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On July 28, 2022, the Departments of Labor, Health and Human Services and the Treasury (collectively, “the Departments”) issued FAQ Part 54 to clarify protections for contraceptive coverage under the Affordable Care Act (the “ACA”). In January 2022, the Departments had issued guidance on the ACA Preventive Care Mandate, including contraception.

## Background

As background, non-grandfathered group health plans must cover certain in-network preventive care items and services without cost-sharing. This includes, with respect to women, contraceptive services.

On December 30, 2021, the Health Resources and Services Administration (“HRSA”) expanded the 2019 recommendation to include contraceptives that are not female-controlled, such as male condoms (which must be covered by the plan when prescribed).

Changes in recommendations or guidelines are typically applicable on the first day of the plan year that begins on or after the date that is one year after the date on which the recommendation or guideline is issued. Therefore, plans and issuers must currently provide coverage consistent with the new 2021 guidelines beginning with plan years starting on and after December 30, 2022 (compliance for calendar year plans begins on January 1, 2023).

## FAQ Part 54

The Departments issued FAQ Part 54:

- In response to reports that individuals continue to experience difficulty accessing contraceptive coverage without cost sharing;
- To clarify application of the contraceptive coverage requirements to fertility awareness-based methods and to emergency contraceptives; and
- To address federal preemption of state law.

The Departments specifically note their commitment to ensuring access to contraceptive benefits without cost-sharing as entitled under the law and will take enforcement action as warranted. Violations may be subject to an excise tax of \$100 per day per affected individuals under Code Sec. 4980D.

Briefly, the FAQs provide the following clarifications:

- Plans must cover, without cost sharing, items and services that are integral to the furnishing of recommended preventive services, such as anesthesia for a tubal ligation procedure or pregnancy tests needed before provision of certain forms of contraceptives, such as an intrauterine device (also known as an IUD), regardless of whether the items and services are billed separately.
- In addition to what's outlined in the HRSA guidelines, plans must cover without cost sharing any contraceptive services and FDA approved, cleared, or granted contraceptive products that an individual and their attending provider have determined to be medically appropriate, whether or not those services or products are specifically identified in the categories listed in the HRSA-guidelines, including contraceptive products more recently approved, cleared, or granted by the FDA.
- Consistent with previous guidance (and as supported by HRSA guidelines), plans must cover, without cost sharing, (1) FDA-approved emergency contraception

(levonorgestrel), and (2) emergency contraception (ulipristal acetate), including OTC products, when the product is prescribed for an individual by their attending provider. This includes when they are prescribed for advanced provision. The Departments encourage (but do not require) plans to cover dispensing of a 12-month supply of contraception (such as oral contraceptives) at one time without cost-sharing.

- Confirms the 2021 HRSA guidelines include “screening, education, counseling, and provision of contraceptives (including in the immediate postpartum period). This includes instruction in fertility awareness-based methods, including lactation amenorrhea.
- The guidance reaffirms that a health savings account (“HSA”), a health reimbursement arrangement (“HRA”) and a health flexible spending account (“FSA”) 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. Plans that cover the costs of OTC contraceptives without a prescription should advise individuals not to seek reimbursement from these tax favored accounts (no double dipping).

The FAQ further highlights when medical management may (and may not) be used for contraceptives. Specifically, the Departments caution plans and issuers of implementing burdensome, unreasonable medical management techniques which included situations such as:

- Denying coverage for all or particular brand name contraceptives, even after the individual's attending provider determines and communicates to the plan or issuer that a particular service or FDA-approved, cleared, or granted contraceptive product is medically necessary with respect to that individual;
- Requiring individuals to fail first using numerous other services or FDA-approved, cleared, or granted contraceptive products within the same category of contraception before the plan or issuer will approve coverage for the service or FDA-approved, cleared, or granted contraceptive product that is medically necessary for the individual, as determined by the individual's attending health care provider.

- Requiring individuals to fail first using other services or FDA-approved, cleared, or granted contraceptive products in other contraceptive categories before the plan or issuer will approve coverage for a service or FDA-approved, cleared, or granted contraceptive product in a particular contraceptive category.
- Imposing an age limit on contraceptive coverage instead of providing these benefits to all individuals with reproductive capacity.
- Requiring a participant or beneficiary to go through the plan's or issuer's internal claims and appeals process to obtain an exception to an adverse benefit determination.

Finally, the Departments specified that federal law would preempt any state law to the extent that it prevents the application of the ACA's preventive care mandate and highlights the Departments enforcement authority over plans.

## Employer Action

Employers sponsoring non-grandfathered group health plans should review the various preventive care requirements effective for their upcoming plan years. Such coverage must be provided in-network, without cost-sharing.

**Fully insured health plans.** Carriers are generally responsible for compliance and should include these benefits as applicable.

**Self-funded health plans.** Discuss with TPAs to ensure coverage is in effect for plan years that begin on or after the applicable effective dates.