

Congress of the United States
House of Representatives

COMMITTEE ON OVERSIGHT AND REFORM

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WASHINGTON, DC 20515-6143

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

May 26, 2022

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

Dear Mr. Paulus:

The Oversight Committee is seeking information regarding no cost-sharing coverage of contraceptives and related services for individuals enrolled in private health plans, as required by the Affordable Care Act (ACA). Information obtained by the Committee suggests that plans and issuers may not be fully complying with the ACA's requirements, potentially depriving enrollees of access to critically important reproductive health care.

Under the ACA, all non-grandfathered private health plans must cover the full range of contraceptives and related services without beneficiary cost-sharing obligations. Although plans and issuers are allowed to use "reasonable medical management techniques" in administering benefits, each plan or issuer must cover at least one form of contraception for each Food and Drug Administration (FDA)-approved method without patient cost-sharing.¹

In 2015, the Centers for Medicare and Medicaid Services (CMS) issued guidance explaining that in order to meet these requirements, plans and issuers must have a cost-sharing exceptions process in place for situations when a health care provider determines that a patient requires a specific contraceptive that is not typically covered without cost-sharing under that patient's plan.² CMS made clear the exceptions process must be "easily accessible, transparent, and sufficiently expedient," and may not be "unduly burdensome on the individual or a provider."³

¹ National Women's Law Center, *Access to Birth Control Without Out-of-Pocket Costs: Improving and Expanding the Affordable Care Act's Contraceptive Coverage Requirement* (Nov. 16, 2021) (online at https://nwlc.org/wp-content/uploads/2021/11/final_Long_nwlc_2021_BC_AffordCareAct-003.pdf).

² Centers for Medicare and Medicaid Services, *FAQs About Affordable Care Act Implementation (Part XXVI)* (May 11, 2015) (online at www.cms.gov/cciiio/resources/fact-sheets-and-faqs/downloads/aca_implementation_faqs26.pdf); National Women's Law Center, *Access to Birth Control Without Out-of-Pocket Costs: Improving and Expanding the Affordable Care Act's Contraceptive Coverage Requirement* (Nov. 16, 2021) (online at https://nwlc.org/wp-content/uploads/2021/11/final_Long_nwlc_2021_BC_AffordCareAct-003.pdf).

³ Centers for Medicare and Medicaid Services, *FAQs About Affordable Care Act Implementation (Part*

However, public reporting and information obtained by the Committee indicates that some plans and issuers, including their pharmacy benefit managers (PBM), have not been in compliance with these requirements. For instance:

- Reports indicate that plans and issuers are routinely not covering without cost-sharing contraceptive products that were recently approved by FDA, in particular after 2011.⁴
- Even when plans and issuers adequately cover contraceptive products without cost-sharing obligations, those same plans and issuers are reportedly failing to cover without cost-sharing the services associated with contraception, such as office visits, counseling, or the insertion of a contraceptive device.⁵
- A recent investigative report found that when patients are denied coverage for a specific contraceptive product, plans and issuers do not always have in place an exceptions process that meets the requirements of CMS's 2015 guidance. The advocacy organization Power to Decide found that out of 42 health plans and PBMs, documents from only two health plans described an exceptions process that appears to meet the standards laid out in the 2015 CMS guidance. Notably, patients and providers may not even be aware that they can request an exception after coverage of a contraceptive product is denied, and calls to customer service representatives to inquire about the exceptions process "were met with ignorance, inadequate information, or misinformation." The report found that patients may be required to utilize a plan's regular formulary exceptions process or prior authorization process, which "do not appear to meet the ACA standards for contraceptive coverage, as they include medical review by the plan, typically set narrow criteria for an exception, and require information beyond what the ACA requires to make a determination of medical necessity."⁶

XXVI) (May 11, 2015) (online at www.cms.gov/cciiio/resources/fact-sheets-and-faqs/downloads/aca_implementation_faqs26.pdf); National Women's Law Center, *Access to Birth Control Without Out-of-Pocket Costs: Improving and Expanding the Affordable Care Act's Contraceptive Coverage Requirement* (Nov. 16, 2021) (online at https://nwlc.org/wp-content/uploads/2021/11/final_Long_nwlc_2021_BC_AffordCareAct-003.pdf).

⁴ National Women's Law Center, *The Biden Administration Must Ensure the Affordable Care Act Contraceptive Coverage Requirement Is Working for All* (Oct. 14, 2021) (online at https://nwlc.org/wp-content/uploads/2021/11/NWLC_BC_AffordCareAct-Oct_2021.pdf); Power to Decide, *When Your Birth Control Isn't Covered: Health Plan Non-Compliance with the Federal Contraceptive Coverage Requirement* (online at <https://powertodecide.org/sites/default/files/2022-04/ACA%20Contraception%20Exception%20Report.pdf>).

⁵ National Women's Law Center, *The Biden Administration Must Ensure the Affordable Care Act Contraceptive Coverage Requirement Is Working for All* (Oct. 14, 2021) (online at https://nwlc.org/wp-content/uploads/2021/11/NWLC_BC_AffordCareAct-Oct_2021.pdf).

⁶ Power to Decide, *When Your Birth Control Isn't Covered: Health Plan Non-Compliance With the Federal Contraceptive Coverage Requirement* (online at <https://powertodecide.org/sites/default/files/2022-04/ACA%20Contraception%20Exception%20Report.pdf>).

For all these reasons, we request that you provide us with the following information by June 9, 2022. Please limit your responses to the questions below to: (1) in-network coverage; (2) formularies for insurance plans that are not subject to a religious exemption under the ACA; (3) formularies for insurance plans that are not considered “grandfathered” plans under the ACA; and (4) FDA-approved products.

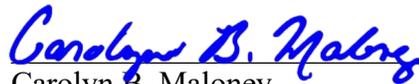
1. For each contraceptive method, please provide a list of the included contraceptive products and the patient’s cost-sharing requirement for each of your formularies.
 - a. For each contraceptive method, please identify any FDA-approved contraceptive products that are excluded from each of your formularies.
 - b. For each contraceptive method, what contraceptive products on each of your formularies were approved by the FDA after 2011?
2. Please describe the process for patients to access a contraceptive product that is not fully covered by the formulary for the patient’s plan when the product is determined necessary and appropriate by a patient’s medical provider.
 - a. What data and supporting documentation are patients required to provide in order to seek and receive an exception?
 - b. Upon the granting of an exception, what is the patient’s cost-sharing obligation (if any)? If this varies by contraceptive product, please provide the patient’s cost-sharing obligation broken down by product.
 - c. To the extent the exceptions process varies by product or formulary, please describe the various exceptions processes utilized by your formularies.
 - d. Is this exceptions process utilized for any services or products other than contraception? If so, for which products or services?
 - e. When a contraceptive product is not covered without cost-sharing, are patients ever required to utilize your appeals process to appeal this decision and obtain coverage?
 - f. On average, how long does it take for an exception request to be processed and granted to a patient seeking access to a contraceptive product?
 - g. Broken down by year, how many exceptions did you process from 2015 through 2021 for any contraceptive product or service?
 - h. Were any exceptions for contraceptive products denied from 2015 through 2021? If so, how many per year?

- i. What information do you provide to patients covered by your formularies regarding the contraception exception process? When and how is this information communicated to patients?
- j. What information do you provide to health care providers regarding the contraception exception process? When and how is this information communicated to providers?

For purposes of this request, “contraceptive method” refers to the category of contraceptive product. “Contraceptive product” refers to the specific product or brand included on your formularies. “Contraceptive services” refers to services provided by a clinician related to contraception. Examples of contraceptive services include, but are not limited to, counseling regarding contraceptive options, IUD insertion or removal, and sterilization procedures.

The Committee on Oversight and Reform is the principal oversight committee of the House of Representatives and has broad authority to investigate “any matter” at “any time” under House Rule X. 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. Thank you for your prompt attention to this matter.

Sincerely,


Carolyn B. Maloney
Chairwoman

Enclosure

cc: The Honorable James Comer, Ranking Member