

FAQS ABOUT AFFORDABLE CARE ACT IMPLEMENTATION (PART XII)

February 20, 2013

Set out below are additional Frequently Asked Questions (FAQs) regarding implementation of various provisions of the Affordable Care Act. These FAQs have been prepared jointly by the Departments of Labor, Health and Human Services (HHS), and the Treasury (collectively, the Departments). Like previously issued FAQs (available at <http://www.dol.gov/ebsa/healthreform/>), these FAQs answers questions from stakeholders to help people understand the new law and benefit from it, as intended.

Limitations on Cost-Sharing under the Affordable Care Act

Public Health Service (PHS) Act section 2707(b), as added by the Affordable Care Act, provides that a group health plan shall ensure that any annual cost-sharing imposed under the plan does not exceed the limitations provided for under section 1302(c)(1) and (c)(2) of the Affordable Care Act. Section 1302(c)(1) limits out-of-pocket maximums and section 1302(c)(2) limits deductibles for employer-sponsored plans.

Q1: Who must comply with the deductible limitations under PHS Act section 2707(b)?

The HHS final regulation on standards related to essential health benefits implements the deductible provisions described in section 1302(c)(2) for non-grandfathered¹ health insurance coverage and qualified health plans offered in the small group market, including a provision implementing section 1302(c)(2)(C) so that such small group market health insurance coverage may exceed the annual deductible limit if it cannot reasonably reach a given level of coverage (metal tier) without exceeding the deductible limit.²

With respect to self-insured and large group health plans, as explained in the preamble to the HHS final regulations, the Departments intend to engage in future rulemaking to implement PHS Act section 2707(b). The Departments continue to believe that only plans and issuers in the small group market are required to comply with the deductible limit described in section 1302(c)(2). Public input is welcome in advance of a future rulemaking, which will implement that only plans and issuers in the small group market will be subject to the deductible limit. Please send comments by April 22, 2013 to e.ohpsca-2707.ebsa@dol.gov.

¹ See The Departments interim final regulations relating to grandfather health plans (June 17, 2010) at 75 FR 34538 (June 17, 2010) and amended interim final regulations at 75 FR 70114 (November 17, 2010).

² Issued February 20, 2013 and available at: <http://cciio.cms.gov/resources/regulations/index.html#pm>.

Until that rulemaking is promulgated and effective, the Departments have determined that a self-insured or large group health plan can rely on the Departments' stated intention to apply the deductible limits imposed by section 1302(c)(2) of the Affordable Care Act only on plans and issuers in the small group market.

Q2: Who must comply with the annual limitation on out-of-pocket maximums under PHS Act section 2707(b)?

As stated in the preamble to the HHS final regulation on standards related to essential health benefits, the Departments read PHS Act section 2707(b) as requiring all non-grandfathered group health plans to comply with the annual limitation on out-of-pocket maximums described in section 1302(c)(1) of the Affordable Care Act.³

The Departments recognize that plans may utilize multiple service providers to help administer benefits (such as one third-party administrator for major medical coverage, a separate pharmacy benefit manager, and a separate managed behavioral health organization). Separate plan service providers may impose different levels of out-of-pocket limitations and may utilize different methods for crediting participants' expenses against any out-of-pocket maximums. These processes will need to be coordinated under section 1302(c)(1), which may require new regular communications between service providers.

The Departments have determined that, only for the first plan year beginning on or after January 1, 2014, where a group health plan or group health insurance issuer utilizes more than one service provider to administer benefits that are subject to the annual limitation on out-of-pocket maximums under section 2707(a) or 2707(b), the Departments will consider the annual limitation on out-of-pocket maximums to be satisfied if both of the following conditions are satisfied:

- (a) The plan complies with the requirements with respect to its major medical coverage (excluding, for example, prescription drug coverage and pediatric dental coverage); and
- (b) To the extent the plan or any health insurance coverage includes an out-of-pocket maximum on coverage that does not consist solely of major medical coverage (for example, if a separate out-of-pocket maximum applies with respect to prescription drug coverage), such out-of-pocket maximum does not exceed the dollar amounts set forth in section 1302(c)(1).

The Departments note, however, that existing regulations implementing Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA)⁴ prohibit a group health plan (or health insurance coverage offered in connection with a group health plan) from applying a cumulative financial requirement or treatment limitation, such as an out-of-pocket maximum, to mental health or substance use disorder benefits that accumulates separately from any such cumulative financial requirement or treatment limitation established for medical/surgical benefits. Accordingly, under

³ See section 1251 of the Affordable Care Act, which limits the application of PHS Act section 2707 to non-grandfathered group health plans and health insurance coverage.

⁴ See 26 CFR 54.9812-1(c)(3)(v), 29 CFR 2590.712(c)(3)(v), and 45 C.F.R. 146.136(c)(3)(v).

MHPAEA, plans and issuers are prohibited from imposing an annual out-of-pocket maximum on all medical/surgical benefits and a separate annual out-of-pocket maximum on all mental health and substance use disorder benefits.

Coverage of Preventive Services

PHS Act section 2713 and the interim final regulations⁵ 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;
- 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 the 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 already included in certain recommendations of the USPSTF.⁶

If a recommendation or guideline does not specify the frequency, method, treatment, or setting for the provision of that service, the plan or issuer can use reasonable medical management techniques to determine any coverage limitations.⁷

These requirements do not apply to grandfathered health plans.⁸

Out-of-Network Services Generally

Q3: My plan does not have any in-network providers to provide a particular preventive service required under PHS Act section 2713. If I obtain this service out-of-network, can the plan impose cost-sharing?

No. While nothing in the interim final regulations generally requires a plan or issuer that has a network of providers to provide benefits for preventive services provided out-of-network, this

⁵ 75 FR 41726 (July 19, 2010).

⁶ “Women’s Preventive Services: Required Health Plan Coverage Guidelines” (HRSA Guidelines) were adopted and released on August 1, 2012, based on recommendations developed by the Institute of Medicine (IOM) at the request of HHS. These recommended women’s preventive services 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.

⁷ See 26 CFR 54.9815-2713T(a)(4), 29 CFR 2590.715-2713(a)(4), 45 CFR 147.130(a)(4).

⁸ Certain non-grandfathered, non-profit religious organizations are not required to cover the contraceptive services recommendation that is part of the HRSA guidelines. For information on these entities, see 77 FR 8725 and <http://cciio.cms.gov/resources/files/prev-services-guidance-08152012.pdf>. See also proposed rules published on February 6, 2013, at 78 FR 8456.

provision is premised on enrollees being able to access the required preventive services from in-network providers. Thus, if a plan or issuer does not have in its network a provider who can provide the particular service, then the plan or issuer must cover the item or service when performed by an out-of-network provider and not impose cost-sharing with respect to the item or service.

United States Preventive Services Task Force (USPSTF)

Q4: The USPSTF recommends the use of aspirin for certain men and women when the potential benefit due to a reduction in myocardial infarctions outweighs the potential harm. Aspirin is generally available over-the-counter (OTC) to patients. Are group health plans and health insurance issuers now required to pay for OTC methods such as aspirin?

Aspirin and other OTC recommended items and services must be covered without cost-sharing only when prescribed by a health care provider.

Q5: If a colonoscopy is scheduled and performed as a screening procedure pursuant to the USPSTF recommendation, is it permissible for a plan or issuer to impose cost-sharing for the cost of a polyp removal during the colonoscopy?

No. Based on clinical practice and comments received from the American College of Gastroenterology, American Gastroenterological Association, American Society of Gastrointestinal Endoscopy, and the Society for Gastroenterology Nurses and Associates, polyp removal is an integral part of a colonoscopy. Accordingly, the plan or issuer may not impose cost-sharing with respect to a polyp removal during a colonoscopy performed as a screening procedure. On the other hand, a plan or issuer may impose cost-sharing for a treatment that is not a recommended preventive service, even if the treatment results from a recommended preventive service.

Q6: Does the recommendation for genetic counseling and evaluation for routine breast cancer susceptibility gene (BRCA) testing include the BRCA test itself?

Yes. HHS believes that the scope of the recommendation includes both genetic counseling and BRCA testing, if appropriate, for a woman as determined by her health care provider.

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 released by HRSA. The USPSTF recommends with a “B” rating that “women whose family history is associated with an increased risk for deleterious mutations in the BRCA1 or BRCA2 genes be referred for genetic counseling and evaluation for BRCA testing.”

The HRSA Guidelines, released by HHS in August 2011, incorporate by reference relevant portions of an Institute of Medicine (IOM) Report, released on July 19, 2011. In some instances, the IOM Committee Report provides additional interpretation of USPSTF recommendations. For the USPSTF BRCA recommendation, the IOM Committee interpreted the recommendation

to include “referral for genetic counseling and BRCA testing, if appropriate.” Thus, genetic counseling and BRCA testing, if appropriate, must be made available as a preventive service without cost-sharing.

Q7: Some USPSTF recommendations apply to certain populations identified as high-risk. Some individuals, for example, are at increased risk for certain diseases because they have a family or personal history of the disease. It is not clear, however, how a plan or issuer would identify individuals who belong to a high-risk population. How can a plan or issuer determine when a service should or should not be covered without cost-sharing?

Identification of “high-risk” individuals is determined by clinical expertise. Decisions regarding whether an individual is part of a high-risk population, and should therefore receive a specific preventive item or service identified for those at high-risk, should be made by the attending provider. Therefore, if the attending provider determines that a patient belongs to a high-risk population and a USPSTF recommendation applies to that high-risk population, that service is required to be covered in accordance with the requirements of the interim final regulations (that is, without cost-sharing, subject to reasonable medical management).

Advisory Committee on Immunization Practices (ACIP)

Q8: Which ACIP recommendations are required to be covered without cost-sharing by non-grandfathered group health plans and health insurance coverage?

PHS Act section 2713 and the interim final regulations require coverage for immunizations for routine use in children, adolescents, and adults that have in effect a recommendation by the ACIP for routine use. The vaccines must be covered without cost-sharing requirements when the service is delivered by an in-network provider. The ACIP makes routine immunization recommendations for children, adolescents, and adults that are population-based (e.g., age-based), risk-based (e.g., underlying medical conditions, work-related, or other special circumstances that increase risk of illness), or are catch-up recommendations.

In some circumstances, the ACIP makes a recommendation that applies for certain individuals rather than an entire population. In these circumstances, health care providers should determine whether the vaccine should be administered, and if the vaccine is prescribed by a health care provider consistent with the ACIP recommendations, a plan or issuer is required to provide coverage for the vaccine without cost-sharing.

New ACIP recommendations will be required to be covered without cost-sharing starting with the plan year (in the individual market, policy year) that begins on or after the date that is one year after the date the recommendation is issued. An ACIP recommendation is considered to be issued on the date on which it is adopted by the Director of the Centers for Disease Control and Prevention (CDC), which is the earlier of: the date the recommendation is published in the *Mortality and Morbidity Weekly Report*, or the date the recommendation is reflected in the Immunization Schedules of the CDC. Therefore plans or issuers with respect to a plan can determine annually what vaccines recommended by ACIP must be covered by checking

<http://www.healthcare.gov/law/features/rights/preventive-care/index.html> prior to the beginning of each plan year.

Women's Preventive Services

Q9: Do the recommendations for women's preventive services in the HRSA Guidelines promote multiple visits for separate services?

No. Section 2713 of the PHS Act and its implementing regulations allow plans and issuers to use reasonable medical management techniques to determine the frequency, method, treatment, or setting for a recommended preventive item or service, to the extent this information is not specified in a recommendation or guideline. Although the HRSA Guidelines list services individually, nothing in PHS Act section 2713 or the regulations requires that each service be provided in a separate visit. Efficient care delivery and the delivery of multiple prevention and screening services at a single visit is a reasonable medical management technique, permissible under the regulations. For example, HIV screening and counseling and Sexually Transmitted Infections counseling could occur as part of a single well-woman visit.

Q10: What is included in a "well-woman" visit?

The HRSA Guidelines recommend at least one annual well-woman preventive care visit for adult women to obtain the recommended preventive services that are age- and developmentally-appropriate, including preconception and prenatal care. The HRSA Guidelines recommend that well-woman visits include preventive services listed in the HRSA Guidelines, as well as others referenced in section 2713 of the PHS Act. HHS understands that additional well-woman visits, provided without cost-sharing, may be needed to obtain all necessary recommended preventive services, depending on a woman's health status, health needs, and other risk factors. If the clinician determines that a patient requires additional well-woman visits for this purpose, then the additional visits must be provided in accordance with the requirements of the interim final regulations (that is, without cost-sharing and subject to reasonable medical management).

Q11: What do health care providers need to know to conduct a screening and counseling for interpersonal and domestic violence, as recommended in the HRSA Guidelines?

Screening may consist of a few, brief, open-ended questions. Screening can be facilitated by the use of brochures, forms, or other assessment tools including chart prompts. One option is the five-question Abuse Assessment Screening tool available here: (<http://www.cdc.gov/ncipc/pub-res/images/ipvandsvscreening.pdf>, page 22). Counseling provides basic information, including how a patient's health concerns may relate to violence and referrals to local domestic violence support agencies when patients disclose abuse. Easy-to-use tools such as patient brochures, safety plans, and provider educational tools, as well as training materials, are available through the HHS-funded Domestic Violence Resource Network, including the National Resource Center on Domestic Violence (<http://www.acf.hhs.gov/programs/fysb/programs/family-violence-prevention-services/programs/centers>).

Q12: In the discussion of “Identified Gaps” within the Cervical Cancer section of the IOM report, the IOM recognized “co-testing with cytology and high-risk Human Papillomavirus (HPV) DNA testing among women 30 years of age and older as a strategy to increase screening intervals to every three years.” When should the HPV DNA test be administered?

The HRSA Guidelines recommend high-risk HPV DNA testing for women with normal cytology results who are 30 years of age or older to occur no more frequently than every 3 years.

Q13: The HRSA Guidelines include a recommendation for annual HIV counseling and screening for all sexually active women. Is the term “screening” in this context defined as actual testing for HIV?

Yes. In this context, “screening” means testing.

Q14: The HRSA Guidelines include a recommendation for all Food and Drug Administration (FDA) approved contraceptive methods, sterilization procedures, and patient education and counseling for all women with reproductive capacity, as prescribed by a health care provider. May a plan or issuer cover only oral contraceptives?

No. 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. Consistent with PHS Act section 2713 and its implementing regulations, plans and issuers may use reasonable medical management techniques to control costs and promote efficient delivery of care. For example, plans may cover a generic drug without cost-sharing and impose cost-sharing for equivalent branded drugs. However, in these instances, a plan or issuer must accommodate any individual for whom the generic drug (or a brand name drug) 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 branded or non-preferred brand version. This generic substitution approach is permissible for other pharmacy products, as long as the accommodation described above exists.⁹ If, however, a generic version is not available, or would not be medically appropriate for the patient as a prescribed brand name contraceptive method (as determined by the attending provider, in consultation with the patient), then a plan or issuer must provide coverage for the brand name drug in accordance with the requirements of the interim final regulations (that is, without cost-sharing, subject to reasonable medical management).

Q15: Do the HRSA Guidelines include contraceptive methods that are generally available over-the-counter (OTC), such as contraceptive sponges and spermicides?

⁹See <http://www.healthcare.gov/news/factsheets/2011/08/womensprevention08012011a.html>

Contraceptive methods that are generally available OTC are only included if the method is both FDA-approved and prescribed for a woman by her health care provider. The HRSA Guidelines do not include contraception for men.¹⁰

Q16: Do the HRSA Guidelines include services related to follow-up and management of side effects, counseling for continued adherence, and for device removal?

Yes. Services related to follow-up and management of side effects, counseling for continued adherence, and device removal are included under the HRSA Guidelines and required to be covered in accordance with the requirements of the interim final regulations (that is, without cost-sharing, subject to reasonable medical management).

Q17: Are intrauterine devices and implants contraceptive methods under the HRSA Guidelines and therefore required to be covered without cost-sharing?

Yes, if approved by the FDA and prescribed for a woman by her health care provider, subject to reasonable medical management.

Q18: The USPSTF already recommends breastfeeding counseling. Why is this part of the HRSA Guidelines?

Under the topic of “Breastfeeding Counseling” the USPSTF recommends interventions during pregnancy and after birth to promote and support breastfeeding. The HRSA Guidelines specifically incorporate comprehensive prenatal and postnatal lactation support, counseling, and equipment rental. Accordingly, the items and services described in the HRSA Guidelines are required to be covered in accordance with the requirements of the interim final regulations (that is, without cost-sharing, subject to reasonable medical management, which may include purchase instead of rental of equipment).

Q19: How are certified lactation consultants reimbursed for their services under the HRSA Guidelines?

Reimbursement policy is outside of the scope of the HRSA Guidelines and the Departments’ regulations.

Q20: Under the HRSA Guidelines, how long after childbirth is a woman eligible for lactation counseling? Are breastfeeding equipment and supplies unlimited?

Coverage of comprehensive lactation support and counseling and costs of renting or purchasing breastfeeding equipment extends for the duration of breastfeeding. Nonetheless, consistent with PHS Act section 2713 and its implementing regulations, plans and issuers may use reasonable medical management techniques to determine the frequency, method, treatment, or setting for a

¹⁰ See 78 FR 8456, 8458, footnote 3, which provides that the HRSA guidelines “exclude services relating to a man’s reproductive capacity, such as vasectomies and condoms.”

recommended preventive item or service, to the extent not specified in the recommendation or guideline.