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LEGAL UPDATE

Federal Agencies Issue FAQs on ACA's Contraceptive Coverage Mandate

On Jan. 22, 2024, the Departments of Labor, Health and Human Services, and the Treasury (Departments) issued a set of frequently asked questions (FAQs) regarding the contraceptive coverage mandate under the Affordable Care Act (ACA). The FAQs reiterate the scope of the mandate, express concern about noncompliance, and describe a new optional approach for using reasonable medical management techniques in the coverage of FDA-approved contraceptive drugs and drug-led devices.

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KEY CONSIDERATIONS

- Given the federal government's focus on contraceptive coverage, employers should review their health plan's contraceptive coverage for compliance with the ACA's mandate.
- Employers should watch for problematic medical management techniques, such as onerous step-therapy protocols, age-related restrictions and burdensome administrative requirements related to the exceptions process.
- Employers should be aware that a new therapeutic equivalence approach may apply to their coverage of contraceptive drugs and drug-led devices.

Contraceptive Coverage Mandate

The ACA requires non-grandfathered health plans and health insurance issuers to cover certain preventive care services without cost sharing, including coverage for contraceptives as outlined in guidelines supported by the Health Resources and Services Administration (HRSA). Exemptions are available to religious employers and eligible employers who object to providing this coverage based on their sincerely held religious beliefs or moral convictions.

According to the Departments, the ACA's contraceptive coverage mandate requires health plans and issuers to cover without cost sharing:

- At least one form of contraception in each of the categories listed in HRSA's guidelines (e.g., intrauterine devices with progestin, injectable contraceptives, oral contraceptives-combined pill and emergency contraception-levonorgestrel); and
- Any contraceptive services and FDA-approved, -cleared or -granted products that an individual's health care provider determines to be medically appropriate (including newer contraceptive products, regardless of whether they are included in HRSA's guidelines).

Health plans and issuers may use **reasonable medical management techniques** within a specified category of contraception (or within a group of substantially similar services or products for categories not described in HRSA's guidelines) when HRSA's guidelines do not specify the frequency, method, treatment or setting for the provision of a recommended contraceptive service or product. When medical management techniques are used, the plan or issuer must provide an easily accessible, transparent and sufficiently expedient **exceptions process** that is not unduly burdensome and allows an individual to access, without cost sharing, the specific contraceptive service or product that is medically necessary, as determined by the individual's health care provider.

Noncompliance Reports

The Departments are aware of reports that health plans and issuers are continuing to impose "widespread barriers" to contraceptive coverage, including unreasonable medical management techniques. Examples of problematic techniques and practices include:

- Requiring individuals to satisfy step-therapy protocols using numerous other services or products within the same category of contraception before the plan or issuer will approve coverage for the service or product that is medically necessary for the individual, as determined by their health care provider;
- Applying age-related restrictions for a contraceptive service or product that is medically necessary for the individual, as determined by their health care provider;
- Imposing unduly burdensome administrative requirements as part of an exceptions process, such as onerous documentation requirements or multiple levels of processes; and
- Requiring cost sharing for services that are integral to the preventive service provided (regardless of whether the items and services are billed separately), such as pregnancy tests needed before the provision of certain forms of contraceptives.

New Optional Approach

To help address compliance problems, the FAQs describe a new optional approach that health plans and issuers may use to comply with the ACA's contraceptive coverage mandate. This new option is called the **therapeutic equivalence approach**. Under this approach, a health plan's or issuer's medical management techniques for FDA-approved contraceptive drugs and drug-led devices within a specified category described in HRSA's guidelines (or a group of substantially similar products not included in a specified category) will be considered reasonable if the plan or issuer:

- Covers all FDA-approved contraceptive drugs and drug-led devices in that category (or group of substantially similar products) without cost sharing, other than those for which there is at least one **therapeutic equivalent drug or drug-led device** that the plan or issuer covers without cost sharing; and
- Provides an **exceptions process** that allows an individual to access without cost sharing the specific contraceptive drug or drug-led device (that is a therapeutic equivalent to the product that is covered without cost sharing) that is medically necessary for the individual, as determined by their health care provider.

A contraceptive drug or device is considered therapeutically equivalent to another drug or device if it is identified as a therapeutic equivalent in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book). The Departments' FAQs include the following example of a reasonable medical management technique under the new approach:

Example: Within the category of "oral contraceptives (combined pill)," a plan covers all FDA-approved oral contraceptives (combined pill) products without cost sharing, other than those for which there is a therapeutic equivalent that is covered without cost sharing. Specifically, the plan covers Pill A, Pill B and generic Pill D without cost sharing. Neither Pill A nor Pill B has a therapeutic equivalent product, according to the Orange Book. Pill W, Pill X and Pill Y, as well as Pill Z (which is a more expensive brand-name product), are all classified in the Orange Book as therapeutic equivalents to Pill D and are not covered by the plan without cost sharing. The health plan also provides an easily accessible, transparent, and sufficiently expedient exceptions process that allows an individual to receive coverage without cost sharing for a therapeutic equivalent to Pill D (i.e., Pill W, Pill X, Pill Y or Pill Z) if the therapeutic equivalent product is determined to be medically necessary for an individual, as determined by their health care provider.