

**Congress of the United States**  
**House of Representatives**  
**Washington, D.C. 20515**

October 6, 2021

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

The Honorable Martin J. Walsh  
Secretary  
U.S. Department of Labor  
200 Constitution Avenue, NW  
Washington, DC 20210

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

Dear Secretary Becerra, Secretary Walsh, and Secretary Yellen:

We are writing to request that the Department of Health and Human Services (HHS), the Department of Labor (DOL), and the Department of the Treasury (Treasury) (collectively, “the Departments”) ensure that the progress made by the Affordable Care Act (ACA) to provide individuals with coverage for the full range of Food and Drug Administration (FDA) approved contraceptives continues to be protected and enforced. We are concerned that health plans are not fully complying with the requirements under the law and accompanying regulations and guidance, and we seek the assistance of the Departments in ensuring that consumers have access to the full range of FDA-approved contraceptives without any cost-sharing.

Recently, we received information regarding numerous denials of coverage and extensive medical management requirements that have limited individuals’ access to the full range of FDA-approved contraceptives. These denials and medical management requirements appear to violate the ACA’s regulations which require group health plans and all issuers of group or individual health insurance coverage (other than grandfathered health plans) to cover without cost-sharing the full range of FDA-approved contraceptives.<sup>1</sup>

The ACA made clear that certain “preventive care and screenings” for women shall be covered without cost-sharing, “as provided for in comprehensive guidelines supported by the Health Resources and Services Administration (HRSA).”<sup>2</sup> These guidelines cover “all Food and

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<sup>1</sup> See 42 U.S.C. Sec. 300gg-13(a)(4); Health Resources and Services Admin., *Women’s Preventive Services Guidelines* ([www.hrsa.gov/womens-guidelines/index.html](http://www.hrsa.gov/womens-guidelines/index.html)) (accessed Oct. 6, 2021).

<sup>2</sup> 42 U.S.C. Sec. 300gg-13(a)(4).

Drug Administration approved contraceptive methods”<sup>3</sup> and the implementing regulations and guidelines published by the Departments further clarify that plans and issuers must cover without cost-sharing at least one form of contraception for each of the methods that is FDA-approved.<sup>4</sup> This means, for example, plans and issuers must cover without cost-sharing at least one hormonal intrauterine device, oral contraceptive pill, implantable rod, vaginal ring, patch, and each of the other approved methods as determined by the FDA.

The regulations and guidelines permit plans and issuers to utilize “reasonable” medical management techniques for coverage of forms *within* each method of contraception. However, the Departments also confirmed that should a plan cover only one form of a certain method of contraception, but a patient’s provider determines their patient needs a different form, then the plan must cover it without cost-sharing.<sup>5</sup> In addition, the Departments emphasized that in making these determinations the plan or issuer “must defer to the determination of the attending provider.”<sup>6</sup> Plans and issuers are also required to “have an easily accessible, transparent, and sufficiently expedient exceptions process that is not unduly burdensome on the individual or a provider (or other individual acting as a patient’s authorized representative).”<sup>7</sup>

Unfortunately, despite these regulations and guidelines, it appears that certain health insurance plans and issuers, as well as their pharmacy benefit managers (PBMs), are using medical management techniques beyond those permitted in regulations and are in contravention of the requirements under the law that ensure individuals can obtain coverage without cost-sharing for the full range of FDA-approved contraceptives.

Examples of these techniques include: denying coverage by requiring individuals to try other contraceptive methods prior to permitting coverage for the desired method; requiring patients try numerous other forms before permitting coverage of the desired form, beyond what could be considered “reasonable;” denying coverage for brand name contraceptive methods for which no generic equivalent exists; and failing to provide an acceptable exceptions process.

The ACA’s guarantee of coverage for the full range of FDA-approved contraceptives without cost-sharing has allowed individuals to choose the best birth control method for

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<sup>3</sup> Health Resources and Services Admin., *Women’s Preventive Services Guidelines* ([www.hrsa.gov/womens-guidelines/index.html](http://www.hrsa.gov/womens-guidelines/index.html)) (accessed Oct. 6, 2021).

<sup>4</sup> U.S. Department of Labor, *FAQs About Affordable Care Act Implementation (Part XXVI)* (May 11, 2015) ([www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-xxvi.pdf](http://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-xxvi.pdf)); *see also* Centers for Medicare & Medicaid Services, *Affordable Care Act Implementation FAQs – Set 12* ([www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca\\_implementation\\_faqs12](http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs12)) (accessed Oct. 6, 2021).

<sup>5</sup> U.S. Department of Labor, *FAQs About Affordable Care Act Implementation (Part XI)* (Feb. 20, 2013) ([www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-xii.pdf](http://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-xii.pdf)) (“If, however, a generic version is not available, or would not be medically appropriate for the patient as a prescribed brand name contraceptive method (as determined by the attending provider, in consultation with the patient), then a plan or issuer must provide coverage for the brand name drug in accordance with the requirements of the interim final regulations (that is, without cost-sharing, subject to reasonable medical management)”).

<sup>6</sup> U.S. Department of Labor, *FAQs About Affordable Care Act Implementation (Part XXVI)* (May 11, 2015) ([www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-xxvi.pdf](http://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-xxvi.pdf)).

<sup>7</sup> *See* note 4.

themselves and has resulted in women increasingly utilizing more effective methods of contraceptives, or utilizing methods, such as oral contraceptives, in a more consistent manner.

Given the serious concerns raised by these denials of coverage, we ask for the Departments' assistance in ensuring appropriate consumer access to the full range of FDA-approved contraceptives as required by law. We request that the Departments examine the appended examples of what we believe constitutes impermissible coverage denials and medical management and evaluate whether additional enforcement actions or the issuance of additional guidance may be merited. We also request a response to our letter and a staff briefing to the committees on the enforcement and oversight efforts by the Departments relating to this matter by October 15, 2021.

If you have any questions about this request, please contact Jacquelyn Bolen of the Energy and Commerce Committee at (202) 225-2927, Zach Baron of the Ways and Means Committee at (202) 225-3625, Daniel Foster of the Education and Labor Committee at (202) 225-3725, and Miles Lichtman of the Oversight and Reform Committee at (202) 225-5051. Thank you for your prompt attention to this important matter.

Sincerely,



Frank Pallone, Jr.  
Chairman  
Committee on Energy and Commerce



Richard E. Neal  
Chairman  
Committee on Ways and Means



Robert C. "Bobby" Scott  
Chairman  
Committee on Education and Labor



Carolyn B. Maloney  
Chairwoman  
Committee on Oversight and Reform