EMConnections
Euclid Managers Compliance Resources

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Tougher Enforcement of the Contraception Mandate on the Horizon

On July 28, 2022, the Departments of Labor, Health and Human Services, and Treasury (the "Departments") issued new FAQs clarifying their interpretation of the ACA's requirement that non-grandfathered health plans provide contraception to participants at no cost. The new FAQs were issued in response to President Biden's recent Executive Order on reproductive health. In addition to providing more detail regarding the requirements themselves, this publication announces that the Departments "are committed to ensuring consumers have access to the contraceptive benefits, without cost sharing, that they are entitled to under the law, and ***will take enforcement action as warranted***." The detailed new guidance on the contraceptive mandate is explained below.

Requirements Related to Categorization of Contraceptives

Covered plans are required to automatically cover a least one form of contraception in each of the categories below without applying medical management.

Sterilization Surgery for Women	Surgical Sterilization via Implant for Women	Implantable Rods
Copper Intrauterine Devices	Intrauterine Devices with Progestin (all durations and doses)	Shot or Injection
Oral Contraception (combined pill)	Oral Contraception (progestin only)	Oral Contraception (extended or continuous use)
Contraceptive Patch	Vaginal Contraceptive Rings	Diaphragms
Contraceptive Sponges	Cervical Caps	Female Condoms
Spermicides	Emergency Contraception (levonorgestrel)	Emergency Contraception (ulipristal acetate)

Other types of contraceptive services or products approved by the FDA must also be covered, even if they do not fall into one of the categories listed above. Medical management is only permitted if multiple, substantially similar services or products are available.

Medical Management

Strict limitations apply to medical management in this area. First, medical management is only permitted within a specific category of contraception. When this is the case, plans must automatically cover at least one option within a given category. Medical management may then be used for other options in that category, provided: (1) the techniques used are reasonable, and (2) the exceptions process discussed below is followed.

The FAQs specifically note that the following techniques would be considered "unreasonable" for this purpose:

- Denying coverage for particular brand name options where a participant's attending provider determines and communicates to the plan that the use of such brand is medically necessary.
- Requiring a participant to fail first using other options within the same category before covering a service or product deemed medically necessary by the individual's attending provider.
- Requiring a participant to fail first using other options in other categories.
- Imposing an age limit on contraceptive coverage.
- Requiring a participant to use the plan's claims and appeals procedures to obtain an exception.

Where access is limited by the plan to any FDA-approved contraceptive method, the plan must provide a "reasonably accessible, transparent, and sufficiently expedient exceptions process that is not unduly burdensome on the individual or their provider." Whether this standard is met is based on the relevant facts and circumstances. However, in any case, to meet this standard, the plan must provide documentation showing:

- That the exception process is accessible without initiating an appeal through the plan's internal claims and appeals procedures;
- The types of information required as part of the exception request; and
- The contact information for a plan representative who can answer questions related to the exceptions process.

This documentation must be included and prominently displayed in relevant plan documentation such as the Summary Plan Description and any other plan materials that describe the contraceptive coverage available under the plan (such as a prescription drug formulary).

The Departments also recommend that plans develop a standard exception form with instructions. To this end, they indicate that the Medicare Part D Coverage Determination Request Form would be a good model for this purpose.

Specific Required Benefits

The FAQs also specifically note that the following items/services are included in the definition of contraception and, therefore, must be covered without cost sharing:

- Items and services integral to furnishing a recommended preventive service, such as anesthesia for a tubal ligation procedure or pregnancy tests needed before the provision of an intrauterine device.
- Clinical services, including patient education and counseling needed to provide any covered contraceptive product or service.
- Counseling and education about fertility awareness-based methods, including lactation amenorrhea.
- Over-the-counter emergency contraception when prescribed by a treating physician, even when such products are prescribed before the need for their use arises. Plans are also permitted to cover such OTC products without a prescription. If an individual's plan does not cover OTC emergency contraception, an HSA, health FSA or HRA may be used to cover such expenses.

The Departments also "encourage" plans to cover a 12-month supply of contraceptives at one time.

Conflicting State Laws

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The guidance also clarifies that the federal mandate will control if there is a conflict between the federal contraception mandate and a state law. Thus, for example, if a state were to ban emergency contraception (commonly referred to as the morning after pill), such a ban would be invalid under federal law. The guidance goes on to specify that in such a case, the Department of Health and Human Services will take direct action to enforce these federal rules.

Enforcement

The FAQs also answer how the DOL will enforce the contraception mandate moving forward. When violations are identified, the DOL will ensure that necessary changes are made and require that improperly denied benefits be re-adjudicated. Further, DOL investigators will work directly with third-party administrators and other plan service providers to obtain corrections across blocks of business (instead of on a plan-by-plan basis). In these circumstances, actions will also be taken to ensure benefits are provided per applicable rules going forward. Similar principles are set forth for how CMS will enforce the contraception mandate for governmental plans exempt from ERISA. Finally, the guidance reiterates that violations of the contraceptive mandate can carry penalties of up to $100 per impacted participant per day.

Religious and/or Moral Objections

The FAQs described in this article follow years of litigation and regulatory debate about the applicability of the contraception mandate to religious organizations. Historically, a complicated set of rules has been applied to these circumstances. Among other things, the historical approach introduced an accommodations structure under which certain employers could opt out of the contraception mandate, but employees remained eligible to receive contraception free of charge through the plan's third-party administrator. To qualify for such accommodations, which are still available, organizations must either self-certify their eligibility or notify HHS in writing of their religious objection. Under new interim final regulations effective in 2019, the accommodations approach is no longer required for non-church entities wishing to opt out of the contraception mandate.

Today, most employers, including publicly held for-profit companies, can opt out of the contraception mandate based on a sincerely held religious belief. Most employers other than publicly held for-profit companies can also opt out based on deeply and sincerely held moral objections. Entities wishing to take advantage of these opportunities are permitted to self-certify or notify the government of their eligibility. Such certifications are not legally required but remain prudent considering the potential penalties for failing to comply with the contraceptive mandate discussed above.

Final Thought

Many plan sponsors providing contraception at no cost to participants will be surprised to realize that their benefits do not meet the contraception mandate as explained by these FAQs. In particular, plans will need to work with their service providers to ensure the abovementioned requirements are met. Detailed attention should be paid to (1) formulary designs, (2) ensuring coverage is automatically available in each contraception category without medical management, and (3) compliant exception processes are in place.

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