December 21, 2015

VIA ELECTRONIC TRANSMISSION

The Honorable Sylvia Mathews Burwell
Administrator Andrew Slavittd
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue SW
Washington, DC 20201

Re: CMS-9937-P; Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2017

Dear Secretary Sebelius and Administrator Slavitt:

Planned Parenthood Federation of America ("Planned Parenthood") and Planned Parenthood Action Fund ("the Action Fund") are pleased to submit these comments in response to the HHS Notice of Benefit and Payment Parameters for 2017, released by the Department of Health and Human Services ("Department") and published on December 2, 2015 at 80 Fed. Reg. 75488 et. seq. As a trusted women's health care provider and advocate, Planned Parenthood supports the Department's commitment to seeking input from stakeholders as it continues to implement the Affordable Care Act ("ACA") and ensure that qualified health plans ("QHPs") provide consumers across the nation with access to quality, affordable health care.

Planned Parenthood is the nation's leading women's health care provider and advocate and a trusted, nonprofit source of primary and preventive care for women, men, and young people in communities across the United States (U.S.). Each year, Planned Parenthood's more than 700 health centers provide affordable birth control, lifesaving cancer screenings, testing and treatment for sexually transmitted diseases (STDs), and other essential care to nearly three million patients. We also provide abortion services and ensure that women have accurate information about all of their reproductive health care options. The majority of Planned Parenthood patients have incomes at or below 150 percent of the Federal Poverty Level ("FPL"). One in five women in the U.S. has visited a Planned Parenthood health center.

Planned Parenthood is dedicated to improving access to health care across the country and strongly supports initiatives that align with that mission—including efforts to expand insurance coverage to millions

of uninsured Americans. Because so many of Planned Parenthood patients are eligible to purchase their health coverage through the Marketplaces, we have a special interest in ensuring that these individuals can enroll in Marketplace plans that meet their needs.

We thank the Department for re-examining current Marketplace regulations and modifying or proposing new provisions with the goal of improving health care coverage and access. As the Department moves forward with this important work, we urge the agency to ensure regulations address the unique needs of women in the health care system. In particular, it is imperative that the Department strengthen the network adequacy and Essential Community Provider (ECP) standards in specific ways to ensure meaningful and timely access to women's health care—in keeping with the promise of the ACA. We also urge the Department to clarify some of the new requirements related to ACA Navigator and consumer assistor programs. Such clarifications will help to support the sustainability of robust consumer assistor programs that empower people with the information and tools they need to select the coverage that works best for them.

I. Section 155.210 – Navigator Program Standards

A. We support the Department's proposal to require that Navigators in all Marketplaces provide targeted assistance to "underserved and vulnerable" populations, and we urge the Department to ensure Navigators receive the additional resources necessary to effectively meet this goal.

We commend the Department for its proposal that Navigators in all Marketplaces provide targeted assistance to "underserved and vulnerable" populations, as defined by their Marketplaces. We agree that, particularly at this stage of the ACA enrollment effort, it is important that Navigators adapt their strategies to prioritize reaching these populations in order to address persistent disparities in health coverage.

As an important source of primary and preventive care for low-income women and men across the country, Planned Parenthood is uniquely familiar with the importance of health coverage in improving health outcomes and achieving equity. Through the ACA, the health system has made significant progress towards addressing disparities by instituting reforms that increase access to preventive and primary care and improve coverage options for people with pre-existing conditions, among other improvements. However, while the ACA has ushered historic overall gains in insurance rates among Americans, certain groups still lag behind. For example, Latino and African American communities – particularly women of color – are still more likely to be uninsured than white Americans.[1] Of the 10.5 million people that remain uninsured and eligible for Marketplace coverage, approximately t one-third are people of color. Latinos in particular are experiencing disproportionate gaps in coverage, representing 19 percent of the group that is uninsured but eligible for Marketplace plans.[2] Lack of coverage is a barrier to care and contributes to health disparities.

[1] U.S. Department of Health and Human Services, *Health Insurance Coverage and the ACA* (Sept 22, 2015), available at https://aspe.hhs.gov/basic-report/health-insurance-coverage-and-affordable-care-act-september-2015.
[2] U.S. Department of Health and Human Services, *ASPE Issue Brief: Health Insurance Marketplace: Uninsured Populations Eligible to Enroll for 2016* (Oct. 15, 2015), available at https://aspe.hhs.gov/sites/default/files/pdf/118606/OE3%20QHP-Eligible%20Uninsured_FINAL_v42%20clean.pdf.

For example, individuals that are uninsured are less likely to access important preventive care, less likely to be able to afford the prescription drugs that they need, and more likely to delay or forgo needed health care.[3]

Among others, Navigators are best positioned to make progress against inequities in health coverage. Indeed, consumer assisters, including Navigators, are more likely than brokers to assist and enroll harder-to-reach populations, including Latinos, persons of limited English proficiency, those lacking internet access, and low-income people eligible for Medicaid.[4] Targeting enrollment efforts will therefore be critical in focusing Navigator resources and tailoring programs to most effectively serve these hard-to-reach populations. We believe the Department's proposed criteria for the identification of target populations – by assessing those populations that are disproportionately without access to coverage or care, or are at a greater risk for poor health outcomes – will ensure that Marketplaces consider racial and ethnic disparities along with other important factors for the particular service areas in question.

Additionally, we ask that Navigators be given the opportunity to receive training, materials, and funding where appropriate to better reach priority populations. We believe outreach to these populations will require a thoughtful, proactive response to the specific needs of harder-to-reach groups – for example, a heightened need for cultural competence or additional language access resources or personnel.

B. We request that the Department take steps to clarify and limit the role of Navigators in providing consumers with post-enrollment and other assistance; require that consumers be notified that consumer assistance personnel are not legal or tax experts; and guarantee that all entities carrying out Navigator functions receive the necessary comprehensive training, guidance, and other support.

We appreciate the Department's intent to increase the range and availability of post-enrollment and other assistance for consumers. For many, consumer assisters are the principal point of contact for enrolling in, and achieving a greater understanding of, available health coverage options under the ACA. In the last enrollment period, a large majority of consumer assistance programs said that nearly all of their clients needed help understanding basic aspects of the ACA and health insurance terms.[5] Navigator personnel are therefore a natural gateway for consumers seeking assistance that extends beyond enrollment. We note that for many Planned Parenthood affiliates, the proposed duties in some ways merely formalize the types of assistance they are already providing. This is consistent with the experiences of other assisters. During the second open enrollment period, nearly 80 percent of consumer assisters helped consumers with post-enrollment issues, of which eligibility appeals and tax-related questions formed a significant proportion.[6] While instruction from the Department on Navigator duties in this area is welcome, it is critical that the Department clearly confine the scope of any new responsibilities to avoid imposing unreasonable burdens

[3] Ibid.
[4] Kaiser Family Foundation, *2015 Survey of Health Insurance Marketplace Assister Programs and Brokers* (Aug. 2015), available at http://files.kff.org/attachment/report-2015-survey-of-health-insurance-marketplace-assister-programs-and-brokers
[5] Ibid.
[6] Ibid.

on participating entities and equip Navigator personnel with the comprehensive training and resources to form partnerships with and direct consumers to community experts that are best suited to address any issues that may arise.

The rule newly proposes that Navigators must specifically provide post-enrollment and other assistance regarding filing eligibility appeals, filing exemptions, providing basic information on the reconciliation of premium tax credits, and helping consumers understand basic concepts related to using their health coverage. These are significant new duties. We reinforce that, as the Department notes in its proposal, many consumer assistance programs already function with serious resource limitations. In fact, one in five consumer assistance programs reported that they had to turn at least some consumers away in the second open enrollment period due to a lack of capacity, indicating that additional support may be required for the execution of current Navigator responsibilities. [7] If Navigators are to carry out additional duties without a corresponding increase in federal support, they may experience a diminished overall capacity and fewer resources dedicated to enrollment assistance or other pre-existing duties. There is also a risk that, unmitigated, the attendant burdens would deter potential applicants from applying for and continuing their participation in the Navigator program. In short, we believe the rule as proposed gives insufficient weight to the burdens that are likely to result from the proposed expansion of duties for Navigators.

In response to these concerns, the Department should take steps to clarify and limit the scope of the new duties. This is particularly crucial regarding assistance for eligibility appeals and the reconciliation of premium tax credits – areas in which special competence or licensure is often required to provide assistance. As the Department notes, Navigator personnel have neither the tax nor legal expertise necessary to provide tax assistance or interpret tax rules and forms. Beyond a basic familiarity, these matters necessarily fall outside of the ordinary purview of Navigator personnel. Thus, we believe the correct role for a Navigator entity in this area is to function not as an independent source of expertise, but instead primarily as a bridge to connect the consumer with the legal and tax experts that are trained and certified to provide the necessary assistance.

In its final rule, we urge the Department to draw a bright line between the provision of basic information incumbent on Navigators and the types of assistance rising above this baseline obligation. For questions extending beyond the most fundamental knowledge on these issues, Navigators should only be responsible for developing and executing policies and procedures for the referral of consumers to community partners that are experts in tax assistance or legal issues. The proposed rule mandates the establishment of these community partnerships, and we agree that they are indispensible in carrying out the new duties. By confining Navigator obligations to the dissemination of baseline information and directing the remainder of consumer questions to experts with whom Navigator entities have established relationships, the Department can properly strike the balance between ensuring that consumers have access to accurate post-enrollment information and assistance and realistically delineating the appropriate responsibilities of Navigators while keeping any additional burdens to a minimum.

[7] Ibid.

We agree with the Department that the rule should require that consumers be notified that consumer assistance personnel are not legal or tax experts and cannot advise consumers on such matters. We believe such a disclaimer would reduce the risk of misunderstanding and ensure consumers are aware that specific questions regarding their taxes must be brought to a tax preparer or other expert. However, a verbal disclaimer or notice during every consumer assistance encounter is unnecessary. Navigators should be able to satisfy this responsibility in a number of ways, including but not limited to the insertion of additional disclaimer language into consent forms.

Finally, the Department should guarantee that all entities carrying out Navigator functions that will be subject to the new responsibilities set forth in the final rule receive comprehensive training, guidance, and other support to ensure they have the adequate knowledge and skills to assist consumers. In a recent survey, 86 percent of consumer assistance programs indicated that they would like additional training on a range of complex issues, including tax-related questions and problems.[8] If Navigators are newly required to provide assistance on these sophisticated topics, it will be even more critical that this need is satisfied.

II. Sections 155.210, 155.225 – The Provision of Gifts in Consumer Assistance Programs

We support the Department's proposed clarifications regarding the permissible distribution of gifts, promotional items, and reimbursement for enrollment-related expenses by consumer assisters.

The Department's proposed clarifications regarding the permissible distribution of gifts, promotional items, and reimbursement for enrollment-related expenses by consumer assisters would provide welcome guidance in this area. Gifts and promotional items of a nominal value serve as an important way to engage potential consumers and enrollees in conversation at outreach and enrollment events.

We agree, however, that gifts or promotional items of any value should not be used for the purpose of inducing enrollment. I n some cases, the use of gifts for this purpose may conflict with the duty of consumer assistance personnel to provide fair and unbiased information. We appreciate the Department's proposal to assess the cumulative value of items distributed at a single encounter to determine whether the nominal value rule is met. We agree this simplifies and reduces the burden of compliance on assisters. Finally, we appreciate the Department's clarification that consumer assistance personnel may provide reimbursement beyond the nominal amount for legitimate expenses, such as travel, incurred in a consumer's effort to receive assistance.

III. Section 155.225 – Standards Applicable to Certified Application Counselors

We urge the Department to ensure that its proposed reporting requirements for certified application counselor (CAC) organizations avoid compelling CACs to report data that could otherwise be ascertained in a less burdensome manner, and to take care to impose as few burdens on CACs as possible if it determines reporting is nonetheless necessary. Additionally, the Department should allow for a means for CACs to voluntarily report additional information that falls outside of the Department's proposed

[8] Ibid.

performance measures. The Department should further consider the requirements on CACs operating in the federally-facilitated Marketplace (FFM) to be the upper-limit on reporting requirements for CACs in all Marketplaces.

We agree with the Department that Marketplaces are better able to reach key populations with clear data on the nature and performance of consumer assistance entities operating in their service areas, including Certified Application Counselor (CAC) organizations. Good decisions require good data. However, the Department should consider the fact that many CAC organizations are already operating at capacity. Relative to other consumer assistance programs, CAC organizations are likely to have a smaller staff and more likely to rely on volunteers, resulting in a lower overall bandwidth to perform administrative requirements.[9] We make the following recommendations to ensure that the process of aggregating and reporting this information does not impose an unreasonable burden on CAC organizations.

First, the Department should take steps to avoid compelling CACs to report data that could otherwise be ascertained in a less burdensome manner. If implemented properly, we believe the Department's investment in tools to actively collect information "on the fly" as assistance is rendered is likely to reduce the time CAC organizations spend preparing and submitting reports and the total resources dedicated to reporting overall. The Department could, for example, integrate the data collection into the enrollment application process. The Department could update pre-existing systems to allow consumers to identify individual CACs that have rendered assistance in the process of applying for coverage. We ask the Department to consider its own role in simplifying and automating the process of obtaining CAC performance data.

If the Department nonetheless determines that the submission of reports regarding some aspects of consumer assistance remains necessary, it should take care to impose as few burdens on CACs as possible in doing so. The Department proposes that CAC organizations submit information monthly. Many CACs, however, experience reduced activity outside of the open enrollment period. It is our view that not only is there a diminished need for ongoing, frequent reporting during the off-season, but preparing and submitting reports is likely to be more challenging for CACs as a practical matter because staff time may be diverted as consumer volume tapers. Monthly reporting would be a significant new responsibility for CACs.

Second, in order to ensure that Marketplaces receive the highest quality information, the Department should incorporate flexibility into the proposed performance measures to allow CAC organizations to *voluntarily* report other formal and informal services that CACs provide to consumers every day. The Department proposes to collect data regarding the number of individuals who have been certified by the organization; the total number of consumers who received application and enrollment assistance from the organization; and of that number, the number of consumers who received assistance applying for and selecting a QHP, enrolling in a QHP, or applying for Medicaid or CHIP. While this information is important, it is not the full picture. For example, CACs provide important pre-application services and may help consumers evaluate their coverage options. These services would not be captured by a measure that looks

[9] Ibid.

only at assistance "applying for and selecting a QHP." We believe many important services provided by CACs evade simple categorization into the scheme proposed by the Department.

Finally, we recommend that the Department prevent non-FFM states from imposing requirements on CACs that exceed the type and frequency of reporting required for CAC organizations operating in the FFM. In other words, the Department's reporting requirements for CAC organizations operating in the FFM should establish an upper-limit or "ceiling" for analogous duties on CACs in non-FFM states. This guidance would help Marketplaces understand what types of information to collect as well as safeguarding CACs from excessively burdensome reporting.

IV. Section 155.605 – Eligibility Standards for Exemptions

We support the proposal to incorporate into regulation the specific events and circumstances, previously laid out in Marketplace guidance, that qualify an individual for a hardship exemption from the individual shared responsibility payment.

The Department has previously set out in guidance specific examples of events and circumstances that qualify an individual for a hardship exemption, including but not limited to: homelessness; eviction or foreclosure; a person experienced domestic violence; a person experienced the death of a family member; and a person is enrolled in a state's Medicaid pregnancy-only coverage program that is not recognized as minimum essential coverage under ACA; among other specific circumstances set out in guidance. The exemption from the fee for not having coverage is critically important for people in these types of specific and often very difficult circumstances. We fully support incorporating the exemption-qualifying events and circumstances into regulation at section 155.605(d)(2).

V. Section 156.122 – Essential Health Benefits Package; Prescription Drug Benefits

A. The Department should clarify that, if a state has state-specific laws for drug formulary exceptions processes, Marketplace plans may follow state-specific rules and satisfy the federal exceptions process in section 156.122 as long as the state-level process is more stringent and more protective than the state's procedures.

A fundamental pillar of the ACA is coverage of Essential Health Benefits (EHB), which enables consumers to access a comprehensive package of items and services under their insurance coverage. In addition to supporting a strong EHB prescription drug standard, we continue to support implementation of clear standards for the drug formulary exceptions process so that enrollees can request and gain access to clinically-appropriate non-formulary drugs through their health plans. This is a necessary and vital part of ensuring that EHB health plans meet the needs of women, their families, and individuals with serious and chronic conditions.

We recognize, as the Department has acknowledged, that some states may have policies or issuer standards in place for enrollees to obtain coverage of non-formulary drugs – and consequently, issuers may have to satisfy two different processes for access to non-formulary drugs. We support the Department's

proposed clarification that, if a state has laws and rules that include a review for non-formulary drugs, a plan may satisfy the federal exceptions process in section 156.122(c) if it meets the state's procedures *as long as* the state's process is "more stringent than" the federal standards in section 156.122(c). However, we are concerned about the statement in preamble that the Department is considering this option where the state-level law or process "conflicts with" the federal exceptions process in section 156.122(c). This may lead to instances where plans follow state-level procedures that are different from, but offer fewer consumer protections than, the federal exceptions process for enrollees to obtain non-formulary drugs.

It is critical to clarify that the exceptions process in section 156.122(c) is a federal minimum that states can build upon. In particular, if the Department amends section 156.122(c) to allow plans to follow state-level requirements for review of non-formulary drugs, it must be clear that this is only permissible where the state-level exceptions process is more stringent than and more protective for consumers who seek to access the medications they need.

B. The Department should reiterate in the preamble to the final rule that health plans must comply with the contraceptive cost-sharing exceptions process under section 2713 of the Public Health Service Act in addition to the EHB formulary exceptions process in section 156.122(c), as these are separate legal requirements under the ACA.

The Department should reiterate that the EHB requirement at § 156.122(c) that plans have procedures in place to allow enrollees to request and gain access to clinically appropriate drugs not covered by the plan is separate from the requirement in section 2713 of the Public Health Service Act (PHSA) that plans have an "expedient exceptions process" for contraceptives.[10] Plans must meet both these requirements to fulfill their obligations under the ACA.

The ACA requires plans to cover *all* FDA-approved contraceptive methods for women without cost-sharing, and in doing so, to cover at least one form of contraception in each of the 18 method categories for women that appear on the FDA's Birth Control Guide.[11] In February 2013, the Departments clarified that a plan must have a process to waive cost-sharing for a specific birth control product recommended by the woman's health care provider if the plan does not regularly cover that method without cost-sharing.[12] The Departments' most recent guidance in May 2015 made it clear again that plans must have a process, further clarifying that if a plan utilizes medical management techniques within a method of contraception, it must have an "expedient exceptions process" so that a woman can access the particular birth control she and her health care provider have determined is medically necessary.[13]

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[10] U.S. Dep't of Health and Human Services, U.S. Dep't of Labor, and U.S. Treasury, FAQs on Affordable Care Act Implementation XXVI (May 11, 2015), *available at* http://www.dol.gov/ebsa/faqs/faq-aca26.html.
[11] *Id*. U.S. Dep't of Health and Human Services, Health Resources Services Admin., Women's Preventive Services Guidelines (July 2011), *available at* http://www.hrsa.gov/womensguidelines/.
[12] U.S. Dep't of Health and Human Services, U.S. Dep't of Labor, and U.S. Treasury, FAQs on Affordable Care Act Implementation XII (Feb. 20, 2013), *available at* http://www.dol.gov/ebsa/faqs/faq-aca12.html.
[13] U.S. Dep't of Health and Human Services, U.S. Dep't of Labor, and U.S. Treasury, FAQs on Affordable Care Act Implementation XXVI (May 11, 2015), *available at* http://www.dol.gov/ebsa/faqs/faq-aca26.html.

Some issuers may believe that implementing the procedures required by section 156.122(c) are sufficient to meet the contraceptive cost-sharing exceptions process. However, they are not. There are several key ways the contraceptive cost-sharing exceptions process provides greater protections than the procedures required by section 156.122(c):

- The contraceptive exceptions process allows women to access coverage of the specific birth control recommended by her attending provider, whether it is on the formulary with cost-sharing or off-formulary, while the procedures required by section 156.122(c) only apply to drugs off-formulary.[14]
- The contraceptive exceptions process requires plans to defer to the attending provider's determination of medical necessity, while the procedures required by section 156.122(c) allow plans to make a determination as to coverage.[15]
- The contraceptive exceptions process requires coverage without cost-sharing of the birth control product, while the procedures required by section 156.122(c) treat the specified drug as an essential health benefit subject to cost-sharing requirements.[16]

In the proposed rule, the Department reiterated that the exceptions process under section 156.122(c) is distinct from the coverage appeals process under section 147.136. In the final rule the Department should also reiterate that the contraceptive cost-sharing exceptions process is required and that it is distinct from the exceptions process requirement under section 156.122(c).

The contraceptive exceptions process is critical to ensuring that a woman gets coverage without cost-sharing for the birth control that she and her health care provider have determined is appropriate for her. If the contraceptive exceptions process is not implemented correctly, it could lead to women forgoing birth control altogether or using an inappropriate method, which could lead to less effective or less consistent use and possibly an unintended pregnancy.

[14] U.S. Dep't of Health and Human Services, U.S. Dep't of Labor, and U.S. Treasury, FAQs on Affordable Care Act Implementation XXVI (May 11, 2015); and Health Insurance Issuer Standards under the Affordable Care Act, Including Standards Related to Exchanges, 45 C.F.R. § 156.122(c) (requiring a process "to request and gain access to clinically appropriate drugs not otherwise covered by the health plan.").

[15] U.S. Dep't of Health and Human Services., U.S. Dep't of Labor, and U.S. Treasury, FAQs on Affordable Care Act Implementation XXVI (May 11, 2015); and Health Insurance Issuer Standards under the Affordable Care Act, Including Standards Related to Exchanges, 45 C.F.R. § 156.122(c)(1)(ii) (requiring that "A health plan must make its determination on a standard exception and notify the enrollee or the enrollee's designee and the prescribing physician (or other prescriber, as appropriate) of its coverage determination no later than 72 hours following receipt of the request.").

[16] U.S. Dep't of Health and Human Services, U.S. Dep't of Labor, and U.S. Treasury, FAQs on Affordable Care Act Implementation XXVI (May 11, 2015); and Health Insurance Issuer Standards under the Affordable Care Act, Including Standards Related to Exchanges, 45 C.F.R. § 156.122(c)(1)(ii) ("In the event that an exception request is granted, the plan must treat the excepted drug(s) as an essential health benefit, including by counting any cost-sharing towards the plan's annual limitation on cost-sharing under §156.130 and when calculating the plan's actuarial value under §156.135.").

VI. Section 156.230 – Network Adequacy Standards

In general, we applaud the Department for recognizing the need to strengthen network adequacy standards and for proposing a number of new provisions that would apply for the 2017 plan year. Network adequacy is a key component to ensuring meaningful health care access. While millions of Americans have gained health insurance over the last two years, that coverage is a hollow promise if consumers cannot access the covered benefits they need.

The consumer experience in Marketplace plans in 2014 and 2015 continues to highlight a need for stronger network adequacy standards. Consumers in the first two open enrollment periods struggled to understand which providers would accept the Marketplace plan options available to them. Even after enrollment, many consumers were not able to find providers willing to provide them with needed care. And other consumers received large bills for services rendered that they believed their Marketplace plan would cover. A recent study published in the *Journal of the American Medical Association* found concerns with insufficient provider networks, particularly outpatient specialty care, raising significant concerns for access to care.[17] In particular, the study found that 13 percent of federal Marketplace plans had no provider in-network for at least one specialty within a 100 mile radius. While certain specialties were more commonly excluded (e.g., endocrinology, rheumatology, and psychiatry), some Marketplace health plans had no in-network OB/GYN providers within a 100 mile radius.[18] The proposed rule takes a significant step towards addressing some of the issues consumers have faced in obtaining needed care under their Marketplace plans.

Strong Marketplace network adequacy standards are especially warranted given that Marketplace plans serve a comparatively vulnerable population. The network adequacy regulations apply to Marketplace plans that serve a high number of low-income individuals, women of reproductive age, individuals with special and chronic health needs, and limited English proficient individuals. For instance, an estimated 85 percent of Marketplace enrollees in 2015 received federal financial assistance and are under 400 percent of the federal poverty level (FPL).[19]

To ensure that Marketplace enrollees across the country have timely access to appropriate, geographically accessible providers who can deliver the health services covered under their plans, the Department must adopt stronger network adequacy standards in regulation to uphold and meaningfully implement the

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[17] Dorner SC, Jacobs DB, Sommers BD. Adequacy of Outpatient Specialty Care Access in Marketplace Plans Under the Affordable Care Act. *JAMA*.2015; 314 (16):1749-1750. doi:10.1001/jama.2015.9375. Available at http://jama.jamanetwork.com/article.aspx?articleid=2466113#Discussion.

[18] Dorner SC, Jacobs DB, and Sommers BD. *Adequacy of Outpatient Specialty Care Access in Marketplace Plans Under the Affordable Care Act.* JAMA. 2015; 314:1749-1750. Researchers examined physician networks in 34 states offering plans through the federal Marketplace in 2015 and looked at the number of in-network physicians in a variety of fields, including obstetrics/gynecology. It is important to note that this report only looked at densely populated areas; rural regions may have an even higher prevalence of health plans without in-network specialty care including OB/GYN care.

[19] U.S. Department of Health and Human Services, ASPE Issue Brief: Health Insurance Marketplaces 2015 Open Enrollment Period: March Enrollment Report, at 24 (Table A1)(Mar. 10, 2015). Available at https://aspe.hhs.gov/sites/default/files/pdf/83656/ib_2015mar_enrollment.pdf.

statutory requirements for network adequacy under the ACA. In particular, network adequacy standards must ensure that networks are sufficient to meet women's health needs and provide timely access to providers that specialize in women's primary health care, including family planning care, women's preventive services, and pregnancy-related care.

A. The Department should establish a minimum network adequacy standard for Marketplace issuers in all states, and clarify that this includes an active review of plan networks using a minimum set of quantitative standards.

The Department must establish a strong network adequacy standard for Marketplace issuers in all states, including the federally-facilitated Marketplace (FMM), state-based Marketplaces, and Partnership Marketplaces. We appreciate that the proposed rule will require issuers in the FFM to meet certain network adequacy metrics, including time and distance and provider-to-enrollee standards. While we support flexibility to states to develop stronger network adequacy standards reflecting the particular needs of each state, we urge the Department to establish a federal baseline for network adequacy in these regulations.

The ACA requires the Secretary to establish network adequacy requirements for ***all*** issuers seeking Marketplace plan certification.[20] The current approach to network adequacy standards has resulted in a patchwork of provisions that vary widely across state lines. Indeed, a number of states with state-based Marketplaces do not actively review plan networks and do not currently use quantitative standards for evaluating network sufficiency. Therefore, in order to comply with and meaningfully implement statutory requirements under the ACA, we urge the Department to adopt a federal minimum network adequacy standard that applies to all states and that requires states to actively review Marketplace plans for network adequacy using a minimum set of quantitative standards.

It is critical, especially in this changing health care environment, with rapidly evolving network designs, that regulators actively seek to identify and address network adequacy problems within a plan's network ***before*** the product is ever sold to and relied upon by consumers. In addition, precise quantitative standards are crucial to ensuring that insurance regulators, consumers, providers, and advocates can equally evaluate whether Marketplace plan networks are adequate to meet enrollees' health needs. Without measurable criteria, insurers and regulators within a state may have very different interpretations of what is sufficient. All stakeholders benefit when the standards are clear and easy to measure.

B. The Department should implement minimum network adequacy standards that incorporate quantitative metrics, including, but not limited to, time and distance standards, appointment wait times, provider-to-enrollee ratios, and an assessment for the range of provider types in a plan's network. Network adequacy standards must reflect the needs of women and ensure

[20] 42 U.S.C. § 18031(c)(1)(B). Also, section 156.230(a)(2) of the federal regulations requires all issuers offering Marketplace plans to maintain a network that is sufficient in number and types of providers to assure that all covered services are accessible without unreasonable delay.

timely access to providers that specialize in women's primary health care, including gynecological, obstetric, and family planning care.

We appreciate the Department's intent to specify more detailed quantitative standards for FFM plans – such as provider-to-enrollee ratios and geographic access standards – in the forthcoming Letter to Issuers. We commend the Department for taking this enormous step to establish quantitative standards for network adequacy in the Marketplaces. As noted above, we strongly support implementing a federal minimum standard for all states, not just in the FFM. As the Department creates its list of specific criteria and metrics for states to use to measure network adequacy, we urge the Department to look beyond just measures of time or distance and minimum provider-to-enrollee ratios for the specialties with the highest utilization rate in the state, as proposed. The Department should establish a broad set of metrics and criteria that includes but is not limited to:

- Time and distance standards;[21]
- Provider-to-enrollee ratio minimums;
- Appointment wait time standards, particularly for family planning services and pregnancy-related care;
- Availability of providers accepting new patients;
- Availability of providers offering the full range of family planning and related services on-site, without requiring a referral; and
- Assessment of the range of provider types in a plan's network.

Consideration of these factors as part of network adequacy review will help ensure that plan networks meet the needs of consumers and provide timely access to covered services. Reproductive health services, such as family planning and pregnancy care, are unique in that they are time sensitive in nature. Just a few days without contraception can result in unintended pregnancy, and delays in prenatal care can result in serious pregnancy complications that have harmful impact on maternal and child health outcomes. A time and distance standard or provider-to-enrollee ratio is not sufficient for fully addressing timely access to care. For example, there is no guarantee a woman will be able to access the care she needs in a timely manner simply because a woman's health care provider is in close proximity to where she lives.

Moreover, it is critical that network adequacy standards and review processes include a specific focus on plans' inclusion of a broad range of provider types, including providers that specialize in women's primary health care, including gynecological, obstetric, and family planning care. At the end of the second open enrollment period, more than half (54%) of the enrollees in the Marketplace are women, and almost one in four (24.3%) Marketplace enrollees are women of reproductive age (ages 18-44).[22] An estimated 2.3

[21] Specific criteria to measure the maximum travel time and distance to providers are common in public programs, such as Medicaid, Medicare, and TRICARE, and have also been adopted by many states. We recommend that the Department's criteria explicitly account for variation in travel patterns, modes of transportation, and geography.
[22] U.S. Department of Health and Human Services, ASPE Issue Brief: Health Insurance Marketplaces 2015 Open Enrollment Period: March Enrollment Report, at 24 (Table A1)(Mar. 10, 2015). Available at https://aspe.hhs.gov/sites/default/files/pdf/83656/ib_2015mar_enrollment.pdf.

million women ages 15 to 49 are currently uninsured and eligible for Marketplace premium assistance,[23] signaling that Marketplace enrollment will continue to grow in future years. It is vital that provider networks meet the needs of these women as they enter the Marketplace. A specific focus on the range of provider types – particularly providers that specialize in women's gynecological, obstetric, and family planning care – is critical to ensuring that women have timely access to providers that furnish the services women need and are guaranteed under the ACA, such as women's preventive care, the full range of contraceptives, and pregnancy-related care.

Additionally, a specific focus on provider types is especially important because of the unique way women experience the health care system and rely on women's health providers for their critical care. The reality is that, for most women of reproductive age, their OB/GYN provider is a critical and primary part of the health care they need. Almost 6 in 10 women (58 percent) report seeing an OB/GYN provider on a regular basis and one-third of women (35 percent) view their OB/GYN provider as their main source of care. For many women (4 in 10), an OB/GYN is the first provider they chose as an adult.[24] Women know OB/GYNs play an important role in their entire adult life – not only providing birth control and breast and cervical cancer screenings, but also information on proper exercise, healthy nutrition, preventive care, and navigating the broader health care system.

Notably, OB/GYN providers play an even stronger role in providing health care for low-income women and women of color. Low-income women (41 percent) and Latina women (47 percent) are far more likely to say that their OB/GYN provider is their main source of care, and 64 percent of African-American women say they see an OB/GYN provider regularly, compared to 58 percent of women overall.[25]

Finally, we recognize that the Department is considering using county-level time and distance standards and provider-to-enrollee minimum ratios that are used in Medicare Advantage program as a starting point for developing standards for Marketplace plans. In general, the Medicare Advantage program's use of five geographic categories (e.g., large metro, metropolitan, micro-metropolitan, rural and Counties with Extreme Access Considerations (CEAC)), which account for geographic variations in provider accessibility and population distribution, may serve as an appropriate starting point for QHP network adequacy standards. However, if the Department takes this approach, it is important to account for differences between Medicare Advantage and Marketplace plans in terms of the covered population and covered services – and supplement criteria and standards accordingly. Existing Medicare Advantage criteria were developed for a different population than the demographic enrolled in Marketplace plans. For example, Marketplace plans enroll high numbers of children, people with disabilities, and women of reproductive age. We recommend that the Department invest in studying and refining criteria over time to take into account these important differences.

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[23] Kaiser Family Foundation, *Data Point: Distribution of Eligibility for ACA Coverage Among Women Ages 15-49 Remaining Uninsured as of 2015.* (Dec. 2015). Available at http://kff.org/other/state-indicator/distribution-of-eligibility-for-aca-coverage-among-women-ages-15-49-remaining-uninsured-as-of-2015/.

[24] PerryUndem Research & Communication. "Women & OB/GYN providers". Research conducted for Planned Parenthood Federation of America, November 2013. Available at http://www.plannedparenthood.org/files/4914/0656/5723/PPFA_OBGYN_Report.FINAL.pdf.

[25] Ibid.

In short, it is imperative that the Department establish strong network adequacy standards – including, in particular, quantitative metrics for states to use in measuring network adequacy – that address how women experience the health care system and ensure timely access to providers that specialize in women's gynecological, obstetric, and family planning care.

C. The Department should modify or eliminate the proposal to require issuers to send notices to a provider's regular patients when the provider is discontinued from the plan's network because of significant confidentiality issues that would result.

Consumers should have up-to-date, accurate information about changes to provider network so they have the information they need when seeking health care. The Department proposes to require Marketplace plans to "make a good faith effort to provide written notice of discontinuation of a provider 30 days prior to the effective date of the change or otherwise as soon as practicable, to enrollees who are patients seen on a regular basis by the provider or who receive primary care." Although we support notice as a key element to ensuring health care access, the proposed approach raises significant confidentiality concerns and may undermine access to reproductive and sexual health care.

In situations where several family members are enrolled in the same health plan (e.g., spouse and dependents), existing issuer practices are such that insurance notices and communications are often sent to the primary policyholder, not necessarily the individual enrollee receiving care. The unintended result is that these notices may disclose sensitive information about enrollees under a plan to the policyholder – threatening confidentiality and undermining access to health care.

Similarly, under this proposal, the issuer may send a notice to the policyholder stating that one or more enrollee in the health plan goes to a certain provider on a regular basis and that provider is no longer in-network. This is problematic if the person does not want the others to have access to information about the providers they are seeing and the services they are accessing, as is often the case with sexual and reproductive health care, among other services. If the discontinued provider's name suggests the type of services offered, the confidentiality of the enrollee's care would be compromised when the primary policyholder receives notice of provider discontinuation.

Unwanted disclosure of information from this type of notice would impact all enrollees in a plan held in another person's name, but the risk is especially acute for minors and young adults insured on their parents' health plan; survivors of interpersonal and domestic abuse or sexual assault; and individuals seeking select services such as reproductive and sexual health care, mental health, substance abuse services. In fact, among women ages 18 to 25, 71 percent report that it is important to them that their use of health services, such as sexual or mental health care services, be kept confidential.[26] Also, teens are

[26] Alina Salganicoff, Usha Ranji, Adara Beamesderfer, and Nisha Kurani. *Women and Health Care in the Early Years of the Affordable Care Act.* Kaiser Family Foundation. (May 2014). Available at https://kaiserfamilyfoundation.files.wordpress.com/2014/05/8590-women-and-health-care-in-the-early-years-of-the-affordable-care-act.pdf.

particularly likely to delay or forgo accessing critical services, such as family planning and testing and treatment for sexually transmitted infections (STIs), because they are worried their parents will find out.[27]

While we appreciate the overall goal of this proposed notice, this is outweighed by the risks and potential to harm access to care. The Department should either not adopt this proposal or adopt alternative methods of notification that protect confidentiality for all enrollees in a plan. For example, in addition to maintaining accurate, up-to-date provider directories, issuers could send on a routine basis *all* enrollees a list of *all* providers that will be discontinued from the plan so that enrollees have information about in-network as well as newly-discontinued providers.

D. The Departments must establish clear provider non-discrimination standards as part of network adequacy rules that ensure Marketplace health plans can accept the full range of providers to participate in their networks, including women's health providers.

The Departments must ensure that Marketplace plan networks are sufficient to meet the health needs of consumers and accept the full range of provider types, including providers that focus on women's health care. The ACA contains several provisions designed to enhance health care access for women, such as elimination of gender rating, direct access to OB/GYN practitioners, access to women's health providers in Marketplace plans through the essential community provider (ECP) provision, and coverage of women's preventive services without cost sharing. Congress designed these provisions to remedy the longstanding health care access barriers women have faced and to guarantee that women have access to the health care services they need from the providers they trust. However, these important provisions may be undermined if plan networks are inadequate to meet women's health needs and ensure access to covered services—including as a result of policies that are designed to undermine access to women's health providers.

Marketplace regulations at 45 CFR § 155.1050(c) include an important non-discrimination provision to prevent any attempts to exclude or restrict specific ECPs from the Marketplace. Likewise, a separate provision in federal law under Section 2706(a) of the Public Health Service Act prohibits group and individual health plans, including Marketplace plans, from discriminating against, with respect to participation under the plan, any health care provider who is acting within the scope of the provider's license or certification under state law.[28] These provisions are an important step in the right direction. At the same time, there are ongoing efforts to undermine access to providers in a variety of ways. In order to build on the existing ACA protections and to ensure that network adequacy rules uphold the fundamental principles behind the ACA access provisions, it is important that the Department outline, as a threshold matter, that qualified health plans, and any entity regulating qualified health plans, cannot discriminate against certain providers on the basis of the services they provide or the population they serve.

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[27] For example, a national survey of teens ages 12 to 17 found that the concern that "their parents will find out they are having sex" was the most commonly cited barrier to testing for sexually transmitted infections (STIs). Abigail English et. al. (July 2012). *Confidentiality for Individuals Insured as Dependents: A Review of State Laws and Policies*. Guttmacher Institute.

[28] Public Health Services Act § 2706(a).

Specifically, we urge the Department to establish clear requirements under 45 CFR 156.230 to prevent efforts to exclude or limit participation of the full range of providers from Marketplace plan networks. The Department should establish clear provisions that ensure that providers are not excluded or otherwise restricted from participation in Marketplace plan networks simply based on the patient population served, the provider category, the services offered or referred for under their scope of practice, because the provider specializes in conditions that require costly treatment, or based on the professional activity or advocacy they engage in to improve the health care system.[29] It should be abundantly clear that Marketplace issuers may not engage in this type of discrimination and that states and Marketplaces may not adopt policies that would force issuers to discriminate against providers based on these reasons.

In line with the Department's ultimate goal to improve patient access to high-quality care, a strong non-discrimination protection in network adequacy regulation will help safeguard and bolster provider participation in Marketplace plan networks and ensure health care provider participation is squarely rooted in a provider's ability to deliver quality care that improves health outcomes.

E. The Department should clarify that, if a state or the Department looks at availability of telehealth options as a factor for assessing a plan's network adequacy, this may not substitute for ensuring a strong network of providers that furnish on-site health care in the plan's service area.

We recognize that the Department may look to the National Association of Insurance Commissioners' (NAIC) newly-updated Health Benefit Plan Network Access and Adequacy Model Act (Model Act) as it modifies network adequacy regulations and sets out specific quantitative standards in the Letter to Issuers. The NAIC Model Act, in its list of criteria that states may adopt and look at when determining network adequacy, includes a factor related to availability of telehealth options. Specifically, reasonable criteria for network sufficiency may include "[o]ther health care service delivery system options, such as telemedicine or telehealth, mobile clinics…."[30]

While we fully support increased access to telehealth and telemedicine health care delivery options, we are concerned that a state or plan's reliance on this type of criterion may potentially lead to increased telehealth options at the detriment of access to local, on-site care. The Department must make it abundantly clear that, if this type of factor is used as part of network adequacy, the availability of telehealth or telemedicine options does not in any way substitute for or supersede the requirement to ensure that plan networks provide timely access to local health care providers in the community.

[29] The Department has recognized provider non-discrimination protections in regulation at 42 CFR § 438.12 as part of the Medicaid managed care program, and the Department recently proposed an additional provider non-discrimination standard at 42 CFR § 438.214(c) to prohibit a Medicaid managed care entity from discriminating against providers that serve high-risk populations or specialize in conditions that require costly treatment.

[30] National Association of Insurance Commissioners, Health Benefit Plan Network Access and Adequacy Model Act (Model Act), at 7 (adopted Oct. 12, 2015).

F. The Department should clarify that costs paid by an enrollee, including balance billed amounts, for an essential health benefit provided by an out-of-network provider at an in-network setting will count towards the enrollee's annual out of pocket maximum.

We appreciate that the Department acknowledges the problems faced by consumers when they receive covered services by an out-of-network provider at an in-network facility, often without their knowledge or control. Consumers reasonably expect that by seeking care at an in-network facility, the health care professionals providing their care are also in-network under the plan. Even when consumers are aware that this is often not the case, they may not be able to control which providers care for them, particularly in emergency room situations. Not unexpectedly, therefore, the "surprise" medical bills that result from out-of-network providers at in-network facilities are a significant cause for consumer complaints and financial hardship.

The Department proposes that, if a person receives care from an out-of-network provider at an in-network setting, cost sharing experienced by the consumer will count towards the annual out of pocket maximum. However, the remedy proposed in section 156.230(f) does very little to address the financial harm that consumers experience in these situations and is significantly weaker than the provisions included in the NAIC's Model Act. In some circumstances, consumers may receive "balance bills" from out-of-network providers for the portion of service charges not paid by the insurer. But, the proposed rule specifically refers to "cost sharing," rather than amounts billed to the consumer, which likely means that balance billing amounts charged to patients in these scenarios would <u>not</u> be required to count towards the annual maximum out-of-pocket limit. This is because the definition of cost sharing at 45 CFR 155.20 specifically excludes balance billing amounts received from non-network providers. As such, it appears that the Department's proposal is a very limited protection.

In order to provide meaningful protection to Marketplace plan enrollees, the Department should revise the rule to clarify that, in circumstances where a person receives care from an out-of-network provider at an in-network setting, the balance billed amounts and cost sharing amounts experienced by the enrollee will count toward an enrollee's maximum out-of-pocket limit.

G. We support the continuity of care transition period for enrollees in active treatment to continue seeing their provider and obtain needed care. But the 90-day transition period should be the minimum (not a maximum) and we urge the Department to consider a longer transition period, particularly for pregnant women to access pregnancy-related services.

We commend the Department for proposing to require issuers to allow enrollees in active treatment to continue seeing their providers, even when those providers are not a part of the plan's current network. The Department should apply this important consumer protection to all Marketplace plans, not just those in the FFM. We generally agree with the definitions of instances of "active treatment" set forth in this section, and we particularly appreciate that the Department has included a catch-all provision to encompass situations where continuity of care for an ongoing course of treatment is needed and the

treating health care provider attests that discontinuing care would worsen the condition or interfere with anticipated outcomes.[31]

There will occasionally be instances where enrollees will require more than 90 days of continued treatment with a nonparticipating provider to ensure continuity of care. We urge the Department to consider a longer continuity of care transition period, particularly for pregnant women to obtain to pregnancy-related services, including, but not limited to, labor and delivery care, postpartum care, lactation counseling and support, and services for post-delivery issues or complications. For example, when a woman contracts gestational diabetes during pregnancy, she may well need ongoing health treatment during the postpartum period. A woman may initiate lactation counseling before or right after delivery and should be able to continue the ongoing course of treatment with her lactation counselor. The 90-day transition period should be the minimum, not the maximum, length of time for patients in active treatment for a life-threatening condition, a serious acute condition, pregnancy, or another health condition that would worsen by discontinuing care by the treating health care provider.

VII. Section 156.235 – Essential Community Provider Standards

Congress designed the Essential Community Provider (ECP) provision in the ACA to ensure that newly-insured Americans have access to the trusted providers in their communities, with a particular emphasis on access to women's health providers. Specifically, Congress identified two categories of ECPs, both of which include family planning providers:

(1) 340B providers, which include Title X family planning clinics; and
(2) Providers described in section 1927(c)(1)(D)(i)(IV) of the Social Security Act, which was principally designed to capture family planning service sites that do not receive Title X funding or other 340B-qualifying funds.

Indeed, in fifteen different letters to the Department, Members of Congress have consistently underscored that, in drafting the ECP provision, they were focused on ensuring access to family planning providers in addition to other essential community providers. Recognizing that expansions in health insurance coverage must be matched with strong network access protections, section 1311(c)(1)(C) of the ACA was designed to ensure that essential community providers are included in Marketplace plan networks—thereby assuring continuity of care and timely access to critical health services.

We commend the Department for making improvements to the ECP standard in last year's 2016 Benefit and Payment Parameters final rule. This year, the proposed rule seeks to modify the ECP standard in a way that will likely significantly reduce access to ECPs and undermine the precise intent of the ECP provision.

[31] "Active treatment" is proposed to include: (1) An ongoing course of treatment for a life-threatening condition; (2) an ongoing course of treatment for a serious acute condition; (3) the second or third trimester of pregnancy; or (4) an ongoing course of treatment for a health condition for which a treating physician or health care provider attests that discontinuing care by that physician or health care provider would worsen the condition or interfere with anticipated outcomes.

We call on the Department to considerably strengthen and clarify the ECP standard in key ways to ensure provider networks are sufficient to meet peoples' needs as they enter the Marketplace.

The following five subsections describe specific clarifications or changes that are vital to meaningful implementation of the ECP provision, followed by additional measures to strengthen the ECP standard.

A. The Department should make a technical correction to the ECP definition in 45 CFR 156.235(c) to clarify that providers in 1927(c)(1)(D)(i)(IV) of the Social Security Act include nonprofit and governmental family planning service sites that do not receive Title X or 340B-qualifying funds. This minor correction is critical to align with congressional intent, what the Department clearly intended to clarify based on preamble language, and to prevent unintended implications for family planning ECPs.

We thank the Department for responding to stakeholder comments in the 2016 Benefit and Payment Parameters rule and incorporating into regulation at 45 CFR 156.235(c) that ECPs include state-owned, governmental, and not-for-profit family planning service sites that do not receive Title X funds or other 340B-qualifying funds. This is an important step in implementing the clear intent of ACA section 1311(c)(1)(C), which Congress designed to protect access to women's health providers in addition to other ECPs. However, the ECP definition text at 45 CFR 156.235(c) does not clarify what the Department clearly intended to clarify based on preamble language, and the regulatory text must be amended to prevent any unintended implications for family planning ECPs. The regulation text states:

> *An essential community provider is a provider that serves predominantly low-income, medically underserved individuals, including a health care provider defined in section 340B(a)(4) of the PHS Act; or described in section 1927(c)(1)(D)(i)(IV) of the Act as set forth by section 221 of Pub. L. 111-8;* ***or*** *a State-owned family planning service site, or governmental family planning service site, or not-for-profit family planning service site that does not receive Federal funding under special programs, including under Title X of the PHS Act, or an Indian health care provider.* (emphasis added).[32]

While the text makes clear that ECPs include non-340B nonprofit family planning service sites, it does so by separating these providers from the category of providers described in section 1927(c)(1)(D)(i)(IV) of the Social Security Act (SSA). By using the term "or" instead of "including", the text creates a separate category of non-340B family planning providers – rather than clarifying that providers described in section 1927(c)(1)(D)(i)(IV) include non-340B family planning providers. This not only adds confusion, but also contradicts congressional intent and may have harmful implications for family planning providers. A minor technical correction is critical for three main reasons:

First, the current construction of the regulation text contradicts congressional intent. Congress specifically designed section 1927(c)(1)(D)(i)(IV) of the SSA to capture non-profit and state-owned family planning service sites that do not receive Title X funding or other 340B-qualifying funds. In particular,

[32] 45 CFR 156.235(c).

section 1927(c)(1)(D)(i)(IV) was added as part of the Omnibus Appropriations Act of 2009 to correct a flaw in the Deficit Reduction Act of 2005, which unintentionally prevented many family planning clinics that do not receive federal funding (such as Title X) from receiving discounted contraceptives. As Senator Stabenow indicated in colloquy with Senate Finance Committee Chairman Baucus, this resulted in many family planning clinics being forced to sustain increases in the price of contraceptives as much as tenfold, which put a "terrible strain on the country's first line of defense against unintended pregnancies."[33]

Congress corrected this flaw by adding section 1927(c)(1)(D)(i)(IV) to the SSA and clarifying that providers described in section 1927(c)(1)(D)(i)(IV) is expressly intended to capture "family planning clinics such as Planned Parenthood" that do not receive Title X funds and do not participate in the 340B program.[34] To implement congressional intent, ECP regulations must be clear that section 1927(c)(1)(D)(i)(IV) of the SSA includes non-profit family planning providers and state-owned family planning providers that do not receive Title X or other 340B-qualifying funds.

Second, the regulation text does not clarify what we believe the Department intended to clarify in the 2016 Benefit and Payment Parameters rule and what the Department has since made clear in ECP guidance. At a few points in preamble to the 2016 Benefit & Payment Parameter proposed and final rule, the Department made clear that non-profit and governmental family planning providers that do not receive Title X or other 340B-qualifying funds are ECPs because they are 340B "look-alike" providers described in section 1927(c)(1)(D)(i)(IV) of the SSA. Specifically:

- In footnote 53 of the proposed rule at 79 Fed. Reg. 70674, 70727 (Nov. 26, 2014), the Department outlines the ECP categories in Table 10 and states: "*For more information on Title X 'Look Alike Clinics, see section 1927(c)(1)(D)(i)(IV) of the Social Security Act."*

- In preamble to the final rule at 80 Fed. Reg. 10750, 10833 (Feb. 27, 2015), the Department reiterates its proposal to clarify that 340B "look alike" providers include non-profit and governmental family planning providers, stating:

  "Additionally, we proposed that ECPs may include not-for-profit or State-owned providers that would be entities described in section 340B of the PHS Act but do not receive Federal funding under the relevant section of law, as these providers satisfy the same 340B requirements and therefore meet the definition of ECPs by virtue of the following description in section 1311(c)(1)(C) of the Affordable Care Act—health care providers defined in section 340B(a)(4) of the PHS Act and providers in section 1927(c)(1)(D)(i)(IV) of the Act. For the same reasons described above, we proposed that such providers also include not-for-profit or governmental family planning service sites that do not receive a grant under Title X of the PHS Act." (emphasis added).

[33] Colloquy between Senate Finance Committee Chairman Baucus and Senator Stabenow, S2817, Congressional Record, March 5, 2009.

[34] S2817, Congressional Record, March 5, 2009. Chairman Baucus and Senator Stabenow also clarified that "[w]ith enactment of this critical legislation…manufacturers should feel confident that they can extend discounts to family planning clinics such as Planned Parenthood and college and university clinics…." *Id.*

- In preamble to the final rule at 80 Fed. Reg. at 10833, the Department uses language from section 1927(c)(1)(D)(i)(IV)[35] to reiterate its intent to clarify that non-profit and governmental family planning providers are ECPs because they are 340B "look like" providers:

  "Comment: A number of commenters supported the clarification that ECPs include not-for-profit or State-owned providers that would be entities described in section 340B of the PHS Act but do not receive Federal funding under the relevant section of law, <u>including</u> not-for-profit or governmental family planning service sites that do not receive a grant under Title X of the PHS Act. These commenters urged that HHS include this clarification in the regulation text…." (emphasis added).

It is clear that the Department intended to specify that non-340B non-profit and governmental family planning providers are ECPs because they are a type of provider described in section 1927(c)(1)(D)(i)(IV) of the SSA. Yet, the final regulation text inadvertently causes confusion by separating non-340B family planning providers from providers described in section 1927(c)(1)(D)(i)(IV) of the SSA.

Additionally, after the final rule modified the text at 45 CFR 156.235(c), the Department has since clarified in federal guidance for the ECP Petition Process that ECPs include both 340B providers and providers "described in section 1927(c)(1)(D)(i)(IV) of the SSA, <u>including</u> governmental family planning service sites and not-for-profit family planning service sites that do not receive funding under Title X of the PHS Act or other 340B-qualifying funding…"[36] To align with the Department's intent and be consistent with subsequent ECP guidance, the Department must make a technical correction to 45 CFR 156.235(c) clarifying that providers described in section 1927(c)(1)(D)(i)(IV) include governmental family planning service sites and not-for-profit family planning service sites that do not receive Title X or other 340B-qualifying funds. As a part of this correction, the Department should amend the language so that it is clear that 1927(c)(1)(D)(i)(IV) providers are not-for-profit family planning service sites that ***do not receive Title X or other 340B-qualifying funds.*** The existing language with respect to funding more ambiguously references "Federal funding under special programs," which does not comport with clear congressional intent and statutory language—and could cause harmful confusion as a result.

<u>Suggested technical correction to 45 CFR 156.235(c):</u>

(c) *Definition. An essential community provider is a provider that serves predominantly low-income, medically underserved individuals, including a health care provider defined in section*

[35] Section 1927(c)(1)(D)(i)(IV) of the SSA describes non-profit providers or state-owned providers that would be entities described in section 340B of the Public Health Service Act because they provide the same type of services to the same population as a 340B entity, but do not receive funding under that section of the law.

[36] U.S. Dep't of Health and Human Services, *Instructions for the Essential Community Provider, Petition for the 2017 Benefit Year* (Dec. 2015)("Under that regulation, ECPs are defined as health care providers who serve predominantly low-income, medically underserved individuals. They include health care providers defined in section 340B(a)(4) of the Public Health Service (PHS) Act and described in section 1927(c)(1)(D)(i)(IV) of the Social Security Act (SSA), <u>including</u> governmental family planning service sites and not-for-profit family planning service sites that do not receive funding under Title X of the PHS Act or other 340B-qualifying funding, and Indian health care providers.")(emphasis added).

340B(a)(4) of the PHS Act; or described in section 1927(c)(1)(D)(i)(IV) of the Act as set forth by section 221 of Pub. L. 111-8~~; or~~ ***including*** *a State-owned family planning service site, or governmental family planning service site, or not-for-profit family planning service site that does not receive* ***340B-qualifying funding*** *~~Federal funding under special programs~~, including under Title X of the PHS Act~~,~~; or an Indian health care provider.*

B. The Department should not allow issuers to count the number of full-time equivalent (FTE) practitioners at a single ECP service site – as opposed to the ECP site itself – for purposes of calculating ECP participation and the issuer's satisfaction of the ECP standard.

While we recognize the Department's goal to improve access to care by looking at the number of clinicians that offer care at ECP locations, there are several reasons why this proposal would not meet this goal, and instead, would undermine access to ECPs and the intent of the ACA's ECP provision. We disagree with the Department's belief "that crediting an issuer more accurately reflects the issuers' ECP participation in its network." Rather, this proposal goes against the well-established rule that Marketplace plans "must have a sufficient number and geographic distribution of essential community providers, where available, to ensure reasonable and timely access to a broad range of such providers."[37]

First, looking at the number of FTE practitioners rather than the number of ECP locations or service sites does nothing to ensure a *geographic distribution* and accessibility of ECPs in local communities, nor does it ensure a *broad range of provider types* capable of meeting enrollees' needs. We are very concerned that an issuer could attempt to meet the ECP participation standard by only contracting with several FTE practitioners at one large facility or hospital. This likely will have a disproportionate impact on access to outpatient care sites and smaller or rural ECPs. This fundamentally undermines the intent of the law to ensure Marketplace consumers have timely access to a geographic distribution and broad range of trusted providers in their local communities.

Second, eligible FTEs fluctuate throughout the year, making this an inconsistent and inaccurate measure. Clinicians may increase or decrease at each service site, yet the number of FTE clinicians would be calculated once per year through the annual ECP petition process. The issuer would calculate ECP participation based on an annual, static FTE estimate that does not take into account normal fluctuations in clinician accessibility. Also, the FTE definition does not capture the full range of advance practice clinicians that furnish care at ECP sites, such as registered nurses or certified midwives who are licensed under state law and accredited with many health plans. Contrary to the Department's goal, this proposal would lead to an inaccurate representation of ECP access and an issuer's ECP participation in its network.

Third, issuers typically contract with a health care facility or organization and then credential individual clinicians so the clinician may bill the issuer. Credentialing often takes time, often 3 months to one year. If the Department's goal is to determine the number of FTE clinicians that are accessible to enrollees in each service area, for purposes of ECP participation, the issuer should *only* be permitted to count FTE clinicians that are credentialed to accept and bill each Marketplace health plan. Otherwise, counting FTE clinicians

[37] 45 CFR 156.235(a).

that are not yet credentialed under the issuer's health plans is an inaccurate representation of ECP access and availability.

From a practical perspective and considering the fundamental goal of the ECP provision to ensure access to a geographic distribution and broad range of ECPs, we strongly urge the Department not to implement this proposal. Likewise, given increasing concerns about the time it takes to complete clinician credentialing under health plans, we call on the Department to encourage issuers to credential qualified clinicians in a timely manner to ensure that the full range of clinicians at essential community providers may continue to provide high quality, expert care to consumers enrolled in Marketplace plans.

C. The Department should clarify that QHP issuers must include at least one ECP in each category per county in the service area.

We strongly urge the Department to clarify that issuers must *include* in their QHP networks (not simply offer a contract to) at least one ECP in each category in each county in the service area. The ECP percentage threshold helps enable access to ECPs overall, but it does nothing to ensure patient access to a *broad range and distribution* of ECP provider types. The ECP categories are distinct in important ways and ECP categories – such as family planning providers, Ryan White providers, Indian Health providers, and ECP hospitals – often provide specific services tailored to meet the needs of certain populations or sub-populations.

In particular, ensuring access to the range of ECP categories—including access to family planning providers in each county in the service area—is especially important because of the unique way women experience the health care system and rely on women's health providers for their critical care. For instance, research found that the services that women say they needed most over the last two years—annual exam, birth control, pre-natal care, and a pap test—are exactly the services provided by women's health providers.[38] OB/GYN providers are more likely to council women about important preventive health care, and these providers are two times more likely than other health care providers to talk to their patients about HIV and birth control.[39] Women's health providers offer services tailored to the needs of women and offer appropriate expertise to meet their medical needs, making it even more critical to ensure that women's health ECPs are included in-network in each county in a plan's service area.

D. The Department should establish a solid foundation for patient access by requiring all states, including state-based and Partnership Marketplaces, to implement at minimum the specific ECP standards in 45 CFR 156.235(a)(2) through (5).

We remain concerned that there are no federal standards to ensure that state-based Marketplaces and Partnership Marketplaces comply with the ACA's essential community provider requirements. Creating a federal floor for all Marketplaces would ensure a baseline protection for patient access across the country.

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[38] PerryUndem Research & Communication. (November 2013). "Women & OB/GYN Providers." Research conducted for Planned Parenthood Federation of America.
[39] *Id.*

The Department can do this by clarifying that issuers must meet the standards outlined in 45 CFR 156.235(a)(2) through (5) to show that the plan's network has a "sufficient number and geographic distribution of essential community providers… to ensure reasonable and timely access to a broad range of such providers."[40]

E. The ECP standard should be strengthened in additional ways to ensure provider networks are sufficient to meet peoples' needs as they enter the Marketplace.

First, the Department should clarify that states, Marketplaces, and issuers may not remove providers from the HHS-developed ECP list. Starting in 2017, ECPs will submit an ECP petition to HHS to update and/or change information about their service cites for the HHS ECP list. This ECP list is critical to enable issuers to identify ECPs in the plan's service area, start the contracting negotiations, and include ECPs in their Marketplace plan networks. It must be clear that, while states may add providers to the ECP list for the purpose of ensuring plan networks meet local needs, any effort to limit the number, scope, or type of providers identified as an ECP fundamentally undermines the purpose of the provision and congressional intent.

Second, we call on the Department to increase the 30 percent ECP percentage threshold to establish a solid foundation for patient access and to take into account Marketplace enrollment that is expected to grow each year. A stronger ECP in-network threshold is a critical step towards improving women's access to care, especially since women's health providers serve as an ongoing source of care for millions of women and often serve as an entry point into the broader health care system. As noted above, at the end of the second enrollment period, more than half (54%) of the enrollees in the Marketplace are women, and almost one in four (24.3%) enrollees are women of reproductive age (ages 18 -44).[41] It is critical that provider networks meet the needs of these women. Importantly, with an estimated 2.3 million women aged 15 to 49 who are currently uninsured and eligible for Marketplace premium tax credits,[42] it is clear that Marketplace plan enrollment *will and should* grow in future years. A stronger ECP in-network threshold is necessary to ensure that, with anticipated plan enrollment growth, Marketplace plan networks have a sufficient number and geographic distribution of women's health ECPs to provide timely access to care.

VIII. Standards for Qualified Health Issuers on Federally-Facilitated Exchanges and State-based Exchanges on the Federal Platform

With respect to State Exchanges on the Federal platform (SBE-FP), we support the Department's proposal to require issuers in SBE-FPs to meet transparency and network standards that are no less strict than the

[40] 45 CFR 156.235(a).
[41] U.S. Department of Health and Human Services, ASPE Issue Brief: Health Insurance Marketplaces 2015 Open Enrollment Period: March Enrollment Report, at 24 (Table A1)(Mar. 10, 2015). Available at https://aspe.hhs.gov/sites/default/files/pdf/83656/ib_2015mar_enrollment.pdf.
[42] Kaiser Family Foundation, *Data Point: Distribution of Eligibility for ACA Coverage Among Women Ages 15-49 Remaining Uninsured as of 2015.* (Dec. 2015). Available at http://kff.org/other/state-indicator/distribution-of-eligibility-for-aca-coverage-among-women-ages-15-49-remaining-uninsured-as-of-2015/.

requirements that apply to issuers in the Federally-facilitated Marketplace. Consistent with this, the Department should continue to allow SBE-FP states to offer state-specific special enrollment periods to their residents to ensure access to coverage and enrollment opportunities that a state has specifically recognized as important for their state residents.

Recognizing that the operation of Marketplaces has changed over the last few years, the Department proposes to establish a new category of Marketplaces, referred to as a State Exchange on the Federal platform (SBE-FP), to account for state-based Marketplaces that utilize Healthcare.gov and other federal operations. We appreciate that the Department clarifies the requirements for this category of Marketplace, as this will help clarify which responsibilities the state Marketplace retains and which functions HHS is responsible for.

We support the requirement that SBE-FPs meet standards that are no less strict than the requirements that apply to issuers in the FFM, including § 156.230 (network adequacy standards); §156.235 (essential community provider standards); and § 156.122(d)(2) (the requirement for QHPs to make available published up-to-date, accurate, and complete formulary drug list on its website in a format and times determined by HHS).[43] This ensures there is a federal baseline not only in terms of access to in-network providers, but also in terms of plan transparency so that consumers can make informed choices about their health plan options.

However, we are concerned that, with respect to eligibility and enrollment in SBE-FPs, the Department is at this time not permitting state customization in policy or operations, such as state-specific special enrollment periods (SEPs).[44] While we recognize there are operational considerations for Healthcare.gov, eliminating state SEPs that are tailored to state needs undermines access to health coverage and care and cuts off enrollment opportunities that a state has specifically recognized as important for their state residents. We call on the Department to consider ways to accommodate state-specific SEPs in SBE-FP states, such as allowing consumers to access state-specific SEPs through the Marketplace call center.

IX. Quality Standards

We commend the Department for requiring issuers to adopt Quality Improvement Strategies (QIS) under 45 CFR 156.1130 and report data and quality metric scores as part of the Quality Rating System (QRS) under 45 CFR 156.1130. These quality initiatives will help inform consumer decisions about Marketplace plans and encourage health care providers and issuers to work together to prioritize and enhance high-quality care for plan beneficiaries.

As the Department implements these quality programs, we urge the Department to actively review and regularly update the QRS measure set to ensure that issuers collect and report on measures that reflect high quality and evidence-based standards of care, particularly measures that reflect high-quality women's health care. For instance, the Office of Population Affairs (OPA) and the Centers of Disease Control and

[43] 80 Fed. Reg. at 75519.
[44] 80 Fed. Reg. at 75554.

Prevention (CDC) recently set forth a developmental contraceptive quality measure that evaluates the proportion of women at risk of unintended pregnancy who choose a contraceptive method that is most effective (e.g., IUD or implant) or moderately effective (e.g., oral contraceptive pills, patch, ring). Several states are actively integrating this measure into their Medicaid programs, and we anticipate that this quality measure will be assessed national accreditation bodies very soon. Inclusion of this and other important women's health measures in the QRS measure set is critical in order to weave reproductive health care into the new innovate Marketplace quality initiatives.

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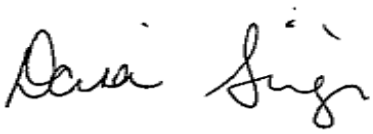
We look forward to working with the Department in this important work to continue implementation of the Affordable Care Act. Thank you for the opportunity to comment on the HHS Notice of Benefit and Payment Parameters for 2017. If you have any questions, please do not hesitate to contact me at 202-973-4800.

Respectfully submitted,



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