Comment Text

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

Many of the proposed FPAR 2.0 data elements do not adhere to modern sexual and reproductive health clinical guide
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 f
“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, administr
repetitive, intrusive, and unnecessary. There is significant potential the proposed elements will hinder and/or harm tru
sensitive nature of sexual and reproductive health. Many of the proposed elements should not be collected at the fede
protected health information.

Many of the proposed FPAR 2.0 data elements, which are medically unnecessary, will also hinder the ability to provi
including comprehensive contraceptive and/or preconception counseling, during a telehealth visit, which typically las

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 chang
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 or submission and reporting. Many Title X providers receive funding from other such federal programs/providers. Many 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 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 colle the existing data collection and reporting system by adding 23 new data elements to FPAR's standard set of data elem every visit).

While Converge appreciates the need for a more robust data system for monitoring and improving program performa current FPAR 2.0 project must be paused. At the same time, OPA must plan and initiate a new process for transitioni 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, requ 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 com
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
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 challenge
facing. Even in the absence of the above challenges, the current timeline for FPAR 2.0 data collection to begin on Jan

Converge 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 out
Planning Annual Report (FPAR) Burden Study , was published in 2009 using data collected from Title X grantees m
developments have taken place that translate to the data collected no longer being relevant.

OPA has not collated recent feedback from the Title X network regarding costs associated with encounter-level data
elements. Estimates in the FPAR Burden Study, where gross non-labor costs were estimated to be $163,300 (or $2,20
estimated at $106,880 (or $1,444 per respondent) , are based on the cost and time burdens of implementing a new FP
encounter-level data reporting and collection). 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
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 each grantee-subrecipient dyad to invest in upgrading to
interoperability between their respective systems

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

It corresponds to the deliberate transition of FPAR from a program monitoring tool to a research dataset, requiring Ti
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 Recomm
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
directly to achieving or preventing pregnancy include screening for breast and cervical cancer," they certainly should
accountability to program goals. We request additional justification for collecting these new data elements beyond the
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 reali
of pregnancy decision making in the very formal time limited way that One Key Question and other intention assessm
intention, collecting data on how people state their desire for a pregnancy does not speak to their contraceptive decisi
related. As the Title X program continues to address the need for noncoercive and equitable care, it is critical to prop
centered and driven by preferences stated by the client. Patients themselves have stated a preference for shared decisi
medical input of their provider A continued focus on "pregnancy intention" leads can lead to a focus on method effe
guided by patient preference for contraceptive methods. Thus, collecting intention around pregnancy both generates c
to patient decision making and it may have the unintended consequence of encouraging non-equitable and even coerc

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 col
patient input speaks to a very narrow focus on clinical outcomes and practices while failing to properly address the cr
funded health care program. In particular on the topic of family planning and reproductive healthcare, there is a lengt
abuse. Failing to value the reported experiences of patients equally with medical health record data does nothing to pr
Converge would propose the uniform usage of a patient reported measure that speaks to the patient-centeredness of c
Counseling measure is one such tool that could be used throughout the Title X program to ensure patient input is bei
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 N
population-level, nationally representative dataset that gathers information on pregnancy and births, infertility, use of
However, while NSFG surveys a representative sample of respondents and allows them to voluntarily respond, the da
FPAR 2.0 will be required for every patient visit. More specifically, OPA has proposed that Title X service sites repo
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 b
relationship. It also is inconsistent with current best practice guidelines, which recommend assessing whether an adul
[unless the patient is at increased risk for infection or is seeking evaluation and treatment for sexually transmitted infe
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 res
questions at every visit, nor would their responses be reported at the encounter level to the federal government. When
for its benefit and requires those accessing services through the safety net to provide such information as a precursor
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 sc
the last five years, HPV test performed at this visit, and HPV test result. Collecting and reporting all five data elemen
with minimal benefit.

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

It is critical to underscore that ASCCP Risk-Based Management Consensus Guidelines for abnormal cervical cancer s
patient age and other risk factors that support screening. As a result, none of these cervical cancer screening-related d
adherence to screening guidelines or track progress towards Healthy People 2030 goals (i.e., increase the proportion o
on the most recent guidelines), as described in the Supporting Statement for the Title X FPAR 2.0. When extracting d
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 cardiovascula
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 interp
be tempered by the age of the patient, anxiety level when blood pressure is measured (i.e., "white coat" hypertension)
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 elemen
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 probl
rationale to record and report body weight at every visit, and OPA does not state why it is necessary to collect this inf
Statement for the Title X FPAR 2.0. Even when collecting a patient's height and weight data is clinically indicated, s
whether that patient is overweight or obese – and, in turn, at risk for cardiovascular disease. Developed for and tested
BMI is not a useful indicator of health, especially for women of color, because it because it fails to account for differe
differences. Furthermore, the practice of weighing clients at every visit – even health education sessions or when not
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. Tit
and should not be subject to weight stigmatization at every visit. Weight stigma invokes psychological stress and eme
exacerbate poor physical health outcomes for obese individuals , with the potential to perpetuate racial/ethnic and soc
It is time to move away from this measure and focus on measures of health that are scientifically valid and designed f

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

Converge requests further clarification on the steps OPA will take to maintain the confidentiality of the sensitive pers
Confidentiality is a hallmark of the Title X program, and all patients, including adolescents, are guaranteed confident
regulations, and case law. Further, they are grounded in medical and ethical standards and reflect research demonstra
patients would not seek needed health services. Despite this assurance, the Supporting Statement for the Title X FPA
confidentiality of the sensitive personal health information it wants to collect through FPAR 2.0. While encounter-le
specifications for how the patient identifier data element will be used in a way that ensures that patient confidentiality
information on the HIPAA Security Rule Standards it will adopt to ensure the appropriate consent and safeguarding c
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higher than the outdated estimates published in the Federal Register (86 FR 9077)

it puts forward data collection requirements that far exceed the minimum amount of data needed to monitor complian
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 exp
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 chal
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) infrastructu
specifications for (i.e., instructions for how to collect) FPAR 2.0's data elements, including how to map each data ele
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 revisi
spent.

Denver Health requests that OPA complete an up-to-date burden study to provide a complete and accurate estimate o
Cost burden estimates in the Public Comment Request are extremely low and based on an inappropriate and incredibl
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estimated at $106,880 (or $1,444 per
respondent)2, are based on the cost and time burdens of implementing a new FPAR system that reports data aggregat
collection). It is
inappropriate for OPA to use data collected from the 2009 FPAR Burden Study to quantify costs for implementing th
proposed, as these
estimates relate to a completely different iteration of the proposed overhaul of FPAR that would be substantially less

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include: giving priority in the provision of family planning services to low-income individuals, reducing invasive cer
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screening, and increasing program efficiency by monitoring the cost of care. However, with the addition of 23 new da
monitoring Title X program compliance and accountability to the above performance goals – FPAR 2.0 represents an
burdensome.

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

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assessing whether an adult or adolescent patient is sexually active only annually [unless the patient is at increased risk
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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 c
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way for Denver Health to differentiate whether an HPV test was done as part of routine screening or as a follow up af
surveillance.

It is critical to underscore that ASCCP Risk-Based Management Consensus Guidelines for abnormal cervical cancer s
patient age
and other risk factors that support screening.8 As a result, none of these cervical cancer screening-related data elemen
screening
guidelines or track progress towards Healthy People 2030 goals (i.e., increase the proportion of females who receive
guidelines), as
described in the Supporting Statement for the Title X FPAR 2.0.9 10 When extracting data to calculate measures, the
interval was
applied.

New Data Elements: Cardiovascular Risk Factors

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pressure, Height,
Weight, and Smoking status (detailed as ever smoker, ex-smoker, smokes daily, occasional smoker, smoker, status u
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elevated, the diagnosis of hypertension cannot be made without multiple measurements on several separate occasions
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Self-reported smoking status also is not helpful as a quality metric. If this topic is a priority for OPA, this data elemen
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Title X FPAR
2.0.12 Even when collecting a patient's height and weight data is clinically indicated, such measurements are not reli
obese – and,
in turn, at risk for cardiovascular disease. Developed for and tested on a sample of predominantly white European me
women of color, because it because it fails to account for differences in body composition, fitness levels, and nutritio
clients at every visit – even health education sessions or when not clinically indicated – may deter clients from access
weight discrimination.14

Patients accessing health services in non-Title X settings are not weighed at every visit unless clinically indicated. Ti
and should not be subject to weight stigmatization at every visit. Weight stigma invokes psychological stress and eme
exacerbate poor physical health outcomes for obese individuals15, with the potential to perpetuate racial/ethnic and s
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contraceptives and
other hormonal contraception) and pre-pregnancy health. While it may be desirable to capture these measures for add
requirement for Title X
providers to obtain information beyond that which is clinically necessary. Accordingly, we should not be required to

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 tr
Accountability Act- (HIPAA)
covered data or those who provide services "incident to" another provider. Furthermore, only advanced practice clini
encounters at Denver
Health are routinely performed by other providers, including registered nurses and health educators. As such, many o
individual NPI
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
Confidentiality is a hallmark of the Title X program, and all patients, including adolescents, are guaranteed confident
regulations, and case law. Further, they are grounded in medical and ethical standards and reflect research demonstra
patients would not seek needed health services.16 Despite this assurance, the Supporting Statement for the Title X FP
confidentiality of the sensitive personal health information it wants to collect through FPAR 2.0.17 While encounter-
specifications for how the patient identifier data element will be used in a way that ensures that patient confidentiality
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Despite a range of opinions about what qualifies as sensitive health information, it generally is considered to be infor
event of disclosure.

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

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

While the WHC appreciates the need for a more robust data system for monitoring and improving program performan
current FPAR 2.0 project must be paused. At the same time, OPA must plan and initiate a new process for transitioni
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FPAR 2.0 puts forward data collection requirements that far exceed the minimum amount of data needed to monitor c
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 p
network's capacity after an estimated one in four service sites left the Title X program in response to the 2019 Title X
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 sa
over 800 being served in one community over the restrictions related to abortion services. Our eight (8) subrecipients
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 al
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 re
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 e
validation efforts, etc.

After making system upgrades, WHC and its subrecipients (which operate eleven (11) service sites) will require a mi
providers and staff on how to collect new data elements, conduct preliminary data collection, run reports to ensure da
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.
EHR systems and one of these subrecipients has only 1 administrative/financial and 1 clinical staff. Instead, these org
aggregate submission. Those service sites without EHRs will not be able to begin reporting FPAR 2.0 data electronic
typically takes 9 to 11 months, with three months for planning and six to eight months for implementation. Instead, if
collect and perform manual data entry of FPAR 2.0's 45 proposed data elements for every visit, and then determine h
transmitted securely. This cumbersome process not only raises concerns about the effective use of Title X resources,
sensitive health information.

WHC requests that OPA complete an up-to-date burden study to provide a complete and accurate estimate of the burd
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-
estimates for program data assessment, data program installation, and training. Furthermore, WHC estimates that eac
$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 t
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 pu

All of our programs rely on some state funding to support various program activities. This year, all state programs we
be that local, county and state governments will have less dollars at their disposal to support Title X program.

WHC has been unable to realistically assess one-time labor costs to implement FPAR 2.0. The reality is that the Gran
Director) and two part-time staff whose responsibilities do not include FPAR data. This estimate is based on the cost
combined 200 hours on tasks related to implementation, which may include: selecting and/or creating a contract with
system upgrades and map out FPAR 2.0's data elements to existing standardized value sets, training health care provi
conducting preliminary data collection, running reports to ensure data mapping is correct, and performing quality ass
also estimate that each of our eight (8) subrecipients will spend an average of eighty (80) hours implementing FPAR
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
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
guidance. We ask for additional opportunities to provide feedback on what additional data elements are feasible to ad
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
Asking these three data points at every visit is burdensome and threatens the patient-provider relationship. It also is in
recommend assessing whether an adult or adolescent patient is sexually active only annually [unless the patient is at i
treatment for sexually transmitted infections (STIs)]. These sexual activity-related data fields also are not needed to m
goals.

When the federal government begins collecting research data for its benefit and requires those accessing services thro
precursor to receive care, it exacerbates medical mistrust, potentially dissuading patients from coming to us for neede

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the last five years, HPV test performed at this visit, and HPV test result. Collecting and reporting all five data elemen
with minimal benefit. Furthermore, there is no way for WHC to differentiate whether an HPV test was done as part o
screening test or for post-treatment surveillance.

It is critical to underscore that ASCCP Risk-Based Management Consensus Guidelines for abnormal cervical cancer s
patient age and other risk factors that support screening. As a result, none of these cervical cancer screening-related d
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differences. Furthermore, the practice of weighing clients at every visit – even health education sessions or when not
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 persona

Given the cybersecurity issues that all organizations currently are facing, it seems imprudent to move forward with F
seeking stakeholder feedback on – the steps that OPA will take to protect FPAR 2.0’s encounter-level data from unau
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 da
confidentiality is preserved. Furthermore, OPA has not provided information on the HIPAA Security Rule Standards
safeguarding of this encounter-level data at the federal, grantee, and subrecipient levels; for example, specifying encr

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

We are striving to see more patients. While we agree that the Title X program needs a more contemporary data syster
such an endeavor cannot come at the expense of serving those in need of services, specifically patients who are low-i
cannot come at the expense of providing Title X patients with the same standard of care as their counterparts who rec
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
build on the existing data collection and reporting system by adding 23 new data elements to FPAR's standard set of
collected at every visit).

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

Under the best of circumstances, OPA's proposal for FPAR 2.0 is flawed. Not only does FPAR 2.0, as proposed, req
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 com
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 p
network's capacity after an estimated one in four service sites left the Title X program in response to the 2019 Title X
feasible for Title X grantees and subrecipients. These organizations are working hard to rebuild and continue providin

NFPRHA requests that OPA establish a new timeline for FPAR 2.0 planning and implementation given the challenge
in the absence of the above challenges, the current timeline for FPAR 2.0 data collection to begin on January 1, 2022
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 FP

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

Data validation: Grantees must work with each of their subrecipients to electronically validate data. Data validation i
are present and, from there, conducting quality assurance to ensure there are no incongruent or incomplete counts, du

Training: After making all necessary system upgrades, grantees must train staff at their organizations and at the subre
there, to ensure full and accurate data collection when systems "go live," grantees will conduct preliminary data colle
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 an
appointment scheduling systems and registries, integrating telehealth platforms with EHRs, providing day-to-day IT s
timeline for such changes.

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

NFPRHA requests that OPA complete an up-to-date burden study to provide a complete and accurate estimate of the 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 incredibl Planning Annual Report (FPAR) Burden Study5, was published in 2009 using data collected from Title X grantees ab FPAR system that reports data aggregately (as opposed to encounter-level data reporting and collection). OPA has no network regarding burden and costs associated with encounter-level data collection and the proposed new FPAR 2.0 The FPAR Burden Study estimated gross non-labor costs to be $163,300 (or $2,207 per respondent) and annualized l is inappropriate for OPA to use data collected from the 2009 FPAR Burden Study to quantify costs for implementing proposed, as these estimates relate to a completely different iteration of the proposed overhaul of FPAR that would be subrecipients. Indeed, it was not until 2012 that OPA engaged an FPAR Expert Work Group consisting of Regional F federal and federally funded stakeholders to assess the feasibility of revising the data elements and transitioning FPA In 2014, OPA requested Office of Management and Budget (OMB) approval to begin assessing the feasibility of enc 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 Informa (HITECH) Act, enacted in 2009, led to changes in the health IT industry that increased costs for these proposed chan Reinvestment Act (ARRA), the HITECH Act allocated $19.2 billion to promote the adoption of use of health IT by p Medicaid. While HITECH Act funds supported some, but not all, Title X service sites to adopt and implement electro health IT industry gave rise to a multitude of EHR vendors and platforms and, in turn, challenges with interoperabilit Health data exchange and interoperability solutions are available to streamline data exchange and electronic reporting hours) and costs for customizations. In addition, HITECH funds were one-time investments, so funding to support up Consequently, there is no "one size fits all" approach for implementing FPAR 2.0 electronic reporting from Title X s subrecipient dyad to invest in upgrading to electronic systems (as applicable) and establishing interoperability betwee Of note, though local and state health departments were eligible to receive HITECH Act funds and understood that IT staff expertise, time, and resources to meet the timelines mandated by HITECH.9 Based on NFPRHA's estimates, alm operated by local and state health departments. Because many of these service sites did not benefit from HITECH fun legacy systems, they lack the IT infrastructures needed to implement FPAR 2.0 in accordance with OPA's project sch statement health departments could not meet the timelines mandated by HITECH, they also cannot implement FPAR

In 2020, NFPRHA began conversations with various grantees and health information system subject matter experts a Based on information collected, NFPRHA estimates that implementing FPAR 2.0 as proposed will amount to $65,00 average of $4,680,000 across all 72 service grantees.10 Spending will be on engaging EHR vendors or other external and perform system upgrades, as well as purchasing or subscribing to a SFTP server. These cost estimates do not incl upgrades and purchased service costs.

Labor costs also will be high. In March 2021, 40 grantee organizations provided NFPRHA with estimates for the num
FPAR 2.0 as currently planned. Based on this data, NFPRHA estimates grantee organizations each will spend 183 ho
on the cost of working on tasks related to implementation, including selecting and/or creating a contract with a vendo
upgrades and map out FPAR 2.0's data elements to existing standardized value sets, training health care providers an
preliminary data collection, running reports to ensure data mapping is correct, and performing quality assurance of pr
hourly wage estimates published in the Supporting Statement for the Title X FPAR 2.0 ($40.12), these burden hours
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 un
and 3,825 service sites.12 Based on information submitted by 36 grantees in March 2021, NFPRHA estimates that ea
implementing FPAR 2.0 as currently planned in 2021. Based on average (weighted) hourly wage estimates published
($40.12), these burden hours will amount to $3,410 in one-time labor costs per subrecipient, or $3,614,812 across all
estimates that current subrecipients will spend an average of $18,000 in one-time non-labor costs, primarily paid to E
changes to their EHRs or practice management systems (e.g., build new or update existing templates, code new data e
subrecipients these one-time non-labor costs amount to $19,080,000. To reiterate, subrecipients will incur these capit
public health emergency – a time when resources have been redirected to emergency response and revenue has dwind
Based on the above estimates, the cost of implementing FPAR 2.0 as currently planned across the Title network is $2
information to substantiate this estimate upon request.

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

NFPRHA believes the 23 additional elements go beyond what is necessary for quality improvement and what is requ
operational guidance. NFPRHA asks for additional opportunities for grantees and other stakeholders to provide feedb
to the current FPAR clinic visit record and would be most helpful for program management and quality improvement

Management of the Title X program entails monitoring progress towards performance goals required by the 1993 Go
which include: giving priority in the provision of family planning services to low-income individuals, reducing invas
infertility through chlamydia screening, and increasing program efficiency by monitoring the cost of care. However,
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, requ
information from patients at every single visit, even though such information is not necessitated by clinical practice g

Some proposed data elements pertain to services that are outside of the core family planning services in the Recomme
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
directly to achieving or preventing pregnancy include screening for breast and cervical cancer," they certainly should
accountability to program goals. We request additional justification for collecting these new data elements beyond the
objectives.

<u>New Data Elements: Sexual Activity</u>

The Supporting Statement for the Title X FPAR 2.0 describes how FPAR 2.0 will supplement the federally funded N
population-level, nationally representative dataset that gathers information on pregnancy and births, infertility, use of
However, while NSFG surveys a representative sample of respondents and allows them to voluntarily respond, the da
FPAR 2.0 will be required for every patient visit. More specifically, OPA has proposed that Title X service sites repo
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 b
relationship. It also is inconsistent with current best practice guidelines, which recommend assessing whether an adul
[unless the patient is at increased risk for infection or is seeking evaluation and treatment for sexually transmitted infe
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 res
questions at every visit, nor would their responses be reported at the encounter level to the federal government. When
for its benefit and requires those accessing services through the safety net to provide such information as a precursor
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-cen
tracking patients' intention to either become pregnant or prevent a pregnancy in the next year. Research suggests that
intentions over the next year; doing so is inconsistent with how they think about and approach their reproductive lives
children or not have children, suggesting that asking about reproductive "intentions" or "plans" may be problematic.2
regardless of the reason for the visit, could compromise the patient-provider relationship by breaking rapport and shif
Reflecting current research that patients prefer to be asked about their service needs than about pregnancy intentions
more patient-centered approach to measurement. An example of an alternative measure that assesses patients' desire
Contraception (SINC)24 question developed by the University of California, San Francisco (UCSF) Person-Centered
Reproductive Justice advocates. Of note, UCSF has an award from OPA to develop a new electronic Clinical Quality
SINC question to define the denominator. As such, use of the SINC question in FPAR 2.0 would be consistent with c
measure also would facilitate the removal of problematic data elements related to sexual activity, which have been in
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 sc
the last five years, HPV test performed at this visit, and HPV test result. Collecting and reporting all five data elemen
with minimal benefit.

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

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

It is critical to underscore that ASCCP Risk-Based Management Consensus Guidelines for abnormal cervical cancer
patient age and other risk factors that support screening.26 As a result, none of these cervical cancer screening-relate
adherence to screening guidelines or track progress towards Healthy People 2030 goals (i.e., increase the proportion
on the most recent guidelines), as described in the Supporting Statement for the Title X FPAR 2.0.27 28 Therefore, th
subrecipients must make to collect and report these additional data elements will produce data with little – if not no –
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 sc
the last five years, HPV test performed at this visit, and HPV test result. Collecting and reporting all five data elemen
with minimal benefit.

The collection of information on a patient's Pap (at current and previous visit) and HPV tests performed may be help
number of tests provided during a specified period, the distribution of abnormal cytology results, or use of different c
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Furthermore, there is no way for grantees and subrecipients to differentiate whether an HPV test was done as part of
screening test or for post-treatment surveillance.

Separate reporting of systolic and diastolic blood pressure measurements does not make sense clinically, as the interp
be tempered by the age of the patient, anxiety level when blood pressure is measured (i.e., "white coat" hypertension)
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 elemen
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 probl
rationale to record and report body weight at every visit, and OPA does not state why it is necessary to collect this inf
Statement for the Title X FPAR 2.0.30 Even when collecting a patient's height and weight data is clinically indicated
whether that patient is overweight or obese – and, in turn, at risk for cardiovascular disease. Developed for and tested
BMI is not a useful indicator of health, especially for women of color, because it fails to account for differences in bo
differences.31 Furthermore, the practice of weighing clients at every visit – even health education sessions or when n
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) o
receive the same standard of care and should not be subject to weight stigmatization at every visit. Weight stigma inv
suggests that this stress can exacerbate poor physical health outcomes for obese individuals33, with the potential to p
disparities in overweight and obesity. It would be more appropriate to focus on measures of health that are scientifica

Screening for cardiovascular risk factors is indicated to support contraceptive decision-making (i.e., to ensure a patien
contraceptives and other hormonal contraception) and pre-pregnancy health. While it may be desirable to capture thes
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
they are not required for those providers who do not transmit Health Information Portability and Accountability Act-
"incident to" another provider. Furthermore, only advanced practice clinicians may obtain an NPI; however, in 2019,
were performed by other types of providers, including registered nurses, registered nurses with an expanded scope of
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 pers
Confidentiality is a hallmark of the Title X program, and all patients, including adolescents, are guaranteed confident
regulations, and case law. Further, they are grounded in medical and ethical standards and reflect research demonstra
patients would not seek needed health services.35 Despite this assurance, the Supporting Statement for the Title X FP
confidentiality of the sensitive personal health information it wants to collect through FPAR 2.0.36 While encounter-
specifications for how the patient identifier data element will be used in a way that ensures that patient confidentiality
information on the HIPAA Security Rule Standards it will adopt to ensure the appropriate consent and safeguarding c
subrecipient levels; for example, specifying encryption standards for data at rest and in motion. Given the cybersecur
seems imprudent to move forward with FPAR 2.0 without releasing more information about – and seeking stakeholde
FPAR 2.0's encounter-level data from unauthorized access, use, and disclosure, as well as what steps grantees will be
Despite a range of opinions about what qualifies as sensitive health information, it generally is considered to be infor
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
Statements for the Title X FPAR that were submitted to OMB (dated June 29, 2010 and October 15, 2010), OPA stat
"Although the FPAR contains several data items of a sensitive nature (e.g., user income and insurance status, user
STD tests
performed, and Pap and HIV test results), individuals cannot be identified because federal regulation (42 CFR Pa
totals. The FPAR
collects no individual identifiers. These sensitive data are required to monitor compliance with statutory requiren
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 submitti

NFPRHA supports investments in Title X program infrastructure, including investment in a more contemporary data
performance; however, such a venture cannot come at the expense of serving those in need of services, specifically pa
insured. Such an effort also cannot come at the expense of providing Title X patients with the same standard of care a
settings, which is just what FPAR 2.0 - with burdensome and unnecessary data elements that are required for every v
pause and re-evaluate FPAR 2.0.

Currently collected in aggregate under OMB No. 0990-0221, this new data collection, Family Planning Annual Repo
the encounter level and build on the existing data collection and reporting system by adding 23 new data elements to
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 pa
would jeopardize patient and provider relationships, interfere with evidence-based practice, and threaten patient confi
sensitive. The proposed FPAR 2.0 data elements risk the trust, confidentiality and privacy that's essential in providin
people we see in our clinic. Patient-provider relationships will be harmed by inquiring about the invasive and unneces
elements, which include details on a patient's sexual activity, intention to become pregnant, sexually transmitted infe

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

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

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

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

While Essential Access appreciates the need for a more robust data system for monitoring and improving program pe
system, the current FPAR 2.0 project must be paused. At the same time, OPA must plan and initiate a new process fo
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
network's capacity after an estimated one in four service sites left the Title X program in response to the 2019 Title X
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
counties. After the regulations were fully implemented, providers across the state were forced to make the difficult de
resources. As a result, the state's Title X provider network was drastically reduced to 237 clinic sites in 20 counties a
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. Thes
Title X and IT staff being diverted to the COVID-19 response, budget shortfalls amidst the need to purchase PPE and
resigning or going on extended leave for personal or health-related reasons, implementation of telehealth services, an
additional burdens have challenged the network to provide low-income individuals with family planning and related

Any attempt to implement FPAR 2.0 in accordance with current timelines will severely disrupt and undermine their a
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
Cost burden estimates in the Public Comment Request are extremely low and based on an inappropriate and incredibl
Planning Annual Report (FPAR) Burden Study, was published in 2009 using data collected from Title X grantees mo
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 c
elements. Estimates in the FPAR Burden Study, where gross non-labor costs were estimated to be $163,300 (or $2,20
estimated at $106,880 (or $1,444 per respondent)3, are based on the cost and time burdens of implementing a new FP
encounter-level data reporting and collection). 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
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 t
between their respective systems. In addition, each sub-recipient utilizes its electronic health record system differentl
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 i
of four staff persons working a combined 2400 hours on tasks related to implementation, including implementing an
accommodate the additional data, updating and testing subrecipient configurations in the new data system, updating a
additional data elements, training subrecipient staff on how to collect new data elements and how to use the new syst
vendors to make updates to EHR systems including new fields and report modifications, and performing quality assu

We also estimate that each of our subrecipients, whose number we expect to increase to approximately 60 organizatio
FPAR 2.0, plus 4 hours of training per service site at an estimated 300 services sites, for an estimated total of 6000 ho
across this single Title X grantee network. Again, OPA is proposing this time commitment take place when we are co
COVID-19 public health emergency. Costs for ongoing operations and maintenance are not included in these estimat
take health care providers and staff at Title X service sites to document more than 20 additional data elements as part
Essential Access estimates that implementing FPAR 2.0 as proposed at the grantee level will amount to $480,000 in c
management system. Furthermore, we estimate that each of our estimated 60 subrecipients will outlay an average of $
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 i
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 statuto
We ask for additional opportunities to provide feedback on what additional data elements are feasible to add to the cu
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 Go
which include: giving priority in the provision of family planning services to low-income individuals, reducing invasi
infertility through chlamydia screening, and increasing program efficiency by monitoring the cost of care. However, v
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 t
research dataset, requiring Title X service sites to collect excessive information from patients at every single visit, ev
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
Planning Services (QFP), including elements related to cardiovascular disease risk factors.4 While, as OPA has affirm
appropriate to deliver in the context of a family planning visit even though they do not contribute directly to achievin
be monitored at the encounter level to monitor accountability to program goals. We request additional justification fo
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 N
population-level, nationally representative dataset that gathers information on pregnancy and births, infertility, use of
However, while NSFG surveys a representative sample of respondents and allows them to voluntarily respond, the da
FPAR 2.0 will be required for every patient visit. More specifically, OPA has proposed that Title X service sites repo
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 b
relationship. It also is inconsistent with current best practice guidelines, which recommend assessing whether an adul
[unless the patient is at increased risk for infection or is seeking evaluation and treatment for sexually transmitted infe
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 res
questions at every visit, nor would their responses be reported at the encounter level to the federal government. When
for its benefit and requires those accessing services through the safety net to provide such information as a precursor
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 s
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.

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

It is critical to underscore that ASCCP Risk-Based Management Consensus Guidelines for abnormal cervical cancer s
patient age and other risk factors that support screening.9 As a result, none of these cervical cancer screening-related
adherence to screening guidelines or track progress towards Healthy People 2030 goals (i.e., increase the proportion o
on the most recent guidelines), as described in the Supporting Statement for the Title X FPAR 2.0.10 11 When extrac
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 cardiovascula
pressure, Height, Weight, and Smoking status.

Separate reporting of systolic and diastolic blood pressure measurements does not make sense clinically, as the interp
be tempered by the age of the patient, anxiety level when blood pressure is measured (i.e., "white coat" hypertension)
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 elemen
offered 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 cli
and report body weight at every visit, and OPA does not state why it is necessary to collect this information and how
X FPAR 2.0. Even when collecting a patient's height and weight data is clinically indicated, such measurements are n
overweight or obese – and, in turn, at risk for cardiovascular disease. Developed for and tested on a sample of predon
indicator of health, especially for women of color, because it fails to account for differences in body composition, fitn
the practice of weighing clients at every visit – even health education sessions or when not clinically indicated – may
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. Tit
and should not be subject to weight stigmatization at every visit. Weight stigma invokes psychological stress and eme
poor physical health outcomes for obese individuals16, with the potential to perpetuate racial/ethnic and socioeconom
to move away from this measure and focus on measures of health that are scientifically valid and designed for diverse

Screening for cardiovascular risk factors is indicated to support contraceptive decision-making (i.e., to ensure a patien
contraceptives and other hormonal contraception) and pre-pregnancy health. While it may be desirable to capture thes
expectation or requirement for Title X providers to obtain information beyond that which is clinically necessary. Acc
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 tra
Act- (HIPAA) covered data or those who provide services "incident to" another provider. Furthermore, only advance
2019, 7.4% of all Title X family planning encounters in the Essential Access network were performed by other servic
practical nurses, health educators, and social workers. As such, many of our providers delivering Title X services do

CONFIDENTIALITY OF SENSITIVE PERSONAL HEALTH INFORMATION
Essential Access requests clarification on the steps OPA will take to maintain the confidentiality of the sensitive pers
Confidentiality is a hallmark of the Title X program, and all patients, including adolescents, are guaranteed confident
regulations, and case law. Further, they are grounded in medical and ethical standards and reflect research demonstra
patients would not seek needed health services.17 Despite this assurance, the Supporting Statement for the Title X FP
confidentiality of the sensitive personal health information it wants to collect through FPAR 2.0.18 Despite a range o
information, it generally is considered to be information that carries with it unusually high risks in the event of disclo
nature, as they relate to sexual behaviors and other deeply personal topics.
While encounter-level data will be de-identified, OPA has not released specifications for how the patient identifier da
confidentiality is preserved. Furthermore, OPA has not provided information on the HIPAA Security Rule Standards
safeguarding of this encounter-level data at the federal, grantee, and subrecipient levels; for example, specifying encr
cybersecurity issues that all organizations currently are facing, it is imprudent to move forward with FPAR 2.0 witho
stakeholder feedback on – the steps that OPA will take to protect FPAR 2.0's encounter-level data from unauthorized
will be required to take.

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

Currently, we estimate it will take approximately 12 months to provide technical assistance to 60 subrecipients to add
technical assistance to help subrecipients update their data reports. In addition, concurrently it will take us an estimate
system and agency configurations inside that system. Extending this timeline is the limited availability of subrecipien
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
care providers and staff on how to collect new data elements, conduct preliminary data collection, run reports to ensu
assurance of preliminary data collected, as needed, for a total of 1200 hours. Initiating upgrades before final specifica
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,
recruiting additional safety net providers to join its network, an ongoing effort since the 2019 Title X Rule took effec
that resulted in 80% fewer Title X patients served in 2020. We are also concerned about losing existing subrecipients
burden.

We are striving to see more patients after unprecedented declines in patient census. While we agree that the Title X p
monitoring and improving program performance, such an endeavor cannot come at the expense of serving those in ne
uninsured, and under-insured. Such an effort also cannot come at the expense of Title X patients receiving the same s
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. Accor
evaluate FPAR 2.0.

Currently collected in aggregate under OMB No. 0990-0221, this new data collection, Family Planning Annual Repo
the encounter level and build on the existing data collection and reporting system by adding 23 new data elements to
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 pa
would jeopardize patient and provider relationships, interfere with evidence-based practice, and threaten patient confi
sensitive. The proposed FPAR 2.0 data elements risk the trust, confidentiality and privacy that's essential in providin
and individuals who are undocumented.

Patient-provider relationships will be harmed by inquiring about the invasive and unnecessary specifics in many of th
details on a patient's sexual activity, intention to become pregnant, sexually transmitted infection testing and more. T
sexual and reproductive health clinical guidelines and have the potential to harm a provider's ability to build and mai
These data elements are irrelevant to monitoring the Title X program for compliance and accountability to performan
program.

Collection of this data would weaken clinics' and providers' ability to serve patients effectively with quality family p
especially telehealth visits, and collecting itemized data and additional personal information from patients would inte
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 sen
data will be shared with the federal government. Many of the proposed elements should not be collected at the federa
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 exponenti
the Federal Register (86 FR 9077); it also puts forward data collection requirements that far exceed the minimum a
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 hig
Register (86 FR 9077); **it also puts forward data collection requirements that far exceed the minimum amount**
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 th**e Family Planning Council of Iowa's (FP**
the program. FPCI has spent roughly the last 18 months desperately trying to recruit and onboard new clinics and pr
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 d
partner with to provide Title X services are Federally Qualified Health Centers and small, localized public hea
adjust systems at these facilities to manage disaster response. The pandemic is not over and any attempt to implem
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 Janua**
FPCI would need to upgrade to its information technology (IT) infrastructure, as would its 13 subrecipients. Howeve
specifications for (i.e., instructions for how to collect) FPAR 2.0's data elements, including how to map each data ele
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
use paper systems to collect FPAR data for aggregate submission. As data system and EHR enhancements typica
and six to eight months for implementation. Instead, if FPAR 2.0 goes into effect on that date, we will need to collect
proposed data elements for every visit, and then determine how to deidentify line-item records so that they can be tra
raises concerns about the effective use of Title X resources, but also about the security and confidentiality of cl

with the addition of 23 new data elements – many of which are irrelevant to monitoring Title X program comp
goals – FPAR 2.0 represents an effort that has no intention of being minimally burdensome. It corresponds to th
monitoring tool to a research dataset, requiring Title X service sites to collect excessive information from patients at e
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
Asking these three data points at every visit is **burdensome and threatens the patient-provider relationship**. It is i
non-Title X settings would not be asked to provide responses to **these personal, guideline-unconcordant questions**
the encounter level to the federal government. When the federal government begins collecting research data for its be
safety net to provide such information as a precursor to receive care, it exacerbates medical mistrust, potentially dissu

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" hyperte
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 hyper
blood pressure has been performed consistent with nationally recognized guidelines.**

Self-reported smoking status also is not helpful as a quality metric. If this topic is a priority for OPA, this data elem
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 problemat
**rationale to record and report body weight at every visit, and OPA does not state why it is necessary to collect
Supporting Statement for the Title X FPAR 2.0.** Even when collecting a patient's height and weight data is clinica
identifying whether that patient is overweight or obese – and, in turn, at risk for cardiovascular disease. Developed fo
European men, BMI is not a useful indicator of health, especially for women of color, because it because it fails to ac
and nutritional differences. Furthermore, the practice of weighing clients at every visit – even health education sessio
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 th
collect through FPAR 2.0.13 While encounter-level data will be de-identified, **OPA has not released specifications
used in a way that ensures that patient confidentiality is preserved.** Furthermore, **OPA has not provided inform
adopt to ensure the appropriate consent and safeguarding of this encounter-level data at the federal, grantee, and subr
standards for data at rest and in motion. Given the **cybersecurity issues that all organizations currently are facing
without releasing more information about – and seeking stakeholder feedback on – the steps that OPA will tak
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 woul
in 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 exponenti
the Federal Register (86 FR 9077); it also puts forward data collection requirements that far exceed the minimum a
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 hig
Register (86 FR 9077); **it also puts forward data collection requirements that far exceed the minimum amount**
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 P**
in the departure of key clinical staff and required the Centers to drastically reduce their operating hours, whic
months. This loss, combined with the onset of COVID-19, has been devastating for PHS' SRH Centers. From 2019 t
Already reeling from staffing and operational challenges related to relinquishing Title X, clinical and operations staff
implementation of telemedicine services.

Even in the absence of the above challenges, **the current timeline for FPAR 2.0 data collection to begin on Janua PHS would need to upgrade to its information technology (IT) infrastructure, as would our five former subrec released final specification**s for (i.e., instructions for how to collect) FPAR 2.0's data elements, including how to ma value sets. In the absence of these specifications, we are in the difficult position of having to wait while the time winc

Currently, we estimate it will take 3 months to implement and test the systems upgrades needed to collect and report need to create new clinical workflows to align with the new FPAR 2.0 framework and modify existing EMR sy to be trained on n**ew workflows and where to code the new fields. IT technical staff and EMR vendors would als 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 h**ow to collect n collection, run reports to ensure data mapping is correct, and perform quality assurance of preliminary data c**

Cost burden estimates in the Public Comment Request are extremely low and based on an inappropriate and i 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.

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

Furthermore, some proposed data elements pertain to services that are outside of the core family planning services in Planning Services (QFP), including elements related to cardiovascular disease risk factors. While, as OPA has affirm appropriate to deliver in the context of a family planning visit even though they do not contribute directly to achievin and cervical cancer," they certainly should not be monitored at the encounter level to monitor accountability to progra **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 **Asking these three data points at every visit is burdensome and threatens the patient-provider relationship. It 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 accountability to program goals

FPAR 2.0 suggests the Title X service sites collect and report **five different data elements related to cervical cance** 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.

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" 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.

PHS believes the collection of height and weight data, presumably to calculate body mass index (BMI), is prob rationale to record and report body weight at every visit, and O**PA does not state why it is necessary to collect this Supporting Statement for the Title X FPAR 2.0.** Even when collecting a patient's height and weight data is clinica identifying whether that patient is overweight or obese – and, in turn, at risk for cardiovascular disease. Developed fo European men, BMI is not a useful indicator of health, especially for women of color, because it because it fails to ac and nutritional differences. Furthermore, the practice of weighing clients at every visit – even health education sessio 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 oral contraceptives and other hormonal contraception) and pre-pregnancy health. While it may be desirable to capture explicit expectation or requirement for Title X providers to obtain information beyond that which is clinically necessa **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 tra Act- (HIPAA) covered data or those who provide services "incident to" another provider. Furthermore, only advance 2019, 15 percent of all Title X family planning encounters at PHS' SRH Centers were performed by other services pr nurses, health educators, and social workers. A**s such, many of our providers delivering Title X services do not ha**

the S**upporting Statement for the Title X FPAR 2.0 fails to address how OPA will maintain the confidentiality to collect through FPAR 2.0.** While encounter-level data will be de-identified, O**PA has not released specification used in a way that ensures that patient confidentiality is preserved. Furthermore, OPA has not provided infor** adopt to ensure the appropriate consent and safeguarding of this encounter-level data at the federal, grantee, and subr

The current timeline for FPAR 2.0 data collection to begin on January 1, 2022 is not feasible. As of April 1, 202
instructions for how to collect) FPAR 2.0's data elements, including how to map each data element and response opti
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 imp
and report encounter-level data through FPAR 2.0. This includes **steps to upgrade the current Title X data system**
their current electronic health record (EHR) or electronic data collection system to report specific data elements and c
data elements map to existing standardized value sets, and data validation efforts.

After making system upgrades, IDPH and its SRs (which operate 19 service sites) will require three months to **train**
data elements, conduct preliminary data collection, run reports to ensure data mapping is correct, and perform
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 suc**
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 Recomme
Services (QFP), including elements related to cardiovascular disease risk factors. While, as OPA has affirmed, these
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**
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**
to collect through FPAR 2.04 While encounter-level data will be de-identified, O**PA has not released specification**
used in a way that ensures that patient confidentiality is preserved. **OPA has not provided information on the HIPA**
appropriate consent and safeguarding of this encounter-level data at the federal, grantee, and subrecipient levels; for e
and in motion.

Despite a range of opinions about what **qualifies as sensitive health information**, it generally is considered to be inf
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 ar**
staff time and technical assistance to build out those missing data elements. In particular, the lack of standard fie
counseling, and the contraceptive method a patient is using as of the end of their visit have presented serious barriers
presents barriers to the implementation of FPAR 2.0. Needs assessments should be conducted to ensure that the data
contraceptive care workflow at the particular agency. The Title X network will need technical support and resources t
systems.
We would welcome OPA's advocacy with government offices like ONC and with EHR vendors around including far
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 s**
in having **three measures of sexual activity for research purposes, it is likely too burdensome to build out and t**
documentation. Likewise, it seems that th**e two "reason for no contraceptive method" data elements are redund**
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 o**
best practice. Will the FPAR 2.0 data system be able to do patient matching (at the health facility level) to see wheth
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 exponenti
than the outdated estimates published in the Federal Register (86 FR 9077); it also puts forward data collection r
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 hig
than the outdated estimates published in the Federal Register (86 FR 9077); **it also puts forward data collection req**
data needed to monitor compliance with statutory and regulatory requirements and to manage the Title X pro

At this time—against the backdrop of a year-long public health emergency that resulted in an unprecedented drop in p
network's capacity after an estimated one in four service sites left the Title X program in response to the 2019 Title X
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 th
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 ter
services—and have reported serving fewer clients, even as they worked tirelessly to maintain access to Title X servic
teleservices.
Most pressing for **sub-recipients is the reality that reduced client volume has translated into reduced revenue**. C
navigated state-level funding and policy changes that threatened the sustainability of the family planning safety net. C
funding. Sub-recipients are concerned that women's health funding appropriated by the Texas Legislature and admini
Commission (HHSC) will not adequately address the increased rates of uninsured and unemployed Texans seeking sa
Texas's sub-recipients rely on HHSC's women's health funding to support their overall family planning projects, dep
**could be adverse impacts on Every Body Texas's Title X Project—including but not limited to reduced client v
closures.**

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

Twenty of Every Body Texas's 37 subrecipients that do not use Ahlers & Associates software or web-based applicati
fields to their EMRs for the new data elements and update extraction methods and tools—in addition to conducting al
subrecipients would require training and operational changes to ensure the new data elements are populated consisten
specifications for (i.e., instructions for how to collect) FPAR 2.0's data elements, including how to map each data ele
the absence of these specifications, we are in the difficult position of having to wait while the time window needed to
**unknowns on the OPA side, coupled with the diversity of our sub-recipients in terms of size and IT capacity, c
implementation**. With that in mind, and assuming that funding and staff for these new activities is available, **we esti**
efforts with our data warehouse and subrecipients to implement and test technologies, train staff and conduct basic m

Every Body Texas requests that OPA complete an up-to-date burden study t**o provide a complete and accurate esti
FPAR 2.0.**

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

Every Body Texas estimates that **implementing FPAR 2.0 as proposed at the grantee-level will amount to $82,00**
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 guidanc**e. 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 affirm appropriate to deliver in the context of a family planning visit even though they do not contribute directly to achievin and cervical cancer," they certainly should not be monitored at the encounter level to monitor accountability to progra **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 **Asking these three data points at every visit is burdensome and threatens the patient-provider relationship. It guidelines, which recommend assessing whether an adult or adolescent patient is sexually active only annually** seeking evaluation and treatment for sexually transmitted infections (STIs)]. These sexual activity-related data fields accountability to program goals.

FPAR 2.0 suggests the Title X service sites collect and report **five different data elements related to cervical cance** 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" hyperte 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
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Supporting Statement for the Title X FPAR 2.0. Even when collecting a patient's height and weight data is clinically
identifying whether that patient is overweight or obese – and, in turn, at risk for cardiovascular disease. Developed fo
European men, BMI is not a useful indicator of health, especially for women of color, because it because it fails to ac
and nutritional differences. Furthermore, the practice of weighing clients at every visit – even health education sessio
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 patie
contraceptives and other hormonal contraception) and pre-pregnancy health. While it may be desirable to capture thes
expectation or requirement for Title X providers to obtain information beyond that which is clinically necessa
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 tra
Act- (HIPAA) covered data or those who provide services "incident to" another provider. Furthermore, only advance
2019, 43% percent of all Title X family planning encounters in Every Body Texas' network were performed by other
practical nurses, health educators, and social workers. **As such, many of our providers delivering Title X services**

the Supporting Statement for the **Title X FPAR 2.0 fails to address how OPA will maintain the confidentiality of**
collect through FPAR 2.0. While encounter-level data will be de-identified, **OPA has not released specifications f**
in a way that ensures that patient confidentiality is preserved. Furthermore, OPA has not provided informatio
adopt to ensure the appropriate consent and safeguarding of this encounter-level data at the federal, grantee, and subr
standards for data at rest and in motion. Given the cybersecurity issues that all organizations currently are facing, it se
releasing more information about – and seeking stakeholder feedback on – the steps that OPA will take to protect FP
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
FPAR's standard set of data elements (for a total of 45 data elements to be collected at every visit). While the NYSD
robust data system for monitoring and improving program performance, **the NYSDOH is concerned that implemen**
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 t**
collect through FPAR 2.0. While encounter-level data will be partially de-identified, OPA has not released specifica
and more particularly in combination with the National Provider ID (NPI), and full birth and visit dates, will be used
preserved.
Furthermore, **OPA has not provided information on the Health Information Portability and Accountability Act**
ensure the appropriate consent and safeguarding of this encounter-level data at the federal, grantee, and subrecipient l
data at rest and in motion. Given the cybersecurity issues that all organizations currently face, OPA should engage wi
that OPA will take to protect FPAR 2.0's encounter-level data from unauthorized access, use, and disclosure, as well

OPA has proposed that **Title X service sites report the following three data fields for patients at every visit: ever**
year. In addition to the forementioned extreme sensitivity of this information, asking these three data points at
provider relationship. It also is inconsistent with current best practice guidelines, which recommend assessing whet
annually [unless the patient is at increased risk for infection or is seeking evaluation and treatment for sexually transm
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 cardiov
blood pressure, height, weight, and smoking status (detailed as ever smoker, ex-smoker, daily smoker, occasion
light smoker).
The NYSDOH believes there is no logical rationale to record and report these data; there is no explicit expectation or
beyond that which is clinically necessary. Accordingly, we should not be required to document and report these meas

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

FPAR 2.0 further suggests that Title X service sites collect and report on a number of different data elements related t
at current visit and multiple results for Chlamydia, gonorrhea, and syphilis, as well testing at current visit, and rapid a
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 su
existing status would be excessively burdensome and would require significant adjustment as laboratory testing techn
that 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 tra
services "incidental to" another provider. Furthermore, only advanced practice clinicians may obtain an NPI; howeve
FPP were performed by other services providers, including registered nurses, licensed practical nurses, health educato
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 th
NYS contracts with Ahlers and Associates to manage its centralized data system. **Compliance with FPAR 2.0 repor**
overhaul of the current system's complex information technology infrastructure, which would incur substantia
overburdened. In the absence of complete specifications, it is difficult to accurately estimate the additional revenu
estimate 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) ven 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 mor**e. While the added cost would be burdensome in general, it would be particula organizations, but also for the larger urban organizations that have struggled to maintain access and service during the Further, neither of these costs includes the **inestimable additional expense required for NYSDOH FPP staff and a 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 sp 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 COVI resulting in closure of a number of the FPP clinics, both temporarily and permanently; implementing and diverting ca the program under the strain of staff redeployed to pandemic response service. Any attempt to implement FPAR 2.0 i 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 the Federal Register (86 FR 9077)**; it also puts forward data collection requirements that far exceed the minimum an 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 hig Register (86 FR 9077); it also **puts forward data collection requirements that far exceed the minimum amount c 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 p
network's capacity after an estimated one in **four service sites left the Title X program in response to the 2019 Tit
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, t**he current timeline for FPAR 2.0 data collection to begin on Janua**
MFHC would need to upgrade to its information technology (IT) infrastructure, as would its 15 subrecipients. Howev
specifications for (i.e., instructions for how to collect) FPAR 2.0's data elements, including how to map each data ele

Currently, we estimate it will take **18-24 month**s to implement and test the systems upgrades needed to collect and re
includes upgrades to MFHC's centralized database, customizing reporting and mapping, working with 8 different EH
mapping, and reporting, data validation and testing, etc. After making system upgrades, MFHC and its subrecipients
months to train health care providers and staff on how to collect new data elements, conduct preliminary data collect
perform quality assurance of preliminary data collected, as needed. Initiating upgrades before final specifications are
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 i
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.
Firstly, OPA has not collated recent feedback from the Title X network regarding costs associated with encounter-lev
elements.

Secondly, **due to challenges with interoperability** (i.e., electronic sharing of data between systems), there is no "one
electronic reporting from Title X service sites to grantees, necessitating each grantee-subrecipient dyad to invest in up
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
hours on tasks related to implementation, including selecting and/or creating a contract with a vendor, working (with
out FPAR 2.0's data elements to existing standardized value sets, training health care providers and staff on how to c
collection, running reports to ensure data mapping is correct, and performing quality assurance of preliminary data co
subrecipients will spend an average of 40 hours implementing FPAR 2.0, for an estimated total of $60,000 in one-tim
Again, OPA is proposing this time commitment take place when we are continuing to respond to – and facing burnou
for ongoing operations and maintenance are not included in these estimates. They also do not include the additional ti
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 comp goals – FPAR 2.0 represents an effort that has no intention of being minimally burdensome. These data elements seer than in a program monitoring tool, requiring Title X service sites to collect excessive information from patients at eve 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 Recomme Services (QFP), including elements related to cardiovascular disease risk factors.4 While, as OPA has affirmed, these deliver in the context of a family planning visit even though they do not contribute directly to achieving or preventing cancer,"5 they certainly should not be monitored at the encounter level to monitor accountability to program goals. **W 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 l year.** Asking these three data points at every visit is burdensome and threatens the patient-provider relationship. It als which recommend assessing whether an adult or adolescent patient is sexually active only annually [unless the patien evaluation and treatment for sexually transmitted infections (STIs)].7 These sexual activity-related data fields also are accountability to program goals

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

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

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" hyperte 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 el
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 pro**
rationale to record and report body weight at every visit, and OPA does not state why it is necessary to collect this inf
Statement for the Title X FPAR 2.0.19 Even when collecting a patient's height and weight data is clinically indicated
whether that patient is overweight or obese – and, in turn, at risk for cardiovascular disease. Developed for and tested
BMI is not a useful indicator of health, especially for women of color, because it because it fails to account for differ
differences.20 Furthermore, the practice of weighing clients at every visit – even health education sessions or when n
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 pa
contraceptives and other hormonal contraception) and pre-pregnancy health. While it may be desirable to capture thes
expectation or requirement for Title X providers to obtain information beyond that which is clinically necessary. Acc
report these measurements for every visit.

the S**upporting Statement for the Title X FPAR 2.0 fails to address how OPA will maintain the confidentiality**
to collect through FPAR 2.0.24 While encounter-level data will be de-identified, OPA has not released specifications
in a way that ensures that patient confidentiality is preserved. Furthermore, **OPA has not provided information on t**
ensure the appropriate consent and safeguarding of this encounter-level data at the federal, grantee, and subrecipient
data at rest and in motion. Given the cybersecurity issues that all organizations currently are facing, it seems imprude
more information about – and seeking stakeholder feedback on – the steps that OPA will take to protect FPAR 2.0's e
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 yea
unprecedented drop in patient census and following a 46% decline in the network's capacity nationwide after an estim
response to the 2019 Title X Rule1 – implementation of FPAR 2.0 simply is not feasible. We are working hard to hold
patients.

Title X providers in our network have reported to us that they have *experienced significant impact as a result of the C*
considerable challenges around logistical changes (e.g., managing waiting room limits, implementing telehealth servi
shifted to other teams to cover COVID-19 needs, increased turnover), and increased patient need (e.g., patients exper
with 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 unknow
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 chal face. 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 t 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 spec 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. to collect FPAR data and an additional six use legacy systems that will need to be redeveloped for FPAR 2.0. If FPA need to collect and perform manual data entry of FPAR 2.0's 45 proposed data elements for every visit. This cumbers effective use of Title X resources and the possibility of subrecipients opting to leave AccessMatters' Network and the 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 o Cost burden estimates in the Public Comment Request are extremely low and based on an inappropriate and incredibl 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 AccessMatters' Title X Network there are 18 subrecipients using estimates that implementing FPAR 2.0 will exceed $1 million in one-time labor and non-labor costs combined for Ac the cost of an internal team at AccessMatters of five staff persons working at least 200 hours to get systems and proce important to note that our estimate is an underrepresentation of total cost to our Network, as these cost estimates do n operations and maintenance in addition to computer and software upgrades and purchased service costs, or (2) the ad 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 Go which include: giving priority in the provision of family planning services to low-income individuals, reducing invasi infertility through chlamydia screening, and increasing program efficiency by monitoring the cost of care. However, 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 da
Healthcare providers need training in trauma-informed care and motivational interviewing to implement best practice
patients. As a grantee with a nationally-recognized training team that has experience providing healthcare providers v
motivational interviewing and delivering trauma-informed care, AccessMatters recommends that OPA outline a detai
deliver trauma-informed, comprehensive counseling and care. This is a critical element that must be addressed before
elements required by FPAR 2.0.

AccessMatters also understands that the sensitive nature of additional data elements could be of great concern to som
receive services through the Title X program because they have concerns about the amount and type of sensitive info
information shared with the federal government.

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

Please see the attachment AccessMatters' Standard Demographic Language for additional detail and recommendation
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 N
population-level, nationally representative dataset that gathers information on pregnancy and births, infertility, use of
However, while NSFG surveys a representative sample of respondents and allows them to voluntarily respond, the da
FPAR 2.0 will be required for every patient visit. More specifically, OPA has proposed that Title X providers inquire
the following three data fields for patients at every visit: Ever had sex, Sex in the last 3 months, and Sex in the last ye
intrusive, burdensome and threatens the patient-provider relationship. It also is inconsistent with current best practice
adult or adolescent patient is sexually active only annually [unless the patient is at increased risk for infection or is se
infections (STIs)]. These sexual activity-related data fields also are not needed to monitor our Title X Network's acco

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 sc
the last five years, HPV test performed at this visit, and HPV test result. Collecting and reporting all five data elemen
with minimal benefit. The collection of information on a patient's Pap (at current and previous visit) and HPV tests p
instance, to compute the number of tests provided during a specified period, the distribution of abnormal cytology res
technologies (cytology-alone, hrHPV-alone, co-testing) during a specified period. However, the utility of collecting c
questionable, as no national guideline recommends cervical cytology alone at a five-year interval, and there is no nati
come back as positive.8 Furthermore, there is no way for AccessMatters to differentiate whether an HPV test was dor
abnormal screening test or for post-treatment surveillance.
It is critical to underscore that ASCCP Risk-Based Management Consensus Guidelines for abnormal cervical cancer s
patient age and other risk factors that support screening.9 As a result, none of these cervical cancer screening-related
adherence to screening guidelines or track progress towards Healthy People 2030 goals (i.e., "increase the proportion
based on the most recent guidelines"), as described in the Supporting Statement for the Title X FPAR 2.0.10 11 Whe
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 cardiovascula
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 interp
be tempered by the age of the patient, anxiety level when blood pressure is measured (i.e., "white coat" hypertension)
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.

Smoking status:
Self-reported smoking status also is not helpful as a quality metric. If this topic is a priority for OPA, this data elemen
offered to tobacco smokers, using those listed by the US Preventive Services Task Force.12

Data Elements: Height, Weight, BMI A
weight data, presumably to calculate body mass index (BMI), is problematic. From a clinical perspective, there is no
every visit, and OPA does not state why it is necessary to collect this information and how it will be used in the Supp
collecting a patient's height and weight data is clinically indicated, such measurements are not reliable for identifying
turn, at risk for cardiovascular disease. Developed for and tested on a sample of predominantly white European men,
women of color, because it because it fails to account for differences in body composition, fitness levels, and nutritio
clients at every visit – even health education sessions or when not clinically indicated – may deter clients from access
size 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 tra
Act (HIPAA) covered data or those who provide services "incident to" another provider. Furthermore, only advanced
24
percent of all Title X family planning encounters in AccessMatters' Network were performed by other service provid
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
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 l
ethical standards, and reflect research demonstrating that, without access to confidential care, some patients would no
Supporting Statement for the Title X FPAR 2.0 fails to address how OPA will *maintain the confidentiality of the sens*
through FPAR 2.0.18 While encounter-level data will be de-identified, OPA has not released specifications for how t
that ensures that patient confidentiality is preserved.

OPA has not provided information on the *HIPAA Security Rule Standards* it will adopt to ensure the appropriate cons
federal, grantee, and subrecipient levels; for example, specifying encryption standards for data at rest and in motion.
currently face, it seems imprudent to move forward with FPAR 2.0 without releasing more information about – and s
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 *mi*
Currently, the Family Planning Annual Report (FPAR) collects *demographic information including family planning*
collect and report family planning user demographics such as date of birth or zip code of residence could compromise
with OPA reporting requirements. If OPA requires encounter-level data that could compromise patient confidentiality
such information.

Sub Recipient Compliance
The DHS Title X subrecipients have expressed concern in changes to reporting family planning user demographics, s
and reported to OPA. The DHS Title X subrecipients have an obligation to provide high-quality, confidential family
This conflict of providing high quality, confidential care and the reporting requirements of the program could result i
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 da
with subrecipients to collect encounter-level data estimates 600 hours to build the FPAR 2.0 requirements. The DHS
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 Tit
VDH staff who would otherwise have been assigned to FPAR 2.0 preparation have been required to prioritize COVI
to reduce their previous efforts to expand family planning services. VDH's Title X program has experienced a 42% d
numerous Title X sites across the Commonwealth were forced to adjust hours or temporarily close. When the panden
resources 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 implen
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, includin
standardized value sets. In the absence of these specifications, VDH is in the difficult position of having to wait whil
narrows.

Currently, VDH estimates it will take 36 months to pilot, implement, test, and revise the modifications necessary to c
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. Hov
uses paper forms and WebVision, a homegrown legacy system that tracks information for billing purposes, to collect
that do not have an EHR will not be able to procure and implement an EHR by January 1, 2022, as EHR implementat
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
effect on January 1, 2022, VDH will need to collect and perform manual data entry of FPAR 2.0's 45 proposed data e
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 an
related to the test. While LabCorp notifies VDH of the patient's test results, VDH does not have an electronic mecha
currently filed in the patient's paper chart and would then become part of the patient's treatment plan. VDH partners
FPAR, *but FPAR 2.0 would require a specific test result to be electronically connected to a specific encounter, a fun*
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 out
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 colle
the existing data collection and reporting system by *adding 23 new data elements to FPAR's standard set of data ele*
every visit). While AFHP appreciates the need for a more robust data system for monitoring and improving program
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, req
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 com
manage the Title X program.

The implementation of the Title X 2019 Rules created an enormous burden and negatively impacted AFHP's capacity
planning and related preventive health services. Significant time was spent on successfully implementing the *2019 Ti*
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 s
subrecipients has shifted to administering the COVID-19 vaccine to health center staff as well as the public. Any atte
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 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 ele *response options to standardized value sets.* In the absence of these specifications, we are in the difficult position of l implement systems changes narrows.

After making system upgrades, AFHP and its 12 subrecipients (which operate over 55 service sites) will require anot 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 bur burden https://www.arizonafamilyhealth.org estimates in the Public Comment Request are extremely low and based o source for estimates, *the Family Planning Annual Report (FPAR) Burden Study 2, was published in 2009 using data ago.* Since this time, several developments have taken place that translate to the data collected no longer being releva the 2009 FPAR Burden Study to quantify costs for implementing the encounter-level data reporting system currently different iteration of the proposed overhaul of FPAR that would be substantially less burdensome on grantees and sub

Secondly, due to challenges with interoperability (i.e., electronic sharing of data between systems), there is no "one s electronic reporting from Title X service sites to grantees, necessitating *each grantee-subrecipient dyad to invest in u 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 ove AFHP estimates that each of its 12 subrecipients will outlay an average of $5,000 in non-labor costs to implement FP costs across this single Title X grantee network. We estimate that implementing FPAR 2.0 will amount to about $6,0 cost of two staff persons working a combined 75 hours on tasks related to implementation. We also estimate that each hours implementing FPAR 2.0, for an estimated total of about $38,000 in one-time labor costs across this single Title maintenance are not included in these estimates. They also do not include the additional time it will take health care p 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 N
population-level, nationally representative dataset that gathers information on pregnancy and births, infertility, use of
However, while NSFG surveys a representative sample of respondents and allows them to voluntarily respond, the da
FPAR 2.0 will be required for every patient visit. More specifically, OPA has proposed that Title X service sites repo
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 b
relationship. It also is inconsistent with current best practice guidelines, which recommend assessing whether an adul
[unless the patient is at increased risk for infection or is seeking evaluation and treatment for sexually transmitted infe

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 sc
the last five years, HPV test performed at this visit, and HPV test result. Collecting and reporting all five data elemen
with minimal benefit.

The collection of information on a patient's Pap (at current and previous visit) and HPV tests performed may be help
number of tests provided during a specified period, the distribution of abnormal cytology results, or use of different c
hrHPV-alone, co-testing) during a specified period. However, the utility of collecting of Pap test in the last five years
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

Separate reporting of systolic and diastolic blood pressure measurements does not make sense clinically, as the interp
be tempered by the age of the patient, anxiety level when blood pressure is measured (i.e., "white coat" hypertension)
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.

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 i
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 fo
– and, in turn, at risk for cardiovascular disease. Developed for and tested on a sample of predominantly white Europ
especially for women of color, because it because it fails to account for differences in body composition, fitness level

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 tra
Act (HIPAA) - covered data or those who provide services "incident to" another provider. Furthermore, only advance
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 individu

Confidentiality is a hallmark of the Title X program, and all patients, including adolescents, are guaranteed confidenti
regulations, and case law. Further, they are grounded in medical and ethical standards and reflect research demonstra
patients would not seek needed health services.17 Despite this assurance, the Supporting Statement for the Title X FP
confidentiality of the sensitive personal health information it wants to collect through FPAR 2.0.18 While encounter-
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 (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 colle
the existing data collection and reporting system by *adding 23 new data elements to FPAR's standard set of data ele*
every visit). While NJFPL appreciates the need for a more robust data system for monitoring and improving program
system, the current FPAR 2.0 project must be paused. At the same time, OPA must plan and initiate a new process fo
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
service sites left the Title X program in *response to the 2019 Title X Rule1* – implementation of FPAR 2.0 simply is n

The current timeline for FPAR 2.0 data collection to begin on January 1, 2022 is unworkable. To implement FPAR 2
technology (IT) infrastructure, as would its 11 Title X subrecipients. Currently, we estimate it will take 3-6 months 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 d*
and response option to standardized value sets. In the absence of these specifications, we are in the difficult position o
implement systems changes narrows.

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

NJFPL requests that *OPA complete an up-to-date burden study* to provide a complete and accurate estimate of the bu burden estimates in the Public Comment Request are extremely low and based on an inappropriate and incredibly out 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 t interoperability between their respective systems*. In NJFPL's Title X network, there are 11 subrecipients using six E Title X family planning provider network, potential subrecipients either not using EHR platforms or transitioning fro for adhering to the proposed FPAR 2.0 requirements. NJFPL estimates that implementing FPAR 2.0 as proposed at th 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 N population-level, nationally representative dataset that gathers information on pregnancy and births, infertility, use of However, while NSFG surveys a representative sample of respondents and allows them to voluntarily respond, the da FPAR 2.0 will be required for every patient visit. More specifically, OPA has proposed that Title X service sites repo 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 b relationship. It also is inconsistent with current best practice guidelines, which recommend assessing whether an adul [unless the patient is at increased risk for infection or is seeking evaluation and treatment for sexually transmitted infe 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-cen tracking patients' intention to either become pregnant or prevent a pregnancy in the next year. Research suggests that intentions over the next year; doing so is inconsistent with how they think about and approach their reproductive lives populations.10 Indeed, not all individuals overtly plan to have children or not have children, suggesting that asking al problematic.11 Asking patients this kind of a question at every visit, regardless of the reason for the visit, could comp 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 more patient-centered approach to measurement. An example of an alternative measure that assesses patients' desire 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 sc
the last five years, HPV test performed at this visit, and HPV test result. Collecting and reporting all five data elemen
with minimal benefit. However, the utility of collecting of Pap test in the last five years and HPV test results are ques
cytology alone at a five-year interval and there is no national benchmark pertaining to the rate of tests that should con
NJFPL to differentiate whether an HPV test was done as part of routine screening or as a follow up after an abnormal

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
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hypertension cannot be made without multiple measurements on several separate occasions. If increasing control of h
element should be reconfigured to identify whether diagnosis of hypertension has been made or if screening for eleva
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New Data Elements: Cardiovascular Risk Factors - Smoking

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

data, presumably to calculate body mass index (BMI), is problematic. From a clinical perspective, there is no logical
and OPA does not state why it is necessary to collect this information and how it will be used in the Supporting State
a patient's height and weight data is clinically indicated, such measurements are not reliable for identifying whether t
for cardiovascular disease. Developed for and tested on a sample of predominantly white European men, BMI is not a
color, because it because it fails to account for differences in body composition, fitness levels, and nutritional differen
every visit – even health education sessions or when not clinically indicated – may deter clients from accessing servic
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 tra
Act- (HIPAA) covered data or those who provide services "incident to" another provider. Furthermore, only advance
some instances, Title X family planning encounters are performed by other service providers, such as registered nurse
workers.

Confidentiality of Sensitive Personal Health Information

NJFPL requests further clarification on the steps OPA will take to maintain the confidentiality of the sensitive person
Confidentiality is a hallmark of the Title X program, and all patients, including adolescents, are guaranteed confident
regulations, and case law. Further, they are grounded in medical and ethical standards and reflect research demonstra
patients would not seek needed health services.23 Despite this assurance, the Supporting Statement for the Title X FP
confidentiality of the sensitive personal health information it wants to collect through FPAR 2.0.24 While encounter-
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

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 ful
such that the data would actually be useful and reliable for the research and program purposes outlined. And adding t
ability and willingness to serve clients under the Title X program. It may actually encourage providers to opt out of th
service to populations most in need.

Marginalized populations may be less likely to seek services at Title X providers because of concerns about collectio
serving some of the most marginalized in the US population. Substantial research indicates that marginalized populat
documentation, and others who are underserved by the health care system are particularly sensitive to privacy concer
private identifiable data collection and transmittal effort for the program designed to serve these populations, FPAR 2
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 colle
the existing data collection and reporting system by adding *23 new data elements to FPAR's standard set of data ele*
every visit). While Unity Health Care appreciates the need for a more robust data system for monitoring and improvi
implementing such a system, the current FPAR 2.0 project must be paused. At the same time, OPA must plan and ini
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 el
response option to standardized value sets. In the absence of these specifications, we are in the difficult position of h
implement systems changes narrows. Currently, we are unable to estimate the full impact of the modification necessa
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 *tra*
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 es
FPAR 2.0. Cost burden estimates in the Public Comment Request are extremely low and based on an inappropriate a
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 N population-level, nationally representative dataset that gathers information on pregnancy and births, infertility, use of However, while NSFG surveys a representative sample of respondents and allows them to voluntarily respond, the da FPAR 2.0 will be required for every patient visit. More specifically, OPA has proposed that Title X service sites repo 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 b relationship. It also is inconsistent with current best practice guidelines, which recommend assessing whether an adul [unless the patient is at increased risk for infection or is seeking evaluation and treatment for sexually transmitted infe

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 sc the last five years, HPV test performed at this visit, and HPV test result. Collecting and reporting all five data elemen with minimal benefit.

The collection of information on a patient's Pap (at current and previous visit) and HPV tests performed may be help number of tests provided during a specified period, the distribution of abnormal cytology results, or use of different c hrHPV-alone, co-testing) during a specified period. However, the utility of collecting of Pap test in the last five years 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 dia hypertension cannot be made without multiple measurements on several separate occasions. If increasing control of h element should be reconfigured to identify whether diagnosis of hypertension has been made or if screening for eleva nationally recognized guidelines.

New Data Elements: Cardiovascular Risk Factors - Smoking

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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 fo – and, in turn, at risk for cardiovascular disease. Developed for and tested on a sample of predominantly white Europ especially for women of color, because it 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 s 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 encoun specifications for how the patient identifier data element will be used in a way that ensures that patient confidentiality

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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 pr 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 ele interoperability between their respective systems. Our network of providers use several different EMR providers.

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

presumably to calculate body mass index (BMI), is problematic. From+ a clinical perspective, there is no logical ratio OPA does not state why it is necessary to collect this information and how it will be used in the Supporting Statemen patient's height and weight data is clinically indicated, such measurements are not reliable for identifying whether tha cardiovascular disease. Developed for and tested on a sample of predominantly white European men, BMI is not a us because it because it fails to account for differences in body composition, fitness levels, and nutritional differences.14 visit – even health education sessions or when not clinically indicated – may deter clients from accessing services due 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 alt contraceptive services is the Self-Identified Need for Contraception (SINC) question developed by the University of Reproductive Health Program in consultation with Reproductive Justice advocates. Of note, UCSF has an award from Measures (eCQMs) of contraceptive provision using the SINC question to define the denominator. As such, use of th other initiatives underway at OPA. Use of this type of measure also would facilitate the removal of problematic data included to identify whether a patient is perceived as "at risk" for pregnancy.

Data Elements: Cervical Cancer Screening

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As of April 9, 2021, OPA has not released final specifications for (i.e., instructions for how to collect) FPAR 2.0’s da
and response option to standardized value sets; nor has it published the anticipated data elements on its website. In th
difficult position of having to wait while the time window needed to implement systems changes narrows. Initiating u
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 O
completely on the services provided by Title X grantees in their communities. Currently, aggregate level data collecti
are of limited utility. Encounter level data collection will allow for richer and more detailed analysis. Several of the n
only recently developed and endorsed (in 2016) or Quality Family Planning guidelines (first released in 2014). The F
clinical encounter. If the clinical encounter includes information collected in FPAR 2.0, only then should it be record
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OPA is prioritizing client confidentiality. Previous consultations with the HHS Privacy Officer indicate that the level
Systems of Record Notice because OPA does not plan on using a personal identifier to retrieve individual records. O
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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If indicated by the clinician, STI testing results should be ordered and recorded in the encounter record for appropriat
the recording of such data. Acknowledging that there are sometimes technical challenges in attaching the STI lab resu
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 annou
to be awarded in FY2021 worth 6-7% of total grant awards. OPA is also reaching out to EHR vendors to assess impl
technical assistance materials for grantees to use when discussing needed changes with EHR/IT staff.

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Based on grantee feedback and surveys, OPA postponed FPAR 2.0 implementation from 2020 to 2021. OPA is upda
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deleted. Additionally, the Patient-Centered Contraceptive Counseling (PCCC) Measure is not intended to be impleme
implemented within the FPAR 2.0 EHR specifications. OPA has plans to develop technical assistance to work with g
of utilization.

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deleted including the referenced three data elements. Additionally, no where in Supporting Statement A is FPAR 2.0
Family Growth. In regards to one element (family planning method use by sex and age, p. 5), it is noted that FPAR 2
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specifically referenced as an inappropriate source of information to represent the Title X population, thus supporting

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Family Growth. In regards to one element (family planning method use by sex and age, p. 5), it is noted that FPAR 2
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NPI/NPI2 to be reported when available. NPI's can be held by healthcare providers other than physicians and includi
(https://www.healthit.gov/cures/sites/default/files/cures/2020-08/Health_Care_Provider_Definitions_v3.pdf).

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of utilization are met. SINC has been included in FPAR 2.0 as an optional data element because it has not yet been N
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OPA appreciates comments expressing concern about the estimated burden of reporting FPAR 2.0 data. The departm
subrecipients to examine changes in workflow, address challenges of interoperability across disparate EHR systems,
training staff, and preparing workflows and systems for encounter-level reporting. However, for the purpose of assess
collect and report the required data elements, not any capital investments needed for system development and enhanc
Additionally, OPA recognizes the burdens of preparatory activities and is providing supplemental funding and techni
further believes that once implemented, a standards-based data collection adopted by EHR vendors and grantees shou
currently collecting input from a small sample of grantees to supplement the previous burden estimates and is review
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 includi
(https://www.healthit.gov/cures/sites/default/files/cures/2020-08/Health_Care_Provider_Definitions_v3.pdf).

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enhance implementation guides, options for file formats, and other guidance for IT representatives from EHR vendor
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Family Growth. In regards to one element (family planning method use by sex and age, p. 5), it is noted that FPAR 2
contraceptive method-mix with a nationally representative sample, such as NSFG. In section 4, Efforts to Identify Du
specifically referenced as an inappropriate source of information to represent the Title X population, thus supporting

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If indicated by the clinician, STI testing results should be ordered and recorded in the encounter record for appropriat
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planning method use by sex and age, p. 5), it is noted that FPAR 2.0 data could be used to compare the program's co
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and is developing plain language technical assistance materials for grantees to use when discussing needed changes w
materials for technical and nontechnical staff to facilitate to grantees' internal training processes and promote reporti
building capacity to report encounter-level data and is working to provide alternate reporting pathways for those who
require project officer approval and a plan to ultimately transition to FPAR 2.0. OPA also notes that the transition to
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Future pregnancy intention was deleted. SINC is included as an optional element as it is still in development and not

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OPA has engaged grantees and EHR vendors in recent years to provide technical specifications and provide uniform
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anticipated 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 vendor
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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 Depart
anticipated 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 vendor
provide flexible options for acceptable file formats, including specifications for submitting flat files (that is, files that

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deleted, including the referenced elements. Additionally, no where in Supporting Statement A is FPAR 2.0 described
Growth. In regards to one element (family planning method use by sex and age, p. 5), it is noted that FPAR 2.0 data c
method-mix with a nationally representative sample, such as NSFG. In section 4, Efforts to Identify Duplication and
referenced as an inappropriate source of information to represent the Title X population, thus supporting the need for

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

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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 annour to be awarded in FY2021 worth 6-7% of total grant awards. OPA is also reaching out to EHR vendors to assess imple technical assistance materials for grantees to use when discussing needed changes with EHR/IT staff.