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BENEFITS BRIEF

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# New Agency FAQs on ACA Preventive Care Services

Introduction

On May 11, 2015, the Department of Labor ("DOL"), the Department of Health and Human Services ("HHS"), and the Treasury Department (collectively the "Departments") issued a set of Frequently Asked Questions (ACA FAQs Part XXVI) clarifying the services that must be provided under the Affordable Care Act's ("ACA") preventive care rules.

Although the new FAQs are billed as clarifications, they do appear to break some new ground. The three FAQs on Food and Drug Administration ("FDA") recommended preventive services, in particular, raise significant concerns about the extent to which group health plans and health insurance issuers will be able to retain their traditional roles in defining medical necessity for purposes of plan administration.

Much of the guidance does not have an effective date, which suggests the FAQs may be effective now – the only exception is the guidance regarding contraceptives, which the FAQs indicate applies to plan years starting 60 days after publication of the new FAQ.

Background

The ACA generally requires group health plans to cover the following preventive care benefits without any imposition of cost-sharing:

- Evidence-based items or services that have in effect a rating of "A" or "B" in the current recommendations of the United States Preventive Services Task Force ("USPSTF") with respect to the individual market, except for the recommendations of the USPSTF regarding breast cancer screening, mammography, and prevention issued on or around November 2009 (which gives a C recommendation to mammography for women under age 50, meaning that such mammograms would not be covered absent the special rule);

- Immunizations for routine use in children, adolescents, and adults that have in effect a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control ("CDC") with respect to the individual involved;

- With respect to infants, children, and adolescents, evidence-informed preventive care and screenings provided for in the comprehensive guidelines supported by the Health Resources Service Administration ("HRSA");

- With respect to women, evidence-informed preventive care and screenings provided for in comprehensive guidelines support by HRSA, to the extent not already included in the current recommendations of the USPSTF.

PHSA § 2713(a); 29 CFR § 2590.715-2713(a).

Where there is an update to a recommendation, such coverage must be provided for plan years beginning on or after one year after the date the recommendation or guideline is issued. 29 CFR § 2590.715-2713(b)(1).

The regulations do permit health plans to place some "reasonable medical management" limits on coverage where a recommendation or guideline does not specify the frequency, method, treatment, or setting for the provision of that service. 29 CFR § 2590.715-2713(a)(4). For example, in February of 2013, the Departments released an FAQ explaining that the HRSA guidelines required the coverage of FDA-approved contraceptive methods, but also provided that plans and issuers may use reasonable medical management techniques to control costs and promote efficient delivery of care. ACA FAQs Part XII, Q.14.

The New FAQs

The new FAQs address the following issues:

- BRCA (breast cancer susceptibility gene) testing (Q&A 1)
- FDA approved contraceptives (Q&As 2-4)
- Sex-specific recommended preventive services (Q&A 5)
- Well-woman visits for dependents (Q&A 6)
- Colonoscopies (Q&A 7)

***BRCA Testing***

One of the USPSTF's B recommendations is that primary care providers screen women who have family members with breast, ovarian, tubal, or peritoneal cancer, and that women with positive screening results receive genetic counseling and, if indicated after counseling, BRCA testing. The new FAQs clarify that a plan must cover, without cost sharing, recommended genetic counseling and BRCA genetic testing even for a woman who previously has had breast cancer, ovarian cancer, or other cancer, as long as she has not been diagnosed with BRCA-related cancer.

***FDA-Approved Contraceptives***

The HRSA women's preventive services guidelines include a recommendation to cover all FDA-approved contraceptive methods, sterilization procedures, and patient education and counseling for all women with reproductive capacity, as prescribed by a health care provider. The new FAQs provide further guidance on the scope of coverage required for contraception and the extent to which plans and issuers may use reasonable medical management techniques to limit coverage.

- Full Range of Methods – Plans must cover without cost sharing the full range of FDA-identified methods, meaning that plans must cover without cost sharing at least one form of contraception in each method (currently 18) that the FDA has identified for women in its most recent birth control guide. The FAQs include a list of these categories.

- Reasonable Medical Management – The FAQs re-state the Departments' position that if multiple services and FDA-approved items within a contraceptive method are medically appropriate for an individual, the plan may use reasonable medical management techniques to determine which specific products to cover without cost sharing with respect to that individual (subject to the exceptions process, explained below). For example, a health plan generally may impose cost sharing (including full cost sharing) on some items and services, such as brand-name contraceptives, to encourage an individual to use other specific items and services (such as generics) within the chosen contraceptive method.

- Exceptions Process – The new FAQs provide that if plans utilize reasonable medical management techniques within a specified method of contraception, they must have "an easily accessible, transparent, and sufficiently expedient exceptions process that is not unduly burdensome on the individual or a provider (or other individual acting as a patient's authorized representative)."

The FAQs provide that if an individual's attending provider recommends a particular service or FDA-approved item based on a determination of medical necessity with respect to that individual, the plan or issuer must cover that service or item without cost sharing. The new FAQs provide that in determining medical necessity "the plan or issuer must defer to the determination of the attending provider."

The new FAQs create some confusion about whether, and in what circumstances, group health plans and health insurance issuers may continue to use their definition of medical necessity. Historically, group health plans and health insurance issuers, and not attending providers, have defined medical necessity. The new FAQs can arguably be seen as part of a recent trend in the Departments' guidance to defer to providers, rather than to plans and issuers, in determining medical necessity.

***Sex-Specific Recommended Preventive Services***

The FAQs also address coverage for recommended preventive services based on gender. The FAQs provide that where an attending provider determines that a recommended preventive service is medically appropriate for the individual, and the individual otherwise satisfies the criteria in the relevant recommendation or guideline as well as all other applicable coverage requirements, the plan must provide coverage for the recommended preventive service, without cost sharing. The FAQs provide that this coverage must be offered regardless of sex assigned at birth, gender identity, or gender of the individual otherwise recorded by the plan.

***Well-Woman Preventive Care for Dependents***

Under the FAQs, health plans also must cover, without cost sharing, well-woman preventive services for dependent children where an attending provider determines that well-woman preventive services are age- and developmentally-appropriate for the dependent.

***Colonoscopies***

The FAQs state that a plan may not impose cost sharing with respect to anesthesia services performed in connection with a preventive colonoscopy if the attending provider determines that anesthesia would be medically appropriate for the individual.

What Plans and Issuers Should be Doing Now

- Make sure that all non-grandfathered plans cover all of the required preventive services, as clarified in the new FAQs.
- Make sure to include an appropriate exceptions process that conforms to the Departments' strict requirements regarding deferring to the determination of attending providers.
- Review the USPSTF's list of recommendations annually to see if new preventive services should be added to plan coverage (there generally are new recommendations added every year).
- If the plan will impose any reasonable medical management techniques, be sure to adopt these limitations as any other plan term (such as through a plan amendment) and communicate to participants.
- Make sure that all plan documents, including SPDs, are updated to reflect the items addressed in the new FAQs and any new recommendations.