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New ACA Guidance on Requirement to Cover Preventive Health Services

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On July 14, 2015, the Internal Revenue Service, Department of Labor and Department of Health and Human Services (the "Departments") jointly finalized interim final regulations issued in July 2010 regarding the Affordable Care Act's ("ACA") requirement to cover certain preventive health services without cost-sharing by non-grandfathered plans. They also finalized the process that "eligible organizations" must follow to object to covering contraceptive services on religious grounds (see: http://www.gpo.gov/fdsys/pkg/FR-2015-07-14/pdf/2015-17076.pdf).

The final regulations come on the heels of FAQs issued by the Departments on May 11, 2015 (FAQs About Affordable Care Act Implementation Part XXVI) regarding the requirement to cover BRCA testing, FDA-approved contraceptives, sex-specific recommended preventive services, certain well-woman preventive care for dependents, and anesthesia services provided in connection with a colonoscopy. This article focuses on the changes and clarifications announced in the final regulations and related FAQs and what plan sponsors must consider as they design their plans for the upcoming plan year. (*Note:* The complete list of preventive health services that a plan must cover may be found at: https://www.healthcare.gov/preventive-care-benefits/).

Background

Section 2311 of the Public Health Service Act, as amended by the ACA, requires non-grandfathered health plans to provide the following preventive health services without any cost-sharing:

- Evidenced-based items or services that have a rating of "A" or "B" in the current recommendations of the United States Preventive Services Task Force ("USPSTF"), except for USPSTF-recommended breast cancer screening, mammography, and prevention in guidance issued in November 2009;
- Immunizations recommended by the Advisory Committee on Immunization Practices ("ACIP") of the Centers for Disease Control and Prevention, for routine use in children and adolescents, and adults;
- For infants, children and adolescents, evidence-informed preventive care and screenings provided for in comprehensive guidelines supported by the Health Resources and Services Administration ("HRSA"); and
- For women, evidence-informed preventive care and screening provided in comprehensive guidelines supported by HRSA, including FDA-approved contraceptives, sterilization

procedures, and patient education and counseling for women with reproductive capacity, as prescribed by a health care provider.

The Departments noted in the July 2010 interim final regulations that a plan or issuer may use reasonable medical management techniques to determine coverage limitations if a recommendation or guideline does not specify the frequency, method, treatment, or setting for the provision of a recommended preventive service.

Final Regulations

The final regulations confirm or clarify the following:

- ***"Primary Purpose" Test Must Be Used to Determine If Cost-Sharing May Be Imposed:*** Affirming the July 2010 interim final regulations, the final regulations state that a plan may not impose cost-sharing for an office visit if a recommended preventive service is not billed separately (or is not tracked as individual encounter data separate) from the visit and the primary purpose of the visit is the delivery of the recommended preventive service. The preamble to the final regulations note that the Departments anticipate that the determination of a visit's "primary purpose" will be resolved through normal billing and coding activities.
- ***Certain Preventive Services Furnished by a Non-Network Provider Must Be Covered Without Cost-Sharing:*** The final regulations clarify that if a plan's network does not include a provider who can provide a particular recommended preventive service, the plan must cover the non-network-provided preventive service without any cost-sharing.
- ***Reasonable Medical Management:*** The final regulations adopt the guidance issued in FAQ, Part II, Q&A 8, permitting plans to rely on the relevant evidence base and established reasonable medical management techniques to determine the frequency, method, treatment or setting for the provision of a recommended preventive service where such limits are not provided for in the applicable recommendation or guideline.
- ***Coverage of Additional Preventive Services:*** Plans are free to cover preventive services beyond those that are required by the ACA and can impose cost-sharing on such "non-recommended" services.
- ***Changes to Recommended Preventive Services:*** Consistent with the July 2010 interim regulations, the final regulations give plans until the first day of the first plan year beginning on or after the date that is one year after the date the relevant recommendation or guideline is issued to commence coverage of the preventive service. The final regulations, however, clarify that if a service or item ceases to be specified as a recommendation or guideline during the middle of a plan year, the plan must continue to provide coverage for the item or service through the last day of the plan year unless the item or service is downgraded from an "A" or "B" rating to a "D" rating, is subject to a safety recall, or is otherwise determined to pose a significant safety concern by a federal agency authorized to regulate the service or item. If any of these exceptions apply, the plan may terminate coverage of the service or item immediately. For example, if the USPSTF downgrades a service from an "A" to a "C" rating on June 1, 2017, a calendar-year

non-grandfathered plan would have to continue covering the particular preventive service without cost-sharing through December 31, 2017.

- ***Coverage of BRCA Testing:*** As provided in the FAQs issued on May 11, 2015, plans must cover recommended genetic counseling and BRCA genetic testing for any woman who previously had breast cancer, ovarian cancer, or other cancer if appropriate as determined by her attending provider, without any cost-sharing. The coverage requirement applies even if the woman was not diagnosed with a BRCA-related cancer (breast cancer susceptibility genes, BRCA 1 or BRCA 2).

- ***Requirement to Cover FDA-Approved Contraceptives:*** The HRSA guidelines recommend coverage for all Food and Drug Administration ("FDA") approved contraceptive procedures, sterilization procedures, and patient counseling for all women with reproductive capacity, as prescribed by a health care provider. The FAQs clarify that plans must cover without cost-sharing at least one form of contraception in EACH of the methods identified by the FDA for women in its current Birth Control Guide, including clinical services such as patient education and counseling. To date, the FDA recommendations include the following 18 methods: (1) sterilization surgery for women; (2) surgical sterilization implant for women; (3) implantable rod; (4) IUD copper; (5) IUD with progestin; (6) shot/injection; (7) oral contraceptives (combined pill); (8) oral contraceptives (or progestin only); (9) oral contraceptives extended/continuous use; (10) patch; (11) vaginal contraceptive ring; (12) diaphragm; (13) sponge; (14) cervical cap; (15) female condom; (16) spermicide; (17) emergency contraception (Plan B/Plan B OneStep/Next Choice); and (18) emergency contraception (Ella).

  Reasonable Exceptions Process: The FAQs state that plans may use reasonable medical management techniques to determine the form of contraception that will be covered without cost-sharing within each method, but must provide for an easily accessible, transparent and expedient exceptions process that is not unduly burdensome on an individual or provider. For example, if an individual's attending provider recommends a specific FDA-approved item based on medical necessity (*e.g.,* severity of side effects, differences in permanence or reversibility, or ability to adhere to the appropriate use of the item), the plan must defer to the provider's determination and cover that service without cost-sharing.

  Some Cost-Sharing Permitted: The FAQs also clarify that plans may impose cost-sharing on some items or services to encourage the use of other specific items and services within the chosen contraceptive method. For example, a plan may impose cost-sharing on brand name pharmacy items versus generic pharmacy items or use cost-sharing to encourage use of one of several FDA-approved IUDs with progestin.

  Note: The above-described contraceptive guidance applies for plan years beginning on or after the date that is 60 days after May 11, 2015 (*i.e.,* January 1, 2016 for a calendar-year plan).

- ***Sex-Specific Recommended Preventive Services:*** The FAQs clarify that a plan may not limit sex-specific recommended preventive services based on an individual's sex assigned

at birth, gender identity or recorded gender. Coverage for a medically appropriate service is determined by the individual's attending provider.

- ***Coverage of Well-Woman Preventive Care for Dependents, Including Recommended Preventive Care Related to Pregnancy, Such as Preconception and Pre-Natal Care:*** The FAQs clarify that if a non-grandfathered plan provides coverage to dependent children, the plan must cover the full range of recommended preventive services applicable to them (*e.g.,* age- and developmentally-appropriate) without cost-sharing. This means that if a dependent child is pregnant, the plan must cover any recommended preventive services related to the dependent's pregnancy, such as prenatal care, for that child.
- ***Coverage of Anesthesia Services in Connection with a Colonoscopy:*** The FAQs clarify that a plan must cover anesthesia services that are performed with a preventive colonoscopy without any cost-sharing, if the attending provider determines that such anesthesia is medically appropriate for the individual.
- ***Objection to Contraceptive Coverage on Religious Grounds:*** The final regulations allow entities to object to the contraceptive mandate and set forth the criteria for certain non-profit religious organizations to provide notice of their objection to the contraceptive coverage requirement.

Unless otherwise specified herein, the FAQs described above are for a calendar year plan, and the final regulations are applicable as of the first plan year beginning on or after September 1, 2015 *(i.e.,* January 1, 2016 for a calendar-year plan). Plan sponsors must review their plan documents and participant communications now to ensure they are able to timely comply. Plan sponsors may also wish to ensure that any third party administrators are aware of the new requirements and will administer the plan's preventive care benefit accordingly. If you have any questions, please contact the author of this article.

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