

Departments Release Updated Guidance for Contraception Coverage

September 1, 2022

Quick Facts

- Under the Affordable Care Act (ACA), all non-grandfathered individual and group health plans are required to provide preventive services coverage with no cost-sharing.
- The list of required preventive services includes contraception.
- The Departments of Labor (DOL), Health and Human Services (HHS), and the Treasury (collectively, the Departments) issued a new set of [frequently asked questions](#) (FAQs) that clarify the requirements for contraception coverage under the Affordable Care Act's (ACA's) preventive services coverage mandate.
- Plans who do not comply with the requirements may be subject to penalties under the Internal Revenue Code (Code) and the Public Service Health Act (PSHA).

Background

In response to the number of complaints the Departments receive, they issued a set of [frequently asked questions](#) (FAQs) in August 2022 that clarify the requirements for contraception coverage under the Affordable Care Act's (ACA's) preventive services coverage mandate.

Under the ACA, all non-grandfathered individual and group health plans are required to provide preventive services coverage with no cost-sharing. The list of preventive services required to be covered at 100% includes:

- Evidence-based items or services that have in effect a rating of "A" or "B" in the current recommendations of the United States Preventive Services Task Force (USPSTF)
- Immunizations for routine use in children, adolescents, and adults that have in effect a recommendation from the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC)
- Evidence-informed preventive care and screenings provided for in the comprehensive guidelines supported by the Health Resources and Services Administration (HRSA) for infants, children, and adolescents
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NOTE: This list is updated by the appropriate departments/agencies over time. The requirements are summarized on [Healthcare.gov](#).

The HRSA guidelines include contraceptives.

Summary of Frequently Asked Questions Part 52

Coverage of Related Items and Services

The requirement for plans and carriers to cover items and services integral to the furnishing of a recommended preventive service also applies to coverage of contraceptive services under the HRSA-Supported Guidelines, including coverage for anesthesia for a tubal ligation procedure or pregnancy tests needed before provision of certain forms of contraceptives (e.g., an intrauterine device, or IUD), regardless of whether the items and services are billed separately.

Coverage of Items and Services Not Described in HRSA-Supported Guidelines

As noted above, plans and carriers must provide 100% coverage of contraceptive products and services that are included in a category of contraception described in the HRSA-Supported Guidelines.

In addition, as previously clarified in [guidance](#) issued earlier this year, plans and carriers must also cover products and services that are not included in a category of contraception described in the HRSA-supported guidelines if a provider has determined the product or service to be medically appropriate for the individual.

Note that this includes products more recently cleared, approved, or granted by the Food and Drug Administration (FDA) that may not be specifically included in the [FDA's Birth Control Guide](#) referenced in the HRSA guidelines. Coverage must also include the clinical services needed for provision of the contraceptive product or service.

Medical Management Techniques and Exceptions

A substantial portion of the FAQs is devoted to clarification of appropriate medical management techniques and exceptions processes.

Medical Management Techniques

A plan or carrier may use medical management techniques:

- For HRSA-recommended contraception within a category so long as at least one method is covered, HRSA guidelines do not speak to the frequency, method, treatment, or setting for the service or product, and there is an exception process when provider determines another method to be medically necessary; and
- For other contraceptive services or FDA-approved products if multiple, substantially similar services or products that are not included in a category described in the guidelines are available and are medically appropriate for the individual and are covered when a provider determines a product or service to be medically necessary, subject to an exceptions process.

Examples of unreasonable medical management techniques include:

- Denying coverage for all or particular brand name contraceptives, even after an individual's provider determines that the service or product is medically necessary;
- Requiring individuals to fail first using other services or products within the same category or before the plan approves coverage for the service or product that a provider deems medically necessary;
- Requiring individuals to fail first using other services or products within other categories of contraception before the plan approves coverage for a service or product; and

- Imposing an age limit on contraceptive coverage instead of providing benefits to all individuals with reproductive capacity.

Exceptions Process

Any exceptions process used must not be unduly burdensome (which is to be determined by facts and circumstances) and must cover a service or FDA-approved, cleared, or granted product that a provider determines is medically necessary for an individual. The guidance outlines requirements for a transparent exceptions process:

- Plans and carriers may not require individuals to use their formal internal claims and appeals process as a means for obtaining an exception.
- Plan documentation (in or alongside the summary plan description [SPD]) should include relevant information regarding the process, including how to request an exception without initiating an appeal.
- The process should be in a format and manner that is readily accessible (electronically or on paper).
- Plans and carriers are strongly encouraged to use a standard form and instructions, similar to the Medicare Part D Coverage Determination Request Form.

Emergency Contraception

Plans and carriers must cover FDA-approved emergency contraception, including emergency contraception that is available over the counter (OTC) when it is prescribed. The guidance also encourages plans to cover OTC emergency contraceptive products with no cost sharing when they are purchased without a prescription.

Coverage of Instruction for Fertility Awareness-Based Methods

Current HRSA guidelines recommend “screening, education, counseling, and provision of contraceptives (including in the immediate postpartum period).” Counseling and education include instruction in fertility awareness-based methods, including lactation amenorrhea for women desiring an alternative method.

Use of Account-Based Plans for OTC Contraceptives

A health savings account (HSA), health flexible spending account (HFSA), or health reimbursement arrangement (HRA) can reimburse an individual for the cost (or portion of the cost) incurred for OTC contraception to the extent that cost is not paid or reimbursed by another plan or coverage.

Dispensing 12-Month Supply at One Time

Plans and carriers are encouraged (although not required) to cover the dispensing of a 12-month supply of contraception, such as oral contraceptives, without cost sharing.

Federal Preemption of State Law

Federal law preempts state laws that prevent coverage of contraception in accordance with the requirements of the preventive services mandate. While states have primary enforcement responsibilities for noncompliance by insurers, HHS will enforce the requirements if it believes a state has failed to do so. The FAQs also describe how the Employee Benefits Security Administration (EBSA), and Centers for Medicare and Medicaid Services (CMS) will work with plans as part of their regulatory oversight to ensure that plans are in compliance with the preventive services mandate as it applies to contraception.

Information for Individuals with Complaints

Finally, the FAQ provides contact information for individuals who have concerns or complaints about how their plans are complying with the preventive services mandate.

Effective Date

The FAQ emphasizes that the most current HRSA guidelines were issued in 2019 and were recently updated in 2021.

- In 2019, HRSA recommended that adolescent and adult women have access to the full range of female-controlled FDA-approved contraceptive methods, effective family practices, and sterilization procedures as part of contraceptive care. Contraceptive care should include contraceptive counseling, initiation of contraceptive use, and follow-up care, along with instruction in fertility-based methods for women desiring an alternative method.¹
- In December 2021, updates were made to the HRSA guidelines regarding access to contraceptives and contraceptive counseling. Specifically, the guidelines clarified that women be allowed to purchase male condoms and updated the definition of contraceptive follow-up care to include the management, evaluation, and changes to a contraceptive (e.g., removal, continuation, or discontinuation of a contraceptive).

Generally, plans must comply with updated coverage requirements one year after those updated recommendations are issued. Therefore, current plans should be in compliance with the 2019 guidelines and should begin complying with the 2021 updates for plan years starting on and after December 30, 2022.

Additionally, as noted above, it is important to remember that plans and carriers must also cover products and services that are not included in a category of contraception described in the HRSA-supported guidelines if an individual and their attending provider have determined the product or service to be medically appropriate for the individual, including contraceptive products more recently approved, cleared, or granted by the FDA.

Penalties for Non-Compliance

Violations may be subject to an excise tax under section 4980D of the Internal Revenue Code or a civil money penalty under section 2723 of the PSHA (generally \$100/day with respect to each participant to whom such failure relates) as applicable.

Conclusion

This latest set of guidance follows a recent letter issued by the Departments encouraging group health plans to full comply with the requirement to cover contraceptives with no cost-sharing.

As the Departments continue to receive complaints of non-compliance, and in light of the myriad issues facing both the preventive services mandate as a whole and the contraceptive coverage requirement in particular (i.e., the recent Supreme Court decision potentially making it more difficult to access abortions; continued questions about the extent of exemptions that apply to religious

¹ The range of identified categories of contraception in the 2019 guidance include: (1) sterilization surgery for women, (2) surgical sterilization via implant for women, (3) implantable rods, (4) copper intrauterine devices, (5) intrauterine devices with progestin (all durations and doses), (6) the shot or injection, (7) oral contraceptives (combined pill), (8) oral contraceptives (progestin only), (9) oral contraceptives (extended or continuous use), (10) the contraceptive patch, (11) vaginal contraceptive rings, (12) diaphragms; (13) contraceptive sponges, (14) cervical caps, (15) female condoms, (16) spermicides, (17) emergency contraception (levonorgestrel), and (18) emergency contraception (ulipristal acetate); and additional methods as identified by the FDA. Plans and carriers must cover without cost sharing at least one form of contraception in each of the categories above.

employers and employers with moral or religious objections to contraception; and another lawsuit challenging the constitutionality of the preventive services mandate now residing before a federal judge in Texas²); the Departments are working to make it as clear as possible what they expect from a compliance perspective and what potential penalties plans, carriers, and even states may face for failure to comply or enforce compliance with the law's requirements as they stand today.

EPIC Employee Benefits Compliance Services

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² [Kelley v. Becerra](#)