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How Expanded Birth Control Coverage May Affect Employers

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The U.S. Departments of Labor, Treasury, and Health and Human Services proposed regulations last month that would expand group health plans' required coverage of preventive services and contraceptives.

Starting in 2026, the proposed rules would require group health plans to: cover, without cost-sharing, over-the-counter contraceptive items and services obtained without a prescription; apply a "therapeutic equivalence" approach to coverage of contraceptive items and services; and provide a notice to participants about the availability of OTC contraceptive coverage.

Group health plans would also be required to offer an exceptions process, pursuant to which the plan would cover, without cost-sharing, any preventive item or service that an individual's attending provider deems medically necessary, without regard to whether it is typically covered without cost-sharing. This requirement would apply on the effective date of the final rules.

To date, the proposal that group health plans cover over-the-counter contraceptives without cost-sharing has garnered considerable attention. However, the proposed requirement that group health plans maintain an exceptions process that defers to the individual's attending provider for all recommended preventive items and services, not just contraceptive coverage, may ultimately prove more significant for some plan sponsors.

This article summarizes the background, key aspects of the proposed rules and implementation issues for employers.

Which preventive services are group health plans required to cover today?

The Affordable Care Act requires that non-grandfathered group health plans cover the following preventive services and items, without participant cost-sharing, when provided in network:

- Evidence-based items or services that have an A or B rating in the current recommendations of the U.S. Preventive Services Task Force;
- Immunizations for routine use that are recommended by the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention;
- Preventive care and screenings for infants, children and teenagers provided in guidelines issued by the Health Resources and Services Administration; and
- Additional preventive care and screenings for women provided in HRSA guidelines.

Earlier this year, the U.S. Court of Appeals for the Fifth Circuit affirmed the portion of a district court's order that invalidated the preventive services mandate for A or B items and services recommended by the USPSTF on or after March 23, 2010, on the basis that the USPSTF members were not constitutionally appointed. In practice, however, most plan sponsors have not made changes to their preventive services coverage in response to this ruling, as the case is ongoing.

May group health plans apply medical management techniques to coverage of preventive services?

Yes. The current regulations implementing the preventive services mandate permit group health plans to "impose reasonable medical management techniques to determine the frequency, method, treatment, or setting for coverage of a recommended preventive health item or service, to the extent not specified in the applicable recommendation or guideline."

The assessment of whether a medical management technique is reasonable is based on all the relevant facts and circumstances. This would change under the proposed rules, however.

Are there special additional rules that apply to required group health plan coverage of contraceptive items and services?

In a word, yes. The requirements that apply to coverage of contraceptives are somewhat detailed.

The departments have interpreted the preventive services mandate to require that non-grandfathered group health plans cover, without participant cost-sharing, when provided in network: (1) at least one form of contraception in each of the categories listed in the HRSA guidelines, and (2) any products and contraceptive services approved, cleared or granted by the U.S. Food and Drug Administration that an individual and their attending provider have determined to be medically appropriate.

The latter requirement applies to the item or service regardless of whether it is listed in the current HRSA-supported guidelines.

In informal FAQs issued over the years, the departments have stated that medical management techniques with respect to contraceptives are not considered reasonable unless the plan maintains an "easily accessible, transparent, and sufficiently expedient exceptions process," whereby a participant could obtain coverage, without cost-sharing, of any service or FDA-approved item that an individual's attending provider determines is medically appropriate for them.

The departments have taken the same position with respect to required coverage of preexposure prophylaxis, or PrEP, for HIV prevention.[1]

What new requirements would apply to group health plans under the proposed rules?

The proposed regulations build on the prior guidance summarized above and expand required preventive services and contraceptive coverage in two key ways.

Expand group health plan coverage of contraceptive items and services.

The current rules only require group health plans to cover OTC contraceptive items and services to the extent that the individual had a prescription for the item or service. The proposed regulations eliminate the prescription requirement, meaning that group health plans would be required to cover OTC contraceptive items and services without cost-sharing, assuming the item or service can be lawfully obtained without a prescription and that the underlying preventive care recommendation does not require one.

That said, the preamble to the proposed rules confirms that plans would still be permitted to apply medical management techniques to OTC contraceptive items and services. For example, if a plan restricts its network to a particular pharmacy, coverage of OTC contraceptive items and services without cost-sharing could be limited to those purchased at that in-network pharmacy.

However, the departments also state in the preamble that age-based or gender-based limitations, fail-first protocols and prior authorization requirements would not be considered reasonable medical management techniques when applied to OTC contraceptive items.

Separately, the proposed regulations mandate that group health plans follow the therapeutic equivalence approach for coverage of contraceptive items and services. This approach was outlined as optional for plans in an ACA FAQ earlier this year.[2]

Under the proposed rules, a group health plan would be required to cover, without cost-sharing, all FDA-approved drugs and drug-led devices within a specified HRSA-supported guidelines category, other than those for which there is a therapeutic equivalent that the plan covers without cost-sharing. Or within a group of substantially similar products or services for items and services not included in the guidelines.

This approach would not apply to OTC contraceptive items. However, because the FDA does not evaluate them for therapeutic equivalence, a plan must cover all OTC contraceptive items without cost-sharing under the proposed rules.

Here is an example of how therapeutic equivalence works in practice.

Assume a health plan covers pills A, B and C without cost-sharing, while pills W, Y and Z are covered with cost-sharing. All pills are within the HRSA-supported category of FDA-approved oral contraceptive combined pill products. Pills W, Y and Z are therapeutic equivalents to pill C. The plan's coverage with respect to this category would be considered reasonable even though the plan requires cost-sharing for pills W, Y and Z, because it does not require cost-sharing for pill C, which is a therapeutic equivalent to pills W, Y and Z.

Note that applying therapeutic equivalence does not relieve a plan of the obligation to maintain an exceptions process and cover, without cost-sharing, any specific contraceptive that is medically necessary for the individual, as explained in more detail below.

Finally, the proposed regulations add a new notice requirement related to the plan's online search tool for cost-sharing estimates. Under the proposal, if a participant requests information about contraceptive items or services, the plan would need to affirmatively provide a notice to the participant explaining that it covers OTC contraceptives without a prescription and without cost-sharing, and would need to direct them to further information about coverage.

Exceptions process would apply to medical management techniques for preventive services.

Currently, group health plans are permitted to use reasonable medical management techniques to determine the frequency, method, treatment or setting for coverage of a recommended preventive service to the extent not specified in the applicable recommendation or guideline.

The proposed rules would require that for a management technique to be reasonable, the plan must have an "easily accessible, transparent, and sufficiently expedient exceptions process." It must not be unduly burdensome to the individual under which the plan would cover the recommended preventive item or service without cost-sharing, according to the frequency, method, treatment or setting that an individual's attending provider determines is medically necessary for them. This exceptions process would be separate from the plan's internal claims and appeals process.

Here is how this would work in practice. Assume a plan covers only the generic version of a tobacco cessation gum without cost-sharing. If the individual's attending provider determines the brand-name version of the gum is medically necessary for the participant, perhaps because the participant cannot tolerate the generic version, the plan would have to make an exception and cover the brand-name gum.

The departments acknowledge there are several open questions about implementing this proposal. Among other topics, they have requested comments on the required time frames that should apply to the exceptions process, the documentation required to substantiate the provider's determination of medical necessity that would override the plan's otherwise applicable medical management rule and the participant disclosures about the exceptions process.

What are the takeaways for employers?

For the time being, the proposed regulations are simply that: proposed. The departments have requested comments on a number of implementation issues in the proposed rulemaking. Employers should consider the impact of the proposed regulations on their plans and consider submitting comments to address any concerns by the Dec. 27 deadline.

Additionally, the departments indicate in the preamble that they intend to issue a separate notice of proposed rulemaking in the near future to address coverage of preventive services more generally. Employers should keep an eye out for this guidance and consider participating in the comment process.

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[1] https://dol.gov/sites/dolgov/files/ebsa/about-ebsa/our-activities/resource-center/faqs/faqs-about-affordable-care-act-implementation-coverage-of-prep-2021.pdf

[2] https://dol.gov/agencies/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-64.

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