Preventive Care Guidelines for Women

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The Affordable Care Act (ACA) requires non-grandfathered health plans to cover certain preventive health services without imposing cost-sharing requirements for the services. The ACA’s preventive care mandate generally became effective for plan years beginning on or after Sept. 23, 2010.

In August 2011, the Department of Health and Human Services (HHS) issued additional preventive care guidelines for women. These additional guidelines, which are generally effective for plan years beginning on or after Aug. 1, 2012, require non-grandfathered health plans to cover women’s preventive health services (such as well-woman visits, breastfeeding support, domestic violence screening and contraceptives) without charging a copayment, a deductible or coinsurance.

Special rules regarding contraceptive coverage apply to religious employers (such as churches) and other religious-based institutions (such as schools, hospitals, charities and universities).

Background

For plan years beginning on or after Sept. 23, 2010, non-grandfathered group health plans must cover certain preventive health services without any cost-sharing. The preventive care mandate does not apply to grandfathered plans. In July 2010, HHS, along with the Departments of Labor (DOL) and the Treasury (Departments), issued interim final rules relating to coverage of preventive health services. The interim final rules identified the following recommended preventive health services as those that must be covered without cost-sharing requirements:

- Evidence-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), including certain preventive care for women, such as mammograms, cervical cancer screenings and prenatal care;
- Immunizations for routine use in children, adolescents and adults that are currently recommended by the Centers for Disease Control and Prevention (CDC) and included on the CDC’s immunization schedules;
- Evidence-informed preventive care and screenings for infants, children and adolescents, as provided for in the Health Resources and Services Administration (HRSA) guidelines; and
- Evidence-informed preventive care and screening for women, as provided in guidelines supported by HRSA, which were required to be developed by August 2011.

More information on the ACA’s preventive care mandate, including specific information on the covered preventive health services, is available at: www.healthcare.gov/what-are-my-preventive-care-benefits.

Coverage Guidelines

On Aug. 1, 2011, HHS issued the HRSA-supported preventive care guidelines for women to fill the gaps in the preventive health services guidelines for women. According to HHS, these guidelines help ensure that women receive a comprehensive set of preventive health services without having to pay a copayment, a deductible or coinsurance.
Non-grandfathered health plans must include these services without cost-sharing for plan years beginning on or after Aug. 1, 2012, subject to the contraceptive coverage exception described below for religious employers.

**Covered Health Services**

The preventive care guidelines for women include the following health services:

- **Anemia screening** on a routine basis for pregnant women.
- **Breast cancer genetic test counseling (BRCA)** for women at higher risk for breast cancer.
- **Breast cancer mammography screenings** every one to two years for women over age 40.
- **Breast cancer chemoprevention counseling** for women at higher risk.
- **Breastfeeding comprehensive support and counseling** from trained providers and access to breastfeeding supplies, for pregnant and nursing women.
- **Cervical cancer screening** for sexually active women.
- **Chlamydia infection screening** for younger women and other women at higher risk.
- **Contraception** for FDA-approved contraceptive methods, sterilization procedures, and patient education and counseling, as prescribed by a health care provider for women with reproductive capacity (not including abortifacient drugs). This does not apply to health plans sponsored by certain exempt religious employers.
- **Domestic and interpersonal violence screening and counseling for all women.**
- **Folic acid supplements** for women who may become pregnant.
- **Gestational diabetes screening** for women 24 to 28 weeks pregnant and those at high risk of developing gestational diabetes.
- **Gonorrhea screening** for women at higher risk.
- **Hepatitis B screening** for pregnant women at their first prenatal visit.
- **HIV screening and counseling** for sexually active women.
- **Human Papillomavirus (HPV) DNA test** every three years for women with normal cytology results who are 30 or older.
- **Osteoporosis screening** for women over age 60 depending on risk factors.
- **Rh incompatibility screening** for all pregnant women and follow-up testing for women at higher risk.
- **Sexually transmitted infections counseling** for sexually active women.
- **Syphilis screening** for all pregnant women or other women at increased risk.
- **Tobacco use screening and interventions** for all women, and expanded counseling for pregnant tobacco users.
- **Urinary tract or other infection screening** for pregnant women.
- **Well-woman visits** to get recommended services for women under age 65.

According to HHS, health plans may use reasonable medical management techniques for women’s preventive care to help define the nature of the covered service, consistent with guidance provided in the interim final rules. For example, health plans may control costs and promote efficient delivery of care by continuing to charge cost-sharing for brand-name drugs if a safe and effective generic version is available. In addition, the interim final rules confirmed that plans may continue to impose cost-sharing requirements on preventive services that employees receive from out-of-network providers.

On Sept. 24, 2013, the USPSTF issued new recommendations with respect to breast cancer. Specifically, the USPSTF revised its "B" recommendation regarding medications for risk reduction of primary breast cancer in women. The new recommendation states:

“The USPSTF recommends that clinicians engage in shared, informed decision-making with women who are at increased risk for breast cancer about medications to reduce their risk. For women who are at increased risk for breast cancer and at low risk for adverse medication effects, clinicians should offer to prescribe risk-reducing medications, such as tamoxifen or raloxifene.”
On Jan. 9, 2014, the Departments issued an FAQ clarifying the changes that plans must make in order to comply with the new recommendation. According to the FAQ, for plan or policy years beginning on or after Sept. 24, 2014, (one year after the date the recommendation was issued) non-grandfathered group health plans and non-grandfathered health insurance coverage offered in the individual or group market will be required to cover these risk-reducing medications for applicable women without cost sharing subject to reasonable medical management.

Also, on Feb. 20, 2013, the Departments issued an FAQ that addresses coverage for:

- Evidence-based items or services with a rating of “A” or “B” in the current USPSTF recommendations; and
- 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.” 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.

An additional FAQ issued on May 11, 2015, clarifies that this 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. 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.” Therefore, 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.

The FAQs issued on May 11, 2015, also clarified that the recommendation to cover all FDA-approved contraceptive methods requires plans and issuers to 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. 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 the ACA’s contraceptive coverage requirement.

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.

If a plan or issuer covers oral contraceptives (such as the extended/continuous use contraceptive pill), it cannot 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). 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 three 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.
**Contraceptive Services and Religious Employers**

**Exemption**

On Aug. 3, 2011, HHS issued an amendment to the interim final rules to allow certain nonprofit religious employers offering health coverage (such as churches) to decide whether or not to cover contraceptive services, consistent with their beliefs. A final rule issued on June 28, 2013, finalizing the exemption to the contraceptive coverage requirement for group health plans of certain nonprofit religious employers.

To qualify for the exemption, the employer must be a nonprofit entity that is referred to in section 6033(a)(3)(A)(i) or (iii) of the Internal Revenue Code. This definition primarily includes churches, other houses of worship and their affiliated organizations.

**Temporary Safe Harbor**

HHS created an enforcement safe harbor for group health plans sponsored by nonprofit organizations that do not provide some or all of the required contraceptive coverage (consistent with state law) because of the organization’s religious beliefs. This safe harbor applies to religious organizations that do not qualify for the exemption, such as schools, charities, hospitals and universities. It applies to plan years beginning before Jan. 1, 2014.

More information on the temporary safe harbor is available in a bulletin prepared by HHS.

**Accommodation Approach**

The final rule provides accommodations for nonprofit religious organizations that do not qualify for the exemption but that object to contraceptive coverage on religious grounds. This accommodation approach is effective for plan years beginning on or after Jan. 1, 2014.

An organization eligible for the accommodation is one that:

- Opposes providing coverage for some or all of any contraceptive services which are required to be covered on account of religious objections;
- Is organized and operates as a nonprofit entity;
- Holds itself out as a religious organization; and
- Self-certifies that it meets these criteria (HHS has provided a self-certification form for this purpose).

Under the accommodation approach, eligible organizations will not have to contract, arrange, pay or refer for any contraceptive coverage to which they object on religious grounds. However, separate payments for contraceptive services will be provided to female employees by an independent third party, such as an insurance company or third-party administrator (TPA), directly and free of charge.

An organization seeking to be treated as an eligible organization needs to self-certify that it is an eligible organization and satisfy the recordkeeping and inspection requirements. In addition, eligible organizations must either provide the issuer or TPA with a copy of the self-certification or provide written notice to HHS that it is an eligible organization and of its religious objection to coverage of all or a subset of contraceptive services. A model notice to HHS has been provided that eligible organizations may, but are not required to, use.

In addition, there are special rules for religious nonprofit organizations that are institutions of higher education. If this type of organization arranges for student health insurance coverage, it is eligible for an accommodation comparable to the type available for a religious organization with an insured group health plan.

**Supreme Court Decision—Closely Held For-profit Companies**

For-profit employers that object to providing contraceptive coverage on religious grounds are generally not eligible for the exemption, the delayed effective date or the accommodations approach that apply to churches and nonprofit religious organizations. However, on June 30, 2014, the U.S. Supreme Court ruled that the ACA’s contraceptive mandate, as applied to closely held corporations with sincere religious objections, violates the Religious Freedom Restoration Act (RFRA) and is unlawful.
The Supreme Court’s ruling creates a narrow exception to the ACA’s contraceptive mandate for closely held businesses that object to providing coverage for certain types of contraceptives based on their sincere religious beliefs. For all other for-profit employers, the contraceptive coverage mandate will continue to apply.

In light of the Court’s decision in Hobby Lobby, the Departments issued a proposed rule on Aug. 27, 2014, that would amend the definition of an “eligible organization” for purposes of the accommodations approach. The amended definition would include a closely held for-profit entity that has a religious objection to providing coverage for some or all of the contraceptive services otherwise required to be covered. This proposed change would extend the accommodations approach available for non-profit entities to group health plans established or maintained by certain closely held for-profit entities with similar religious objections to contraceptive coverage.

Thus, under the proposed rules, a qualifying closely held for-profit entity would not be required to contract, arrange, pay or refer for contraceptive coverage. Instead, payments for contraceptive services provided to participants and beneficiaries in the eligible organization’s plan would be provided or arranged separately by an issuer or a TPA.

**Coverage of Sex-specific Recommended Preventive Services**

The FAQs issued on May 11, 2015, also clarified that plans or issuers cannot limit sex-specific recommended preventive services based on an individual’s sex assigned at birth, gender identity or recorded gender. Whether a sex-specific recommended preventive service that is required to be covered without cost-sharing 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**

In addition, if a plan or issuer covers dependent children, the plan or issuer is also 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. The ACA’s preventive care coverage requirement applies with respect to 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, those dependent children must be provided the full range of recommended preventive services applicable to them (for example, for their age group) without cost-sharing and subject to reasonable medical management techniques.

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. Therefore, 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**

Finally, if a colonoscopy is scheduled and performed as a preventive screening procedure for colorectal cancer pursuant to the USPSTF recommendation, a plan or issuer is not permitted to 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.