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FAQs on Preventive Care Services

New Frequently Asked Questions (FAQs), prepared jointly by the Departments of Labor (DOL), Health and Human Services (HHS), and the Treasury (collectively, the Departments), further clarify the responsibilities of group health plans and insurers to cover contraceptives and other preventive services. The healthcare reform law requires non-grandfathered group health plans to cover certain preventive care services (such as mammograms, colonoscopies and immunizations) without cost-sharing. The coverage offered must be consistent with published recommendations and guidelines from the United States Preventive Services Task Force (USPSTF), the Centers for Disease Control and Prevention Advisory Committee on Immunization Practices (ACIP), and the Health Resources and Services Administration (HRSA).

Coverage of Contraceptives: The HRSA Guidelines include a recommendation for all FDA-approved contraceptive methods, sterilization procedures, and patient education and counseling for all women with reproductive capacity, as prescribed by a healthcare provider. Previously, the Departments issued an FAQ stating that the HRSA Guidelines ensure women's access to the full range of FDA-approved contraceptive methods including, but not limited to, barrier methods, hormonal methods, and implanted devices, as well as patient education and counseling, as prescribed by a healthcare provider. The FAQ further clarified that plans may use reasonable medical management techniques to control costs and promote efficient delivery of care, such as covering a generic drug without cost sharing and imposing cost sharing for equivalent branded drugs. However, in these instances, the FAQ stated that a plan must accommodate any individual for whom a particular drug (generic or brand name) would be medically inappropriate, as determined by the individual's healthcare provider, by having a mechanism for waiving the otherwise applicable cost sharing for the brand or non-preferred brand version.

The new FAQs provide further guidance on the scope of coverage required for contraception and the extent to which plans may utilize reasonable medical management. Specifically:

- Group health plans must cover, without cost sharing, at least one form of contraception in each of the methods (currently 18) that the FDA has identified in its current Birth Control Guide. These are:
  - sterilization surgery for women;
  - surgical sterilization implant for women;
  - implantable rod;
  - IUD copper;
  - IUD with progestin;

- shot/injection;
- oral contraceptives (combined pill);
- oral contraceptives (progestin only);
- oral contraceptives extended/continuous use;
- patch;
- vaginal contraceptive ring;
- diaphragm;
- sponge;
- cervical cap;
- female condom;
- spermicide;
- emergency contraception (Plan B/Plan B One Step/Next Choice); and
- emergency contraception (Ella).

  This coverage must also include the clinical services, including patient education and counseling, needed for provision of the contraceptive method.

- Within each method, plans may utilize reasonable medical management techniques. A plan 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 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 use of one of several FDA-approved intrauterine devices (IUDs) with progestin.
- If utilizing reasonable medical management techniques within a specified method of contraception, plans 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).
  - 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 must cover that service or item without cost sharing. The plan 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.
  - This 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.

Because the Departments believe that their earlier guidance may have been interpreted in good faith as not requiring coverage without cost sharing of at least one form of contraceptive in each method, the Departments will only enforce this clarifying guidance with respect to plan years beginning on or after July 10, 2105 (the date that is 60 days after publication of these FAQs).

Other Preventive Services: The FAQs include other clarifications of covered preventive services.

- *BRCA testing.* The USPSTF's recommendation for genetic counseling and evaluation for routine breast cancer susceptibility gene (BRCA) testing includes the BRCA test. The law requires that plans cover, without cost-sharing, preventive services with an A or B rating

from the USPSTF, if appropriate. The new FAQs clarify that a plan must cover, without cost sharing, recommended genetic counseling and BRCA genetic testing for women who have not been diagnosed with BRCA-related cancer, but who previously had breast cancer, ovarian cancer, or other cancer.

- *Sex-specific recommended preventive services.* The FAQs provide that plans may not limit sex-specific recommended preventive services based on an individual's sex assigned at birth, gender identity or recorded gender, when the service is determined to be medically appropriate for a particular individual by the individual's attending provider. For example, providing a mammogram or pap smear for a transgender man who has residual breast tissue or an intact cervix – 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 the coverage.
- *Well-woman preventive care for dependents.* The FAQs clarify that a plan that covers dependent children, is required to cover, without cost sharing, recommended women's preventive care services for dependent children, including recommended preventive services related to pregnancy, such as preconception and prenatal care, where an attending provider determines that well-woman preventive services are age- and developmentally-appropriate for the dependent. For example, the HRSA Guidelines recommend well-woman visits for adult women to obtain the recommended preventive services that are age- and developmentally-appropriate, including preconception care and many services necessary for prenatal care.
- *Anesthesia service in connection with preventive colonoscopy.* The FAQs clarify that a plan may not impose cost sharing with respect to anesthesia services performed in connection with a colonoscopy scheduled and performed as a preventive screening procedure for colorectal cancer, if the attending provider determines that anesthesia would be medically appropriate for the individual.

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