

VIA ELECTRONIC MAIL:

June 27, 2022

Dear Group Health Plan Sponsors and Issuers:

We are writing on behalf of the Department of Health and Human Services, the Department of Labor, and the Department of the Treasury (collectively, the Departments) regarding contraceptive coverage. The Affordable Care Act (ACA) ensures access to coverage, without cost-sharing, for birth control and contraceptive counseling for individuals enrolled in group health plans and group and individual health insurance coverage.¹ In 2020 alone, 58 million women had access to preventive services without cost sharing as a result of the ACA.² The Departments oversee this provision of the law and work together to ensure that individuals have access to this critical coverage. Regrettably, there have been troubling and persistent reports of noncompliance with these requirements.³

For this reason, we are calling on your organizations to remove impermissible barriers and ensure individuals in your plans have access to the contraceptive coverage they need, as required under the law. It is more important than ever to ensure access to contraceptive coverage without cost sharing, as afforded by the ACA.

Despite the ACA contraceptive coverage requirement being over a decade old, the Departments continue to receive complaints of non-compliance. We continue to be concerned about these complaints and may take enforcement or other corrective actions as appropriate.

Non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual health insurance coverage must comply with the requirements under section 2713 of the Public Health Service (PHS) Act (incorporated into section 715 of the Employee Retirement Income Security Act (ERISA) and section 9815 of the Internal Revenue Code (Code))

¹ See 26 CFR 54.9815-2713; 29 CFR 2590.715-2713; 45 CFR 147.130. See also HRSA Women's Preventive Service Guidelines, available at <u>https://www.hrsa.gov/womens-guidelines/index.html</u>; and FAQs About Affordable Care Act Implementation (Part XII) (Feb. 20, 2013), available at <u>https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-xii.pdf</u> and <u>https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs12.</u>

² The 58 million estimate includes women 19-64 years old who had non-grandfathered private health coverage in 2020. ASPE, Access to Preventive Services without Cost-Sharing: Evidence from the Affordable Care Act (Jan. 11, 2022), available at <u>https://aspe.hhs.gov/sites/default/files/documents/786fa55a84e7e3833961933124d70dd2/preventive-services-ib-2022.pdf</u>.

³ Reports of noncompliance have been documented by Members of the U.S. House of Representatives (in <u>2021</u> and <u>2022</u>) and the U.S. Senate (in <u>2021</u> and <u>2022</u>), the <u>National Women's Law Center</u>, other <u>nonprofit organizations</u>, and <u>media reports</u>.

and its implementing regulations, by providing coverage without cost sharing for preventive care and screenings. This requirement importantly includes coverage of the full range of contraceptive products approved, cleared, or granted by the Food and Drug Administration (FDA). The Departments have published multiple rounds of federal guidance since 2013⁴ to clarify and reinforce these requirements. Our position is clear: efforts by plans and issuers to implement costcontrol measures cannot outweigh the law protecting consumers' health and contraceptive needs, as determined by their attending provider in consultation with the patient.

The ACA requires that all FDA-approved, cleared, or granted contraceptive products that are determined by an individual's medical provider to be medically appropriate for the individual must be covered under the individual's non-grandfathered group health plan or health insurance coverage without cost sharing.

Specifically, plans and issuers are required to cover without cost sharing at least one form of contraception in each contraceptive category, as well as contraceptive services or FDA-approved, cleared, or granted contraceptive products that an individual and their attending provider have determined to be medically appropriate for the individual.⁵ This coverage must also include the clinical services, including patient education and counseling, needed for the provision of the contraceptive product or service, and items and services that are integral to the furnishing of the recommended preventive service, regardless of whether the item or service is billed separately. Within each category, plans and issuers may utilize reasonable medical management techniques but may not apply medical management techniques across categories. If using reasonable medical management take an easily accessible, transparent, and sufficiently expedient exceptions process that is not unduly burdensome on the individual or their provider (or other individual acting as a patient's authorized representative) and must defer to the recommendation of the attending provider.

We strongly encourage plans and issuers to immediately ensure they are in compliance with these standards to avoid future enforcement actions. Steps should include:

- Developing an easily accessible, transparent, and sufficiently expedient exceptions process for contraceptive products that is not unduly burdensome to the individual, provider, or other

⁴ <u>See</u> FAQs About Affordable Care Act Implementation (Part XII) (Feb. 20, 2013), available at <u>https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-xii.pdf</u> and <u>https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs12;</u>

FAQs About Affordable Care Act Implementation (Part XXVI) (May 11, 2015), available at https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-xxvi.pdf and https://www.cms.gov/CCIIO/resources/fact-sheets-and-faqs/downloads/aca_implementation_faqs26.pdf;

FAQs About Affordable Care Act Implementation Part 31, Mental Health Parity Implementation, and Women's Health and Cancer Rights Act Implementation (April 20, 2016), available at

https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-31.pdf and https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-31_Final-4-20-16.pdf;

and FAQs About Affordable Care Act Implementation Part 51, Families First Coronavirus Response Act and Coronavirus Aid, Relief, and Economic Security Act Implementation (Jan. 10, 2022), available at https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-51.pdf and https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-Part-51.pdf.

⁵ <u>See</u> FAQs About Affordable Care Act Implementation Part 51, Families First Coronavirus Response Act and Coronavirus Aid, Relief, and Economic Security Act Implementation (Jan. 10, 2022), available at <u>https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-51.pdf</u> and <u>https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-Part-51.pdf</u>.

individual acting as a patient's authorized representative) if one is not already in place (i.e., not requiring individuals to appeal an adverse benefit determination for a contraceptive using the plan's or issuer's internal claims and appeals process as the means to obtain an exception).

- Reviewing exceptions processes for contraceptive products to ensure that these processes are easily accessible, transparent, sufficiently expedient, and not unduly burdensome on the individual or provider (or other individual acting as a patient's authorized representative).
- Developing and using a standard form and instructions for the exceptions process. (See the Medicare Part D Coverage Determination Request Form if a model for developing a standard exception form is needed.⁶)
- Ensuring that information regarding the availability of and the instructions for the exceptions process, including any standard form, are clearly described to individuals and their providers in plan documentation and online resources.
- Deferring to an attending provider's recommendation regarding a contraceptive product based on a determination of medical necessity in consultation with their patient.
- Eliminating the application of overly-burdensome, inappropriate, and unreasonable medical management techniques.

Plans and issuers must meet their obligations to ensure access to contraception.

Shortly, the Departments will convene a meeting with national leaders where we expect commitment from the industry to promptly correct all areas of potential non-compliance and to take specific actions to ensure that covered individuals have critical access to contraceptive services. We invite you to contact us if you have any questions on ensuring compliance with section 2713 of the PHS Act (as incorporated into ERISA and the Code) and implementing regulations and guidance. If you have any questions regarding this matter, please contact Contraception Complaints@cms.hhs.gov.

Sincerely,

Xavier Becerra Secretary Department of Health and Human Services

Janet L. Yeller

Janet L. Yellen Secretary Department of Treasury

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Martin J. Walsh Secretary Department of Labor

⁶ A copy of Medicare Part D Coverage Determination Request Form is available at <u>https://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/CoverageDeterminations-</u>.