October [x], 2023

The Honorable Xavier Becerra Secretary U.S. Department of Health and Human Services 200 Independence Ave, SW Washington, DC 20201

The Honorable Janet Yellen Secretary U.S. Department of Treasury 1500 Pennsylvania Ave, NW Washington, DC 20220

The Honorable Julie A. Su Acting Secretary U.S. Department of Labor 200 Constitution Ave, NW Washington, DC 20210

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

We urge you to improve health insurance coverage, both public and private, of the full range of FDA-approved, granted, or cleared contraceptive products—including birth control that is available over-the-counter (OTC) without requiring a prescription for coverage. Over 19 million women live in counties with limited access to health care providers that offer comprehensive contraceptive services, ¹ and about one-third of women who have received prescription contraceptives have reported barriers to access. ² Expanding access to affordable coverage for eligible, uninsured populations would improve the quality of contraceptive care that patients receive.

In recent months, the Biden-Harris Administration has taken several major steps toward this goal. First, on June 23, President Biden issued an executive order on "Strengthening Access to Affordable, High-Quality Contraception and Family Planning Services," which directed each of your departments to take steps to improve access to contraception. Second, on July 13, the Food and Drug Administration (FDA) approved the first-ever OTC birth control pill for sale in the United States, a groundbreaking advancement in contraceptive access. Most recently, on September 29, the Centers for Medicare and Medicaid Services (CMS), the Internal Revenue Service, and the Employee Benefit Services Administration (EBSA) issued a Request of

¹ https://powertodecide.org/what-we-do/contraceptive-deserts

² https://www.kff.org/report-section/contraception-in-the-united-states-a-closer-look-at-experiences-preferences-and-coverage-findings/.

³ https://www.whitehouse.gov/briefing-room/presidential-actions/2023/06/23/executive-order-on-strengthening-access-to-affordable-high-quality-contraception-and-family-planning-services/

⁴ <u>https://www.fda.gov/news-events/press-announcements/fda-approves-first-nonprescription-daily-oral-contraceptive</u>

Information regarding the application of the preventive services requirements under section 2713 of the Public Health Service Act to OTC preventive services, including OTC contraceptive products.⁵

We applaud these efforts and ask that you undertake additional actions to ensure coverage for OTC contraceptive products—including the new OTC birth control pill once it becomes available in 2024—without cost-sharing and without the need for a prescription in all federally and state-regulated private health plans and federally and state-regulated and run coverage programs.

The availability of safe and effective OTC birth control products has enormous potential to help people overcome significant barriers to consistent contraceptive use, including the many logistical and financial challenges to obtaining a prescription. The FDA's approval of Opill is a milestone; however, for an OTC birth control pill to meet its potential and be truly accessible, federal departments must ensure that it is covered without cost-sharing and without the need for a prescription as a condition of coverage. Even prior to the FDA's approval of Opill, several states have expanded access to OTC contraceptives and other lifesaving ACA preventive services to ensure that patients continue to receive quality care.⁶ Additional training and billing guidance for pharmacists and other health care providers would support state efforts to expand access to covered ACA preventive services like OTC contraceptives.

Currently, existing Frequently Asked Questions (FAQ) guidance on the Affordable Care Act's (ACA) contraceptive coverage requirement from the Departments of Labor, Health and Human Services, and Treasury ("tri-departments") allows federally and state-regulated private health plans to require a prescription for OTC contraceptives as a condition of coverage without cost sharing. This significantly reduces the advantages to consumers of an OTC product. To expand access to affordable contraception, we urge the tri-departments to issue new guidance that reflects current HRSA guidelines and clarifies that federally and state-regulated private health plans must cover OTC contraceptive products without cost-sharing, including when purchased without a prescription. We request that you do this as soon as possible and encourage the Federal Employees Health Benefits (FEHB) Program to adopt parallel changes for the next plan year.

In addition to new guidance, your departments may need to take one or more discrete steps as soon as possible to:

- Cover the new OTC birth control pill and other OTC contraceptives by adding it to an existing coverage requirement and/or formulary;
- Eliminate any otherwise-required cost-sharing and prior authorization for OTC contraceptives;
- Eliminate any prescription requirement for OTC contraceptive coverage;
- Work with providers, pharmacy chains, health plans, and other stakeholders to make coverage for OTC contraceptives function as smoothly as possible at pharmacies and via mail order;

⁵ https://www.cms.gov/cciio/resources/regulations-and-guidance/downloads/cms-9891-nc.pdf

 $^{^{6\ 6}\ \}underline{\text{https://powertodecide.org/what-we-do/information/resource-library/state-actions-expand-contraceptive-coverage}$

⁷ https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-54.pdf

- Provide notice to beneficiaries, providers, and other stakeholders about any changes to coverage, as well as information about how to navigate and facilitate coverage of OTC contraceptives without a prescription;
- Provide guidance to encourage state Medicaid programs to cover OTC contraceptives without a prescription for Medicaid beneficiaries; and
- Provide guidance to pharmacies, health care providers, and insurers to improve claims processing and reimbursement for OTC contraceptives.

These steps would be in line with the goals and directives of the June 2023 executive order, including its directive to "promote increased access to affordable over-the-counter contraception, including emergency contraception."

We appreciate your ongoing commitment to these goals for improving coverage of and access to the full range of contraceptives, including OTC contraception, and look forward to continuing to work together to achieve them. Given the increased need for access to contraception in the wake of the *Dobbs* decision, this issue is incredibly timely and important. Thank you in advance for considering this request.

Sincerely,

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Cc: The Honorable Kiran Ahuja, Director of the U.S. Office of Personnel Management (OPM)

⁸ https://www.whitehouse.gov/briefing-room/presidential-actions/2023/06/23/executive-order-on-strengthening-access-to-affordable-high-quality-contraception-and-family-planning-services/