FAQS ABOUT AFFORDABLE CARE ACT IMPLEMENTATION (PART XXVI)

May 11, 2015

Set out below are additional Frequently Asked Questions (FAQs) regarding implementation of the Affordable Care Act. These FAQs have been prepared jointly by the Departments of Labor (DOL), Health and Human Services (HHS), and the Treasury (collectively, the Departments). Like previously issued FAQs (available at http://www.dol.gov/ebsa/healthreform/ and http://www.cms.gov/cciio/resources/fact-sheets-and-faqs/index.html), these FAQs answer questions from stakeholders to help people understand the Affordable Care Act and benefit from it, as intended.

Coverage of Preventive Services

Section 2713 of the Public Health Service Act (PHS Act) and its implementing regulations relating to coverage of preventive services[1] require non-grandfathered group health plans and health insurance coverage offered in the individual or group market to provide benefits for, and prohibit the imposition of cost-sharing requirements with respect to, the following:

- Evidenced-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 involved, except for the recommendations of the USPSTF regarding breast cancer screening, mammography, and prevention issued in or around November 2009;
- Immunizations for routine use in children, adolescents, and adults that have in effect a recommendation from the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC) with respect to the individual involved;
- With respect to 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
- With respect to women, evidence-informed preventive care and screening provided for in comprehensive guidelines supported by HRSA, to the extent not included in certain recommendations of the USPSTF.[2]

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[1] 26 CFR 54.9815-2713, 29 CFR 2590.715-2713, 45 CFR 147.130.

[2] "Women's Preventive Services: Required Health Plan Coverage Guidelines" (HRSA Guidelines) were adopted and released on August 1, 2011, based on recommendations developed by the Institute of Medicine (IOM) at the request of HHS. Women's preventive services recommended therein are required to be covered without cost sharing for plan years (or, in the individual market, policy years) beginning on or after August 1, 2012. Under the HRSA Guidelines, group health plans established or maintained by religious employers (and group health insurance coverage provided in connection with such plans) are exempt from the requirement to cover contraceptive services under section 2713 of the PHS Act, as incorporated into the Employee Retirement Income Security Act and the Internal Revenue Code. 45 CFR 147.131(a). Additionally, accommodations are available to group health plans

If a recommendation or guideline does not specify the frequency, method, treatment, or setting for the provision of a recommended preventive service, the plan or issuer may use reasonable medical management techniques to determine any such coverage limitations.[3]

Coverage of BRCA Testing

As described in a previous FAQ,[4] PHS Act section 2713 addresses coverage for evidence-based items or services with a rating of "A" or "B" in the current recommendations of the USPSTF, as well as coverage for preventive care and screenings as provided for in comprehensive guidelines supported by HRSA. The USPSTF recommends with a "B" rating to "screen women who have family members with breast, ovarian, tubal or peritoneal cancer with 1 of several screening tools designed to identify a family history that may be associated with an increased risk for potentially harmful mutations in breast cancer susceptibility genes (BRCA 1 or BRCA 2). Women with positive screening results should receive genetic counseling and, if indicated after counseling, BRCA testing."[5] The previous FAQ clarified that HHS believes that the scope of this recommendation includes both genetic counseling and BRCA testing, if appropriate, for a woman as determined by her health care provider.[6]

Some confusion remains as to whether the recommendation applies to women who have had a prior non-BRCA-related breast cancer or ovarian cancer diagnosis, even if those women are currently asymptomatic and cancer-free. A woman with a personal history of cancer may have an increased risk of a harmful mutation even if no other family members are known to have such a history.[7] Primary care screening, genetic counseling and genetic testing if indicated, may help her prevent other future cancers.

Q1: Must a plan or issuer cover without cost sharing recommended genetic counseling and BRCA genetic testing for a woman who has not been diagnosed with BRCA-related cancer but who previously had breast cancer, ovarian cancer, or other cancer?

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established or maintained by certain eligible organizations (and group health insurance coverage provided in connection with such plans), as well as student health insurance coverage arranged by eligible organizations, with respect to the contraceptive coverage requirement.

[3] See 26 CFR 54.9815-2713(a)(4), 29 CFR 2590.715-2713(a)(4), 45 CFR 147.130(a)(4).

[4] See Frequently Asked Questions about Affordable Care Act Implementation, Part XII, Q6, available at http://www.dol.gov/ebsa/faqs/faq-aca12.html and http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs12.html.

[5] See USPSTF recommendation, available at: http://www.uspreventiveservicestaskforce.org/Page/Topic/recommendation-summary/brca-related-cancer-risk-assessment-genetic-counseling-and-genetic-testing.

[6] See Frequently Asked Questions about Affordable Care Act Implementation, Part XII, Q6, available at http://www.dol.gov/ebsa/faqs/faq-aca12.html and http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs12.html.

[7] Nelson HD, Fu R, Goddard K, Mitchell JP, Okinaka-Hu L, Pappas M, Zakher B. Risk Assessment, Genetic Counseling, and Genetic Testing for BRCA-Related Cancer: Systematic Review to Update the U.S. Preventive Services Task Force Recommendation. Evidence Synthesis No. 101. AHRQ Publication No. 12-05164-EF-1. Rockville, MD: Agency for Healthcare Research and Quality; 2013.

Yes. The USPSTF recommends that "primary care providers screen women who have family members with breast, ovarian, tubal, or peritoneal cancer with 1 of several screening tools designed to identify a family history that may be associated with an increased risk for potentially harmful mutations in breast cancer susceptibility genes (BRCA1 or BRCA2). Women with positive screening results should receive genetic counseling and, if indicated after counseling, BRCA testing." The USPSTF's Final Recommendation Statement related to BRCA testing indicates that the recommendation "applies to asymptomatic women who have not been diagnosed with BRCA-related cancer."[8] Therefore, as set out in the recommendations described above, as long as the woman has not been diagnosed with BRCA-related cancer, a plan or issuer must cover preventive screening, genetic counseling, and genetic testing without cost sharing, if appropriate, for a woman as determined by her attending provider, consistent with PHS Act section 2713 and its implementing regulations.[9]

Coverage of Food and Drug Administration (FDA)-approved 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 health care provider. On February 20, 2013, 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 health care provider.[10] The FAQ further clarified that plans and issuers 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 or issuer must accommodate any individual for whom a particular drug (generic or brand name) would be medically inappropriate, as determined by the individual's health care provider, by having a mechanism for waiving the otherwise applicable cost sharing for the brand or non-preferred brand version.[11]

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[8] See USPSTF Final Recommendation Statement. BRCA-Related Cancer: Risk Assessment, Genetic Counseling and Genetic Testing (December 2013), available at http://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/brca-related-cancer-risk-assessment-genetic-counseling-and-genetic-testing.

[9] See 26 CFR 54.9815-2713, 29 CFR 2590.715-2713 and 45 CFR 147.130.

[10] The Departments' previous FAQ referred to categories of specific contraceptive delivery mechanisms including, "barrier methods, hormonal methods, and implanted devices." See Frequently Asked Questions about Affordable Care Act Implementation, Part XII, Q14, available at http://www.dol.gov/ebsa/faqs/faq-aca12.html and http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs12.html. The FDA Birth Control Guide identifies the different contraceptive methods. See FDA Birth Control Guide at http://www.fda.gov/downloads/ForConsumers/ByAudience/ForWomen/FreePublications/UCM356451.pdf. To reduce confusion and for ease of use, these FAQs hereinafter refer to "methods" when referring to the 18 birth control methods for women currently referenced in the FDA Birth Control Guide that must be covered under PHS Act section 2713 and its implementing regulations, and also refer to "FDA-approved items" when referring to specific products currently approved or cleared by the FDA within a method.

[11] See Frequently Asked Questions about Affordable Care Act Implementation, Part XII, Q14, available at http://www.dol.gov/ebsa/faqs/faq-aca12.html and http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs12.html.

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

1) Plans and issuers must cover without cost sharing at least one form of contraception in each of the methods (currently 18) that the FDA has identified for women in its current Birth Control Guide.[12] 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 utilize 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 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.

3) If utilizing reasonable medical management techniques within a specified method of contraception, plans and issuers 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).

    a. If an individual's attending provider[13] 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 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.

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[12] The contraceptive methods for women currently identified by the FDA include: (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 (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 One Step/Next Choice); and (18) emergency contraception (Ella). The FDA Birth Control Guide additionally lists sterilization surgery for men and male condoms, but the HRSA Guidelines exclude services relating to a man's reproductive capacity. See Preamble to Proposed Rules regarding coverage of certain preventive services at 78 FR 8458 (February 6, 2013). See also FDA Birth Control Guide at http://www.fda.gov/downloads/ForConsumers/ByAudience/ForWomen/FreePublications/UCM356451.pdf. See also FDA publication, "Birth Control: Medicines to Help You," available at http://www.fda.gov/ForConsumers/ByAudience/ForWomen/FreePublications/ucm313215.htm#Hormonal_Methods.

[13] An attending provider means an individual who is licensed under applicable state law, who is acting within the scope of the provider's license, and who is directly responsible for providing care to the patient relating to the recommended preventive services. Therefore, a plan, issuer, hospital, or managed care organization is not an attending provider.

b. 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' prior guidance may reasonably have been interpreted in good faith as not requiring coverage without cost sharing of at least one form of contraception in each method identified by the FDA, the Departments will apply this clarifying guidance for plan years (or, in the individual market, policy years) beginning on or after the date that is 60 days after publication of these FAQs.

Q2: If a plan or issuer covers some forms of oral contraceptives, some types of IUDs, and some types of diaphragms without cost sharing, but excludes completely other forms of contraception, will the plan or issuer comply with PHS Act section 2713 and its implementing regulations?

No. Plans and issuers must cover without cost sharing the full range of FDA-identified methods. Thus, plans and issuers must cover without cost sharing at least one form of contraception in each method that is identified by the FDA. The FDA currently has identified 18 distinct methods of contraception for women. A plan or issuer generally may use reasonable medical management techniques and impose cost sharing (including full cost sharing) to encourage an individual patient to use specific services or FDA-approved items within the chosen contraceptive method. If utilizing reasonable medical management techniques, plans and issuers 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) to ensure coverage without cost sharing of any service or FDA-approved item within the specified method of contraception as described in Q&A-3 below. In this example, even though the plan provides coverage in multiple methods, the plan's exclusion of some of the methods for women currently identified by the FDA means the plan fails to comply with PHS Act section 2713 and its implementing regulations.

Q3: If multiple services and FDA-approved items within a contraceptive method are medically appropriate for an individual patient, what is a plan or issuer required to cover without cost sharing?

If multiple services and FDA-approved items within a contraceptive method are medically appropriate for an individual, the plan or issuer may use reasonable medical management techniques to determine which specific products to cover without cost sharing with respect to that individual. However, if the 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 plan or issuer must defer to the determination of the attending provider with respect to the individual involved. As previously stated, the plan or issuer must cover at least one service or item within each of the methods (currently 18) identified by the FDA for women.

Q4: If a plan or issuer covers oral contraceptives (such as the extended/continuous use contraceptive pill), can it impose cost sharing on all items and services within other FDA-identified hormonal contraceptive methods (such as the vaginal contraceptive ring or the contraceptive patch)?

No. The FDA currently identifies 18 distinct methods of contraception for women, and the HRSA Guidelines are designed to provide women's access to the full range of these contraceptive methods identified by the FDA, as prescribed by a health care provider. Thus, plans and issuers must cover without cost sharing at least one form of contraception within each method the FDA has identified. For the hormonal contraceptive methods, coverage therefore must include (but is not limited to) all 3 oral contraceptive methods (combined, progestin-only, and extended/continuous use), injectables, implants, the vaginal contraceptive ring, the contraceptive patch, emergency contraception (Plan B/Plan B One Step/Next Choice), emergency contraception (Ella), and IUDs with progestin. Accordingly, a plan or issuer may not impose cost sharing on the ring or the patch.

Coverage of Sex-specific Recommended Preventive Services

Q5: Can plans or issuers limit sex-specific recommended preventive services based on an individual's sex assigned at birth, gender identity or recorded gender?

No. Whether a sex-specific recommended preventive service that is required to be covered without cost sharing under PHS Act section 2713 and its implementing regulations is medically appropriate for a particular individual is determined by the individual's attending provider. Where an attending provider determines that a recommended preventive service is medically appropriate for the individual – such as, 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 or issuer must provide coverage for the recommended preventive service, without cost sharing, regardless of sex assigned at birth, gender identity, or gender of the individual otherwise recorded by the plan or issuer.

Coverage of Well-woman Preventive Care for Dependents

Q6: If a plan or issuer covers dependent children, is the plan or issuer 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?

Yes. Non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual health insurance coverage must cover specified recommended preventive care services without cost sharing, consistent with PHS Act section 2713 and its implementing regulations, for all participants and beneficiaries under a group health plan (and all individuals enrolled in individual market coverage). If the plan or issuer covers dependent children, such dependent children must be provided the full range of recommended preventive services applicable to them (e.g., for their age group) without cost sharing and subject to

reasonable medical management techniques, in accordance with the requirements of PHS Act section 2713 and its implementing regulations.[14] 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.[15] Therefore, consistent with PHS Act section 2713 and its implementing regulations, plans and issuers must cover without cost sharing these recommended preventive services for dependent children where an attending provider determines that well-woman preventive services are age- and developmentally-appropriate for the dependent.

Coverage of Colonoscopies Pursuant to USPSTF Recommendations

Q7: If a colonoscopy is scheduled and performed as a preventive screening procedure for colorectal cancer pursuant to the USPSTF recommendation, is it permissible for a plan or issuer to impose cost sharing with respect to anesthesia services performed in connection with the preventive colonoscopy?

No. The plan or issuer may not impose cost sharing with respect to anesthesia services performed in connection with the preventive colonoscopy if the attending provider determines that anesthesia would be medically appropriate for the individual.

[14] Section 2714 of the PHS Act and the implementing regulations provide that a group health plan or health insurance issuer that makes available dependent coverage of children must make such coverage available for children until attainment of 26 years of age. 29 CFR 2590.715.2714 (a)(1) and 45 CFR 147.120(a)(1). The rules also provide that nothing in the regulations requires a plan or issuer to make coverage available for the child of a child receiving dependent coverage. 29 CFR 2590.715-2714(c) and 45 CFR 147.120(c).

[15] See HRSA Guidelines, available at http://www.hrsa.gov/womensguidelines/. See also Frequently Asked Questions about Affordable Care Act Implementation Part XII for additional clarifications about well-woman visits and other HRSA guidelines, available at http://www.dol.gov/ebsa/faqs/faq-aca12.html and http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs12.html.