National
Family Planning
& Reproductive Health Association

April 9, 2021

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

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

Dear Sherrette Funn:

The National Family Planning and Reproductive Health Association (NFPRHA) welcomes the opportunity to submit comments in response to the Department of Health and Human Services' (HHS) Agency Information Collection Request 0990-New-60D on Family Planning Annual Report 2.0, issued on February 11, 2021. We write to express our serious concerns with the Office of Population Affairs' (OPA) proposal for new encounter-level data collection for the Title X Family Planning Program ["Population Research and Voluntary Family Planning Programs" (Public Law 91-572)] Family Planning Annual Report (FPAR). Currently collected in aggregate under OMB No. 0990-0221, this new data collection system, "FPAR 2.0", proposes to collect visit information at the encounter level and build on the existing data collection and reporting system by adding 23 new data elements to FPAR's standard set of data elements (for a total of 45 data elements to be collected at every visit). While NFPRHA appreciates the need for a modern data system for monitoring and improving program performance, the current FPAR 2.0 project must be paused. The 23 additional elements go beyond what is necessary for quality improvement and what is required by statutory requirements, regulations, and operational guidance. Accordingly, NFPRHA requests that OPA plan and initiate a different process for transitioning to a new data collection and reporting system with continued stakeholder involvement.

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

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

Under the best of circumstances, OPA's proposal for FPAR 2.0 is flawed. Not only does FPAR 2.0, as proposed, require cost and time (i.e., burden hour) investments that are exponentially higher than the outdated estimates published in the Federal Register (86 FR 9077); it also puts forward data collection requirements that far exceed the minimum amount of data needed to monitor compliance with statutory and regulatory requirements and to manage the Title X program. At this time – against the backdrop of a year-long public health emergency that resulted in an unprecedented drop in patient census and following a 46% decline in the network's capacity after an estimated one in four service sites left the Title X program in response to the 2019 Title X Rule[2] – implementation of FPAR 2.0 simply is not feasible for Title X grantees and subrecipients. These organizations are working hard to rebuild and continue providing critical services to patients.

Timeline

NFPRHA requests that OPA establish a new timeline for FPAR 2.0 planning and implementation given the challenges all Title X grantees and service sites are facing.

Even in the absence of the above challenges, the current timeline for FPAR 2.0 data collection to begin on January 1, 2022 is unworkable. To implement FPAR 2.0, Title X grantees and subrecipients must upgrade existing information technology (IT) infrastructure. However, as of April 9, 2021, OPA has not released final specifications for (i.e., instructions for how to collect) FPAR 2.0's data elements, including how to map each data element and response option to standardized value sets; nor has it published the anticipated data elements on its website. In the absence of these specifications, grantees are in the difficult position of having to wait while the time window needed to implement systems changes narrows. Initiating upgrades before final specifications are available would be wasteful, as inconsistencies would require revisions that carry additional costs and burden hours spent.

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

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

[1] C Fowler, J Gable, B Lasater, and K Asman, *Family Planning Annual Report: 2019 National Summary* (Washington, DC: Office of Population Affairs, 2020).
[2] Mia R Zolna, Sean Finn, and Jennifer J Frost, *Estimating the Impact of Changes in the Title X Network on Patient Capacity* (New York: Guttmacher Institute, 2020).

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

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

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

Accuracy of Estimated Burden

NFPRHA requests that OPA complete an up-to-date burden study to provide a complete and accurate estimate of the burden associated with implementing encounter-level data collection and reporting through FPAR 2.0.

Cost burden estimates in the Public Comment Request are extremely low and based on an inappropriate and incredibly outdated source. The source for estimates, the Family Planning Annual Report (FPAR) Burden Study[5], was published in 2009 using data collected from Title X grantees about the cost and time burdens of implementing a new FPAR system that reports data aggregately (as opposed to encounter-level data reporting and collection). OPA has not collected more recent feedback from the Title X network regarding burden and costs associated with encounter-level data collection and the proposed new FPAR 2.0 data elements.

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

[3] Office of Population Affairs, "Service Delivery Improvement Projects," accessed March 19, 2021, https://opa.hhs.gov/research-evaluation/title-x-services-research/service-delivery-improvement-projects.
[4] Roboam R Aguirre, et al., "Electronic Health Record Implementation: A Review of Resources and Tools," *Cureus* 11, no. 9 (2019): e5649, doi:10.7759/cureus.5649.
[5] RTI International, *Family Planning Annual Report Burden Study* (Research Triangle Park, NC: RTI, 2009).
[6] *Supporting Statement for the Title X Family Planning Annual Report 2.0, Submitted to Office of Management and Budget, Office of Information and Regulatory Affairs* (Washington, DC: Department of Health and Human Services, Office of the Assistant Secretary for Health, Office of Population Affairs; February 5, 2021).

for implementing the encounter-level data reporting system currently proposed, as these estimates relate to a completely different iteration of the proposed overhaul of FPAR that would be substantially less burdensome on grantees and subrecipients. Indeed, it was not until 2012 that OPA engaged an FPAR Expert Work Group consisting of Regional Program Consultants, grantee representatives, and other federal and federally funded stakeholders to assess the feasibility of revising the data elements and transitioning FPAR reporting to an enhanced encounter-level system.[7] In 2014, OPA requested Office of Management and Budget (OMB) approval to begin assessing the feasibility of encounter-level data collection and the proposed new FPAR 2.0 data elements,[8] but that assessment was not completed.

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

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

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

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[7] *Supporting Statement for the Title X Family Planning Annual Report 2.0, Submitted to Office of Management and Budget, Office of Information and Regulatory Affairs* (Washington, DC: Department of Health and Human Services, Office of the Assistant Secretary for Health, Office of Population Affairs; November 19, 2014).
[8] Ibid.
[9] Adil Moiduddin and Michael Millman, *Assessing the status and prospects of state and local health department information technology infrastructure* (Washington, DC: Assistant Secretary for Planning and Evaluation, 2013).
[10] $65,000 x 72 grantees = $4,680,000

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

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

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

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

Again, OPA is proposing this time commitment take place when grantees and subrecipients are continuing to respond to – and facing burnout from – the COVID-19 public health emergency. Costs for ongoing operations and maintenance are not included in these estimates. They also do not include the additional time it will take health care providers and staff at Title X service sites to document more than 20 additional data elements as part of every single Title X visit.

Burden, Necessity and Utility of FPAR 2.0 Data

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

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

stakeholders to provide feedback on what additional data elements are feasible to add to the current FPAR clinic visit record and would be most helpful for program management and quality improvement.

Management of the Title X program entails monitoring progress towards performance goals required by the 1993 Government Performance and Results Act (Pub. L. 103-62), which include: giving priority in the provision of family planning services to low-income individuals, reducing invasive cervical cancer through Pap testing, reducing infertility through chlamydia screening, and increasing program efficiency by monitoring the cost of care. However, with the addition of 23 new data elements – many of which are irrelevant to monitoring Title X program compliance and accountability to the above performance goals – FPAR 2.0 represents an effort that has no intention of being minimally burdensome These data elements seem to map more to the elements in a research database than in a program monitoring tool, requiring Title X service sites to collect excessive information from patients at every single visit, even though such information is not necessitated by clinical practice guidelines or other evidence-based standards.

Furthermore, some proposed data elements pertain to services that are outside of the core family planning services in the *Recommendations for Providing Quality Family Planning Services* (QFP), including elements related to cardiovascular disease risk factors.[16] While, as OPA has affirmed, these "related preventive health services… are appropriate to deliver in the context of a family planning visit even though they do not contribute directly to achieving or preventing pregnancy include screening for breast and cervical cancer,"[17] they certainly should not be monitored at the encounter level to monitor accountability to program goals. NFPRHA requests additional justification for collecting these new data elements beyond the rationale provided by the Healthy People 2030 health objectives.

The following data elements are of particular concern to NFPRHA and its members:

New Data Elements: Sexual Activity

The Supporting Statement for the Title X FPAR 2.0 describes how FPAR 2.0 will supplement the federally funded National Survey for Family Growth (NSFG), a population-level, nationally representative dataset that gathers information on pregnancy and births, infertility, use of contraception, and general and reproductive health.[18] However, while NSFG surveys a representative sample of respondents and allows them to *voluntarily* respond, the data elements that will be collected and reported through FPAR 2.0 will be required for every patient visit. More specifically, OPA has proposed that Title X service sites report the following three data fields for patients at every visit: Ever had sex, Sex in the last 3 months, and Sex in the last year. Asking these three data points at every visit is burdensome and threatens the patient-provider relationship. It also is inconsistent with current best practice guidelines, which recommend assessing whether an adult or adolescent patient is sexually active only annually [unless the patient is at increased risk for infection or is seeking evaluation and treatment for sexually

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

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

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

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

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

New Data Element: Future Pregnancy Intention Reported

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

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

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

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

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

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

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

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

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

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

Data Elements: Cervical Cancer Screening

FPAR 2.0 suggests the Title X service sites collect and report five different data elements related to cervical cancer screening: Pap test at this visit, Last Pap result, Pap test in the last five years, HPV test performed at this visit, and HPV test result. Collecting and reporting all five data elements for every Title X visit would carry substantial burden with minimal benefit. The collection of information on a patient's Pap (at current and previous visit) and HPV tests performed may be helpful as quantitative measures; for instance, to compute the number of tests provided during a specified period, the distribution of abnormal cytology results, or use of different cervical cancer screening technologies (cytology-alone, hrHPV-alone, co-testing) during a specified period. However, the utility of collecting of Pap test in the last five years and HPV test results are questionable, as no national guideline recommends cervical cytology alone at a five-year interval and there is no national benchmark pertaining to the rate of tests that should come back as positive.[25] Furthermore, there is no way for grantees and subrecipients to differentiate whether an HPV test was done as part of routine screening or as a follow up after an abnormal screening test or for post-treatment surveillance.

It is critical to underscore that ASCCP Risk-Based Management Consensus Guidelines for abnormal cervical cancer screening tests and cancer precursors are dependent on patient age and other risk factors that support screening.[26] As a result, none of these cervical cancer screening-related data elements can be used to monitor adoption and adherence to screening guidelines or track progress towards Healthy People 2030 goals (i.e., increase the proportion of females who receive a cervical cancer screening based on the most recent guidelines), as described in the Supporting Statement for the Title X FPAR 2.0.[27] [28] Therefore, the time and resource investments that grantees and subrecipients must make to collect and report these additional data elements will produce data with little – if not no – value for monitoring and improving program performance.

New Data Elements: Cardiovascular Risk Factors

FPAR 2.0 suggests that Title X service sites collect and report on five different data elements related to cardiovascular health: Systolic blood pressure, Diastolic blood pressure, Height, Weight, and Smoking status (detailed as never smoker, ex-smoker, smokes daily, occasional smoker, smoker, status unknown, heavy smoker, light smoker).

Separate reporting of systolic and diastolic blood pressure measurements does not make sense clinically, as the interpretation of a single measurement at a point in time must be tempered by the age of the patient, anxiety level when blood pressure is measured (i.e., "white coat" hypertension), and other factors. Unless the systolic and diastolic pressures are quite elevated,

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

[26] Ibid.

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

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

the diagnosis of hypertension cannot be made without multiple measurements on several separate occasions. If increasing control of high blood pressure is a priority for OPA, this data element should be reconfigured to identify whether diagnosis of hypertension has been made or if screening for elevated blood pressure has been performed consistent with nationally recognized guidelines.

Self-reported smoking status also is not helpful as a quality metric. If this topic is a priority for OPA, this data element should be reconfigured to report the intervention(s) offered to tobacco smokers, using those listed by the US Preventive Services Task Force.[29]

NFPRHA believes the collection of height and weight data, presumably to calculate body mass index (BMI), is problematic. From a clinical perspective, there is no logical rationale to record and report body weight *at every visit*, and OPA does not state why it is necessary to collect this information, and how it will be used, in the Supporting Statement for the Title X FPAR 2.0.[30] Even when collecting a patient's height and weight data is clinically indicated, such measurements are not reliable for identifying whether that patient is overweight or obese – and, in turn, at risk for cardiovascular disease. Developed for and tested on a sample of predominantly white European men, BMI is not a useful indicator of health, especially for women of color, because it fails to account for differences in body composition, fitness levels, and nutritional differences.[31] Furthermore, the practice of weighing clients at every visit – even health education sessions or when not clinically indicated – may deter clients from accessing services due to experiences of body shame and weight discrimination.[32]

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

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

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

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

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

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

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

New Data Element: National Provider Identifier (NPI)
NPI is yet another proposed data element in FPAR 2.0 that has little or no value to grantees and subrecipients. While most advanced practice clinicians have a NPI number, they are not required for those providers who do not transmit Health Information Portability and Accountability Act- (HIPAA) covered data or those who provide services "incident to" another provider. Furthermore, only advanced practice clinicians may obtain an NPI; however, in 2019, 32% percent of all Title X family planning encounters were performed by other types of providers, including registered nurses, registered nurses with an expanded scope of practice, licensed practical nurses, health educators, and social workers.[34] As such, many providers delivering Title X services do not have individual NPI to report for FPAR 2.0.

Confidentiality of Sensitive Personal Health Information
NFPRHA requests further clarification on the steps OPA will take to maintain the confidentiality of the sensitive personal health information collected by FPAR 2.0.

Confidentiality is a hallmark of the Title X program, and all patients, including adolescents, are guaranteed confidential services. Such protections are grounded in the statute, regulations, and case law. Further, they are grounded in medical and ethical standards and reflect research demonstrating that, without access to confidential care, some patients would not seek needed health services.[35] Despite this assurance, the Supporting Statement for the Title X FPAR 2.0 fails to address how OPA will maintain the confidentiality of the sensitive personal health information it wants to collect through FPAR 2.0.[36] While encounter-level data will be de-identified, OPA has not released specifications for how the patient identifier data element will be used in a way that ensures that patient confidentiality is preserved. Furthermore, OPA has not provided information on the HIPAA Security Rule Standards it will adopt to ensure the appropriate consent and safeguarding of this encounter-level data at the federal, grantee, and subrecipient levels; for example, specifying encryption standards for data at rest and in motion. Given the cybersecurity issues that all organizations currently are facing, it seems imprudent to move forward with FPAR 2.0 without releasing more information about – and seeking stakeholder feedback on – the steps that OPA will take to protect FPAR 2.0's encounter-level data from unauthorized access, use, and disclosure, as well as what steps grantees will be required to take.

Despite a range of opinions about what qualifies as sensitive health information, it generally is considered to be information that carries with it unusually high risks in the event of disclosure. Several data elements within FPAR are sensitive in nature, as they relate to sexual behaviors and other deeply personal topics.

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

> "Although the FPAR contains several data items of a sensitive nature (e.g., user income and insurance status, user race, type of contraceptive method used or adopted, STD tests performed, and Pap and HIV test results),

[34] C Fowler, et al., *Family Planning Annual Report: 2019 National Summary*, 2020.
[35] Liza Fuentes, Meghan Ingerick, Rachel Jones, and Laura Lindberg, "Adolescents' and Young Adults' Reports of Barriers to Confidential Health Care and Receipt of Contraceptive Services," *Journal of Adolescent Health* 62, no. 1 (2018): 36-43, https://doi.org/10.1016/j.jadohealth.2017.10.011.
[36] Ibid.

> individuals cannot be identified because federal regulation (42 CFR Part 59) requires that grantees report only aggregate user totals. The FPAR collects no individual identifiers. These sensitive data are required to monitor compliance with statutory requirements."[37] [38]

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

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

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The current FPAR 2.0 project stands to severely disrupt Title X providers' operations during already uncertain times. NFPRHA's members are striving to see more patients after unprecedented declines in patient census. NFPRHA supports investments in Title X program infrastructure, including investment in a more contemporary data system for monitoring and improving program performance; however, such a venture cannot come at the expense of serving those in need of services, specifically patients who are low-income, uninsured, and under-insured. Such an effort also cannot come at the expense of providing Title X patients with the same standard of care as their counterparts who receive care in non-Title X settings, which is just what FPAR 2.0 - with burdensome and unnecessary data elements that are required for every visit – would do. Accordingly, NFPRHA urges OPA to pause and re-evaluate FPAR 2.0.

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

Sincerely,

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

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[37] *Supporting Statement for the Title X Family Planning Annual Report 2.0, Submitted to Office of Management and Budget, Office of Information and Regulatory Affairs* (Washington, DC: Department of Health and Human Services, Office of the Assistant Secretary for Health, Office of Population Affairs; June 29, 2010).
[38] *Supporting Statement for the Title X Family Planning Annual Report 2.0, Submitted to Office of Management and Budget, Office of Information and Regulatory Affairs* (Washington, DC: Department of Health and Human Services, Office of the Assistant Secretary for Health, Office of Population Affairs; October 15, 2010).
[39] *Supporting Statement for the Title X Family Planning Annual Report 2.0, Submitted to Office of Management and Budget, Office of Information and Regulatory Affairs*, 2021.