

# Congress of the United States

## House of Representatives

COMMITTEE ON OVERSIGHT AND ACCOUNTABILITY

2157 RAYBURN HOUSE OFFICE BUILDING

WASHINGTON, DC 20515-6143

MAJORITY (202) 225-5074  
MINORITY (202) 225-5051  
<https://oversight.house.gov>

May 16, 2024

Mr. Mostafa Kamal  
President and Chief Executive Officer  
Prime Therapeutics, LLC  
2900 Ames Crossing Road  
Eagan, MN 55121

Dear Mr. Kamal:

I write requesting information on Prime Therapeutics' plans for complying with guidance related to health plan coverage of contraception that was promulgated on January 22, 2024, by the Departments of Labor, Health and Human Services, and the Treasury (the Tri-Departments). Adopting the Tri-Departments' recommended approach on coverage of contraception is vital to ensuring that millions of women of reproductive age have increased access to no-cost contraception—something that is particularly important as Republicans continue to enact stringent bans on abortion across the country. I urge you to expeditiously enact the recommended approach, as well as respond to our request for information.

In May 2022, Oversight Committee Democrats requested information from four of the largest pharmacy benefit managers (PBMs), including you, and five of the largest health insurers in light of reports that health plans and issuers may not be fully complying with the Affordable Care Act's (ACA) requirement that contraceptive products be covered at no-cost to patients.<sup>1</sup> Specifically, we requested information related to patient cost-sharing obligations for Food and Drug Administration (FDA) approved contraceptive products, as well as the process patients can use to request a cost-sharing exception to access a contraceptive product at no cost when that product is not fully covered by the patient's plan.<sup>2</sup>

In October 2022, the Oversight Committee issued a report showing that most insurers and PBMs imposed cost-sharing requirements or coverage exclusions for more than 30 birth control

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<sup>1</sup> Committee on Oversight and Reform, *Press Release: Chairwoman Maloney Seeks Answers from Insurers and Pharmacy Benefit Managers on Birth Control Coverage* (May 27, 2022) (online at <https://oversightdemocrats.house.gov/news/press-releases/chairwoman-maloney-seeks-answers-from-insurers-and-pharmacy-benefit-managers-on>).

<sup>2</sup> Letter from Chairwoman Carolyn B. Maloney, Committee on Oversight and Reform, to Kenneth Paulus, President and Chief Executive Officer, Prime Therapeutics, LLC (May 26, 2022) (online at <https://oversightdemocrats.house.gov/sites/evo-subsites/democrats-oversight.house.gov/files/2022-05-26.CBM%20to%20Paulus-Prime%20Therapeutics%20re%20Contraceptive%20Mandate.pdf>).

products reviewed. These products were disproportionately likely to be newer products approved by the 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.<sup>3</sup> Our report also found that the nine companies surveyed denied requests to waive patients’ payment obligations for contraceptive products on average four or more times out of ten, despite Tri-Department guidance requiring that all products deemed “medically appropriate” by a patient’s medical provider be covered by that patient’s plan without cost-sharing.<sup>4</sup>

In light of these findings, the Committee recommended that the Tri-Departments update their guidance to encourage all FDA-approved contraceptive products that do not have a therapeutic equivalent be covered without cost-sharing as part of every plan or formulary. This would allow health plans and PBMs to use reasonable medical management techniques to prioritize the use of generic medications where possible, while ensuring that patients have access without cost-sharing to products that do not yet have a generic version.<sup>5</sup> A recent analysis by Oversight Committee Democratic staff determined that adopting the revised federal guidance for contraceptive coverage could make contraceptive products more affordable for tens of millions of women.<sup>6</sup>

On January 22, 2024, the Tri-Departments issued updated guidance for implementing the preventive services coverage provisions of the ACA, which includes coverage of contraceptive products. In this guidance, the Tri-Departments stated they “will generally consider” the approach recommended by the Oversight Committee in the 117th Congress—namely, an approach where plans and issuers cover without cost-sharing all FDA-approved contraceptive products without a therapeutic equivalent—as “reasonable” medical management by plans and issuers that is in line with Tri-Department guidance.<sup>7</sup> This provides plans and issuers with a clear path forward to ensure they are in compliance with Tri-Department guidance by adopting the Committee’s recommended approach to plan and formulary construction. This approach

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<sup>3</sup> 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/evo-subsites/democrats-oversight.house.gov/files/2022-10-25.COR%20PBM-Insurer%20Report.pdf>).

<sup>4</sup> *Id.*; 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](http://www.cms.gov/files/document/faqs-part-54.pdf)).

<sup>5</sup> 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/evo-subsites/democrats-oversight.house.gov/files/2022-10-25.COR%20PBM-Insurer%20Report.pdf>).

<sup>6</sup> Committee on Oversight and Accountability Democrats, *Staff Analysis: Revised Federal Guidance Regarding Contraceptive Coverage Could Benefit Millions of Women* (Dec. 6, 2023) (online at <https://oversightdemocrats.house.gov/sites/evo-subsites/democrats-oversight.house.gov/files/2023-12-06.COA%20DEMS%20Contraceptive%20Guidance%20Staff%20Analysis.pdf>).

<sup>7</sup> Department of Health and Human Services, Department of Labor, and Department of the Treasury, *FAQs About Affordable Care Act Implementation Part 64* (Jan. 22, 2024) (online at [www.cms.gov/files/document/faqs-part-64.pdf](http://www.cms.gov/files/document/faqs-part-64.pdf)).

would also decrease the number of patients covered by health plans and PBMs who need to rely on the plan or PBM's exceptions process to access contraceptive products deemed medically appropriate by their health care providers. This is particularly beneficial to health plans and PBMs because the Tri-Departments also emphasized in their January 2024 guidance that they "remain concerned that many [existing] exceptions processes do not meet the criteria outlined in the Departments' prior guidance."<sup>8</sup> The Committee has also found that processes in place to receive exceptions to cost-sharing requirements can be burdensome for patients and providers.<sup>9</sup>

Given the Committee's investigative findings that the coverage offered by health insurers and PBMs, including Prime Therapeutics, disproportionately imposed cost-sharing requirements on certain contraceptive products, and in light of the Tri-Department's recent guidance to better ensure that patients have no-cost access to those products, we request written responses to the following questions, as well as a staff briefing by May 30, 2024, on how Prime Therapeutics is responding to the Tri-Department's January 22, 2024, guidance and ensuring that all patients covered by your formularies have access at no-cost to the contraceptive products deemed medically appropriate by their health care providers.

1. Does Prime Therapeutics plan to adopt the approach recommended by the Tri-Departments in the January 22, 2024, guidance, in which plans and issuers would cover without cost-sharing all FDA-approved contraceptive products without a therapeutic equivalent?
  - a. If yes, by what date will this policy take effect at Prime Therapeutics?
  - b. How will this be communicated to patients and health care providers?
  - c. If not, why not?
2. Since the Committee's report in October 2022, what additional steps has Prime Therapeutics taken to ensure that all patients have access to contraceptive products deemed medically appropriate by their health care provider, in light of the Committee's findings in the 117th Congress that certain contraceptive products disproportionately require cost-sharing and that companies' exceptions processes are not adequate to ensure no-cost access to birth control?

The Committee on Oversight and Accountability is the principal oversight committee of the House of Representatives and has the broad authority to investigate "any matter" at "any time" under House Rule X.

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<sup>8</sup> *Id.*

<sup>9</sup> 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/evo-subsites/democrats-oversight.house.gov/files/2022-10-25.COR%20PBM-Insurer%20Report.pdf>).

Mr. Mostafa Kamal

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An attachment to this letter provides additional instructions for responding to this request. If you have any questions regarding this request, please contact Committee staff at (202) 225-5051.

Sincerely,



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Jamie Raskin  
Ranking Member

Enclosure

cc: The Honorable James Comer, Chairman