HOUSE COMMITTEE ON
OVERSIGHT AND ACCOUNTABILITY
DEMOCRATS
RANKING MEMBER JAMIE RASKIN

Staff Analysis: Revised Federal Guidance Regarding Contraceptive Coverage Could Benefit Millions of Women

Contraception and family planning are critical elements of public health and have widely recognized benefits.[1] Research has found that access to contraception can reduce the likelihood of pregnancy-related morbidity and mortality, as well as certain reproductive cancers. Further, the ability to delay and space pregnancies is linked to improved outcomes for both mothers and babies, as well as greater educational and economic opportunities for young women such as improved female engagement in the workforce and economic self-sufficiency for women.[2]

In June 2023, the Biden-Harris Administration issued an Executive Order titled "Strengthening Access to Affordable, High-Quality Contraception and Family Planning Services," as part of the Administration's ongoing efforts to ensure just and equitable access to contraceptive products.[3] The Affordable Care Act and related guidance issued by the Departments of Health and Human Services, Labor, and Treasury (collectively, the Tri-Departments) currently require private health plans and issuers of health insurance coverage, including pharmacy benefit managers (PBMs), to cover the full range of Food and Drug Administration (FDA) approved contraceptive methods and services without cost-sharing.[4] Cost-sharing refers to the share of costs patients pay out of pocket under their insurance plans, and generally includes deductibles, coinsurance, and copayments, or similar charges.[5] Yet the Committee on Oversight and Reform's 2022 investigation into the five largest health insurers' and the four largest PBMs' coverage of contraceptive products for people enrolled in private health plans revealed that patients continue to face financial barriers to accessing birth-control without cost-sharing. These findings are supported by independent research. For example, a recent report by the Kaiser Family Foundation found that only 70% of women surveyed were fully covered by their insurance without cost-sharing when obtaining their most recent contraceptive method. Of those who had to pay out of pocket, 24% reported paying $50 or more for their preferred method.[6] The Biden-Harris Administration's Executive Order provides an opportunity for the federal government to address these concerns, in line with findings and recommendations issued by the Committee on Oversight and Reform in the 117th Congress. By implementing the Committee's proposed revisions to federal

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[1] American College of Obstetricians and Gynecologists, *Committee Opinion: Access to Contraception* (Reaffirmed 2022) (online at www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2015/01/access-to-contraception).

[2] *See* Guttmacher Institute, *Contraception and Beyond: The Health Benefits of Services Provided at Family Planning Centers* (July 2013) (online at www.guttmacher.org/sites/default/files/report_pdf/health-benefits.pdf); Power to Decide, *The Benefits of Birth Control in America: Getting the Facts Straight* (2014) (online at https://powertodecide.org/sites/default/files/resources/primary-download/benefits-of-birth-control-in-america.pdf); American College of Obstetricians and Gynecologists, *Committee Opinion: Access to Contraception* (Reaffirmed 2022) (online at www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2015/01/access-to-contraception).

[3] Exec. Order No. 14101, FR Doc. 2023-13889 (June 23, 2023).

[4] Committee on Oversight and Reform, *Barriers to Birth Control: An Analysis of Contraceptive Coverage and Costs for Patients with Private Insurance* (Oct. 25, 2022) (online at https://oversightdemocrats.house.gov/sites/democrats.oversight house.gov/files/2022-10-25.COR%20PBM-Insurer%20Report.pdf).

[5] Cost Sharing, HealthCare.gov (online at www healthcare.gov/glossary/cost-sharing/#:~:text=The%20share%20of%20costs%20covered,cost%20of%20non%2Dcovered%20services).

[6] Kaiser Family Foundation, *Contraception in the United States: A Closer Look at Experiences, Preferences, and Coverage* (Nov. 3, 2022) (online at www.kff.org/report-section/contraception-in-the-united-states-a-closer-look-at-experiences-preferences-and-coverage-findings/).

guidance, the Tri-Departments could ensure that millions of women of reproductive age have increased access to no-cost contraception.

I. 2022 OVERSIGHT COMMITTEE INVESTIGATION REVEALED THAT UPDATED FEDERAL GUIDANCE COULD ENSURE ACCESS TO NO-COST CONTRACEPTIVES

In 2022, the Committee investigated cost-sharing requirements and coverage exclusions for 120 contraceptive products across approximately 68 health plans and PBM lists of covered medication called formularies. The Committee found that most insurers and PBMs imposed cost-sharing requirements or coverage exclusions for more than 30 birth control products reviewed. These products were disproportionately likely to be newer products approved by FDA after 2011, and many provide particular clinical benefit to patients with distinct health care needs. Of these 30 products, 12 had no therapeutic equivalents—typically a generic medication—on the market as of October 2022.[7]

Currently, Tri-Department guidance requires companies to have in place an "easily accessible" and "transparent" exceptions process to ensure patients do not have to pay out-of-pocket for any FDA-approved, cleared, or granted product that the individual's attending provider recommends based on a determination that the contraceptive product is medically appropriate for the individual.[8] In other words, any contraceptive product that a patient's medical provider deems medically appropriate should be covered by that person's health plan and PBM without cost to the patient. If that product is not covered without cost-sharing, health plans and PBMs must have in place an "easily accessible" and "transparent" exceptions process to waive cost-sharing. However, the Committee found that the processes companies had in place for patients to receive exceptions to cost-sharing requirements and coverage restrictions could be burdensome for patients and providers. The Committee's investigation also revealed that companies denied exception requests on average four or more times out of ten.[9] If these exceptions processes do not work as intended, patients may be forced to pay out of pocket even for a contraceptive product deemed medically appropriate by their health care provider.

Given these findings, the Committee made two recommendations for the Tri-Departments: (1) that they should update guidance to clarify requirements regarding *appropriate* medical management for coverage of contraceptives, and (2) they should encourage exceptions processes that are automatic at the point of prescribing.[10] As of December 2023, the Tri-Departments have not implemented the recommendations.

Clarifying the Tri-Departments' July 2022 guidance would help ensure it is working as intended. Under the July 2022 guidance, all patients whose health care provider determines that a

Recommendations for the Tri-Departments

Clarify requirements regarding *appropriate medical management* for coverage of contraceptives. The Tri-Departments could issue guidance clarifying that all FDA-approved contraceptive products that do not have a therapeutic equivalent should be covered without cost-sharing as part of every plan or formulary—allowing health plans and PBMs to use medical management techniques to prioritize the use of generic pharmaceuticals where possible, while ensuring that patients have access without cost-sharing to products that do not yet have a generic version.[1]

Encourage exceptions processes that are automatic at the point of prescribing. To ensure the exceptions process is "easily accessible, transparent, and sufficiently expedient," this process could be automatic at the point of prescribing, so that a patient's provider would not have to take any additional steps to ensure the patient has access to medically appropriate contraceptive products without cost-sharing. The exceptions process would remain important even if all contraceptive products without a therapeutic equivalent are covered without cost-sharing, because some patients will be unable to use the therapeutic equivalent to a branded product—for example, some patients may be allergic to the color, flavoring, or preservatives used.

[7] Committee on Oversight and Reform, *Barriers to Birth Control: An Analysis of Contraceptive Coverage and Costs for Patients with Private Insurance* (Oct. 25, 2022) (online at https://oversightdemocrats.house.gov/sites/democrats.oversight house.gov/files/2022-10-25.COR%20PBM-Insurer%20Report.pdf).

[8] Department of Health and Human Services, Department of Labor, and Department of the Treasury, *FAQs About Affordable Care Act Implementation Part 54* (July 28, 2022) (online at www.cms.gov/files/document/faqs-part-54.pdf).

[9] Committee on Oversight and Reform, *Barriers to Birth Control: An Analysis of Contraceptive Coverage and Costs for Patients with Private Insurance* (Oct. 25, 2022) (online at https://oversightdemocrats.house.gov/sites/democrats.oversight house.gov/files/2022-10-25.COR%20PBM-Insurer%20Report.pdf).

[10] *Id.*

certain contraceptive product is medically appropriate for that patient should have access to that contraceptive product without cost-sharing—whether the product is a brand name product or a therapeutic equivalent, typically a generic medication. For some patients, this is because the contraceptive product is included on their formulary without cost-sharing, while other patients would have to use an exceptions process to access that product. Under the Committee's recommendation to revise the guidance, patients would continue to have free access to the contraceptive products that their doctors consider medically appropriate, but fewer patients would be forced to utilize the exceptions processes because brand name products would be presumptively included on formularies without cost-sharing unless a therapeutic equivalent exists. This is important because of the Committee's findings that health plans and PBMs are not adequately ensuring access to no-cost contraception through their exceptions processes.

II. REVISED FEDERAL GUIDANCE COULD POTENTIALLY BENEFIT 49 MILLION WOMEN

Some states already have laws in place that reflect the Committee's recommended updates to federal guidance. To determine the number of individuals who could benefit from the Tri-Departments' implementation of the Committee's recommendations, the Democratic Staff of the Committee on Oversight and Accountability analyzed state-level contraceptive coverage laws and compared this to Census data regarding the number of women of reproductive age who live in each state and data from America's Health Insurance Plans (AHIP) detailing state to state health care coverage.

This analysis showed that 11 states and the District of Columbia currently have laws in place that reflect the Committee's recommendations to the Tri-Departments. These laws require that health plans cover all FDA-approved contraceptives without cost-sharing unless a therapeutic equivalent—typically a generic medication—exists. Generally, if a therapeutic equivalent exists, these state laws allow health plans to require cost-sharing for equivalent products, including the brand name product, as long as at least one therapeutic equivalent is covered at no cost to the patient. When a patient's medical provider determines that the therapeutic equivalent included without cost-sharing is not medically appropriate for that patient, the health plan is generally required to provide the branded product or another equivalent at no cost.[11] Approximately 22.4 million women of reproductive age live in these 11 states and the District of Columbia.

The remaining 39 states vary in whether state law has explicit provisions related to insurance coverage for contraception:

- Twelve states require health plans to cover contraceptive products, but do not have laws prohibiting cost-sharing.[12]
- Five states require health plans to cover contraceptive products, including a prohibition on cost-sharing that does not reflect the Committee's proposed federal guidance regarding therapeutic equivalents.[13]

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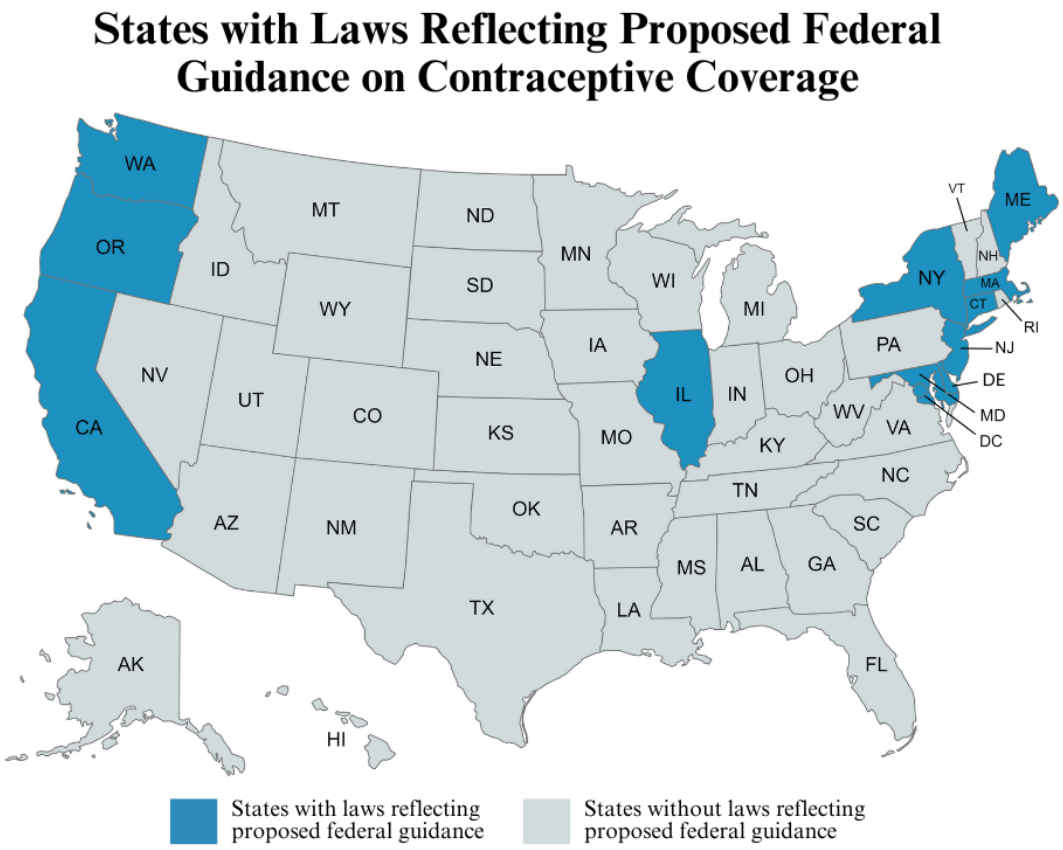
[11] *See* Appendix A, detailing relevant laws in California, Connecticut, Delaware, Illinois, Maine, Maryland, Massachusetts, New Jersey, New York, Oregon, Washington, and Washington, D.C. (online at https://oversightdemocrats.house.gov/sites/democrats.oversight house.gov/files/Contraceptive%20Law%20Analysis%20-%20Appendix%20A.pdf).

[12] *See* Appendix A entries for Arizona, Colorado, Georgia, Hawaii, Iowa, Michigan, Missouri, Montana, North Carolina, Rhode Island, West Virginia, and Wisconsin (online at https://oversightdemocrats.house.gov/sites/democrats.oversight house.gov/files/Contraceptive%20Law%20Analysis%20-%20Appendix%20A.pdf).

[13] *See* Appendix A entries for Nevada, New Hampshire, New Mexico, Vermont, and Virginia (online at https://oversightdemocrats.house.gov/sites/democrats.oversight house.gov/files/Contraceptive%20Law%20Analysis%20-%20Appendix%20A.pdf).

- Twenty-two states do not have explicit laws in place related to insurance coverage of contraception.[14]



Source: Committee on Oversight and Accountability, Democratic staff analysis of state laws.

Many Americans are enrolled in self-funded insurance plans through their employer-provided health insurance. Under self-funded insurance plans, employers pay for their employees' medical claims and fees, in effect acting as their own insurers.[15] Self-funded insurance plans provide cost savings for companies, including by allowing them to avoid the cost of complying with certain state requirements.[16] Self-funded insurance plans are the dominant form of insurance coverage. According to the Kaiser Family Foundation, as of 2022, 65% of covered workers are in a self-funded health plan.[17] This number appears to be increasing, with the Kaiser Family Foundation determining that the percentage of workers enrolled in a self-funded plan across companies of all sizes increased from 51% in 1999 to 65% in 2022. This increase is particularly stark for large employers, with the

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[14] *See* Appendix A entries for Alabama, Alaska, Arkansas, Florida, Idaho, Indiana, Kansas, Kentucky, Louisiana, Minnesota, Mississippi, Nebraska, North Dakota, Ohio, Oklahoma, Pennsylvania, South Carolina, South Dakota, Tennessee, Texas, Utah, and Wyoming (online at https://oversightdemocrats.house.gov/sites/democrats.oversight house.gov/files/Contraceptive%20Law%20Analysis%20-%20Appendix%20A.pdf).

[15] Collective Health, *Self-Funded or Fully-Insured Health Plans: What's Best for Your Company?* (May 4, 2022) (online at https://collectivehealth.com/blog/benefits-shop-talk/self-funded-or-fully-insured/); *see also* Connecticut State Office of the Healthcare Advocate, *For Employers: Differences Between State and Federal Regulation* (online at https://portal.ct.gov/OHA/ODCO/For-Employers/Self-vs-Fully-Funded).

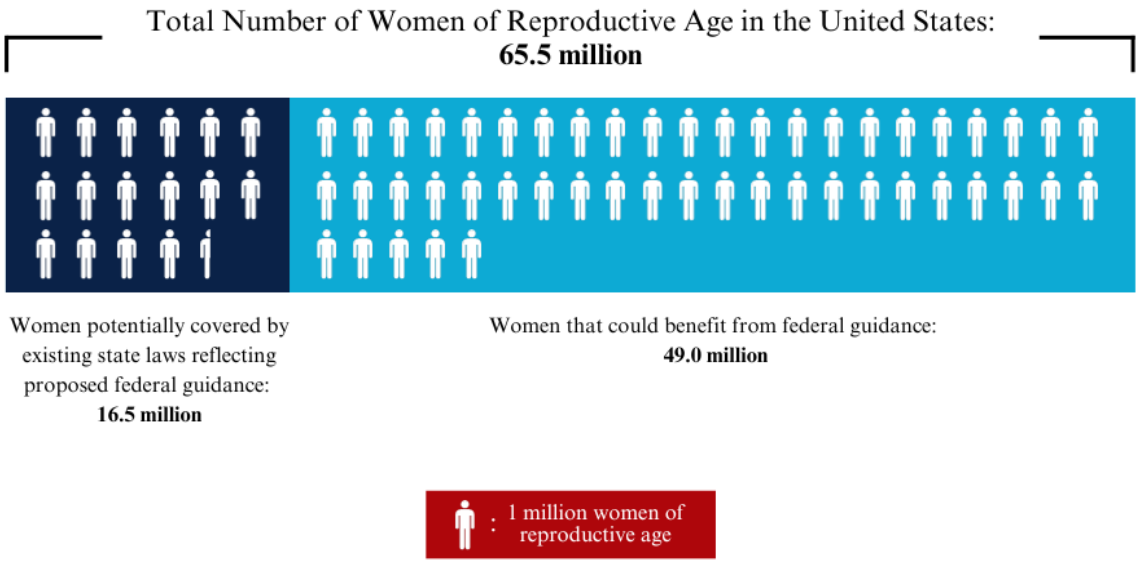
[16] *For Millions of Insured Americans, State Health Laws Don't Apply*, CNN Money (Nov. 21, 2017) (online at https://money.cnn.com/2017/11/21/pf/insured-americans-state-health-laws/index.html).

[17] Kaiser Family Foundation, *2022 Employer Health Benefits Survey* (Oct. 27, 2022) (online at www.kff.org/report-section/ehbs-2022-section-10-plan-funding/#:~:text=Sixty%2Dfive%20percent%20of%20covered,number%20of%20workers%20and%20dependents).

percentage of workers enrolled in self-funded plans for companies with 1,000 or more workers rising from 62% in 1999 to 88% in 2022.[18]

These self-funded insurance plans are not subject to most state insurance laws.[19] For individuals covered by self-funded plans, the only consumer protections available are federal.[20] As a result, millions of women of reproductive age could benefit from federal guidance that requires health plans to cover all FDA-approved contraceptive products that do not have a therapeutic equivalent without cost-sharing as part of every plan or formulary. This includes approximately 41.7 million women of reproductive age that live in the 39 states without state laws regarding cost-sharing for contraceptives reflecting the Committee's proposed guidance regarding therapeutic equivalents. It also includes approximately 22.4 million women of reproductive age who live in the other 11 states and the District of Columbia that have existing laws requiring coverage of branded contraceptives without cost-sharing unless a therapeutic equivalent exists, because those women are enrolled in self-funded insurance plans that are not subject to those state laws. Federal guidance could ensure that all people have access to no-cost contraception, including a substantial number of women in self-funded insurance plans across the country. As these 11 states and the District of Columbia demonstrate, codifying cost-sharing requirements to protect women of reproductive age is not novel or unfeasible.

Women of Reproductive Age Who Could Benefit from Proposed Federal Guidance on Contraceptive Coverage



Numbers have been rounded to the nearest half million.

Source: United States Census Bureau. Numbers represent women ages 15 to 44.

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[18] Kaiser Family Foundation, *2022 Employer Health Benefits Survey* (Oct. 27, 2022) (online at www.kff.org/report-section/ehbs-2022-section-10-plan-funding/).

[19] *See* National Health Law Program, Contraceptive Equity & Self Insurance (Dec. 2021) (online at https://healthlaw.org/wp-content/uploads/2021/12/CE-Self-Insurance-12082021-final.pdf) (Explaining that "fully-insured plans must comply with both state and federal contraceptive coverage laws, including state laws that mandate a higher level of benefits." In contrast, "employee-sponsored self-funded plans…are not subject to state mandates because their regulation is preempted by the Employee Retirement Income Security Act of 1974 (ERISA). Any for-profit company or non-profit organization can self-insure, and therefore not be required to comply with contraceptive equity laws, while the federal birth control requirement does apply to those plans.")

[20] Kaiser Family Foundation, *2016 Employer Health Benefits Survey* (Sept. 14, 2016) (online at www kff.org/report-section/ehbs-2016-section-ten-plan-funding/).

Access to contraception is particularly important for women of reproductive age in the United States in light of the Supreme Court's 2022 decision in *Dobbs v. Jackson Women's Health Organization*, which overturned the constitutional right to abortion. The 39 states that do not guarantee coverage without cost-sharing of all products—or a therapeutic equivalent—are disproportionately likely to have abortion bans or restrictive abortion laws.[21] For example, Alabama, Arkansas, Idaho, Indiana, Kentucky, Louisiana, Mississippi, North Dakota, Oklahoma, South Dakota, Tennessee, and Texas—none of which have state laws protecting contraception—represent 12 of the 14 states that currently ban abortion entirely.[22] In addition, these states overlap in large part with states where pregnant women and infants have worse health outcomes.[23]

These worse health outcomes disproportionately affect women of color, who already receive worse quality health care and have less access to care than white women.[24] For example, Black women are three to four times more likely to die in pregnancy than white women and five times more likely to die from pregnancy-related cardiomyopathy and blood pressure disorders than white women.[25] Black women are also disproportionately likely to live in the 26 states that had banned, or were likely to soon ban, abortion as of June 2023.[26] Notably, the majority of women of color—including the majority of Black women—access health insurance through employer-sponsored options.[27] As discussed above, employer-sponsored insurance includes self-funded plans where state laws protecting access to contraception would not apply. By implementing the Committee's proposed revisions to federal guidance, the Tri-Departments could ensure that millions of women of reproductive age have increased protections ensuring access to contraception without out-of-pocket costs.

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[21] *See* Guttmacher Institute, *State Policy Trends 2022: In a Devastating Year, U.S. Supreme Court's Decision to Overturn Roe Leads to Bans, Confusion and Chaos* (Dec. 19, 2022) (online at www.guttmacher.org/2022/12/state-policy-trends-2022-devastating-year-us-supreme-courts-decision-overturn-roe-leads).

[22] *Tracking Abortion Bans Across the Country*, New York Times (Sept. 29, 2023) (online at www nytimes.com/interactive/2022/us/abortion-laws-roe-v-wade html).

[23] See *States with the Toughest Abortion Laws Have the Weakest Maternal Supports, Data Shows*, NPR (Aug. 18, 2022) (online at www npr.org/2022/08/18/1111344810/abortion-ban-states-social-safety-net-health-outcomes).

[24] Department of Health and Human Services, Office on Women's Health, *Addressing Minority Women's Health* (last updated May 31, 2022) (online at www.womenshealth.gov/30-achievements/28).

[25] The Network for Public Health Law, *Racial Disparities in Women's Health* (Aug. 1, 2022) (online at www networkforphl.org/news-insights/racial-disparities-in-womens-health/).

[26] National Partnership for Women & Families, *State Abortion Bans Harm More than 15 Million Women of Color: Dobbs Impact Felt Nationwide* (June 2023) (online at https://nationalpartnership.org/report/state-abortion-bans-harm-woc/).

[27] National Partnership for Women & Families, *Despite Significant Gains, Women of Color Have Lower Rates of Health Insurance Than White Women* (Apr. 2019) (online at https://nationalpartnership.org/wp-content/uploads/2023/02/women-of-color-have-lower-rates-of-health-insurance-than-white-women.pdf); National Partnership for Women & Families, *Black Women Experience Pervasive Disparities in Access to Health Insurance* (Apr. 2019) (online at https://nationalpartnership.org/wp-content/uploads/2023/02/black-womens-health-insurance-coverage.pdf).