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Biden Administration Reminds Employers that Contraception is Required under ACA's Preventive Care Mandate with a Few Surprises

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On July 28, 2022, the federal regulators (referred to as the "Departments") released a new set of FAQs (Part 54) under the Affordable Care Act ("ACA") to clarify the scope of the preventive care mandate, in particular, with respect to the coverage of contraception, and to "emphasize the Departments' commitment to enforcement" of that mandate. The FAQs follow a recent executive order directing federal agencies to take various actions to promote access to reproductive healthcare services in the wake of the Supreme Court's overturn of *Roe v. Wade*.

Under the ACA and in accordance with guidelines promulgated by the Health Resources and Services Administration (HRSA), employer-sponsored health plans are required to provide the full range of FDA-approved contraceptive methods to all covered adolescent and adult women for free (with no cost-sharing), including at least one form of contraception in each of the categories enumerated by the HRSA-Supported Guidelines.

Guidelines for Services not Included in the HRSA-Supported Guidelines

The Departments interpret the HRSA-Supported Guidelines to require plans to 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 for the individual, whether or not those services or products are specifically identified in the categories listed in the HRSA-Supported Guidelines.

For such contraceptive services or FDA-approved, cleared, or granted contraceptive products that are not included in a category described in the HRSA-Supported Guidelines, plans may use reasonable medical management techniques to determine which specific services or products to cover without cost sharing only if multiple, substantially similar services or products are available and are medically appropriate for the individual. In addition, at least one such service or product must be available at no cost. (However, it is unclear what techniques could be used, because the exceptions process must apply in any event. See next section below.)

The FAQ continues by providing if an individual's attending provider recommends a particular service or FDA-approved, cleared, or granted product not included in a category described in the HRSA-Supported Guidelines based on a determination of medical necessity with respect to that individual (including if there is

only one service or product that is medically appropriate for the individual, as determined by their attending provider), the plan must cover that service or product without cost sharing. The FAQ states that the plan must defer to the determination of the attending provider, and make available an easily accessible, transparent, and "sufficiently expedient exceptions process" that is not unduly burdensome so the individual or their provider (or other individual acting as the individual's authorized representative) can obtain coverage for the medically necessary service or product without cost sharing as required under the ACA.

Sufficiently Expedient Exceptions Process

The Departments note that a "sufficiently expedient exceptions process" does not include an internal appeal of an adverse benefit determination. Specifically, the Departments state if plans are utilizing reasonable medical management techniques, requiring individuals to appeal an adverse benefit determination using the plan's internal claims and appeals process as the means to obtain an exception would be unduly burdensome on the individual.

The Departments state that whether a plan's exceptions process is easily accessible, transparent, expedient, and not unduly burdensome is based on all the relevant facts and circumstances, including whether and how the plan notifies participants of the exceptions process, and the steps the individual must take to utilize the exceptions process. The Departments will consider an exceptions process to be easily accessible if plan documentation includes relevant information regarding the exceptions process under the plan, including how to access the exceptions process without initiating an appeal pursuant to the plan's internal claims and appeals procedures, the types of information the plan requires as part of a request for an exception, and contact information for a plan representative who can answer questions related to the exceptions process.

At the same time, the Departments state that an exception will be considered transparent if, at a minimum, the plan includes and prominently displays information relevant to the exceptions process (including, if used, a form with instructions) in plan documents, the summary plan description and in any other plan materials that describe the terms of the plan's coverage of contraceptive products and services. The Departments also encourage the use of a standard exceptions form with instructions as a way to meet the requirements for an exceptions process but note that this is not required. If the plan materials are also available electronically (which they likely will be), the Departments also encourage plans to make the information available electronically (in addition to, we presume, the summary plan description and other materials that would be posted electronically as well).

EBSA Enforcement

It is also interesting (some would say peculiar) that the Departments also included two pages on how EBSA, as well as individual plan participants, can enforce the preventive coverage requirements. In the FAQ, the Departments noted that when EBSA identifies violations in a particular group health plan, EBSA will work to

ensure that the plan makes the necessary changes to any noncompliant plan provision and re-adjudicates any improperly denied benefit claims. To achieve the greatest impact, EBSA investigators often work with plan service providers to obtain broad corrections, not just for the particular plans investigated, but for other plans that contract with the service provider, the Departments stated. Last, the Departments said that EBSA also will work to ensure that the plan corrects the violation prospectively, or in other words, for the remainder of the plan year and for future plan years so that participants and beneficiaries receive the benefits to which they are entitled.

The FAQ also lists all the various phone numbers and websites that individuals can call or visit, if the individual believes that a plan is not satisfying its preventive care coverage requirements.

Key Takeaways

While the Departments billed this FAQ as a reminder of the preventive care coverage for contraception, it is clear that there is more information in this FAQ than a simple reminder.

1. *Plans Must Implement a Special Exceptions Process.* The Departments noted that the internal claims and appeals procedures cannot be used for exceptions to provider-recommended contraception services or products. Rather, plans must have a sufficiently expedient exceptions process, and such process must be outlined in the plan document and SPD. Because the preventive care rules apply to both prescription drugs and contraceptive services, both a plan's medical TPAs and its prescription drug TPA will need an exceptions process.

2. *Exceptions Process Appears to Apply to any Contraceptive Services or FDA-Approved Contraceptive Product.* The Departments interpret the HRSA-Supported Guidelines to require plans to 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 for the individual, whether or not those services or products are specifically identified in the categories listed in the HRSA-Supported Guidelines. This appears to mean that any contraceptive service or FDA-approved product must be covered at no cost share if the provider determines that it is medically appropriate. Plans may apply reasonable medical management techniques to adjudicate and authorize such provider determinations. But, regardless of whether any techniques apply, the exceptions process also must apply.

3. *EBSA Will Investigate Plans and their Service Providers.* The Departments typically do not discuss enforcement mechanisms in every piece of guidance that is released. In fact, the Departments almost never mention enforcement to the degree mentioned in this FAQ. (The one exception is FAQ 45, with respect to mental health and substance use disorder parity and the comparative analysis for nonquantitative treatment limitations.) The fact that the Departments discussed enforcement to this degree in this case and in addition mentioned all the ways individuals can enforce the contraception mandates shows that the

Departments will make this issue a priority in any investigation or audit.