THE BEACON
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ADDITIONAL GUIDANCE ISSUED REGARDING CONTRACEPTIVE CARE COVERAGE MANDATE

Amid reports that many health insurance plans continue to impose barriers to contraceptive coverage, The Departments of Labor, Health and Human Services, and Treasury (collectively, The Departments) have issued additional FAQ guidance addressing first-dollar coverage of contraceptives under the Affordable Care Act's (ACA's) preventive health services rules.

Citing the Biden Administration's clear desire to see that women have access to contraceptive care, these FAQs include a new therapeutic equivalence approach alternative for complying with the ACA's contraceptive mandate.

The ACA's Contraceptive Care Mandate

Under the ACA's contraceptives rules, non-grandfathered group health plans and health insurers must provide first-dollar coverage of all Food and Drug Administration (FDA)-approved contraceptive methods, sterilization procedures, and patient education and counseling for women with reproductive capacity, as prescribed by a health provider. Plans and insurers must cover, without any cost-sharing, at least one form of contraception in each of the methods identified for women by the FDA in its current Birth Control Guide. This current list includes the following:

- Sterilization surgery for women;
- Implantable rods;
- Copper intrauterine devices or intrauterine devices with progestin (all durations and doses);
- Injectable contraceptives;
- Oral contraceptives (combined pill, progestin only, or extended/continuous use);
- The contraceptive patch;
- Vaginal contraceptive rings;
- Diaphragms;
- Contraceptive sponges;
- Cervical caps;
- Condoms;
- Spermicides;

- Emergency contraception (levonorgestrel or ulipristal acetate); and
- Any additional contraceptives that are approved, cleared, or granted by the FDA.

In July 2022, the Departments issued contraceptive mandate guidance reinforcing that plans and insurers must cover, without cost-sharing:

- At least one form of contraception in each of the categories listed in the Health Resources and Services Administration (HRSA)-supported Birth Control Guide; and
- Any contraceptive services and FDA-approved, cleared, or granted products that an individual and their attending health provider have determined are medically appropriate for the individual.

Newly Available Compliance Option: The Therapeutic Equivalence Approach

This latest January 2024 guidance provides an additional method for plans and insurers to comply with the ACA's contraceptive mandate: the therapeutic equivalence approach. Therapeutic equivalence is simply the substitution of a less expensive but clinically equivalent therapy for a therapy that already exists. In context of contraceptive care and the ACA mandate, this often involves using a drug in tandem with a drug-led device to clinically replace one of the contraceptive methods identified in the FDA's Birth Control Guide. A drug-led device is a combination product comprised of both a drug and device, but for which the drug provides the primary, most important therapy.

Putting it succinctly, under this alternative approach, the Departments will generally consider a plan/insurer to be in compliance with the ACA's contraceptive mandate if it covers, without cost-sharing, all FDA-approved contraceptive drugs/drug-led devices except those for which there is at least one therapeutically equivalent drug/drug-led device that the plan/insurer instead covers without cost-sharing.

A contraceptive drug/drug-led device is considered therapeutically equivalent to another drug/drug-led device if it is identified as a therapeutic equivalent in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, also known as the "Orange Book." If the Orange Book has not identified any therapeutic equivalents for a particular drug or drug-led device, the Departments will view that drug or drug-led device as not having a therapeutic equivalent for purposes of complying with the ACA's contraceptive mandate. In this case, plans/insurers that choose to take advantage of this new compliance option will need to cover the applicable FDA-approved contraceptive drug/drug-led device without cost-sharing, as no therapeutically equivalent option is available.

Mandatory Exceptions Process Remains in Place

All plans/insurers must have an "easily accessible, transparent, and sufficiently expedient" exceptions process in place that allows an individual to access (without cost-sharing) a specific contraceptive their doctor has deemed medically necessary, regardless of the compliance approach the plan/issuer has chosen or whether or not the contraceptive is covered under the plan.

The Departments have expressed serious concerns over reports of plans establishing unreasonable exceptions processes and other potentially non-compliant practices. These practices include but are not limited to:

- Requiring individuals to "fail first" using other products within the same contraception method before a plan/insurer will approve coverage for the product that the individual's health care provider has deemed medically necessary;
- Applying age-related restrictions for contraceptive services or products that the individual's provider has deemed medically necessary for the individual; and
- Imposing an exceptions process that includes burdensome administrative requirements.

We encourage plans/issuers to ensure that their contraceptive care policies do not include any of these prohibited practices. In response to their ongoing concerns, the Departments are sending out communications to plan sponsors reminding them of their contraceptive care obligations under the ACA, and the Centers for Medicare & Medicaid Services has sent letters urging plans, issuers, and pharmacy benefit managers to ensure they are providing full coverage, without cost-sharing, of preventive services, as required by federal law.

As always, MZQ Consulting is available to answer questions or help to clarify this new guidance. Please do not hesitate to reach out to us.