



ADVOCATES FOR
COMMUNITY
HEALTH

December 4, 2023

Office of Health Plan Standards and Compliance Assistance
Employee Benefits Security Administration
200 Constitution Avenue NW.
Washington, DC 20210
Room N-5653

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1784-P
P.O. Box 8016
Baltimore, MD 21244-8016.

RE: File Code 1210–ZA31: HHS Requests Public Input on Coverage of Over-the-Counter (OTC) Preventive Services, Including Contraception, Tobacco Cessation, and Breastfeeding Supplies

To the Office of Health Plan Standards and Compliance Assistance and Administrator Brooks-LaSure:

Advocates for Community Health (ACH) is pleased to share our response to the [Request for Information: Coverage of Over-the-Counter Preventive Services](#), which includes contraception, tobacco cessation, and breastfeeding supplies. ACH is a membership organization comprised of leading federally qualified health centers (FQHCs) focused on health equity and innovation to drive health care systems, policies, and health programs. Our members serve over two million people in 14 states, the District of Columbia, and Puerto Rico, and provide high-quality, comprehensive primary health care, mental health services, preventive care, and social services to patients most in need.

Below, we provide recommendations regarding the utilization of OTC contraceptive products, health equity with regards to OTC items, and outline implementation challenges FQHCs may experience.

Over the Counter (OTC) Contraceptives

ACH supports the availability of oral contraceptives OTC. Oral contraceptives are the [most commonly used](#) method of reversible contraception in the U.S. The ability to access oral contraceptives without a prescription from a clinician saves time and money otherwise spent

traveling to and from clinical appointments and prevents needed time off from work or school. Studies [suggest](#) that OTC access to oral contraceptives would increase the use of contraception, facilitate [continuity of use](#), and [reduce the risk](#) of unintended pregnancies.

According to the [Kaiser Family Foundation \(KFF\) 2023 report, “Over-the-Counter Oral Contraceptive Pills,”](#) research suggests that OTC oral contraceptives can be especially beneficial to populations who have historically faced barriers to accessing contraceptive care, including [young adults and adolescents](#), the [uninsured](#), and the 19 million individuals living in [contraceptive deserts](#) (areas with limited access to health centers offering the full range of contraceptive methods).

Widespread Stakeholder Support for OTC Contraception

According to the American College of Obstetricians and Gynecologists ([ACOG](#)), barriers to access are a common reason for inconsistent/nonuse of contraception. The requirement for a prescription can be an obstacle for some contraceptive users. The [American Medical Association](#) and the [American Academy of Family Physicians](#) also support making oral contraceptives available OTC in order to reduce the access disparities among different populations.

Implementation Issues

Pharmacy and Billing Related Issues

Although 27 states and the District of Columbia allow pharmacists to prescribe oral contraception, pharmacies and pharmacists can choose to opt-out, and [state laws](#) regarding stocking operations and coverage of oral contraception vary. Additionally, [billing](#) protocols vary widely by plan and within state Medicaid programs, leading to additional confusion for some pharmacists, and communication with regards to billing for non-prescribed OTC contraception between pharmacies, Pharmacy Benefit Managers (PBMs), health plans, and state insurance departments are limited.

Recommendation: ACH suggests clear operationalization guidelines that different stakeholders can use to implement the distribution of contraceptives OTC. We also recommend standardized billing and explicit federal guidance regarding plan coverage requirements.

Affordability and Coverage Challenges

While OTC contraceptives can make access easier, OTC items are not necessarily covered by insurance and that has cost implications. The current average [monthly cost](#) for oral contraceptives ranges from \$0 for people with health insurance to about \$50 for those without. Copays may hinder access to OTC contraceptives, and copay amounts and service limits also vary by state.

According a recent Johns Hopkins University Bloomberg School of Public Health [article](#), non-prescription and OTC contraceptives must be affordable and covered by insurance to have a meaningful impact on patients. As of August 2023, only 6 [states](#) (7, effective 2024) require OTC contraceptive methods to be covered by Medicaid and private plans without a prescription, meaning consumers can generally only obtain OTC contraception at the pharmacy counter if they have evidence of their insurance coverage. There has been little outreach about this

covered benefit to pharmacies in states where OTC contraception is covered without a prescription, and there seems to be low awareness of the benefits and billing procedures.

The majority of FQHC patients who have health insurance [rely on Medicaid for their health insurance coverage](#). As the [National Health Law Program](#) discusses, federal law requires state Medicaid programs to cover “family planning services and supplies” without cost-sharing, but states have discretion to determine which family planning services and supplies are covered, as long as they are “sufficient in amount, duration, and scope to reasonably achieve its purpose.” Those with [private self-funded employer health insurance](#) are not subject to state insurance requirements, further complicating payment and reimbursement for clinicians and patients.

Recommendation: We agree with the [National Conference of State Legislatures' \(NCSL\)](#) recommendations to optimize Medicaid for family planning services. More specifically, NCSL advises states to clarify the scope of services covered in the state program’s family planning benefit. Additionally, states can create family planning-only benefits for individuals who would otherwise be considered ineligible. NCSL also suggests that Medicaid programs cover contraception services by various health providers, such as nurses and pharmacists. Finally, state Medicaid programs should invest in strategies to increase public knowledge of the covered services (program websites, hotlines, and community outreach). These recommended strategies apply to all OTC products.

Federal Guidance for FQHCs and OTC Products

The Health Resources and Services Administration (HRSA) oversees the federal Health Center Program. Currently, compliance manuals do not include policies for OTC drugs for health centers and their pharmacies. According to the HRSA Health Centers [compliance manual](#), a community health center (CHC) may elect to provide supplies or equipment (such as eyeglasses or prescription drugs) that are related to, but not included, in the service itself as part of its standards of care. In these cases, the center determines the equipment costs and must inform patients of the charge.

HRSA follows the [Women’s Preventive Services Initiative \(WPSI\)](#) recommendations, which propose over the counter access for contraception or comprehensive breastfeeding and lactation services and supplies in its [guidelines](#). The United States Preventive Services Task Force (USPSTF) also recommends over the counter utilization of folic acid supplements, low-dose aspirin, tobacco cessation products, and other valuable supplies and supplements.

Recommendation: We recommend that federal policy guidance, whether from HRSA, CMS or another federal entity, explicitly include all OTC contraceptive methods, as reminded in the President’s recent [executive order](#), as well as provide guidance for other OTC products.

Considerations for FQHCs and OTC Products

Community health centers vary by size, location, and population, and we recommend the administration consider the operational challenges that are experienced by FQHCs and other safety-net providers when it comes to access to contraceptives.

Rural Communities: FQHC patients in rural communities are often faced with provider shortages and geographic challenges; these communities may benefit the most from expanded access to hormonal contraception and other OTC medicines.

340B Program Challenges: Most FQHCs use the 340B program, but only some centers have an in-house pharmacy. According to a 2022 [NACHC study](#), 86% of all CHCs used contract pharmacies, meaning that the center has an arrangement with a different pharmacy to provide such services. Twenty four percent of CHCs use between one and four contract pharmacies, and 14% use more than 50 different contract pharmacies, which will most likely affect the operationalization of OTC services. In addition, an FQHC often only can use 340B pricing if the medication has a prescription, even for OTC products like extra-strength ibuprofen.

OTC Sales at FQHCs: Some FQHCs with in-house pharmacies pay the wholesale price of OTC drugs and provide it to the community (not just the patient) with a 20% markup on the wholesale, with profits funneled back into community services. These centers often provide laminated cards with OTC product labels; anyone can pick up a card and pay for the OTC medication with the receptionist.

Medicaid Program Considerations: State Medicaid policies differ with regard to OTC products. States may have OTC drugs on their Medicaid Preferred Drug List, a list of preferred products that Medicaid will cover without prior authorization. However, each state enforces unique policies that may affect access. For example, while Connecticut's Medicaid Preferred Drug List includes OTC drugs, it's also the [only state](#) that prohibits vending machines from dispensing OTC drugs (including the morning-after pill), which directly affects access. Additionally, in some states there is [no uniform](#) Preferred Drug List for the state's MCOs.

Donated OTC Products: Some FQHCs provide OTC medications to their patients through donations. One of the biggest challenges for OTC products is physical space, and therefore, centers carry the OTC products that are most in demand. For example, one of ACH's FQHC members carries Plan B, donated by a non-profit humanitarian organization, Direct Relief. The charity sends an email twice a month about which drugs are available, and Plan B is prioritized at sites with a women's clinic. The centers also provide other donated products, such as toothbrushes, soaps, and breastfeeding products. Often, health centers serve communities that require the most basic needs, and these donations serve as an essential vehicle to provide such basic and vital care.

Accessibility Challenges

OTC access to contraceptives requires culturally sensitive community outreach and pharmacist/provider training to successfully increase access across all patient populations and encourage greater health equity.

Narcan is a prime example of how making medications available OTC does not necessarily increase access and demonstrates the need for such training and outreach. In the case of OTC Narcan, some states require Narcan to be sold behind a pharmacy counter, causing concern among experts about "[unpredictable retail price, sporadic availability in stores, and general consumer confusion](#)" about asking a pharmacist to retrieve the product. Some community health workers already conduct live demos, especially in the Latino/Hispanic community in California, to raise awareness about how to acquire and use Narcan since many are unfamiliar.

The same anticipated stigma/judgment of these interactions may make people feel uncomfortable asking for OTC contraception and reversible contraceptives as well. The uninsured and those who don't feel comfortable using their insurance to purchase the pills, people in abusive relationships, or minors whose parents don't support them becoming sexually active may be deterred by having to interact with a pharmacist and if the retail price is high.

Pharmacists may not know or receive proper training about OTC contraceptives, and patients may not be aware the option exists. Accessibility will also depend on which retailers choose to stock the drug. Without proper education and awareness, these barriers to access will persist.

We also see this issue with tobacco cessation products. Although public and private health insurance may cover these products, FQHC patients still often [cannot obtain](#) tobacco cessation products because of lack of insurance, limited transportation, and different allowances from their insurance plan. Like OTC contraception, coverage of 340B pricing varies by insurance plan and by state.

Recommendation: We urge the administration to encourage partnerships and campaigns to educate the community about OTC products, including OTC contraceptives, and FQHCs may be uniquely positioned to assist in this effort. FQHCs often serve as the lifeline to the community, already partner with other key stakeholders, and have earned the trust with patients through their continued culturally and linguistically competent care.

We also recommend guidance federally and from the state for providers, patients, pharmacies and retailers regarding what is accessible to patients and how it is accessible. Where there are barriers, education and awareness from partnerships help.

Thank you for this opportunity to comment. We appreciate the administration's support of increasing access to necessary medicines and supplies through over-the-counter mechanisms. For more information or to discuss this further, please contact me at apearskelly@advocatesforcommunityhealth.org.

Sincerely,

A handwritten signature in black ink, appearing to read 'Amanda Pears Kelly', with a stylized flourish at the end.

Amanda Pears Kelly
Chief Executive Officer