November 18, 2024

Minnesota Department of Commerce
85 7th Place East
St. Paul, MN 55101

Re: Coverage for Over-the-Counter Contraceptives

To Whom It May Concern,

The National Health Law Program (NHeLP) appreciates the opportunity to respond to the Request for Information on Coverage for Over-the-Counter (OTC) Contraceptives from the Minnesota Department of Commerce (the Department). NHeLP protects and advances the health rights of low-income and underserved individuals. Founded in 1969, NHeLP advocates, litigates, and educates at the federal and state levels. Consistent with this mission, NHeLP works to ensure that all people in the United States have access to comprehensive preventive health services, including contraception.

Control over one's contraceptive decisions is critical for all individuals to be equal, participating, and productive members of society. Contraception is essential health care and access to contraception improves overall health, increases economic security, and advances reproductive autonomy.[1] Additionally, the ability afforded by contraception to time and space pregnancies improves both maternal and infant health outcomes.[2]

More than a decade after the implementation of the Affordable Care Act, individuals continue to face multiple and persistent barriers to contraception.[3] These barriers to contraception fall hardest on Black, Indigenous, and people of color (BIPOC), young people, rural communities, LGBTQ+ individuals, those working to make ends meet, and people with disabilities.[4] Therefore, the proposed mandate requiring coverage of OTC contraception without cost-sharing and without a prescription

at point-of-sale will advance contraceptive equity and reproductive justice.

NHeLP supports this proposed health benefit mandate and urges the Department and legislature to consider expanding the proposed mandate to include measures that involve education, implementation, and enforcement of this mandate.

1. If the proposed health benefit mandate were signed into law, how would it impact individuals' access to health care? In your response, please consider access under current coverage requirements, whether additional steps are required to access care (e.g., the need for prior authorization for a service or item), and if the change in coverage associated with the proposed mandate would impact certain populations more than others.

If the proposed health benefit mandate were signed into law it would greatly increase individuals' access to contraception. Multiple contraceptive methods 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. However, under the current law individuals who want coverage for OTC contraceptives must first obtain a prescription.

Prescription requirements often limit or delay an individual's access to their preferred method of contraception and contribute to lapsed or inconsistent contraceptive use.[5] A prescription requirement often means that people either forgo the use of their insurance and pay the full price for OTC contraceptives, or are forced to obtain a medically unnecessary prescription from a health care provider, which entails other types of financial and logistical costs and burdens. Prescription requirements necessitate access to a clinician (which can be costly), travel to both a clinician's office and a

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Note: We employ "women" in limited instances when necessary to accurately reference legal terms or cisgender women-centered research and to honor how advocates or groups self-identify. More inclusive policy language and research is needed to better service the needs of all people who need equitable access to reproductive and sexual health care.

[1] Contraceptive Access Initiative, *Why Contraceptive Access Matters* (2024), https://static1.squarespace.com/static/5d35f1b39760f8000111473a/t/659edc9e3ecbbd781fc753a0/1704909982619/Why+Contraceptive+Access+Matters_Jan+2024.pdf.

[2] Kelleen Kaye et al., *The Benefits of Birth Control in America*, POWER TO DECIDE, at 15-18 (2014), https://powertodecide.org/sites/default/files/resources/primary-download/benefits-of-birth-control-in-america.pdf.

[3] Comm. on Oversight and Reform U.S. House of Representatives, Staff Report, Barriers to Birth Control: An Analysis of Contraceptive Coverage and Costs for Patients with Private Insurance (Oct. 25, 2022), https://oversightdemocrats.house.gov/sites/democrats.oversight.house.gov/files/2022-10-25.COR%20PBM-Insurer%20Report.pdf.

[4] *See* Christina Piecora & Michelle Yiu, *Insurance Coverage for OTC Contraception*, NAT'L HEALTH L. PROG. (Dec. 2023), https://healthlaw.org/insurance-coverage-for-otc-contraception/.

[5] Kate Grindlay, *Prescription Birth Control Access Among U.S. Women at Risk of Unintended Pregnancy*, 25 J. WOMEN'S HEALTH 249 (March 2016), https://pubmed.ncbi.nlm.nih.gov/26666711/ (finding that of the 68% of women who had tried to get a prescription for hormonal contraception, 29% reported having problems obtaining a prescription or refills).

pharmacy, and generally requires time off work, as well as paying for transportation and possibly childcare.[6] People with disabilities, those living in contraceptive deserts, and those with lower incomes suffer the cost, travel, and time burden most acutely.[7]

Many Minnesotans experience barriers to accessing contraceptive care.[8] In Minnesota, 37% of rural counties have no publicly funded sexual health clinics.[9] Approximately 283,400 Minnesotans can become pregnant and need contraception but live in contraceptive deserts (counties that lack reasonable access to the full range of methods) and 50,500 live in counties without a single health center that provides the full range of contraceptive methods.[10] Therefore these residents must travel greater distances to receive low cost or no-cost contraceptive care than their peers in Metro areas. If the proposed health benefit mandate were signed into law these residents in contraceptive care deserts would face fewer barriers to accessing contraception because they could obtain OTC contraception directly from a local pharmacy or retailer without a prescription.

Aside from the prescription requirements necessitating numerous trips to a medical provider and pharmacy in order to access coverage for OTC contraception, many providers also require medically unnecessary pelvic exams before issuing prescriptions for contraceptives.[11] The prospect of a gynecological examination may deter an individual, especially a person who is disabled, an LGBTQ+ individual, or someone who has experienced assault from having a clinical visit that could facilitate their use of contraception.[12] Eliminating the prescription requirement for coverage of OTC contraception would also increase access for these communities.

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[6] Katherine Key et al., *Challenges Accessing Contraceptive Care and Interest in Over-the-Counter Oral Contraceptive Pill Use among Black, Indigenous, and People of Color: An Online Cross-Sectional Survey*, 120 CONTRACEPTION (April 2023), https://www.contraceptionjournal.org/article/S0010-7824(23)00003-3/fulltext#tbl0001. *See also* Amanda Dennis & Daniel Grossman, *Barriers to Contraception and Interest In Over-the-Counter Access Among Low-Income Women: A Qualitative Study*, 44 PERSPECT. SEX REPROD. HEALTH 84, 84-87 (March 2012), https://pubmed.ncbi.nlm.nih.gov/22681423/; Claudia Hui et al., *Behind the Counter: Findings from the 2022 Oral Contraceptives Access Survey*, ADVOCATES FOR YOUTH (2022), https://www.advocatesforyouth.org/wp-content/uploads/2022/09/BehindTheCounter-OralContraceptivesAccessReport-2022-1.pdf.

[7] *See also* Dennis & Grossman, *supra* note 6.

[8] Minnesota Dep't. of Health, Family Planning Special Projects Program (2024), https://www.health.state.mn.us/people/womeninfants/srhs/fpspfact2024.pdf.

[9] *Id.*

[10] *Id.*

[11] Am. Coll. Obstetricians & Gynecologists, Comm. Op. No. 615: Access to Contraception (Jan. 2015) https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2015/01/access-to-contraception#:~:text=Expanding%20access%20to%20publicly%20funded,at%20publicly%20funded%20centers%208. *See also* Jillian T. Henderson et al*., Pelvic Examinations And Access To Oral Hormonal Contraception,* 116(6) OBSTET. GYNECOL. 1257-1264 (Dec. 2010), https://pmc.ncbi.nlm.nih.gov/articles/PMC3745305/.

[12] *See* Hunter Holt et al., *Delayed Visits for Contraception Due to Concerns Regarding Pelvic Examination Among Women with History of Intimate Partner Violence*, 36(7) J. GEN. INTERN. MED. 1883-1889 (Nov. 2020), https://pmc.ncbi.nlm.nih.gov/articles/PMC8298732/;

Black, Indigenous, and Other People of Color (BIPOC) also face substantial barriers to accessing contraceptives in the United States.[13] These inequities are driven by intersecting systems of oppression, including systemic racism, community disinvestment, and reproductive coercion. A national survey of people who identify as BIPOC found that nearly half experienced at least one challenge to accessing contraception in 2022 and 76% of those who had experienced challenges said they were likely to use an OTC oral contraceptive.[14]

While Black women have a more difficult time accessing reproductive health care, they disproportionately suffer from reproductive health challenges like uterine fibroids and polycystic ovary syndrome, which can be managed by contraception.[15] BIPOC communities have been historically oppressed by coercive contraceptive policies and practices.[16] This history has contributed to decreased rates of contraceptive use among these groups and distrust of health systems.[17] Coverage of OTC contraception without a prescription would allow BIPOC individuals the bodily autonomy and freedom to access contraception on their own terms and give them greater control over their reproductive health and lives.

Young people would also greatly benefit from the passage of this health benefit mandate. In 2022, Advocates for Youth conducted the Oral Contraceptives Access Survey Report, in which 88% of those surveyed indicated they experienced at least one barrier to obtaining a prescription for oral contraception when they were young.[18] In fact, 75% of all respondents reported experiencing multiple barriers, including logistical, financial, legal, and/or cultural factors. More than half of all respondents (55%) reported that one or more of these barriers had prevented them as a teen or young adult from obtaining a prescription for contraceptive pills.[19] And the majority of these

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Willi Horner-Johnson, et al., *Experiences of Women With Disabilities in Accessing and Receiving Contraceptive Care*, 50(6) J. OBSTET. GYNECOL. NEONATAL NURS. 732-741 (Nov. 2021), https://pubmed.ncbi.nlm.nih.gov/34389287/; Sandy E. James et al., *The Report of the 2015 U.S. Transgender Survey*, NAT.'L CENTER FOR TRANSGENDER EQUALITY (dec. 2017), https://transequality.org/sites/default/files/docs/usts/USTS-Full-Report-Dec17.pdf. *See also* Dana Lavergne, *Queer People Navigating Experiences with Health Care Providers and Contraception*, LOYOLA UNIV. CHICAGO (2018), https://ecommons.luc.edu/cgi/viewcontent.cgi?article=4748&context=luc_theses.

[13] Madeline Sutton et al., *Racial and Ethnic Disparities in Reproductive Health Services and Outcomes*, 2020, 137 OBSTETRICS & GYNECOLOGY 225 Feb (2021), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7813444/.

[14] Key et al., *supra* note 6.

[15] Bridget J. Goosby et. al., *Uterus Keeps the Score: Black Women Academics' Insights and Coping with Uterine Fibroids, Journal of Health and Social Behavior*, AM. SOCIOLOGICAL ASS'N (Sept. 2024). https://doi.org/10.1177/00221465241268434.

[16] In Our Own Voice: Nat'l Black Women's Reprod. Just. Agenda, Contraceptive Equity For Black Women at 2, http://blackrj.org/wp-content/uploads/2020/04/6217-IOOV_ContraceptiveEquity.pdf.

[17] *Id.*

[18] Claudia Hui et al., *Behind the Counter: Findings from the 2022 Oral Contraceptives Access Survey*, ADVOCATES FOR YOUTH (2022), https://www.advocatesforyouth.org/wp-content/uploads/2022/09/BehindTheCounter-OralContraceptivesAccessReport-2022-1.pdf.

[19] *Id.*

respondents (57%) reported going off contraceptive pills because they could not schedule or attend an appointment with a clinician in time for a prescription renewal.[20] For many, missing the beginning of a new birth control pill pack resulted in disruption of their menstrual cycle, a pregnancy scare, and/or an unintended pregnancy.[21]

Data shows that access to OTC contraception leads to higher rates of use and continuation.[22] A national survey found that more than three-quarters (77%) of reproductive age females favored making birth control pills available OTC without a prescription if research showed they are safe and effective.[23] However, a key driver to OTC contraception is affordability and insurance coverage. One study found that 39% of adults and of 29% teens reported they would likely use an OTC progestin-only hormonal contraceptive pill. But if covered by insurance, the likelihood of use greatly increased, to approximately 46% among adults and 40% among teens.[24] In another more recent study of 550 adults and 115 adolescents, 83% of respondents reported likely use of an OTC progestin-only pill.[25] Primary reasons for interest included convenience (81%), ease of access (80%), and saving time (77%) and money (64%).[26] Additionally, a study published in the *Journal of Women's Health Issues* found that no-cost OTC contraception would fill current gaps in contraceptive access and decrease unintended pregnancies.[27]

By making OTC contraceptives more accessible at point-of-sale, more people would avoid potentially harmful delays and gaps in contraceptive use, avoid having to rely on a contraceptive method that fails to meet their needs, or avoid having to forgo contraceptive use entirely. It would also reduce the barriers that rural communities,

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[20] *Id.*
[21] *Id.*
[22] Joseph Potter et al., *Continuation of Prescribed Compared With Over-The-Counter Oral Contraceptives*, 117 OBSTETRICS & GYNECOLOGY 551 (2011), https://journals.lww.com/greenjournal/Fulltext/2011/03000/Continuation_of_Prescribed_Compared_With.6.as.
[23] Michelle Long et al., *Interest in Using Over-the-Counter Oral Contraceptive Pills: Findings from the 2022 KFF Women's Health Survey*, KFF. (Nov. 3, 2022), https://www.kff.org/womens-health-policy/issue-brief/interest-using-over-the-counter-oral-contraceptive-pills-findings-2022-kff-womens-health-survey/.
[24] Kate Grindlay et al., *Interest in Over-the-Counter Access to a Progestin-Only Pill Among Women in the U.S.,* 28 WOMEN'S HEALTH ISSUES 144, 145-151 (Jan. 29, 2018), https://www.whijournal.com/article/S1049-3867(17)30292-X/fulltext; Ibis Reprod. Health, *New Study Confirms People Want Over-The-Counter Access to Birth Control, Including Progestin-Only Pills* (Feb. 2018), https://www.ibisreproductivehealth.org/news/new-study-confirms-people-want-over-counter-access-birth-control-including-progestin-only-pills.
[25] Kate Grindlay et al., *Interest in Continued Use After Participation in a Study of Over-the-Counter Progestin-Only Pills in the U.S.*, 3 WOMEN'S HEALTH REPORTS 904 (Nov. 2022), http://doi.org/10.1089/whr.2022.0056.
[26] *Id.*
[27] Alexandra Wollum et al., *Modeling the Impacts of Price of an Over-the-Counter Progestin-Only Pill on Use and Unintended Pregnancy among U.S. Women*, 30 WOMEN'S HEALTH ISSUES 153, 154-160 (May-Jun 2020), https://www.ibisreproductivehealth.org/sites/default/files/files/publications/PIIS1049386720300037.pdf.

those living in contraceptive deserts, people who are disabled, LGBTQI+ individuals, BIPOC individuals, and young people face when trying to access contraception. Ultimately, increasing accessibility translates into more reproductive autonomy, less reproductive coercion, and more consistent contraceptive use.

2. Are there any currently established health care policies related to this proposed health benefit mandate that Commerce should consider during their evaluation?

The Department should look to the ten states and the District of Columbia that allow coverage of some OTC contraceptives without a prescription.[28] The Department should also look to the recent federal Notice of Proposed Rulemaking on Enhancing Coverage of Preventive Services Under the Affordable Care Act, which contains information in the preamble about why coverage for OTC contraceptives is necessary.[29]

The Department should note that over 100 countries currently provide oral contraceptive pills OTC without a prescription.[30] The Department should also consider that leading medical associations such as the American College of Obstetricians and Gynecologists, the American Academy of Family Physicians, the American Medical Association, and the American Public Health Association, all support OTC access to contraception without a prescription.[31]

The Department should also look at insurance programs that already successfully cover OTC products. For example, the U.S. military's health insurance plan, TRICARE, provides coverage of Plan B emergency contraception without copayments and without a prescription.[32] Additionally, many Medicare Advantage plans cover OTC products

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[28] See Karen Diep et al., *Oral Contraceptive Pills: Access and Availability*, KFF (March 2024), https://www.kff.org/womens-health-policy/issue-brief/oral-contraceptive-pills-access-and-availability/; Michelle Long et al., *Insurance Coverage of OTC Oral Contraceptives: Lessons from the Field*, KFF (Sept., 2024) https://www.kff.org/womens-health-policy/report/insurance-coverage-of-otc-oral-contraceptives-lessons-from-the-field/.

[29] U.S. Dep'ts of Labor, Health & Human Servs., & Treasury, Enhancing Coverage of Preventive Services Under the Affordable Care Act, 89 Fed. Reg. 85750 (proposed Oct. 28, 2024), https://www.federalregister.gov/documents/2024/10/28/2024-24675/enhancing-coverage-of-preventive-services-under-the-affordable-care-act.

[30] Free the Pill, OTC Birth Control Pill Access World Map (last updated Sept. 7, 2023) https://freethepill.org/otc-access-world-map.

[31] Daniel Grossman, *Over-the-Counter Access to Oral Contraceptives*, 42 OBSTETRICS AND GYNECOLOGY CLINICS OF NORTH AMERICA 4 (Dec. 2015), https://www.sciencedirect.com/science/article/abs/pii/S088985451500073X?via%3Dihub; Am. Col. Obstetricians & Gynecologists, *Comm. Op. No. 788: Over-the-Counter Access to Hormonal Contraception* (Oct. 2019), https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2019/10/over-the-counter-access-to-hormonal-contraception.

[32] Tricare. "Contraception Chart." (March 2023). https://www.tricare.mil/HealthWellness/Public-Health/SexualHealth/Contraception-Chart.

without a prescription.[33] In fact, according to a 2022 KFF survey, 87% of Medicare Advantage plans offered some kind of benefit for OTC items like adhesive or elastic bandages and allergy medicine.[34] These benefits commonly take the form of OTC benefit cards that are preloaded with a quarterly spending allowance and that can be used like a credit card to purchase approved items at specific retailers.[35] Similar benefit cards are also commonly used for purchasing OTC products by those with health savings accounts (HSAs) and health flexible spending arrangements (health FSAs).[36]

Researching states and plans that already allow coverage of OTC products can help with implementing coverage at point-of-sale, educating patients, providers, and insurance plans, and ensuring enforcement of the coverage requirement.

3. Based on the Data Availability and Sources (Appendix A) outlined in the RFI, are there resources or considerations Commerce should assess during their evaluation of the proposed health benefit mandate (e.g., journal articles, databases, etc.)?

The Department should look at the following resources:

- Adam Sonfield, *Why Family Planning Policy and Practice Must Guarantee a True Choice of Contraceptive Methods,* GUTTMACHER INSIT. (2017) https://www.guttmacher.org/gpr/2017/11/why-family-planning-policy-and-practice-must-guarantee-true-choice-contraceptive-methods.
- Alexandra Wollum et al., *Modeling the Impacts of Price of an Over-the-Counter Progestin-Only Pill on Use and Unintended Pregnancy among U.S. Women*, 30 WOMEN'S HEALTH ISSUES 153, 154-160 (May-Jun 2020), https://www.ibisreproductivehealth.org/sites/default/files/files/publications/PIIS1049386720300037.pdf.
- Am. Coll. Obstetricians & Gynecologists, Comm. Op. No. 615: *Access to Contraception* (Jan. 2015) https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2015/01/access-to-

[33] *See* AARP, *What Is A Medicare Flex Card?* (March 2023), https://www.aarp.org/health/medicare-qa-tool/what-is-a-medicare-flex-card.html. Certain Medicare Advantage plans use a Medicare flex card. These cards are updated with a quarterly allowance and can be scanned at retail checkout, with the money automatically applied to eligible items. Some flex cards work for online purchases too. For example, CareOregon Advantage allows enrollees to buy over 90,000 eligible items online or in certain stores using a pre-loaded debit card. (https://www.careoregonadvantage.org/members/careoregon-advantage-carecard).

[34] Meredith Freed et al., *Medicare Advantage 2023 Spotlight: First Look*, KFF (November 2022), https://www.kff.org/medicare/issue-brief/medicare-advantage-2023-spotlight-first-look/.

[35] *See* United Healthcare, *Medicare UCard* (2023), https://www.uhc.com/medicare/shop/ucard.html; Humana, *Humana Medicare Account Card* (2023), https://www.humana.com/medicare/medicare-programs/healthy-spending-account; Anthem, *Medicare Member OTC Benefits*, (2023) https://www.anthem.com/member-resources/medicare-member-otc-benefits; Select Health, *Over-the-Counter (OTC) Benefit* (2023), *https://selecthealth.org/medicare/resources/over-the-counter-benefit*.

[36] *See* HAS Store, https://hsastore.com/articles/learn-hsa-reimbursement-facts.html.

contraception#:~:text=Expanding%20access%20to%20publicly%20funded,at%20publicly%20funded%20centers%208.

- Am. Coll. Obstetricians & Gynecologists, Comm. Op. No. 788: *Over-the-Counter Access to Hormonal Contraception* (Oct. 2019), https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2019/10/over-the-counter-access-to-hormonal-contraception.
- Amanda Dennis & Daniel Grossman, *Barriers to Contraception and Interest In Over-the-Counter Access Among Low-Income Women: A Qualitative Study*, 44 PERSPECT. SEX REPROD. HEALTH 84, 84-87 (March 2012), https://pubmed.ncbi.nlm.nih.gov/22681423/.
- Christina Piecora, Response to RFI on Coverage of OTC Preventative Services, NAT'L HEALTH L. PROG. (Oct. 2023), https://healthlaw.org/resource/response-to-rfi-on-coverage-of-otc-preventative-services-specifically-contraception/.
- Daniel Grossman, *Over-the-Counter Access to Oral Contraceptives*, 42 OBSTETRICS AND GYNECOLOGY CLINICS OF NORTH AMERICA 4 (Dec. 2015), https://www.sciencedirect.com/science/article/abs/pii/S088985451500073X?via%3Dihub.
- Free the Pill, Resource Library, https://freethepill.org/resource-library.
- Kate Grindlay et al., *Interest in Over-the-Counter Access to a Progestin-Only Pill among Women in the U.S.*, 28 WOMEN'S HEALTH ISSUES 144, 145-151 (January 29, 2018), https://www.whijournal.com/article/S1049-3867(17)30292-X/fulltext.
- Kate Grindlay et al*., Interest in Continued Use After Participation in a Study of Over-the-Counter Progestin-Only Pills in the U.S.*, 3 WOMEN'S HEALTH REPORTS 904 (Nov. 2022), http://doi.org/10.1089/whr.2022.0056.
- Katherine Key et al., *Challenges Accessing Contraceptive Care and Interest in Over-the-Counter Oral Contraceptive Pill Use among Black, Indigenous, and People of Color: An Online Cross-Sectional Survey*, 120 CONTRACEPTION (April 2023), https://pubmed.ncbi.nlm.nih.gov/36641098/.
- Kelly Cleland et al., *Access to Emergency Contraception in the Over-the-Counter Era*, 26 WOMEN'S HEALTH ISSUES 622, 623 (Nov-Dec 2016), https://www.whijournal.com/article/S1049-3867(16)30115-3/fulltext.
- Liz McCaman Taylor, *Model Contraceptive Equity Act: Legislative Language and Issue Brief* (Updated 2023), NAT'L HEALTH L. PROG. https://healthlaw.org/wp-content/uploads/2022/10/NHeLP-Model-Act-Updated-for-2023-final.pdf.
- Liz McCaman Taylor, Contraceptive Equity in Action: A Toolkit for State Implementation, NAT'L HEALTH L. PROG. (July 2019), https://healthlaw.org/resource/contraceptive-equity-in-action-a-toolkit-for-state-implementation/.
- Michelle Long et al., Considerations for Covering Over-the-Counter Contraception, KFF (Nov. 2023), https://www.kff.org/policy-watch/considerations-covering-over-the-counter-contraception/.
- Power to Decide, *State Actions to Expand Contraceptive Coverage*, (June 2023), https://powertodecide.org/what-we-do/information/resource-library/state-actions-expand-contraceptive-coverage.

- Rachel K. Jones, *Beyond Birth Control: The Overlooked Benefits Of Oral Contraceptive Pills*, GUTTMACHER INST. (Nov. 2011), https://www.guttmacher.org/sites/default/files/pdfs/pubs/Beyond-Birth-Control.pd.

4. Would you expect there to be a difference in the cost of services or items covered under the proposed health benefit mandate for patients? for Payers/issuers?

If the proposed health benefit mandate was passed, patients would save on the cost of OTC contraceptives by eliminating the out-of-pocket cost for those with state regulated insurance plans.

The negative impact and associated costs of requiring a prescription for coverage of OTC contraception can be seen in the utilization of levonorgestrel emergency contraception (EC). Levonorgestrel EC was approved for OTC sale in 2006 and became available OTC to all ages in 2013. But most insurance companies still require a prescription for coverage of levonorgestrel EC even though it must be taken within 72 hours of unprotected sex.[37] Despite multiple brand-name and generic products on the market, the cost of levonorgestrel EC remains at $40 to $50, on average.[38] This price point has resulted in disparate utilization.[39] A 2015 study found that women with incomes above 100% of the federal poverty level were more likely to have used EC compared to women below this threshold, and the likelihood of ever having used EC increased as wealth increased.[40] The study determined that higher income levels are associated with higher rates of EC use, indicating that cost may be a key barrier to accessing EC.[41] Accordingly, the most crucial step in ensuring accessibility of OTC hormonal contraception is to require insurance coverage without a prescription.

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[37] Maria Godoy, *Emergency Contraception Pills Are Safe and Effective, But Not Always Available*, NPR (June 8, 2022), https://www.npr.org/sections/health-shots/2022/06/28/1105830606/emergency-contraception-pills. *See also M*ary T. Hickey, *Emergency Contraception Update*, 3 WOMEN'S HEALTHCARE 21 (June 2022) (stating that the cost of OTC EC has frequently been reported as a barrier to use, particularly for adolescents and women living in or close to poverty), https://www.npwomenshealthcare.com/wp-content/uploads/2022/06/June-WH-ISSUE-Emergency-con.pdf

[38] *Id.*

[39] Kelly Cleland et al., *Access to Emergency Contraception in the Over-the-Counter Era*, 26 WOMEN'S HEALTHCARE ISSUES 622, 623 (Nov-Dec 2016), https://www.whijournal.com/article/S1049-3867(16)30115-3/fulltext; Tina Caliendo & Ashley Dao, *Addressing Barriers to Emergency-Contraceptive Access*, 46 US PHARMACIST 8 (Sept. 21, 2021), https://www.uspharmacist.com/article/addressing-barriers-to-emergencycontraceptive-acces.

[40] Rubina Hussain, *Changes In Use Of Emergency Contraceptive Pills In The U.S. From 2008 To 2015*, 10 CONTRACEPTION 1, 3 (May 2021), https://www.sciencedirect.com/science/article/pii/S2590151621000125?via%3Dihub. *See also* Tia Palermo et al., *Knowledge and use of Emergency Contraception: A Multicountry Analysis*, 40 INT'L PERSP. ON SEXUAL AND REPROD. HEALTH 79, 79-86 (2014), https://www.jstor.org/stable/10.1363/4007914.

[41] *Id.*

Payers and issuers would also save on the cost of covering clinical visits every time an individual needs or wants OTC contraception. Additionally, the time and money spent on coverage of OTC contraceptives would likely cost insurers much less than the health issues caused without these services. Covering OTC contraceptives without a prescription or cost-sharing would prevent unintended pregnancies, which in turn would reduce maternal and infant comorbidities and lead to lower costs for insurers.[42]

No evidence of fraud, waste, or abuse has been shown in states that have expanded coverage for OTC contraception without cost sharing and without a prescription. As such, fraud prevention mechanisms, including prescription requirements, are medically unnecessary and would limit the easy coverage and access that people deserve and would stymie the equity, economic, and overall health benefits of OTC contraception.

5. Are there other cost considerations or outcomes that may be impacted under the proposed health benefit mandate (e.g., health outcomes)?

Passage of the proposed health benefit mandate would result in positive health and economic outcomes. The preventative benefits of contraception, named as one of the 10 great public health achievements of the 20th century by the Centers for Disease Control and Prevention, are widely recognized and include reduced infant, child, and maternal deaths, healthier pregnancies, and economic self-sufficiency for women.[43]

Studies modeling the potential benefits of OTC oral contraceptives have found that if OTC oral contraceptives were offered without cost-sharing, unintended pregnancies would decrease an estimated 7–25%.[44] Unplanned pregnancies increase the chances of unhealthy pregnancies, preterm delivery and low-birth-weight births, and maternal morbidity and mortality.[45] Additionally, a number of chronic conditions can be exacerbated by an unplanned pregnancy.[46]

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[42] Adam Sonfield, *Contraceptive Coverage at the U.S. Supreme Court: Countering the Rhetoric with Evidence*, GUTTMACHER INST. (March 7, 2015), https://www.guttmacher.org/gpr/2014/03/contraceptive-coverage-us-supreme-court-countering-rhetoricevidence#:~:text=Moreover%2C%20studies%20comparing%20the%20cost,the%20most%20cost%2Deffective%20ones.
(citing J. Trussell et al., *Cost Effectiveness Of Contraceptives In The U.S.,* CONTRACEPTION, 2009, 79(1):5–14)

[43] Adam Sonfield et al., *The Social And Economic Benefits Of Women's Ability To Determine Whether And When To Have Children*, GUTTMACHER INST. (2013), http://www.guttmacher.org/pubs/social-economic-benefits.pdf.

[44] Diana Foster et al., *Potential Public Sector Cost-Savings From Over-The-Counter Access To Oral Contraceptives*, 91 CONTRACEPTION 373 (Feb. 2015), https://pubmed.ncbi.nlm.nih.gov/25732570/#:~:text=Conclusions%3A%20If%20out%2Dof%2D,contraceptives%20as%20an%20OTC%20product.

[45] Am. Coll. Obstetricians & Gynecologists, *supra* note 11.

[46] Judith A. Berg & Nancy Fugate Woods, *Overturning Roe V. Wade: Consequences For Midlife Women's Health And Well-Being*, 6 WOMENS MIDLIFE HEALTH 1 (Jan. 2023), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9824972/.

Moreover, contraception access is linked to educational, employment, and economic benefits for individuals and families. Access to contraceptive pills is responsible for nearly one-third of the convergence of the gender wage gap in the 1990s and has been shown to significantly reduce the probability of female poverty.[47] Research also demonstrates generational benefits for children whose parents had expanded access to contraception, including reduced child poverty rates and increased college completion, labor force participation, wages, and family incomes decades later.[48] Expanding access to OTC contraception by requiring coverage without cost-sharing and without a prescription has the potential to advance equity by broadening the reach of these proven economic benefits of contraception to a wider population.

Thank you for your attention to our comments. If you have any questions or need any further information, please contact Christina Piecora (piecora@healthlaw.org).

Sincerely,

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[47] Stephanie P. Browne & Sara LaLumia, *The Effects of Contraception on Female Poverty*, 33 J. POL'Y ANALYSIS & MGMT. 602 (2014), https://onlinelibrary.wiley.com/doi/abs/10.1002/pam.21761.
[48] Martha J. Bailey, *Fifty Years of Family Planning: New Evidence on the Long-Run Effects of Increasing Access to Contraception*, BROOKINGS PAPERS ON ECON. ACTIVITY 341 (2013), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4203450/; Martha J. Bailey et al., *Does Access to Family Planning Increase Children's Opportunities? Evidence from the War on Poverty and the Early Years of Title X*, 54 J. HUM. RES. 825 (2019), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6876122/.