assess implementation burden and develop technical assistance materials for grantees to use when discussing needed changes with EHR/IT staff.

The FPAR 2.0 data collection builds on data already reported in FPAR 1.0 and adds additional detail that will allow OPA to understand more completely on the services provided by Title X grantees in their communities. Currently, aggregate level data collection is of limited utility. Encounter level data collection will allow for richer and more detailed analysis. Several of the new elements are only recently developed and endorsed (in 2016) or Quality Family Planning guidelines (first released in 2014). The FPAR 2.0 data collection will include the clinical encounter. If the clinical encounter includes information collected in FPAR 2.0, only then should it be recorded as an element in every single encounter. Data should only be collected if needed for the encounter. In response to this and other feedback, the following elements were deleted, including the three referenced elements.

Future pregnancy intention was deleted. SINC is included as an optional element as it is still in development and not yet finalized.

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NPI/NPI2 to be reported when available. NPI's can be held by healthcare providers other than physicians and including other health professionals (https://www.healthit.gov/cures/sites/default/files/cures/2020-08/Health_Care_Provider_Definitions_v3.pdf).

OPA is prioritizing client confidentiality. Previous consultations with the HHS Privacy Officer indicate that the level of detail reported in the Systems of Record Notice because OPA does not plan on using a personal identifier to retrieve individual records. OPA is working with the data systems for the Enterprise Performance Life Cycle (EPLC) and Authority to Operate (ATO) process. OPA is working with the data systems to ensure that the procedures using best practices and in accordance with all federal regulations.

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OPA has engaged grantees and EHR vendors in recent years to provide technical specifications and provide uniform data. Earlier this year, OPA began information- and requirements-gathering meetings with grantees from each Department to anticipate reporting challenges and approaches for minimizing reporting burden. OPA is also currently establishing enhance implementation guides, options for file formats, and other guidance for IT representatives from EHR vendors to provide flexible options for acceptable file formats, including specifications for submitting flat files (that is, files that

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The Patient-Centered Contraceptive Counseling (PCCC) Measure is not intended to be implemented within an EHR system. FPAR 2.0 data elements. OPA has plans to develop technical assistance to work with grantees to implement the PCCC measure.

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