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## Agencies Release FAQs Addressing Plans and Issuers' Coverage of PrEP and Reconstructive Surgery

The Departments of Labor, Health and Human Services, and Treasury (the Departments) issued a set of FAQs addressing the preventive services coverage requirement under the Affordable Care Act (ACA) as it applies to Pre-Exposure Prophylaxis (PrEP) and coverage for breast reconstruction under the Women's Health and Cancer Rights Act (WHCRA).

#### PrEP Coverage

The ACA generally requires non-grandfathered group health plans and health insurance issuers to cover, without the imposition of any cost-sharing requirements: (1) evidence-based items or services that have been recommended by the United States Preventive Services Task Force ("USPSTF"); (2) routine immunizations; (3) certain preventive care for infants, children, and adolescents; and (4) with respect to women, certain additional preventive care and screenings. In 2019, the USPSTF recommended coverage of the HIV prevention medication PrEP. At that time, the USPSTF identified one FDA-approved formulation of PrEP, a daily oral medication. In 2023, USPSTF added to its recommendation two additional FDA-approved formulations of PrEP, one oral medication and one injectable medication.

FAQs Part 68, which the Departments released on October 21, 2024, addresses how plans and issuers must comply with the updated 2023 recommendations. The FAQs provide that in order to comply with the USPSTF's 2023 recommendation for PrEP, plans and issuers must cover, without cost sharing, specified oral and injectable formulations of PrEP, as well as specified baseline and monitoring services, for plan or policy years beginning on or after August 31, 2024. The FAQs also state that, consistent with previous FAQs released by the Departments, plans and issuers may use reasonable medical management techniques to encourage individuals prescribed PrEP to use specific items and services. However, with respect to the three USPSTF-recommended types of PrEP, plans and issuers may not use medical management techniques to direct an individual to use one formulation over the other.

The FAQs also provide detailed information regarding the coding standards for preventive health items and services under the ACA.

#### Reconstructive Surgery After a Mastectomy

The FAQs also address coverage under the WHCRA, which provides protections for individuals who elect breast reconstruction in connection with a mastectomy. The WHCRA requires that if a group health plan or health insurance issuer offering group or individual health insurance coverage covers mastectomies, then the plan or issuer must provide coverage for certain breast reconstructive services in connection with the procedure.

The FAQs provide that plans and issuers offering group or individual health insurance coverage that cover mastectomies are *required* to provide coverage for "chest wall reconstruction with aesthetic flat closure" as a type of breast reconstruction under WHCRA. This requirement applies if the patient elects

this type of reconstruction in consultation with the attending physician in connection with the mastectomy, as a required type of reconstruction.

## IRS Ruling Addresses Treatment of Retiree Medical Account Benefits

The Internal Revenue Service's (IRS) recent private letter ruling addressing medical retiree accounts serves as a reminder to pension plan sponsors of the requirements for establishing such an account, including the requirement that the medical benefits must be "subordinate" to the retirement benefits provided by the plan.

#### Background

Under Internal Revenue Code ("Code") section 401(h), a pension plan may provide for the payments of benefits for the medical expenses of retired employees, their spouses, and their dependents, but only if certain requirements are met. One of those requirements is that such benefits are "subordinate" to the retirement benefits provided by the plan. Under the regulations implementing Code section 401(h), medical benefits generally are subordinate to retirement benefits if the employer's aggregate contributions for medical benefits do not exceed 25% of total plan contributions.

Employers may set up 401(h) medical retiree accounts to help employees pay for eligible medical expenses, and, once the employee dies, to pay for the expenses of the surviving spouse and any dependents.

#### **IRS Ruling**

In a <u>ruling</u> published at the end of October, the IRS considered a scenario where an employer sponsored a pension plan and also maintained a retiree medical account that was established after the pension plan was established. The terms of the plan's retiree medical account provided that postretirement medical benefits provided by the account must be subordinate to the retirement benefits provided by the pension plan. The employer made its most recent contribution to the pension plan's retiree medical account in Year 3, the contribution amount of which corresponded to the contributions to the pension plan for Years 3-6. In addition, the value of the plan's assets exceeded the plan's funding target for the relevant plan year. The employer wanted to make an additional contribution to the retiree medical account and asked the IRS whether this would be permissible.

The IRS ruled that the postretirement benefits provided by the retiree medical account will be subordinate to the retirement benefits of the pension plan because the contributions to the retiree medical account (including the proposed additional contribution) do not exceed 25% of the total contributions to the plan.

#### **Takeaways**

The IRS's ruling is an important reminder to employers that 401(h) medical retiree accounts must adhere to the rules outlined in Code section 401(h) and the corresponding regulations. As a reminder, private letter rulings can only be relied upon by the employer who requested the ruling. Thus, while no other plan sponsor can technically rely on this ruling when establishing their own 401(h) medical retiree account, private letter rulings are generally seen as a sign of the IRS's general thinking on a particular matter.

## Proposed Regulations Would Require First-Dollar Coverage of Over-the-Counter Contraceptives Obtained Without a Prescription

New proposed regulations would require group health plans to provide first-dollar coverage of over-the-counter (OTC) contraceptives and curtail the ability of plans to use medical management techniques to limit mandatory coverage of preventive care. The Departments of Health and Human Services, Labor, and Treasury jointly issued the proposed regulations on October 21, 2024, and they were published in the October 28 edition of the Federal Register.

#### **OTC Contraceptives**

In general, the Affordable Care Act requires non-grandfathered group health plans to cover certain preventive services on a first-dollar basis without any cost-sharing. The preventive services that must be covered are determined by cross-referencing certain standards set by the United States Preventive Services Task Force (USPSTF) and the Health Resources Services Administration (HRSA), among others.

Existing rules already require non-grandfathered plans to cover certain over-the-counter contraceptives, but only in cases where they have been prescribed by a physician. The proposed rules would eliminate the prescription requirement.

#### Medical Management Techniques

The USPSTF, HRSA, and other recommendations for preventive services do not always specify the frequency or other parameters that are relevant what plans must cover to comply with the preventive services mandate. Under current rules, plans have flexibility to use "reasonable" medical management techniques to set those parameters in these circumstances.

The proposed rules would modify this standard to require plans utilizing medical management techniques for this purpose to "provide an easily accessible, transparent, and sufficiently expedient exceptions process that allows an individual to receive coverage without cost sharing for the preventive service according to the frequency, method, treatment, or setting that is medically necessary for them, as determined by the individual's attending provider, even if that service is not generally covered under their plan or coverage."

#### Outlook

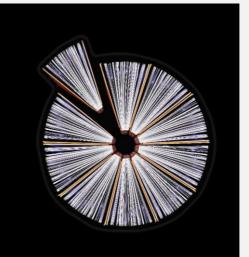
Comments on the proposed rule are due by December 27, 2024. It is highly unlikely that final regulations will be issued before President Biden leaves office on January 20, 2025, so it will be up to the incoming Trump Administration to determine whether and how to move forward with these proposals.



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