

December 4, 2023

VIA ELECTRONIC SUBMISSION

Re: Request for Information; Coverage of Over-the-Counter Preventive Services (File code 1210–ZA31)

Dear Secretary Becerra, Acting Secretary Yu, and Secretary Yellen:

Physicians for Reproductive Health (PRH) is pleased to have the opportunity to respond to this request for information regarding the application of the preventive services requirements under section 2713 of the Public Health Service Act (PHS Act) to over-the-counter (OTC) preventive items and services, including contraception, PrEP, folic acid, and breast/chestfeeding¹ supplies, available without a prescription by a health care provider. We welcome the opportunity to submit information to the Departments of Health and Human Services, Labor, and the Treasury (the Departments) and provide input on the importance of access to and coverage for OTC preventive items and services without cost-sharing.

PRH is a physician-led national advocacy organization that organizes, mobilizes, and amplifies the voices of medical providers to advance reproductive health, rights, and justice. Our programs combine education, advocacy, and strategic communications to ensure access to comprehensive sexual and reproductive health care. We believe this work is necessary for all people to live freely with dignity, safety, and security. As a network of physicians who care for people and provide the full spectrum of family planning care, we are committed to ensuring that all people have access to essential preventive sexual and reproductive health care. PRH strongly supports the Departments' goal of increasing access to high-quality preventive care and submits the following for full consideration by the Departments.

Availability of No Cost OTC Preventive Items and Services is Essential for Ensuring Full Access to Sexual and Reproductive Health Care.

As physicians, we understand the importance of access to the full spectrum of sexual and reproductive health care services for all people without barriers. Access to OTC preventive items without cost-sharing is an important first step to ensuring the availability and accessibility of preventive items and services that support a person's well-being. Utilization of preventive sexual and reproductive health care can reduce rates of unintended pregnancies, sexually transmitted infections (STIs), HIV infections, infant morbidity and mortality, and maternal morbidity and mortality.ⁱ However, there are interconnected barriers that limit a person's ability to access the full spectrum of care, including the cost, lack of insurance coverage, lack of access to reproductive and sexual health care providers, and lack of culturally competent providers.ⁱⁱ

No-cost access to reproductive and sexual health care preventives items, including OTC contraceptives, pre-exposure prophylaxis (PrEP), folic acid supplements, and breast/chestfeeding

¹ The language "breast/chestfeeding" is utilized throughout this comment to recognize that not all lactating people or parents associate with the term "breastfeeding" or the term "chestfeeding." The term "breast/chestfeeding" is meant to encompass people of all gender identities.

supplies will help mitigate the barriers to preventive care many people face and will increase access and use of preventive care, improving reproductive and sexual health outcomes. Following this RFI, the Departments must take action to reduce barriers to these essential preventive care and services by ensuring that people have access to reproductive and sexual health care preventives items without cost-sharing regardless of insurance status. No-cost coverage for OTC preventive items will ensure that individuals can consistently and effectively use these methods of preventive care, advancing positive reproductive and sexual health outcomes for all.

OTC Contraceptive Coverage.

As physicians, we believe it is essential that every individual can make informed choices about pregnancy prevention. People seek out and utilize different contraceptive methods throughout their lifetimes for multiple reasons, including personal preference, safety, effectiveness, and availability. There are multiple methods of contraceptives that are available OTC without a prescription, including external and internal condoms, contraceptive sponges, spermicides, levonorgestrel emergency contraceptive (EC) pills, and the recently FDA-approved progestin-only oral contraceptive pill, Opill™.ⁱⁱⁱ As physicians we also know the importance of access to the full spectrum of contraceptives so that individuals can access the method(s) that are best for them. For people to access all forms of contraception, cost must not interfere with a person's ability to obtain any contraceptive method. Research has found that up to 40 percent of people with low incomes would use a different form of contraception or start using contraceptives if cost was not a factor for accessing care.^{iv} No-cost OTC contraceptives help ensure that people can make informed decisions without having to consider whether they can afford the cost of a method.

Although contraception is a key component to people's health and well-being, Black, Indigenous, and other people of color, young people, immigrants, LGBTQ+ people, people with low socio-economic status, and people living with disabilities disproportionately face barriers to contraceptive care. One study examining the desire for OTC oral contraceptives among Black, Indigenous, and other people of color found that 45 percent of all participants faced at least one barrier in accessing contraception in the past year.^v A survey conducted by Advocates for Youth found that 88 percent of participating young people struggled to access contraception and 55 percent faced so many barriers to care that they could not start taking contraceptives on their preferred timeline.^{vi} Another study examining barriers to family planning services for people with disabilities found that people living with disabilities received less family planning care, including contraceptive care, compared to able-bodied people.^{vii} Finally, research on contraception use as a part of postpartum care for immigrant women² has found that low-income immigrant women are less likely to have access to any form of contraceptive care compared to non-immigrant women.^{viii} These inequities in contraceptive access are driven by intersecting systems of oppression, including systemic racism, discriminatory immigration policies,

² The use of gendered language is reflective of the data available and is not meant to exclude people who would benefit from increased access to contraceptive care who are gender diverse and/or do not identify with the identity of "woman." All people along the gender identity spectrum deserve equal access to preventive health care.

community disinvestment, and reproductive coercion. Access to no cost OTC contraceptives is an important first step to alleviating these barriers.

Under the Affordable Care Act (ACA) and its implementing regulations, most private health insurance plans are required to provide coverage without cost-sharing requirements for all forms of contraceptives. However, many private health plans require an individual to first obtain a prescription to OTC forms of contraception before providing coverage. Prescription requirements for insurance coverage of OTC contraceptives bar people from being able to access cost-free OTC contraceptives. One study found that nearly one third (29%) of women have faced barriers to obtaining and refilling a prescription for contraception.^{ix} Prescription requirements for no-cost coverage for OTC contraceptives disproportionately impact people within systematically oppressed communities. People of color and people with low-socioeconomic status face pronounced barriers to seeing a provider to get a prescription and are less likely to be able to afford the costs associated with a medical appointment, including cost-sharing for the visit, loss of wages due to missing work, cost of childcare, and transportation costs. People who live far from a prescriber, including Indigenous people living on reservation land, people living in geographically isolated areas, and people living in contraceptive deserts, may be forced to travel hundreds of miles to access a provider in order to obtain a prescription for OTC contraceptives.^x While over-the-counter access to oral contraceptives could help eliminate these access barriers, if insurers require a prescription for coverage, those barriers will remain.

People who cannot obtain a prescription for OTC methods of contraceptives must pay out-of-pocket for OTC contraceptives. The cost of OTC contraceptives bars access to care, as many people cannot afford it. For example, a box of external condoms purchased at CVS can cost anywhere between \$5 to \$40, depending on brand, type, size, and quantity.^{xi} The average cost of a box of three contraceptive sponges is \$15.^{xii} Spermicide can cost between \$8-\$15 per kit.^{xiii} The most expensive form of OTC contraception are EC pills, which can cost \$35 to \$50 when bought in person without a prescription.^{xiv} These costs can prevent people from being able to access OTC contraceptive options. Prior to the passage of the ACA, cost-sharing as low as \$6 prevented people from accessing their preferred method of contraception, and the cost forced some people to forgo contraceptives altogether.^{xv} In particular, the high out-of-pocket cost for OTC contraceptives prevents young people from being able to afford these options. A study examining the affordability of OTC oral contraceptives found that young people are typically only able to pay ten dollars or less for OTC contraception.^{xvi}

Increasing access to OTC methods of contraceptives can also help alleviate the harm that is caused when a person must seek care from a provider that discriminates against them. Women of color are more likely to suffer discrimination, abuse, and stigma while attempting to obtain reproductive health care than white women.³ A study found that 33 percent of Indigenous women, 25 percent of Latina women, and 23 percent of Black women report being mistreated by reproductive health care providers.^{xvii} LGBTQ+ people also face barriers to accessing effective reproductive and sexual health care due to a lack of providers who can provide culturally

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competent care.^{xviii} Ensuring that people can access the entire spectrum of OTC methods of contraceptives without cost and without a prescription will alleviate barriers related to discrimination that people face in accessing care, as they will be better positioned to seek out the methods of contraception that work best for them without having to seek care through a provider.

Although providing no-cost coverage for OTC contraceptives will not address all existing barriers to contraceptive access, it will make significant strides to ensure people can utilize the contraception of their choice. Numerous studies have found that if available, people will utilize no-cost OTC contraceptives. One study found that 57 percent of survey participants who do not currently use any form of contraceptives would utilize OTC oral contraceptives if readily available.^{xix} Another study found that a significant population of women⁴ would be more likely to use OTC contraceptives if there was no cost associated with the methods.^{xx} No-cost coverage of all forms of OTC contraceptives is crucial for ensuring that people are empowered to make real choices about their reproductive and sexual well-being.

PrEP and Other HIV Prevention Coverage.

As physicians we recognize that HIV prevention is crucial for improving the quality of life of people at risk for infection. HIV infection has severe consequences on a person's health and well-being. HIV attacks an individual's immune system and puts them more at risk for infections and chronic illnesses, including tuberculosis and certain forms of cancer. In 2021, there were approximately 36,000 new diagnosed cases of HIV infections in the U.S.^{xxi} People need access to the full range of HIV prevention tools, including PrEP, condoms, and other harm reduction services so they can make informed decisions about their own well-being.

HIV infections disproportionately affect people of color and LGBTQ+ people. In particular, Black people are most affected by HIV compared to other racial groups, as rates of new HIV infections are almost eight times higher among Black people than among white people.^{xxii} In 2021, 40 percent of all newly diagnosed HIV cases were among Black people, which was higher than new HIV cases among Hispanic and Latinx individuals (29%) and white people (25%).^{xxiii} Gay and bisexual cisgender men have the highest rates of HIV infections compared to people with other sexualities, as approximately 67 percent of all new HIV cases in 2021 were transmitted by male-to-male⁵ sexual contact.^{xxiv} Transgender women also face significant rates of HIV infections, in comparison to people who identify with other gender identities. Approximately 40 percent of transgender women living in seven of the major U.S. cities live with HIV.^{xxv} Disparities in HIV infections among communities of color and the LGBTQ+ community are due in part to systemic oppression, stigma and discrimination from the medical community, income disparities, economic disparities, and education disparities.^{xxvi}

⁴ The use of gendered language is reflective of the data available and is not meant to exclude people who would benefit from increased access to contraceptive care who are gender diverse and/or do not identify with the identity of "woman." All people along the gender identity spectrum deserve equal access to preventive health care.

⁵ The use of gendered language is reflective of the data available and is not meant to erase people who are gender diverse or identify outside the gender binary.

PrEP significantly reduces a person's chance of an HIV infection from sexual intercourse or injection drug use. When used correctly, PrEP can lower a person's chances of infection from intercourse by 99 percent and can lower a person's chances of infection from sharing injection equipment by 70 percent.^{xxvii} Approximately 30 percent of people within the U.S. could benefit from using PrEP to help prevent HIV infection.^{xxviii} Improved access to PrEP will alleviate some of the disparities in HIV infection rates that disproportionately impact marginalized communities. In particular, transgender women endure social and economic factors that create significant barriers to accessing PrEP, including transphobia, stigma, and experiencing homelessness or unemployment.^{xxix} A recent survey found that although 92 percent of HIV-negative transgender women were aware of PrEP to prevent HIV infection, only 32 percent were using PrEP.^{xxx} PrEP coverage without cost-sharing will help ensure people who would most benefit from PrEP usage will have access to the medication.

Barriers to PrEP access create significant disparities in HIV prevention. The cost of PrEP, including the cost of the medication itself and the cost of related clinical services, is a significant barrier for people who could most benefit from using PrEP from accessing the medication.^{xxxi} Current PrEP coverage is unevenly distributed among people based on their gender, as coverage for PrEP is almost three times higher for cisgender men than it is for cisgender women.^{xxxii} Although the Biden-Harris Administration has taken great strides to increase funding for PrEP coverage since 2022, there are still financial barriers to PrEP medications. No-cost coverage of PrEP medication will alleviate some of the financial barriers that prevent people from accessing a crucial aspect of HIV prevention. Further, ensuring that people can access PrEP medication at a pharmacy will reduce barriers to care imposed by the current lack of clinics and providers that provide PrEP.

Condoms also play a major part in preventing HIV infections. When used correctly and consistently, external condoms are estimated to be 90 percent effective in preventing HIV transmission and internal condoms are estimated to be 94 percent effective.^{xxxiii} Latex and polyurethane condoms help prevent the spread of HIV by creating a barrier that significantly limits the risk of spreading HIV through bodily fluids. Latex condoms provide the best protection against the spread of HIV, however polyurethane and synthetic rubber condoms can provide protection against HIV for people with latex allergies and sensitivities.^{xxxiv} Water-based and silicone-based lubricants help condoms prevent HIV infections by significantly decreasing the risk of a condom breaking or slipping off during intercourse.^{xxxv} Condoms also help prevent the transmission of other sexually transmitted infections (STIs), including gonorrhea, chlamydia, and syphilis, which are more easily transmissible than HIV.^{xxxvi} Providing no-cost coverage of all forms of condoms, including both internal and external condoms and latex and plastic-based condoms, is crucial to ensuring people can use preventive measures to protect their sexual health.

Folic Acid Coverage.

Neural tube defects are one of the most common forms of birth defects in the U.S., as an estimated 3,000 pregnancies each year are affected.^{xxxvii} Common neural tube birth defects include spina bifida, anencephaly, and encephalocele. It is estimated that spina bifida occurs in 3.9 per 10,000 live births, anencephaly in 2.5 per 10,000 live births, and encephalocele in 1 per

10,000 live births in the U.S.^{xxxviii} Neural tube defects disproportionately impact people who already face significant overarching health disparities. In particular, Hispanic women have the highest rates of giving birth to an infant affected by spina bifida, as 3.8 per 10,000 live births among Hispanic women will be affected by spina bifida, whereas only 2.73 per 10,000 live births among Black women and 3.09 per 10,000 live births of white women will be affected.^{xxxix} Neural tube defects are often caused by low folate levels of the pregnant person.^{xl} In order to address the risk of neural tube defects, people capable of becoming pregnant are recommended to take folic acid supplements each day as a preventive measure.^{xli}

Although all people capable of pregnancy are urged to have a daily intake of folic acid in case of an unintended pregnancy, barriers to folic acid supplements make consistent daily folic acid supplementation inaccessible for many. There has been a significant decline in daily folic acid supplementation among people capable of pregnancy, particularly for young people ages 18 to 24.^{xlii} One barrier to consistent folic acid supplement intake can be the out-of-pocket cost. On average, a thirty-day supply of folic acid supplements costs around ten dollars, adding up to around 120 dollars a year.^{xliii} At Walgreens, folic acid supplements can cost anywhere between six dollars to forty-two dollars, with the most expensive supplements being specifically marketed towards pregnant people as prenatal vitamins.^{xliv} A consistent regime of folic acid supplements is not an expense that everyone can afford and having to pay out-of-pocket stops many people from being able to take the supplement at all.

Ensuring that people have access to folic acid supplements will advance the health and well-being of people who are able to get pregnant. Removing cost and prescription barriers will make folic acid supplementation accessible. Increasing access to no-cost folic acid supplements can help alleviate some of the ongoing disparities in infant morbidity and mortality and maternal morbidity and mortality, ensuring that people of color, people with low socio-economic status, and young people who are capable of being pregnant have access to preventive care items.

Breastfeeding Supplies Coverage.

We support each person's decision regarding how they feed their infant, including their decision to breastfeed. People choose a feeding method for many reasons, including personal preference, health impacts, time and cost constraints, and infants' preference.^{xlv} Breast/chestfeeding has positive health impacts for both the breast/chestfeeding person and the infant. In infants, breast/chestfeeding can help reduce the risk of asthma, severe lower respiratory disease, gastrointestinal infections, sudden infant death syndrome (SIDS), and type 1 diabetes.^{xlvi} In breast/chestfeeding people, it can help reduce the risk of ovarian and breast cancer, high blood pressure, and type 2 diabetes.^{xlvii} How long a person chooses to breastfeed also can impact the infant's health, as there are decreased risks of respiratory infections and mortality for the infant and decreased risks of breast cancer and cardiovascular disease for the breast/chestfeeding person the longer a person breastfeeds.^{xlviii} Breast/chestfeeding has also been found to be linked to future behaviors including increased resiliency to psychosocial stressors and decreased childhood maltreatment.^{xlix} Due to the positive health impacts of breast/chestfeeding to both the infant and the breast/chestfeeding person, the American Academic of Pediatrics recommends that infants are exclusively breastfed for the first six months of their lives and for the

breast/chestfeeding parent to continue breast/chestfeeding. If a pregnant or parenting person decides to breastfeed, they should have access to supplies that provide breast/chestfeeding support without cost.

Although many people seek to breastfeed, many pregnant and parenting people are not able to due to barriers that make breast/chestfeeding inaccessible. Specifically, there are significant financial barriers to breast/chestfeeding that make it a nonviable option to many pregnant and parenting people. A recent study conducted by researchers at Yale found that a year of breast/chestfeeding can cost a family between \$7,940 to \$10,585.¹ This cost includes both the direct and indirect costs of breast/chestfeeding, including the price of equipment, modified nutritional intake of the person breast/chestfeeding, vitamin supplementation, and time dedicated to pumping or feeding and potential associated lost wages.^{li}

The cost of breast/chestfeeding supplies alone can be prohibitive for many. Breast pumps can range from \$25 for the manual pumps, \$70 dollars for inexpensive electric pumps, to \$200 or more for a hospital-grade pump.^{lii} Breast milk bags can cost approximately \$15 per one hundred bags and bottles can cost \$25 per set.^{liii} Finally, nursing supplies that make breast/chestfeeding easier and more comfortable are also expensive. Nursing-related items including nipple cream, nursing bras, nursing pads, and a nursing pillow can cost a breast/chestfeeding person up to \$150.^{liv}

Throughout the U.S., there are disparities in the rates of breast/chestfeeding initiation and duration. Breast/chestfeeding initiation rates are often lower among people of color compared to white people.^{lv} Approximately, 77.3 percent of Black infants and 81.9 percent of Hispanic infants are ever breastfed, whereas 85.3 percent of white infants and 87.1 percent of Asian infants are breastfed.^{lvi} Additionally, families eligible for and receiving Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) are less likely to breastfeed compared to families that are ineligible for WIC.^{lvii} Young parents of infants are also significantly less likely to breastfeed in comparison is older parents of infants. Only 78.6 percent of breast/chestfeeding capable parents between the ages of 20 to 29 ever breastfeed, while 85.7 percent breast/chestfeeding capable parents over the age of 30 breastfeed.^{lviii}

There are multiple interconnected factors that contribute to the disparities in breast/chestfeeding rates, including historical, cultural, social, economic, political, psychosocial, and structural factors. Significant structural factors, including the socioeconomic status and the need for the breast/chestfeeding capable parent to return to work, deeply impact whether a person chooses to pursue breast/chestfeeding.^{lix} People with low socioeconomic status and people who must return to work shortly following birth are likely be more hesitant to pursue breast/chestfeeding due to the costs associated with it. Breast/chestfeeding supplies make breast/chestfeeding a more accessible option for people who must return to work. However, the price of supplies may prevent people from being able to reasonably choose to breastfeed. By removing the cost associated with breast/chestfeeding supplies, no-cost coverage of supplies can help address the disparities in breast/chestfeeding rates in the country.

Ensuring people have coverage for breast/chestfeeding supplies without cost-sharing can significantly help mitigate costs associated with breast/chestfeeding and make it a more accessible decision for people who find the option too cost-prohibitive to pursue. Although OTC coverage without cost-sharing will not alleviate all financial barriers to breast/chestfeeding nor address all structural factors that contribute to disparities in breast/chestfeeding rates, no-cost coverage of breast/chestfeeding supplies, including nursing-related items, will make breast/chestfeeding an accessible option for all pregnant and parenting people.

Conclusion

In order to meet the full potential of the recommended policy changes, the Departments must commit to providing vigilant oversight and enforcement of the ACA's preventive services requirement, including all OTC preventive reproductive and sexual health items. We ask that the Departments ensure that all OTC preventive items that protect and advance reproductive and sexual health, including contraceptives, PrEP and other forms of HIV prevention, folic acid supplements, and breast/chestfeeding supplies, are covered by health plans without cost-sharing and without prescription requirements for coverage. We also request that the Departments explore options to ensure to the extent feasible that people without insurance coverage can access these essential items at reduced or no cost.

We appreciate the opportunity to provide comments and recommendations on this important new option for expanding the availability of OTC preventive items and services, and we look forward to discussing these and other ideas with the Departments. If Physicians for Reproductive Health can answer any additional questions or provide any additional information please reach out to Mackenzie Darling, mdarling@prh.org, and MiQuel Davies, mdavies@prh.org.

Sincerely,

Dr. Kristyn Brandi MD, MPH, FACOG
Board of Directors Chair
Physician for Reproductive Health

ⁱ [Health People 2030: Family Planning](https://health.gov/healthypeople/objectives-and-data/browse-objectives/family-planning#:~:text=Interventions%20to%20increase%20use%20of,for%20women%20and%20their%20infants), U.S. Department of Health and Human Services, OASH, <https://health.gov/healthypeople/objectives-and-data/browse-objectives/family-planning#:~:text=Interventions%20to%20increase%20use%20of,for%20women%20and%20their%20infants> (last visited Nov. 27, 2023).

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ⁱⁱⁱ Michelle Long, et al., [Over-the-Counter Oral Contraceptive Pills](https://www.kff.org/womens-health-policy/issue-brief/over-the-counter-oral-contraceptive-pills/), KFF (Sept. 14, 2023), <https://www.kff.org/womens-health-policy/issue-brief/over-the-counter-oral-contraceptive-pills/>.

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- xxxi *Id.*
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- xxxiii Condom Fact Sheet, USAID (April 2015), <https://www.usaid.gov/sites/default/files/2022-05/condomfactsheet.pdf>.
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