Factors Influencing Access to Long-Acting Reversible Contraceptives at Federally Qualified Health Centers

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Medicines 360 undertook this research project in collaboration with Waxman Strategies and Camber Collective. Medicines 360 is a global non-profit pharmaceutical company focused on women's health and is the developer of the long-acting reversible contraceptive (LARC) product, LILETTA®.







Executive Summary

Federally Qualified Health Centers (FQHCs) provide a wide range of primary care services, including family planning, for medically underserved populations. While FQHCs play an important role in delivering publicly funded family planning care to patients across the country, evidence suggests many FQHCs face challenges in offering the full range of contraceptive methods, including counseling and services related to long-acting reversible contraceptive (LARC) methods. Previous studies have identified a number of barriers that FQHCs encounter in providing comprehensive family planning services, such as insufficient financial support, inadequate numbers of trained providers, and various operational difficulties.

Building on existing research, this study examines the underlying factors that most strongly influence the availability of LARC methods and related services at FOHC sites. Survey responses from FOHCs, alongside deeper interviews with select respondents, reinforced the importance of various operational, financial, and policy considerations in the ability of FOHCs to make LARC methods available to their patients. In particular, three key findings emerged. First, the study confirmed that LARC access at FQHC sites was influenced by various financing and other economic factors, including Title X grant funding availability, adequate payment and reimbursement, and the price at which LARC products are purchased and stocked. Second, access to LARC methods was constrained by both provider factors - including provider knowledge and attitudes as well as the sufficiency of staff – and patient attitudes. Third, a site's ability to offer same-day IUD insertion was linked to several factors, including whether an FQHC used an on-site pharmacy to supply LARC products. Also, the study identified questions for further consideration, including a deeper inquiry into the factors that influence FQHCs' use of 340B pricing for LARC products, and the relationship between timely access to LARC-related services and FOHCs' use of off-site contract pharmacies. The interplay of the factors discussed above influence LARC availability in different ways depending on which of these factors present as enablers or barriers to the unique FQHC clinic.

After discussing these findings in the broader public policy context, this paper makes a series of policy recommendations tailored to enhance the ability of FQHCs

to deliver a broader range of contraceptive care, including patient-centered counseling and services related to LARC methods. At the federal level, policymakers should take action to (1) establish new opportunities for technical assistance and training to enable FQHCs to provide patient-centered counseling and services related to the full range of FDA-approved contraceptive methods, consistent with national clinical recommendations; (2) protect and expand grant funding, including Title X funding, for FQHCs while maintaining evidence-based guidelines; and (3) collect and report additional data on family planning care provided to patients at FQHC sites. At the state level, policymakers should (1) design Medicaid reimbursement rates and policies that better support FQHCs providing LARC methods; (2) ensure state scopeof-practice and licensure policies do not restrict the ability of providers, including non-physician personnel such as advanced practice registered nurses (APRNs), to provide LARC-related services; and (3) enhance the sharing of information, training, and best practices between stakeholders through the creation of state-level "learning collaboratives."

Because this research focused on the availability of LARC methods, this paper and its recommendations emphasize LARC methods. However, the Centers for Disease Control and Prevention (CDC) and the Department of Health and Human Services (HHS) Office of Population Affairs (OPA) recommend that providers generally follow the Quality Family Planning (QFP) recommendations. First issued in 2014, the QFP guidelines instruct family planning providers to counsel on and provide access to the full range of FDA-approved contraceptive methods using a patient-centered approach.

Background

Overview of Federally Qualified Health Centers.

Established by Section 330 of the Public Health Service Act, the federal Health Center Program, administered by the Health Resources and Services Administration (HRSA), makes grants to eligible organizations for the purpose of providing a wide range of primary care services for medically underserved populations. Recipients of Section 330 grant funds, known as Federally Qualified Health Centers (FQHCs), must adhere to a number of service requirements by virtue of their participation. For example, FQHCs must offer comprehensive primary care

services, serve patients regardless of their ability to pay, offer care on a sliding fee scale, maintain a governing board a majority of which is composed of patients, and meet other standards designed to ensure underserved communities have access to quality care.

Today, FQHCs are responsible for providing a comprehensive scope of services to more than 27 million people nationwide.² In recent years, the size of the patient population that FQHCs serve has grown significantly. Between 2001 and 2017, the total number of patients served by health centers grew by an estimated 164 percent, or 17 million additional patients.³ This increase is due, in part, to coverage expansion and investment in the safety net achieved under the Affordable Care Act (ACA). Though the network of FQHCs funded under Section 330 has successfully established critical access points for primary and preventive care in low-income and underserved communities, both workforce issues⁴ and periodic threats to federal funding for FQHCs⁵ continue to present overall challenges for the Health Center Program.

Providing Family Planning in FQHCs. As part of their obligations under Section 330, FQHCs must provide or arrange for access to voluntary family planning and reproductive health services. FQHCs are an important source of publicly funded family planning services in the U.S. In 2013, FQHCs served nearly 5.8 million women of reproductive age nationwide. In 2015, FQHCs served 30 percent of all female patients who obtained contraceptive care at a publicly funded family planning center – approximately 2 million patients in total.

Since family planning services are broadly defined under Section 330, and because FQHCs can either provide these services directly or through referral to other health care providers, individual FQHCs vary considerably in the scope and quality of family planning services they deliver. Although virtually all FQHCs furnish some level of family planning services directly, there is an identified need to improve the scope and quality of such care. Research suggests that most FQHCs do not provide a comprehensive offering of family planning services. For example, many do not provide LARC methods onsite – in one study, only 59 percent of FQHCs reported dispensing IUDs, and only 36 percent reported dispensing implants, at their largest site. For those that do furnish on-site access to LARC methods, evidence suggests

that many FQHCs require at least two patient visits for the prescription and placement of the product. ¹⁰ Major challenges FQHCs face in providing quality family planning services include the cost of care coupled with the financial realities associated with serving low-income populations, difficulties attracting and retaining specialized clinical and counseling staff, and issues associated with how best to communicate the value and importance of family planning services to patients and communities. These challenges are discussed in greater detail below.

Financing Family Planning at FQHCs. Section 330 grants are only one of several grant funding sources for FOHCs. Another prominent funding source is the Title X family planning program, the only federal grant program dedicated solely to providing individuals with comprehensive family planning and related preventive health services. Approximately 26 percent of Title X service sites are FQHC sites. 11 By virtue of Title X's service requirements, including the statutory requirement that grantees offer a "broad range" of family planning methods and services, 12 FQHCs that receive Title X funding are likely to offer a wider array of contraceptive methods compared to FQHCs that do not.13 The Trump administration has made efforts to change the Title X program rules in ways that evidence suggests may affect access to LARC methods and the full range of family planning care at Title X locations. 14 In the past, program guidance has unambiguously instructed Title X grantees to offer all 18 FDA-approved methods of contraception. ¹⁵ By contrast, recently finalized regulations have construed Title X's "broad range" requirement more loosely, instead stating that projects are "not required to provide every acceptable and effective family planning method or service."16 Likewise, after omitting all mention of "contraception" from its fiscal year 2018 funding announcement for Title X,¹⁷ HHS's next funding announcement added language merely specifying that projects should provide "hormonal methods."18

FQHCs are eligible to enroll in the 340B drug pricing program as a result of receiving a Section 330 grant. The 340B program requires that prescription drug manufacturers provide drug discounts to covered entities, which primarily serve low-income or medically underserved individuals. While detailed data is not available, it is estimated that 340B discounts range between an estimated 20 and 50 percent reduction from

the price that would otherwise be paid for the product. 19

FOHCs also rely on reimbursement by third-party payers. including insurance programs such as Medicaid, to finance family planning services. By far, the largest source of reimbursement for care provided at FQHCs is Medicaid.²⁰ Across all provider types, Medicaid pays for 75 percent of publicly funded family planning services provided in the U.S.²¹ In part, Medicaid's large role in family planning is attributable to changes in the program that have permitted states to expand family planning coverage. For example, the ACA amended the Social Security Act to establish the Medicaid Family Planning State Option, an optional family planning eligibility group that states could make permanent through a state plan amendment (SPA).²² While full benefit Medicaid eligible individuals receive a wide array of care under other Medicaid coverage categories, individuals in this optional eligibility group are covered only for family planning services and family planning related services. In most states that have adopted a family planning option, an individual's eligibility for family planning-only coverage is determined solely by income. Fifteen states have exercised the option to expand access to family planning services through a SPA and 10 others have a temporary waiver program, for a total of 25 states.²³

In general, FQHCs receive Medicaid payments through the Prospective Payment System (PPS), which differs from the traditional fee-for-service model. Under PPS, FQHCs receive payments that are not cost-based reimbursement, but rather bundled payments for each qualifying patient visit, often called the "encounter rate." 24 While PPS is viewed as a successful model for financing and ensuring the quality of general primary care services at FQHCs, its encounter rate formula often does not appropriately account for the costs of providing more specialized services which, by their nature, may entail more staff time and other expenses. For this and other reasons, some states have adopted alternatives to replace or supplement PPS. This includes over 20 states that have taken the option to implement their own alternative payment models (APMs), which introduces greater flexibility into the payment system.²⁵

Challenges to Providing LARCs at FQHCs. FQHCs face a number of challenges in providing patients the full range of contraceptive methods, especially LARC methods. For

example, maintaining an adequate network of available providers who are trained in providing LARC methods has been a challenge for states.²⁶ Providers must be trained in the placement and removal of LARC products, as well as culturally appropriate and patient-centered counseling about the available options, benefits, and risks. Patientcentered counseling includes ensuring patients have access to complete and accurate information and counseling on the full range of contraceptive methods in accordance with the Quality Family Planning (QFP) recommendations, jointly issued in 2014 by the Centers for Disease Control and Prevention (CDC) and the Office of Population Affairs (OPA), Title X's administering office, within the Department of Health and Human Services (HHS).²⁷ Using a patient-centered approach may be particularly important when providing care to certain groups, including women of color, immigrant women, and women with disabilities, because of the well-documented history of reproductive coercion by U.S. public health authorities targeting these populations.²⁸ Given the risk of perpetuating this harm, provider training should ensure that patients are supported in choosing the contraceptive method that works best for them.

Inadequate reimbursement has also been identified as a barrier to LARC access. PPS rates may not account for product costs or the longer or more complex visits that are often necessary for LARC placement.²⁹ This can disincentivize FQHCs from providing LARCs, driving providers toward other, less effective forms of contraception.

On top of training and financing barriers, FQHCs may face operational and logistical challenges to providing LARC-related services. For example, FQHCs may face difficulties in offering same-visit or same-day LARC services. In many cases, stocking products for same-visit dispensing can be cost-prohibitive. If same-visit insertion is not available, the woman must see the provider twice, first to get the LARC prescription and then for placement. One study found that nearly half of patients did not return for the second visit, which may contribute to the risk of unintended pregnancy.30 Also, incorrect medical billing and coding of a visit can lead to denied insurance claims, which further limits the financial capabilities of a clinic to invest in keeping more LARC products in stock.31 Finally, 340B program requirements may present barriers as well. FQHCs eligible for 340B program pricing must be clear on state and program rules for using 340B-purchased

drugs or products for Medicaid patients in order to prevent improper reimbursement or "duplicate discounts." Covered entities not in compliance may be subject to audit by the 340B program or manufacturers and may be liable to manufacturers for any improper discounts. 33

Compounding existing challenges for FQHCs, the Trump administration has also attempted to limit Planned Parenthood's participation in federal health programs such as Medicaid and Title X. These actions would significantly shift the burden for providing publicly funded family planning services onto FQHCs and other publicly funded providers.³⁴ In the wake of the ACA's coverage expansions, FQHCs have already struggled to meet increased demand for services.³⁵ These circumstances amplify the importance of addressing the barriers identified in this study.

Study Overview

The purpose of this study was to identify the underlying factors that most strongly influence the availability of LARC methods at FQHC sites. Data inputs included existing literature, publicly available data, FQHC clinic surveys and interviews. Work on this project began in December 2018 and concluded in June 2019. The research period was between January and April 2019.

After completing a literature review of existing evidence regarding the factors influencing LARC provision at FQHCs, a survey instrument was developed with the input of experts and FOHC administrators and providers. The final survey was then administered to health care providers and administrators in leadership positions at FQHCs. In general, the survey contained questions about each respondent's primary site within the FQHC, which family planning methods (including LARCs) that site provided, and details about their provision, including cost to patient, counseling, stocking, and other factors hypothesized to affect access. In order to ascertain these factors, respondents were specifically asked about the key "enablers" or "barriers" to the ability of FQHCs to provide LARC methods. Responses were received from 116 FQHC networks representing 37 states plus Washington, DC. Post-survey interviews were also conducted with 11 respondents to obtain additional detail and context.

A full description of the study methodology appears in Appendix B of this paper.

Key Findings

Financing and other economic factors. The survey and subsequent interviews found that the ability of FQHCs to offer a broad range of contraceptive methods, including one or more LARC methods, was influenced by a variety of financing and other economic factors. A health center's receipt of Title X grant funds was highly correlated with its ability to offer some or all LARC methods. Moreover, 70 percent of Title X-funded FQHCs that shared pricing information reported charging low-income patients \$0 for IUD product and insertion, compared to only 25 percent of non-Title X FQHCs. Consistent with these findings, half of Title X-funded FQHCs identified grant funding as an enabler of offering LARC methods.

Respondents also identified the availability of adequate reimbursement and payment for LARC-related services as major financing issues. More than half of respondents (56 percent) identified sufficient reimbursement rates as an enabler to offering LARC methods. Likewise, a quarter of respondents said that LARC methods being "carved out" of, or unbundled from, the Medicaid Prospective Payment System (PPS) encounter rate was an enabler of LARC access. Post-survey interviews reinforced that the fixed PPS rate was typically too low to cover the cost of providing LARC products and services. All the above factors relating to reimbursement and payment were found to be of heightened importance to Title X-funded FQHCs.

More than one-third of respondents (38 percent) rated low acquisition and stocking costs as an enabler of LARC provision, and FOHCs that failed to offer sameday IUD insertion pointed to stocking issues as a significant barrier to doing so. Yet the 340B program, which allows enrolled FQHCs to purchase IUDs and other pharmaceutical products at a significant discount, appeared underutilized by respondents. Nearly onethird (27 percent) of FOHCs offering LARCs reported not using 340B-purchased products for some or all Medicaid patients. Title X status appeared to determine 340B use: a much larger proportion of Title X-funded FQHCs reported awareness and use of 340B-purchased LARC products than non-Title X FOHCs (95 percent versus 54 percent). This disparity based on Title X status held true for the use of 340B products for Medicaid patients as well. Moreover, awareness and use of 340B pricing for LARCs was considerably lower at FOHCs with off-site contract

pharmacies compared to those with on-site pharmacies, with 27 percent versus 14 percent respectively, selecting "no" or "do not know" in response to the question about using 340B pricing for LARCs.

Provider and patient factors. Access to LARC methods also appeared to be constrained by provider factors including provider knowledge and attitudes and sufficient staffing - as well as provider-reported patient beliefs. Among the enablers of providing LARC methods, the factor most frequently cited by respondents (61 percent) was adequate training for providers and staff. Having a sufficient number of providers and staff was identified as an enabler with almost the same frequency (59 percent). Both FQHCs with and without Title X grant funding were in near agreement about the importance of these provider factors. Of respondents that did not offer same-day IUD insertion, a significant proportion said this was, in part, rooted in provider unwillingness; for example, 38 percent of respondents said the fact that "provider does not want to provide same-day insertion" constituted a barrier. Respondents also identified the scarcity of time as barrier to same-day IUD insertion - implying, among other things, staffing issues at the site-level. Post-survey interviewees similarly conveyed that clinician comfort, training, and knowledge play a large role in IUD provision.

Attitudinal and knowledge barriers were not completely confined to providers and staff. In post-survey interviews, respondents also identified patients' beliefs – for example, negative perceptions or outdated or inaccurate information regarding IUDs – as barriers.

Factors linked to same-day IUD insertion. The availability of same-day IUD insertion correlated to whether products were dispensed on-site or supplied through arrangements with off-site contract pharmacies. Specifically, more than one-third (36 percent) of FQHCs that only used off-site contract pharmacies failed to offer same-day IUD insertions. By contrast, among respondents that only dispensed IUDs on-site, only 9 percent did not offer same-day services. Factors cited by respondents as barriers in the provision of same-day insertion included billing issues, stocking issues, time constraints, and provider attitudes. As previously mentioned, FQHCs with off-site contract pharmacies also reported lower awareness and use of 340B pricing for LARC products.

Tables and figures relating to these key findings can be found in Appendix A of this paper.

Discussion

While FQHCs are a key source of primary and preventive care for underserved and low-income women of reproductive age, evidence suggests FOHCs encounter challenges in effectively meeting their communities' needs for services related to a broad range of contraceptive methods, including highly-effective LARC methods. This study updates and adds to the literature on the key factors and barriers that influence the availability of LARC methods and services at FOHC sites. These results are broadly consistent with previous findings and reinforce the importance of various operational, financial, and policy considerations in the ability of FOHCs to make LARC methods accessible. This study also contributes novel questions for further consideration, including questions regarding the factors that influence FQHCs' use of 340B pricing for LARC products and the relationship between LARC access and the use of off-site contract pharmacies.

Financing and other economic factors. Consistent with previous studies, the survey and subsequent interviews found that financing and other economic factors determine the availability of LARC methods at FOHC sites. With respect to Title X, this study found that an FQHC's receipt of Title X grant funds influenced the likelihood that it offered some or all LARC methods: respondents further identified the receipt of funds as an enabler of LARC provision. This may be explained by Title X's program requirements. Under federal law, Title X recipients must offer a "broad range" of family planning services and methods. Moreover, Title X-funded providers generally follow the QFP recommendations issued jointly by the CDC and OPA within HHS. The QFP guidelines instruct family planning providers to counsel on and provide access to the full range of FDA-approved contraceptive methods. In addition to supporting direct services, Title X grant funds may be used to cover infrastructure, staff time, and upfront costs necessary for organizations to deliver LARC methods - a key challenge for non-Title X funded clinics who cited these as ongoing issues in the provision of LARC services. Also, Title X sites must charge self-pay patients in accordance with a strictly calibrated schedule of discounts, sliding to zero for patients at or below 100 percent of the Federal Poverty Level (FPL). This latter point

illuminates our finding that the median lowest cost that Title X FQHCs charge for IUD services is \$0, lower than the median lowest cost that non-Title X FQHCs charge.

Reimbursement and payment were noted as particularly important factors in LARC provision by Title X-funded FQHCs. This finding supports the notion that LARC availability in FQHCs exists on a continuum, from the networks that can offer LARC methods only under conditional circumstances to the networks that can offer LARCs consistently and sustainably. Located on one end of the continuum are FQHCs that, lacking trained staff, infrastructure, financial resources, may struggle to include one or more LARC methods in their service mix. On the other end are FQHCs whose family planning programs have matured to offer one or more LARC methods such as Title X-funded FQHCs, whose LARC offerings are bolstered by grant funding and shaped by program guidelines. Having attained appropriate staffing and infrastructure for LARC provision, these FQHCs are more likely to pursue sustainable reimbursement and payment for services in order to provide large volumes of LARC methods to desiring patients on a consistent basis.

Despite Title X's status as a LARC enabler, administrative burdens may make participation in Title X too burdensome for some FOHCs, according to post-survey interviews. For example, obtaining a Title X grant ordinarily entails submitting time-consuming applications, making significant changes to electronic record systems, meeting new financial and performance reporting requirements, and so on. Also, FOHCs may be deterred from partnering with Title X because the program has recently been the target of heightened political scrutiny and intervention. As described above, recent changes in Title X guidance and rules have loosened the statutory requirement that projects must offer a "broad range" of family planning methods and have removed the instruction that projects provide all FDA-approved forms of contraception. These and other issues have raised significant questions about Title X's future and whether it will remain grounded in its successful evidence-based approach.

Another key finding was that reimbursement and payment policies influenced the availability of LARC methods at FQHC sites. While state Medicaid programs and managed care organizations exercise considerable discretion in setting reimbursement, FQHCs are ordinarily paid using a PPS encounter rate – a flat encounter-based payment

intended to reflect the costs of an average primary care visit. As noted by respondents, the PPS encounter rate alone is usually insufficient to capture the cost of a LARC product, let alone its placement. Many states fail to reimburse separately for LARC products or insertion, which can be accomplished by unbundling or "carving" out" LARC-related services from PPS. The results of this study suggest that bundling LARC services into the PPS rate prevents some FQHCs from sustainably offering LARC methods. On top of the inadequacy of the PPS encounter rate, a variety of other reimbursement- and paymentrelated issues may present barriers. For instance, in some states, due to Medicaid reimbursement policy, providers must assign products to particular patients. If the patient does not use the product, the providers must absorb the cost of the unused products. Furthermore, states and managed care organizations may place additional limitations on coverage of LARC-related services, including covering initial insertions but not follow-up services, or imposing strict utilization controls. These and other variations in reimbursement policies are likely to disincentivize some FOHCs from offering LARC methods.

In principle, stocking and acquisition costs could be reduced if FQHCs purchased LARC products via the 340B discount drug program, under which enrolled FQHC sites are entitled to purchase pharmaceutical products at discounted rates. Although respondents noted that upfront costs - such as the acquisition and stocking of products - were key factors in LARC access, they reported low awareness and use of 340B pricing for LARC products. This trend was especially pronounced among FOHCs that did not receive Title X. A few possible explanations for 340B underutilization should be considered. First, the disparity between Title X and non-Title X FQHCs suggests that the shortcoming might be attributable to a simple lack of knowledge among respondents. It is possible, for example, that Title X-funded FQHCs are more likely to learn of operational "best practices," such as the routine use of 340B pricing for LARC products, through contacts with the Title X National Family Planning Training Center, other Title X grantees, membership in trade groups, and various training opportunities. By contrast, these relationships may not be as common among FQHCs outside of Title X.

Second, FQHCs may be discouraged from using 340B pricing for LARC products for Medicaid patients due to a perceived risk of noncompliance with 340B rules; this influence is likely amplified for FQHCs relying on

off-site contract pharmacies to supply LARC products. Under federal law, state Medicaid programs are barred from claiming Medicaid rebates on products obtained at the 340B price. The responsibility to avoid "duplicate discounts" falls both on states and 340B-participating entities and often results in a significant administrative burden. Some states have attempted to eliminate duplicate discount concerns by categorically barring providers from using 340B products for Medicaid patients. But even in states that have not done so, FQHCs may still be reluctant to furnish 340B-purchased LARC products to Medicaid patients because of the perceived risk. Furthermore, because using a contract pharmacy introduces additional complexity into the process of avoiding duplicate discounts, the chilling effect is likely stronger for FQHCs using contract pharmacies to supply LARC products to Medicaid patients. This helps to interpret the finding, noted above, that FOHCs using off-site contract pharmacies for LARC products were less likely to leverage the 340B program to purchase LARC products for use with Medicaid patients. Alternatively, all three variables - Title X status, whether contract pharmacies are used, and whether 340B pricing is used for LARC products - might be traced to a more fundamental issue. Given this study's relatively small sample size, further investigation will be needed to ascertain whether an FOHC's size and operational capabilities - especially in terms of the number of trained personnel, on-site pharmacy use, and size of its patient population - are more directly related to its ability to offer LARC products.

Provider and patient factors. As noted, LARC access at FQHC sites was limited by provider knowledge and attitudes as well as sufficient staffing. This is consistent with previous findings that some providers hold outdated and inaccurate beliefs about IUDs, which in turn affect access to counseling and services.³⁶ For example, providers may believe IUDs are inappropriate for adolescents and young people, people in nonmonogamous relationships, and women who have never been pregnant. This, combined with the perception that payment for LARC services is inadequate, leaves few incentives for providers to seek out training and maintain up-to-date knowledge on the full array of contraceptive methods. Title X centers, including Title X-funded FQHCs, have access to resources and trainings via the National Family Planning Training Center, but providers at other

FQHCs likely do not have convenient access to similar training opportunities.

On top of adequate training, recruiting and retaining a sufficient number of clinicians is key to the provision of safety-net family planning care, particularly in rural or underserved communities. Health professional workforce concerns were central to Congress's establishment of the federal National Health Service Corps (NHSC), administered by HRSA. NHSC provides incentives to health professionals who agree to serve communities defined as medically underserved. Some states also assist in loan repayment or offer other incentives to clinicians to achieve similar ends. Although the postsurvey interviewees acknowledged that the NHSC and similar programs may play a role in boosting the capacity of FQHCs to provide family planning services, respondents noted that this benefit is limited because of challenges in retaining providers after these programs are completed. Finally, whether and under what conditions non-physician clinical personnel can perform and will be reimbursed for LARC-related services may also contribute to workforce shortage concerns. These policies are determined by insurers and states and vary across jurisdictions.

Factors linked to same-day IUD insertion. The study found an inverse relationship between the use of off-site contract pharmacies and the availability of same-day IUD insertion. There is generally no medical reason to schedule separate visits on different days for IUD insertion,³⁷ and doing so is undesirable from the perspective of quality care and equitable access. particularly for clients with low incomes who face issues accessing transportation or taking time off work. This finding may be explained by the manner in which off-site pharmacies operate. The use of an off-site pharmacy for IUD services typically involves multiple patient visits. For example, during the first visit, the patient is instructed to pick up the prescribed product off-site, only to return for another appointment for IUD placement. Due to scheduling and logistical constraints, it is not uncommon for this second appointment to occur on a later date. The use of off-site contract pharmacies also appears to bear a negative association to the use of 340B pricing to purchase LARC products. Although integrating an onsite pharmacy may alleviate these barriers, many FQHCs may lack the financial resources, physical space, and perceived patient demand to do so sustainably.

Policy Recommendations

Federal-Level Recommendations

1. Provide targeted training and technical assistance.

The findings suggest that FOHC providers would benefit from expanded access to clinical training opportunities on topics relating to family planning, including patientcentered counseling and services related to LARC methods alongside the full range of FDA-approved contraceptive methods, consistent with national QFP guidelines. FOHC administrators, moreover, could benefit from access to technical assistance on topics related to sustainability, such as the use of LARC products purchased at 340B prices. Targeting training resources at communities with the highest unmet need for publicly funded family planning services would produce the largest impact. Policymakers could, for example, explore authorizing additional funds or repurposing existing resources to scale the efforts of the National Family Planning Training Center to serve all FOHCs, not just those that are Title X recipients. Or policymakers could consider directing additional resources to the existing Women's Preventive Services Initiative – a partnership between the federal government and the American College of Obstetricians and Gynecologists (ACOG) – for the purpose of creating additional training opportunities for FQHC providers.

2. Protect and expand grant programs and use of evidence-based guidelines. On top of receiving funding through the Section 330 program, many FOHCs also cite Title X grants as a key factor in their ability to offer LARC methods. This study's findings demonstrate that Title X-funded FOHCs were more likely to offer LARCs as compared to non-Title X centers. At minimum, policymakers should sustain funding levels for Title X and Section 330 and ensure stable administration of both programs. This study also found that Title X-funded FQHCs were more likely to offer LARC methods than centers without Title X, suggesting that safeguarding Title X's evidence-based guidelines, including the national QFP recommendations, would help enable their continued ability to do so. Additionally, it would be advisable for policymakers to clarify FOHCs' requirements with respect to family planning. For example, required family planning services at FQHCs could be defined to include a broad range of methods or all 18 FDA-approved methods of

contraception, and policymakers could ensure FQHC sites offer affordable access to LARCs for self-pay patients. Policymakers should also consider establishing supplemental sources of funding for FQHCs seeking to expand their family planning service delivery.

3. Collect and report data on family planning care **provided at FQHC sites.** Data to fully understand the role that FQHCs play in providing family planning is currently unavailable. The Health Center Program should collect, analyze, and report detailed data on the performance of FQHCs in the family planning context and measure their impact. For example, information collections could include client-level data on publicly funded family planning users (particularly uninsured, low-income, and self-pay patients), data on the Contraceptive Care Measures endorsed by National Quality Forum, availability of contraceptive services and counseling at FOHCs, and other insights into family planning delivery at FOHCs. Collections could be integrated into existing reporting obligations for FQHCs, such as through HRSA's Uniform Data System (UDS). This would better inform efforts to identify and address gaps in access and could help assess and hold organizations accountable for patient health outcomes.

State-Level Recommendations

- 1. Design optimal Medicaid reimbursement rates and policies. The survey and subsequent interviews found that the adequacy of reimbursement rates and payment policies were a key factor in LARC access at FQHC sites. States have significant latitude to set Medicaid policy within the broad contours of federal law. In states that have not already done so, policymakers and Medicaid officials should consider unbundling or "carving out" LARC product and service reimbursements from PPS encounter rates. Also, states should avoid placing restrictions on the use of LARC products purchased under 340B on Medicaid patients, and explore other options to reduce barriers to LARC methods in Medicaid, such as by taking actions recommended by the Center for Medicaid and CHIP Services (CMCS) in its 2016 informational bulletin.³⁸
- **2. Reform state scope-of-practice and licensing laws.** The findings suggest that shortfalls in the supply of trained providers limit timely access to LARC methods. Although non-physician clinicians such as advanced practice

registered nurses (APRNs) and midwives are trained in the provision of a range of services, various legal and reimbursement challenges may prevent them from helping to meet the need for family planning. State policymakers responsible for licensure and scope-of-practice rules should consider removing barriers to full practice for APRNs with sufficient education in family planning methods, including patient-centered LARC counseling and placement services, in order to increase the number of trained and available LARC providers in rural and underserved communities. Similarly, policymakers should assure that trained primary care physicians, such as family practice doctors and general practitioners, can provide and be fully reimbursed for LARC-related services without restriction.

3. Enhance collaboration, training, and sharing of **best practices.** As noted above, existing opportunities for FQHCs to receive clinical training and technical assistance may be inadequate. Prioritizing peer learning and collaboration among providers and administrators should be examined as an approach to extend existing resources and expertise. States could convene key family planning stakeholders - for example, Title X grantees, Title V maternal and child health programs, public health officials, primary care associations, and others - into "learning collaboratives" in order to establish referral systems; identify potential trainers and technical assistance providers as well as share resources; and share best practices among providers on the full range of family planning services, including patient-centered LARC counseling, placement, and other related activities. These collaboratives should build on the successes and insights of past efforts, such as the multi-state Association of State and Territorial Health Officials (ASTHO) Increasing Access to Contraception Learning Community, 39 and the efforts by the U.S. Department of Health and Human Services (HHS) to encourage state-level collaboration to expand access to contraception in light of the Zika outbreak.40

Appendix A: Tables and Figures

Fig. 1 – Key enablers to offering LARCs and Title X status (n=104)

LARC enablers	FQHCs with Title X funding (n=44)	FQHCs without Title X funding (n=60)	AII (n=104)
Sufficient provider/staff training	66%	57%	61%
Sufficient # of providers/staff	64%	55%	59%
Sufficient reimbursement	66%	48%	56%
Patient assistance programs	43%	45%	44%
Low acquisition/stocking cost	52%	28%	38%
Grant funding	50%	10%	27%
PPS LARC carve-out	36%	17%	25%
ACA no cost sharing requirement	18%	14%	15%
= financial factor			

Fig. 2 – LARC method availability: Title X versus non-Title X FQHCs

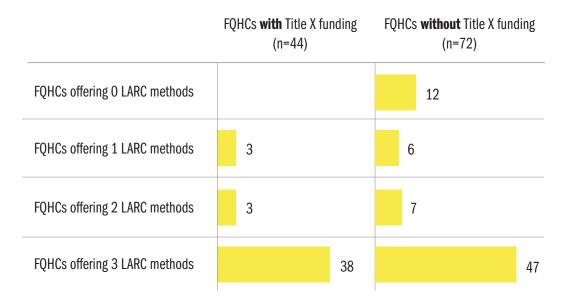


Fig. 3 – Title X status and median low/high end of IUD sliding scale (n=26)

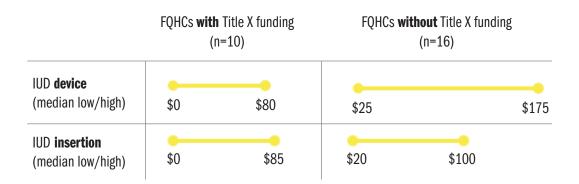


Fig. 4 – 340B and Title X (n=116)

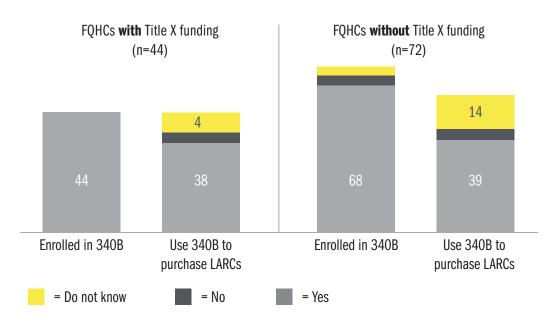


Fig. 5 – 340B devices and Medicaid-covered patients (n=58)

	# FQHCs
340B devices used for Medicaid FFS and MCO patients*	30
340B devices used for Medicaid FFS but not MCO patients	1
340B devices used for Medicaid MCO but not FFS patients	6
340B devices not used for Medicaid FFS or MCO patients	16
340B pricing not used to purchase any LARCs	5

^{*} FFS = Medicaid Fee For Service; MCO = Medicaid Managed Care Organization

Fig. 6 – IUD insertion and pharmacy type

	FQHCs with in-house pharmacy only (n=33)	FQHCs with both inhouse & off-site contract pharmacies (n=13)	FQHCs with off-site contract pharmacy only (n=36)
FQHC offers same-day insertion	3	2	7
FQHC offers same-visit insertion	7	2	2
FQHC offers both same-day and same-visit insertion	20	6	14
FQHC offers neither same-day nor same-visit insertion	3 (9%)	3 (23%)	13 (36%)

Appendix B: Methodology

Literature Review and Pre-Survey Interviews. To begin our research, we completed a literature review on enablers and barriers to LARC provision in FQHCs. Foundational literature for our market research included the following:

- "Accessibility of long-acting reversible contraceptives (LARCs) in Federally Qualified Health Centers (FQHCs)" (Beeson et al., 2013)
- "The Organization and Delivery of Family Planning Services in Community Health Centers" (Goldberg et al., 2015)
- Intrauterine Devices and Implants: A Guide to Reimbursement, Second Edition (<u>Armstrong et al., July 2015</u>)
- "Publicly Funded Family Planning Clinics in 2015: Patterns and Trends in Service Delivery Practices and Protocols" (Zolna and Frost, 2015)
- "Four aspects of the scope and quality of family planning services in US publicly funded health centers: Results from a survey of health center administrators" (Carter et al., 2015)
- "Sustainability Solutions: How Title X and FQHCs Can Work Together" (NFPRHA, 2017)
- A Framework for Quality Improvement Family Planning and Patient-Centered Specialty Practice Toolkit (NFPRHA, 2017)
- "State Strategies to Increase Access to LARC In Medicaid: Unbundling Reimbursement for LARC in Georgia" (National Institute for Children's Health Quality, 2017)
- "'Birth Control Can Easily Take a Back Seat': Challenges Providing IUDs in Community Health Care Settings" (Biggs et al., 2018)
- "The Power of the IUD: Effects of Expanding Access to Contraception through Title X Clinics" (Kelly et al., 2019)

In particular, we designed our survey to align closely with one comprehensive and widely fielded family planning survey from Kaiser Family Foundation (KFF) and George Washington University (GWU). This survey was fielded to FQHCs between May and July 2017 and was built on a survey that GWU fielded in 2011. KFF and GWU's 2017 survey received responses from 546 FQHC networks located in all 50 states plus Washington, DC. KFF published its research findings in a March 2018 report called "Community Health Centers and Family Planning in

an Era of Policy Uncertainty." Key findings relevant to our research included:

- Provision of all LARC methods has increased since 2011, while OC provision had dropped
- Sites with Title X funding consistently provide a larger range of contraceptive methods
- Rural or suburban health centers are less likely to provide the full range of contraceptives
- Two-thirds of health centers offer access to FP services for new patients on a walk-in basis

We spoke with an author on the KFF/GWU report to align on research questions that would add value to the existing body of research about barriers to LARC provision in FQHCs. We built the following research questions into our survey:

- What percentage of FQHCs provide no LARC methods or only some LARC methods?
- How does the Prospective Payment System (PPS) for FQHCs influence LARC service provision?
- How does the interplay between 340B drug pricing and Medicaid programs influence LARC service provision?
- How does Title X funding affect out-of-pocket sliding scale payment for LARCs in FQHCs?
- What key factors enable same-day or same-visit IUD insertion in FOHCs?

Through an iterative process, we developed a pre-survey interview guide, incorporating feedback from several external stakeholders and experts, and then used that guide to conduct three pre-survey interviews with FQHC healthcare providers/administrators to inform survey development.

Surveys. Targeting and Execution. Our primary market assessment method was an online survey distributed via email to healthcare providers (HCPs) and administrators in leadership positions at FQHCs. We collected no more than one survey response per FQHC network. Eligible providers and administrators received a \$50 honorarium for completing the survey.

 Wave 1: We began our outreach by emailing 1,010 individuals that Medicines360 could match to an FQHC and for whom Medicines360 had an email address available in its Salesforce database. In total, this target list represented 450 FQHCs.

- Wave 2: Wave 1 yielded very few sites offering some or no LARC methods, so we decided to specifically target these sites in our second wave. We used a proprietary database developed by a third-party organization to identify 70 additional networks identified as not providing any LARC methods. We manually gathered contact information for each of the networks identified. Although this outreach intended to collect responses from FQHCs not offering LARCs, the majority of respondents from this wave reported that they did offer one or more LARC method.
- Wave 3: We distributed our survey to 250
 FQHCs for which contact information was
 publicly available online as part of the Essential
 Community Providers database.
- Wave 4: Using the same database in Wave 2, we manually gathered an additional 100 contacts for sites identified as not offering LARCs. Again, we found that many sites identified in the third-party organization's database as not offering LARCs reported to us that they did offer one or more method.
- Wave 5: Several Primary Care Associations (PCAs), the organizations representing FQHCs on a regional level, agreed to help distribute a link to our survey to their networks. Because we did not distribute the survey directly through this wave, we do not know how many FQHCs received a link to our survey.

Fig. 7 - Summary of survey outreach waves and response metrics

Wave	Networks Targets	Surveys Completed	Response Rate ⁴³
1. M360 database	450	80	18%
2. Third-party database "No LARC" networks	70	7	10%
3. Essential Community Providers list	250	13	5%
4. Third-party database "No LARC" networks	100	6	6%
5. Primary Care Associations	NA	10	NA

Finally, we considered conducting but did not initiate a sixth wave of outreach through a nonprofit health IT provider with close connections to safety net clinics. Preliminary conversations with that organization mirrored our findings that very few FQHCs offer no LARC methods. Importantly, our research examined a range of barriers to LARC access, rather than simply considering clinic-reported LARC availability as a binary indicator of access for all patients.

Content. Broadly, our survey asked about the respondent's primary site within the FQHC, which family planning methods (including LARCs) that site provided, and details about their provision, including cost to patient, counseling, stocking, and other factors hypothesized to affect access. In addition, we asked directly about LARC enablers for sites providing all LARCs and barriers to LARC provision for sites not providing LARCs.

Responses. We asked survey respondents to answer questions about LARC provision in their primary service site, rather than in their network as a whole. For providers working in multiple service sites, we defined primary service site as the site where the provider spends the most time. For network-level administrators, we defined primary service site as the largest service delivery site in the network. Over the course of the survey period, we collected responses from 116 FQHC networks from 37 states plus Washington, DC.

Other Data Sources. In addition to our primary research, we used three external data sources for survey analysis:

- Health Resources and Services Administration (HRSA) Office of Pharmacy Affairs (OPA) Medicaid Exclusion File, updated 2019 Q2: used to determine 340B carve-in/carve-out status of respondents' sites
- Health Resources and Services Administration (HRSA) Health Center <u>Program Uniform Data</u> <u>System (UDS) Resources</u>, updated 2017: used to determine FQHC's percentage of Medicaid patients, percentage uninsured patients, total number of patients in network, and number of sites in network
- Kaiser Family Foundation (KFF) <u>Medicaid</u>
 <u>Managed Care Market Tracker</u>, updated 2018:
 used to determine percentage of Medicaid
 population in managed care plans

Post-Survey Interviews. *Targeting and Execution.* In addition, we conducted follow-up interviews with 11 survey respondents who indicated willingness for follow-up. We reached out to both Title X and non-Title X FQHCs across a range of geographies, community types, network sizes, and number of LARC methods offered. Each interview lasted between 50 and 90 minutes long. 10 interviews were conducted over the phone, while one was conducted during a site visit. Providers and administrators received a \$500 honorarium for participating in an interview or site visit.

Content: We customized interview guides based on the respondent's survey responses. We asked in greater depth about the barriers and/or enablers to LARC provision at the interviewee's networks and sites. Key themes discussed included sufficient state-level Medicaid reimbursement (including LARCs being carved out of the PPS), state/federal grant funding, low acquisition cost for certain LARCs, network leadership, clinic staffing, and HCP training against misconceptions.

Sample Representativeness and Data Limitations.

The data gathered from the market research portion of this project, while informative and directional, is limited. Our sample size is small, representing only around 9% of all FQHCs (116 out of around 1,293 networks nationwide). Because we limited survey responses to only one respondent per network site, either an HCP or an administrator, we necessarily captured an incomplete picture of barriers and enablers in any given FQHC. For example, a 340B administrator may have detailed information about 340B compliance, but very little about how providers counsel on IUDs. However, a provider might be unlikely to know details about the FQHC's contract pharmacy arrangement.

Guidance from NFPRHA, researchers at GWU, several PCAs, and at least one FQHC administrator raised the concern of survey fatigue—that FQHCs are overburdened with data requests and likely to ignore requests for more information, especially when they receive those requests cold and unsolicited, like the majority of our outreach. Interviewees also hypothesized that the recent political climate around family planning may have had a chilling effect on survey responses, due to concerns around phishing or data mining by antagonistic actors.

If sites that provide more limited family planning services are smaller, resource-limited, and strapped for time, they may have been less likely to respond to our survey. skewing our sample towards family planning providers. In addition, sites aligned with Medicines 360's mission to expand access to birth control may have been more likely to complete our survey, skewing our sample in the same direction. We suspect that both HCPs and administrators are likely to overstate the family planning services available at their primary site. Also skewing our research towards those indicating LARC availability, we asked network-level administrators to respond on behalf of their largest single service site, which may be the most likely service site to offer LARCs and means that we do not capture barriers for smaller and/or more remote sites not offering LARCs.

Compared to the "Community Health Centers and Family Planning in an Era of Policy Uncertainty" report, our respondents were more likely to offer contraceptive implants (86% versus 63%), more likely to offer copper IUDs (76% versus 55%), and more likely to offer hormonal IUDs (82% versus 64%).

For compliance purposes, our initial email and survey itself disclosed the parties administering the survey—Medicines360 and Camber Collective. Some respondents were likely familiar with Medicines360 as a mission-driven nonprofit organization, but others may have been aware that Medicines360 provides LILETTA, a hormonal IUD, to 340B covered entities including FQHCs. This background knowledge, while not given in the survey or email, could have tainted survey responses.

Furthermore, because the majority of survey completions came from Wave 1 outreach (in which we identified contact information through Medicines 360's list of contacts) it is very likely that our sample size are disproportionately LILETTA users.

Appendix C: Summary of Survey Respondents

Fig. 8 – Respondents by job function/title (n=116)



Fig. 9 – Respondent's primary service site receives Title X funding (n=116)

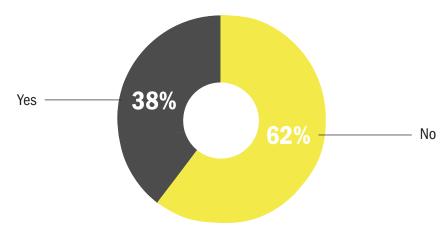


Fig. 10 – Respondent's primary service site community type (n=116)

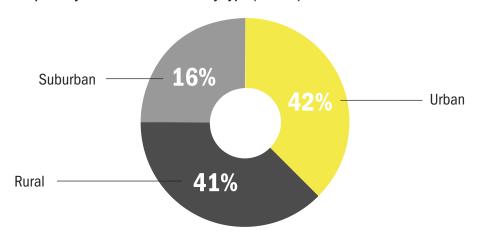
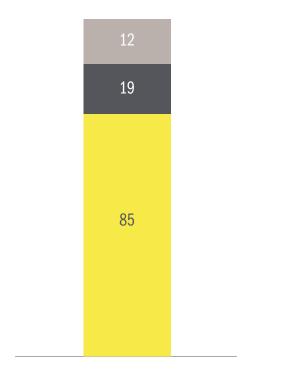


Fig. 11 – LARCs offered at respondent's primary service site (n=116). We defined LARC methods as contraceptive implants (NEXPLANON), copper IUDs (PARAGARD), and hormonal IUDs (KYLEENA, LILETTA, MIRENA, and/or SKYLA).

Fig. 12 – LARC methods offered at respondent's primary service site among sites offering some or all LARCs (n=104). We defined LARC methods as contraceptive implants (NEXPLANON), copper IUDs (PARAGARD), and hormonal IUDs (KYLEENA, LILETTA, MIRENA, and/or SKYLA).



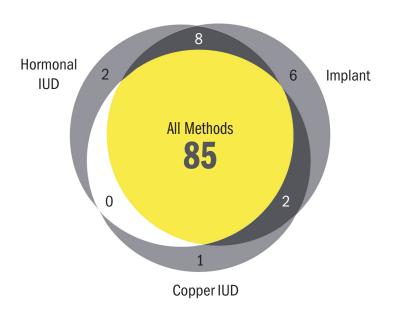
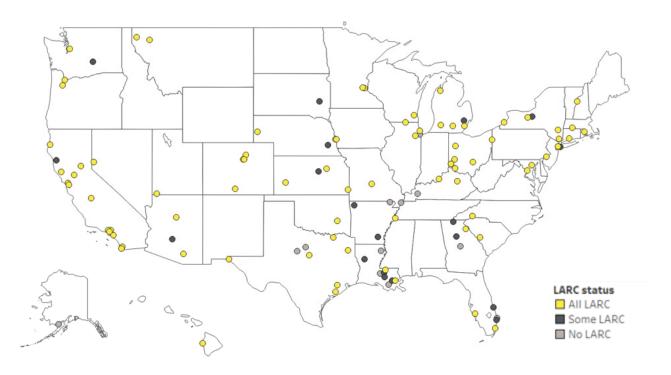


Fig. 13 – Geographic distribution of survey respondents (n=116). Survey respondents mapped according to ZIP code of respondent's primary service site.



Endnotes

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