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Federal Agencies Issue FAQs for Women's Contraceptive Coverage under the ACA

On July 28, 2022, the Departments of Health and Human Services, Labor, and the Treasury ("the Departments") issued guidance in the form of frequently asked questions (the FAQs) clarifying protections for contraceptive coverage under the preventive services mandate of the Affordable Care Act (ACA). The FAQs follow an executive order issued by President Biden to support access to reproductive care following the Supreme Court decision overturning *Roe v. Wade* on June 24th. The guidance makes clear that non-grandfathered group health plans and health insurance issuers without a religious or moral exemption must provide mandated contraceptive coverage, including emergency contraception, at no cost to participants.

This guidance reiterates many of the existing contraceptive and reproductive health coverage requirements with the intent to remind plans and insurers of their obligations under the ACA. In function, the FAQs are less about breaking new ground and more about the Departments providing additional examples of required coverage and permitted plan administration. However, the emphasis on coverage and preemption is evident, and the Departments have made clear that this will be an enforcement priority.

What we already knew

Under the ACA's preventive services mandate, group health plans and insurers must cover, without cost sharing, women's contraceptives consistent with guidelines issued by the Health Resources and Services Administration (HRSA). Group health plans and issuers must cover these items and services no later than the plan year beginning one year after HRSA publishes a guideline (or updates guidance for an existing guideline). The most recent HRSA guidelines appeared in 2019, updated in December 2021, and received additional clarifications in January 2022.

The 2019 guidelines require plans and insurers to provide the full range of female-controlled and FDA-approved contraceptive methods, effective family planning practices, and sterilization procedures to prevent unintended pregnancy and improve birth outcomes. This coverage includes counselling, initiation of contraceptive use, and follow-up care, as well as instruction in fertility awareness-based methods for individuals interested in alternative methods of contraception.

The December 2021 guidance, effective for plan years beginning in 2023, included several updated recommendations for breastfeeding services and supplies, contraceptives, and HIV screening along with other services. In that guidance, the Department of Health and Human Services (HHS) and HRSA clarified that the ACA's preventive services mandate includes coverage for women to obtain male condoms for pregnancy prevention with a prescription. The guidance also defined contraceptive follow-up care to include the management, evaluation of, and changes to a contraceptive (e.g., the removal, continuation, or discontinuation of a contraceptive).

In January 2022, HHS issued additional guidance restating that plans and insurers must cover, without cost-sharing, all FDA-approved, cleared, or granted contraceptive products deemed medically appropriate by an individual's provider, even when the FDA does not specifically identify the product its Birth Control Guide.

The new FAQs

The FAQs include 14 questions and answers clarifying various aspects of the ACA's existing contraceptive coverage requirements. Highlights from the FAQs appear below. References to "plans" generally means a combination of medical and prescription drug coverage.

- Integral Items and Services: Plans must cover items and services that are integral to providing a recommended preventive service. For example, they must cover anaesthesia for a tubal ligation procedure or a pregnancy test before insertion of an IUD. Plans and insurers must cover these integral services without cost sharing even when providers bill the preventive item or service separately.

- Fertility Awareness-Based Methods: The FAQs confirm that plans must cover instruction in fertility awareness-based methods of contraception, including the lactation amenorrhea method. The Departments explain that, while the updated guidelines no longer recommend this specific coverage, they consider it part of "screening, education, counselling, and provision of contraceptives."[1]

- Coverage Extends Beyond HRSA-Specified Categories: The FAQs restate that plans must cover, at least one form of contraception in each HRSA category without cost sharing. The plan must also cover any contraceptive services and FDA-approved, cleared, or granted contraceptive products that a provider determines to be medically appropriate. This means the plan must cover the contraceptive products and services even if they are not included in one of the eighteen (18) categories of contraception listed in the HRSA guidelines (e.g., copper IUDs, oral and emergency contraception).

- Emergency Contraception: Plans must cover FDA-approved emergency contraception without cost sharing when prescribed by a provider, including products sold over-the-counter (OTC). While not required, the FAQs encourage plans and insurers to cover OTC emergency contraceptives without cost sharing even when purchased without a prescription.

- HSAs, FSAs, and HRAs for OTC Contraception: The FAQs clarify that HSAs, HRAs, and health FSAs may reimburse the cost of OTC contraceptives as long as another plan or form of coverage does not pay for or reimburse the expense (i.e. no tax-free double dipping on the same expense). Plans covering OTC contraceptives should communicate this spending account reimbursement limitation to participants.

- Reasonable Medical Management: Plans may use reasonable medical management techniques within a specified category of contraception, but only to the degree a HRSA recommendation or guideline does not specify the frequency, method, treatment, or setting for the provision of a recommended product or service. denying coverage for a particular contraceptive product despite a provider's declaration of medical necessity or imposing an age limit on contraceptive coverage.

  The FAQs also clarify that plans and insurers should make available a transparent, accessible, and expedient exceptions process to obtain these services. Requiring a participant to appeal an initial adverse benefit determination through the normal claims and appeals process does not meet this standard.

  The FAQs provide examples of unreasonable techniques, including:

  (1) Denying coverage for all or particular brand name contraceptives even after deemed medically necessary by a health care provider for a participant;

  (2) Requiring individuals to "fail first" using contraceptives in the same category of contraception before the plan will approve coverage for a different medically necessary contraceptive product;

[1] https://www.hrsa.gov/womens-guidelines/index.html

(3) Requiring individuals to "fail first" using contraceptives in other contraceptive categories before the plan will approve coverage in a different contraceptive category; and

(4) Imposing an age limit on contraceptive coverage.

- Preemption of More Restrictive State Laws: The FAQs restate that federal law preempts any state law that prevents complying with the ACA's contraceptive coverage mandate. While states have primary enforcement authority over insurers regarding the preventive services requirements, HHS will assume enforcement responsibility if it determines that a state fails to substantially enforce them. The FAQs remind plans and insurers that the Departments can impose civil monetary penalties for failing to comply with these requirements and require reprocessing of mishandled claims.

Next steps

Employers sponsoring self-insured plans should review their plan design and administration with their third party administrators to confirm the plan complies with the clarifying guidance from the FAQs. Employers may also wish to confirm this information with their legal counsel. Employers sponsoring fully insured coverage should be able to rely on confirmation from the insurer that a plan complies with the ACA's preventive services mandate.

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