



August 9, 2017

Scott Gottlieb, M.D., Commissioner
U.S. Food and Drug Administration
Department of Health and Human Services
10903 New Hampshire Avenue
Silver Spring, MD 20993

Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue SW.,
Washington, DC 20201

Dear Commissioner Gottlieb and Administrator Verma:

On behalf of the American Academy of Family Physicians (AAFP), which represents 129,000 family physicians and medical students across the country, I write to urge the U.S. Food and Drug Administration (FDA) and the Centers for Medicare & Medicaid Services (CMS) endorse and implement policies and coverage decisions that allow adolescents, regardless of age, be included in the over-the-counter (OTC) oral contraceptives studies required by the FDA (e.g., label comprehension study, actual use study). Including them in such studies would help determine whether OTC access is appropriate for this population. This request stems from a resolution adopted by the AAFP's policy-making body, the Congress of Delegates.

Furthermore, we request your agencies review and revise, as necessary, its consideration and coverage of contraceptive options to include coverage of all FDA-approved contraceptive options for men and women of reproductive age enrolled in Medicare and Medicaid. The AAFP believes there are benefits to having access to all FDA-approved contraceptive options for those who wish to use them.

Although the majority of Medicare beneficiaries are ages 65 and older, almost 920,000 women ages 18 to 44 received insurance coverage through Medicare in 2011. Contraception is an often-overlooked aspect of care for women with chronic conditions and disabilities. Among the 19.4 million women ages 15 and older with full Medicaid benefits in 2011, those in their reproductive years (ages 15 to 49) accounted for 70 percent of enrollment nationwide. All Medicaid programs must cover family planning services and supplies without cost-sharing. However, since there is no federally defined standard for family planning, the range of contraceptive products and services that states cover varies by state and differs depending on how an individual qualifies for Medicaid.

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We urge the FDA and CMS to improve contraceptive coverage for Medicaid patients by defining a standard applicable across all states.

The AAFP has a policy of supporting Medicare coverage for all FDA-approved methods of contraception and other policies in support of reversible contraception methods, including long-acting reversible contraceptives, and over-the-counter oral contraceptives. Many men and women insured through public programs, like Medicare and Medicaid, do not benefit from the same comprehensive contraceptive coverage as those with private health insurance without cost-sharing. Hence, these men and women are vulnerable to gaps in contraceptive coverage and/or shouldering higher out-of-pocket costs for birth control.

Affordable access to all FDA-approved contraception options is still not within the reach of all men and women in the U.S. Therefore, we respectfully ask the FDA and CMS to expand its coverage of contraceptive options to all FDA-approved contraceptive options for men and women of reproductive age, enrolled in Medicare and Medicaid.

We appreciate the opportunity to provide this recommendation and request a response. Please contact Robert Bennett, Federal Regulatory Manager, at 202-232-9033 or rbennett@aafp.org with any questions or concerns.

Sincerely,

A handwritten signature in black ink that reads "Wanda D. Filer, MD". The signature is written in a cursive, flowing style.

Wanda D. Filer, MD, MBA, FAAFP
Board Chair