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REFORM UPDATE

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FREQUENTLY ASKED QUESTIONS (FAQS) ON PREVENTIVE CARE SERVICES

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The Departments of Labor (DOL), Health and Human Services (DHHS), and the Treasury jointly published FAQs related to the preventive care services requirements of the Affordable Care Act (ACA). The FAQs are designed to provide additional guidance to stakeholders regarding how various preventive care services will need to be covered by health plans.

The ACA requires non-grandfathered group health plans to cover certain preventive care items and services without participant cost-sharing, including:

- Evidenced-based items or services that have an "A" or "B" rating from the United States Preventive Services Task Force (USPSTF);
- Immunizations for children, adolescents and adults as recommended by the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention;
- Preventive care and screenings for infants, children and adolescents as recommended by the Health Resources and Services Administration (HRSA); and
- Preventive care screenings for women, in accordance with guidelines supported by HRSA.

Certain exemptions and exclusions with regard to contraceptive coverage are available for specific religious and religious-affiliated employers.

The recommendations of these organizations can change. In general, health plans have a year to adopt any new preventive care recommendations. They can be adopted as of the first day of the first plan year following 12 months after the recommended change.

The Departments believe that health plans are not necessarily covering preventive services in the manner required by the ACA. These FAQs are designed to provide clarification on various preventive care coverage situations.

COLONOSCOPIES

The FAQs provide clarification on coverage for preventive colonoscopies. If a colonoscopy is performed as a preventive screening for colorectal cancer pursuant to the USPSTF recommendation, the plan cannot impose cost-sharing on the related in-network anesthesia services, if the attending physician determines that anesthesia is medically appropriate for the patient.

BRCA TESTING

The FAQs provide more information on coverage for BRCA testing. This is an expensive genetic test designed to identify women with harmful mutations in either the BRCA1 or BRCA2 genes. Women with this mutation are five times more likely to develop breast cancer, and their risk of ovarian cancer is about ten to thirty times higher than that of a woman without the BRCA mutation. Many stakeholders were unsure about their obligation to cover this test under the preventive services requirements.

The USPSTF recommends, with a "B" rating, that primary care providers screen women with family members who were diagnosed with breast, ovarian, tubal or peritoneal cancer. Women with positive screening results should receive genetic counseling and, if indicated after counseling, the BRCA testing. The USPSTF states that this recommendation applies to asymptomatic women who have not been diagnosed with BRCA-related cancer. As long as a woman has not been diagnosed with a BRCA-related cancer, a plan must cover the screening, genetic counseling and genetic testing without member cost-sharing, if these services are determined to be appropriate by her attending provider.

CONTRACEPTIVE METHODS

The HRSA guidelines include the recommendation to cover FDA-approved contraceptive methods, sterilization procedures, patient education and counseling for all women with reproductive capacity, as prescribed by a health care provider without cost-sharing. The HRSA wants to ensure a woman's access to the full range of FDA-approved contraceptive methods, which include (but are not limited to) barrier methods, hormonal methods and implanted devices. The guidelines allow plans to apply reasonable medical management techniques to control costs and promote efficient delivery of care. However, the plan needs to accommodate any individual for whom a specific drug or method is medically required. Member cost-sharing must be waived in those situations.

The Departments are concerned that many plans are not covering contraceptive services as intended by the ACA. Additional details are provided on the parameters that plans must adopt when covering contraceptive services:

1. Plans and issuers **must cover without cost-sharing at least one form of contraception in each of the 18 methods that the FDA has identified for women in its current Birth Control Guide**. This coverage must also include the clinical services, including patient education and counseling, needed for provision of the contraceptive method.
2. Within each method, plans and issuers **may adopt reasonable medical management techniques**. A plan or issuer generally may **impose cost-sharing (including full cost-sharing) on some items and services to encourage an individual to use other specific items and services within the chosen contraceptive method**. For example, a plan may discourage the use of brand-name pharmacy items over generic pharmacy items through the imposition of cost-sharing. Similarly, a plan may use cost-sharing to encourage the use of one of several FDA-approved intrauterine devices (IUDs) with progestin.
3. If applying reasonable medical management techniques to a specified method of contraception, plans must have an easily accessible, transparent and sufficiently expedient "exceptions" process. This process cannot be unduly burdensome on the individual or a provider:
    a. 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, then the plan or issuer must cover that service or item without cost-sharing. **The plan or issuer**

must defer to the determination of the attending provider. Medical necessity may include considerations such as severity of side effects, differences in permanence and reversibility of contraceptives, and ability to adhere to the appropriate use of the item or service, as determined by the attending provider.

b. The "exceptions" process must make a determination of the claim according to a timeframe and in a manner that takes into account the nature of the claim (e.g., pre-service or post-service) and the medical exigencies involved for a claim involving urgent care.

The Departments' prior guidance may have reasonably been interpreted in good faith as not requiring coverage without cost-sharing for at least one form of contraception in each method identified by the FDA. As a result, the Departments **will apply this clarifying guidance for plan years beginning on or after the date that is 60 days following publication of these FAQs**. Plans should ensure their contraceptive coverage meets these guidelines as of the first day of the first plan year following July 10, 2015.

A number of specific questions were addressed about this new clarification:

- **Can a plan cover some forms of oral contraceptives, some types of IUDs and some forms of diaphragms without cost-sharing but completely exclude other forms of contraceptives?**
  No, plans must cover without cost-sharing the full-range of FDA approved methods. However, plans must cover without cost-sharing at least one form of contraception in each of the 18 distinct methods identified for women by the FDA. A plan may generally use medical management or impose cost-sharing to encourage a patient to use specific services or FDA-approved items within a chosen contraceptive method.
- **If multiple services and FDA approved items within a contraceptive method are medically appropriate for a patient, what is a plan required to cover without cost-sharing?**
  The plan may use reasonable medical management techniques to determine which specific products and services will be covered without cost-sharing. However, if a patient's attending physician recommends a particular service or item based on medical necessity in relation to the patient, the plan must cover that service or item without cost-sharing. The plan **MUST DEFER** to the attending physician's determination with respect to that individual.
- **If a plan covers oral contraceptives with no cost-sharing, can it impose cost-sharing on all other items and services within the other FDA-identified hormonal contraceptive methods, such as the vaginal contraceptive ring or the contraceptive patch?**
  No, plans must cover at least one form of contraception within each method without cost-sharing. For hormonal contraception, coverage must include all three oral methods (combined, progestin only, and extended/continuous use), injectables, implants, the vaginal contraceptive ring, the contraceptive patch, emergency contraception (plan B), emergency contraception (Ella) and IUDs with progestin. A plan may not impose cost-sharing on the ring or patch.

Plans should review their coverage for contraceptive services. Many are not currently covering at least one option in each of the 18 distinct categories of contraceptive services.

COVERAGE OF SEX-SPECIFIC RECOMMENDED PREVENTIVE SERVICES

The FAQs address the coverage of sex-specific preventive services for individuals who have undergone gender reassignment.

Plans cannot limit sex-specific recommended preventive services based on an individual's sex assigned at birth, gender identity or recorded gender. Instead, the plan must allow the attending physician to determine which gender-specific preventive care services should be covered for the individual.

COVERAGE OF WELL-WOMAN PREVENTIVE CARE FOR DEPENDENTS

The FAQs also addressed a topic that has challenged many health plans, which is the extent to which well-woman preventive care services must be covered for dependent children enrolled in the plan.

If a plan covers dependent children, they must be provided with the full range of recommended preventive care services applicable for their gender and age. These services will be covered without cost-sharing, although they are subject to any reasonable medical management techniques applied by the plan. If an attending physician determines that well-woman visits are age and developmentally appropriate for a dependent, then these services must be covered. Such services may include pre-conception and several services related to prenatal care.

CONCLUDING THOUGHTS

Non-grandfathered plans are required to cover specific preventive care services with no member cost-sharing. The coverage of preventive services is complicated, because the services are determined by several different governmental agencies. Health insurance carriers and plan administrators need to pay close attention, as these agencies regularly review and modify the recommended preventive services.

The government is concerned that many health plans are not properly covering many of the preventive care services. These new FAQs are designed to provide additional detail, in order for insurance carriers and administrators to better understand how various services need to be covered. For example, the FAQs offer expanded guidance on coverage for contraceptive services. This clarification on contraceptive services will affect health plans as of the first day of the first plan year beginning on or after July 10, 2015.