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Compliance Directions

FAQs Provide Guidance on Preventive Care and Women's Health and Cancer Rights Act

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On October 21, 2024, the Departments of Labor, Health and Human Services, and the Treasury (the Departments) issued FAQs Part 68 relating to preventive services and the Women's Health and Cancer Rights Act.

Background: Preventive Services

The Patient Protection and Affordable Care Act (ACA) requires non-grandfathered group health plans to provide certain preventive services without cost-sharing. The required preventive services come from recommendations issued by four entities: the U.S. Preventive Services Task Force (USPSTF), the Advisory Committee on Immunization Practices (ACIP), the Health Resources and Services Administration's (HRSA's) Bright Futures Project, and the HRSA-sponsored Women's Preventive Services Initiative (WPSI). If a recommendation or guideline does not specify the frequency, method, treatment, or setting for the provision of a recommended preventive service, then the plan may use reasonable medical management techniques to determine coverage limitations. To the extent not specified in a recommendation or guideline, a plan may rely on the relevant clinical evidence base and established reasonable medical management techniques to determine the frequency, method, treatment, or setting for coverage of a recommended preventive item or service. Additionally, plans must cover, without cost sharing, items and services that are integral to the furnishing of a recommended preventive service, regardless of whether the item or service is billed separately.

Coverage of Pre-Exposure Prophylaxis (PrEP)

In 2019, the USPSTF released a recommendation with an "A" rating that clinicians offer PrEP with "effective antiretroviral therapy to persons who are at high risk of HIV acquisition." Therefore, plans were required to cover PrEP according to the recommendation for plan years beginning on or after June 30, 2020. The Departments subsequently issued an FAQ clarifying that, consistent with CDC guidelines, the 2019 USPSTF recommendation for PrEP encompasses FDA-approved PrEP antiretroviral medications as well as specified baseline and monitoring services that are essential to the efficacy of PrEP. In June 2019, the only formulation of PrEP approved by the FDA

for use in the United States in persons at risk of sexual acquisition of HIV infection was once-daily oral treatment with combined tenofovir disoproxil fumarate and emtricitabine (TDF/FTC; brand name Truvada®). On August 22, 2023, the USPSTF updated its recommendation with respect to PrEP to include:

- Emtricitabine/tenofovir alafenamide (TAF/FTC; brand name Descovy®), the second daily oral medication approved by the FDA for PrEP in October 2019; and
- Cabotegravir (brand name Apretude®), the first long-acting injectable PrEP medication approved by the FDA in December 2021.

The 2023 USPSTF recommendation also clarified that the recommendation for PrEP applies to sexually active adults and adolescents weighing at least 35 kg (77 lb) who do not have HIV and are at increased risk of HIV acquisition. The 2023 USPSTF recommendation continues to recommend TDF/FTC, as well as baseline and monitoring services, consistent with the CDC guidelines.

For plan years beginning on or after August 31, 2024 (January 1, 2025 for calendar year plans), plans must cover, without cost sharing, specified oral and injectable formulations of PrEP, as well as specified baseline and monitoring services, consistent with the 2023 USPSTF recommendation. Plans may use reasonable medical management techniques to encourage individuals prescribed PrEP to use specific items and services, to the extent the frequency, method, treatment, or setting is not specified in the relevant USPSTF recommendation. Because the 2023 USPSTF recommendation for PrEP specifies three formulations of medications approved by the FDA for use as PrEP, plans must cover, without cost sharing, the three FDA-approved PrEP formulations (two oral and one injectable) and are not permitted to use medical management techniques to direct individuals prescribed PrEP to utilize one formulation over another.

Coding for Recommended Preventive Items and Services

To ensure that individuals receive covered preventive care without cost-sharing, the Departments reminded plans of the importance of medical service codes appropriately identifying when items and services are furnished as preventive, and that plans correctly process those claims as preventive. When claims denote that a furnished item or service is a recommended preventive item or service (or that it is integral to the furnishing of a recommended preventive item or service), plans should cover them without imposing cost-sharing, unless the plan has individualized information that establishes that the furnished item or service is not preventive.

Industry-standard coding practices are intended to identify when items and services are furnished as a recommended preventive item or service, and not for diagnostic, therapeutic, or other non-preventive purposes. The Departments issued several FAQs relating to coding for preventive services, summarized here.

- When an in-network provider submits claims for items or services using industry-standard coding practices that identifies the items or services as recommended preventive items or services, plans should cover them without cost sharing, unless the plan has individualized information to establish that they are not preventive with respect to the individual.
- If a plan receives a claim from an in-network provider that identifies an item or service as a recommended preventive item or service using industry-standard coding practices, but the plan has individualized information that allows the plan to establish that it is not preventive care with respect to the individual, the plan may impose cost sharing. Of course, in the event of an adverse benefit determination, the participant has the right to appeal under the plan's appeal and external review process.

Example. An in-network provider submits a claim to a plan for furnishing a screening mammography to a 39-year-old woman. The currently applicable USPSTF recommendation for breast cancer screening recommends that women aged 40 and older receive a screening mammography, with or without clinical breast examination, every 1-2 years. Because the recommendation applies only to women aged 40 years and older, the plan covers the mammography claim but imposes cost sharing for the service. The plan is not in violation the preventive care requirements because, based on information maintained by the plan (i.e., the individual's date of birth), the plan has sufficient individualized information to establish that the service was not furnished consistent with the applicable USPSTF recommendation for breast cancer screening.

- If, using industry-standard coding practices, a claim identifies an item or service as a recommended preventive item or service, but the plan has separate information that suggests (but does not establish) that it may not have been furnished as preventive, the plan should not impose cost sharing unless and until the plan has individualized information to establish that it was not preventive after verifying relevant information

with the provider. If the claimant or provider has not submitted sufficient information, before imposing cost-sharing (or, if applicable, denying a claim), plans should communicate with claimants and providers, as appropriate, to obtain the information the plan needs to provide a full and fair review. In cases where a plan has information separate from a claim that suggests (but does not establish) that the item or service may not have been furnished as a recommended preventive item or service with respect to an individual, the Departments generally will not consider a plan to be in violation of the preventive care requirements if the plan has made reasonable and unsuccessful efforts to obtain the information necessary from the provider to determine whether the item or service was furnished as preventive, prior to imposing cost sharing (or denying coverage). However, the Departments would consider a plan to be in violation if the plan does not promptly reverse the cost-sharing requirements (or coverage denial) upon being made aware that the item or service was furnished as (or integral to the furnishing of) a recommended preventive item or service.

- Plans and carriers should review their coding guidelines, claims processing systems, and other relevant internal protocols and make any necessary modifications to ensure that claims are properly processed as preventive care, when applicable. The Departments stated that they expect plans to educate their network providers and provide clear guidance on the availability and proper usage of service codes and modifiers to denote when an item or service is furnished as, or integral to the furnishing of, a recommended preventive item or service. The Departments also advised plans to regularly review published industry standards to ensure individuals are not charged cost sharing or denied coverage for recommended preventive care, and ensure that their network providers are similarly aware of such standards.

Women's Health and Cancer Rights Act (WHCRA) Guidance

WHCRA provides protections for individuals who elect breast reconstruction in connection with a mastectomy. Under WHCRA, if a group health plan covers mastectomies, the plan must provide, in a manner determined in consultation with the attending physician and the patient, coverage for all stages of reconstruction of the breast on which the mastectomy was performed, surgery and reconstruction of the other breast to produce a symmetrical appearance, prostheses, and treatment of physical complications of the mastectomy, including lymphedema. In the FAQs, the Departments confirm that this includes coverage for chest wall reconstruction with aesthetic flat closure, if elected by the patient in consultation with the attending physician in connection with a mastectomy.

Action Steps

Non-grandfathered group health plans subject to the ACA preventive care mandate should ensure they are covering, without cost sharing, all required preventive care, including, for plan years beginning on or after August 31, 2024, specified oral and injectable formulations of PrEP and specified baseline and monitoring services. Additionally, plans should work with claims administrators to ensure they correctly process claims for preventive care. Group health plans that cover mastectomies should be aware that the required coverage includes chest wall reconstruction with aesthetic flat closure if elected by the individual.

The intent of this article is to provide general information on employee benefit issues. It should not be construed as legal advice and, as with any interpretation of law, plan sponsors should seek proper legal advice for application of these rules to their plans.