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Preventive Care Guidelines for Women

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 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.

This ACA Overview provides a summary of the ACA's additional preventive care coverage requirements for women, including certain exemptions for religious employers.

LINKS AND RESOURCES

- In July 2010, HHS, the Department of Labor (DOL) and the Treasury (Departments) issued interim final rules relating to coverage of preventive health services.
- 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.

HIGHLIGHTS

WOMEN'S PREVENTIVE CARE

Additional preventive care coverage guidelines for women apply for plan years beginning on or after Aug. 1, 2012.

Under these guidelines, non-grandfathered plans must generally cover the following women's preventive health services:

- Well-women visits;
- Breastfeeding support;
- Domestic violence screening; and
- Contraceptives

RELIGIOUS EMPLOYERS

Special rules regarding contraceptive coverage apply to:

- Religious employers (such as churches); and
- Other religious-based institutions (such as schools, hospitals, charities and universities).

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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. The 2010 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.

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. Coverage of comprehensive lactation

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support and counseling and costs of renting or purchasing breastfeeding equipment extends for the duration of breastfeeding.

- *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.

  FAQs issued May 11, 2015, clarified that this recommendation requires plans and issuers to cover, without cost-sharing, the full range of FDA-identified methods. Thus, **plans and issuers must cover at least one form of contraception in each method that is identified by the FDA**.

- 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 all 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

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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.

Additional Clarifications Related to Breast Cancer

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.

Additional Clarifications Related to BRCA Testing

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.

Finally, an FAQ issued on Oct. 23, 2015, clarifies which women must receive coverage without cost sharing for genetic counseling and, if indicated, testing for harmful BRCA mutations. According to this FAQ, women found to be at increased risk using a screening tool designed to identify a family history that may be associated with an increased risk of having a potentially harmful gene mutation must receive coverage without cost-sharing for genetic counseling and, if indicated, testing for harmful BRCA mutations. This is true regardless of whether the woman has previously been diagnosed with cancer, as long as she is not currently symptomatic of or receiving active treatment for breast, ovarian, tubal or peritoneal cancer. For questions about this guidance, contact CCIIO at 1-888-393-2789, or the DOL at www.askebsa.dol.gov or 1-866-444-3272.

Additional Clarifications Related to Contraceptive Coverage

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.

Additional Clarifications Related to Breastfeeding and Lactation Counseling

On Oct. 23, 2015, the Departments issued additional FAQs related to lactation counseling. According to these FAQs, while the ACA's preventive services requirements do not include specific disclosure requirements, other applicable laws require disclosure of lactation counseling providers available under the plan or coverage. For example:

- The ACA requires group health plans and health insurance issuers offering group or individual health insurance coverage to provide a Summary of Benefits and Coverage (SBC) that includes an internet address (or other contact information) for obtaining a list of the network providers.
- Group health plans subject to ERISA must provide a Summary Plan Description (SPD) that describes provisions governing the use of network providers, the composition of the provider network and whether (and under what circumstances) coverage is provided for out-of-network services.
- Issuers of qualified health plans (QHPs) in the individual market Exchanges and the SHOPs currently must make their provider directories available online.

These FAQs also clarify that it is not permissible for a plan to impose cost-sharing with respect to out-of-network lactation counseling services if the plan's network does not include lactation counseling providers. As stated in a previous FAQ, while nothing in the ACA's preventive services requirements requires a plan or issuer that has a network of providers to provide benefits for preventive services provided out-of-network, these requirements are premised on enrollees being able to access the required preventive services from in-network providers. If a plan or issuer does not have a provider in its network who can provide a 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. Therefore, if a plan or issuer does not have in its network a provider who can provide lactation counseling services, the plan or issuer must cover the item or service when performed by an out-of-network provider without cost-sharing.

Under the ACA, subject to reasonable medical management techniques, lactation counseling must be covered without cost-sharing when it is performed by any provider acting within the scope of his or her license or certification under applicable state law. In cases where a state does not license lactation

counseling providers, lactation counseling could be provided by another provider type acting within the scope of his or her license or certification (for example, a registered nurse), and the plan or issuer would be required to provide coverage for the services without cost-sharing.

If a recommendation or guideline does not specify the frequency, method, treatment or setting for the provision of a recommended preventive service, then the plan or issuer may use reasonable medical management techniques to determine any applicable coverage limitations. However, it is not a reasonable medical management technique to limit coverage for lactation counseling to services provided on an in-patient basis. Some births are never associated with a hospital admission (for example, home births assisted by a nurse midwife), and it is not permissible to deny coverage without cost-sharing for lactation support services in this case. Moreover, coverage for lactation support services without cost-sharing must extend for the duration of the breastfeeding, which, in many cases, extends beyond the in-patient setting for births that are associated with a hospital admission. In addition, the requirement to cover the rental or purchase of breastfeeding equipment without cost-sharing extends for the duration of breastfeeding, provided the individual remains continuously enrolled in the plan or coverage.

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 Code Section 6033(a)(3)(A)(i) or (iii). 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.

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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.

An FAQ issued on Oct. 23, 2015, clarifies how a qualifying non-profit or closely held for-profit employer that sponsors an ERISA-covered self-insured plan and that has a sincerely held religious objection to providing coverage of contraceptive services would effectuate the religious accommodation, relieving itself of any obligation to contract, arrange, pay or refer for that coverage. According to this FAQ, the following two methods may be used:

- **Complete the EBSA Form 700 and provide it to the plan's TPA(s)**—In this instance, the EBSA Form 700 will be a plan instrument that relieves the employer from any obligation to contract, arrange or pay for contraceptive services to which it objects, and that has the legal effect of designating the TPA as the ERISA plan administrator responsible for separately providing payments for those services.
- **Provide appropriate notice of the objection to HHS (a model notice is available)**—In this instance, HHS will forward the information to the DOL, which will send a notification to the TPA, designating it as the ERISA plan administrator responsible for separately providing coverage for any contraceptive services to which the employer objects. The notice of objection sent to HHS will be a plan instrument that relieves the employer from any obligation to contract, arrange or pay (or refer) for contraceptive services to which it objects, but will not have the legal effect of designating the TPA as the ERISA plan administrator for those services. Instead, the notification sent from the DOL to the TPA will be a separate plan instrument, and that separate instrument will serve to designate the TPA as the ERISA plan administrator responsible for separately providing payments for any contraceptive services to which the employer objects.

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.

Executive Order

On May 4, 2017, President Donald Trump issued an executive order aimed at promoting free speech and religious liberty. The executive order directs the Departments to consider issuing amended regulations, consistent with applicable law, to address conscience-based objections to the ACA's preventive care mandate. The Department of Health and Human Services (HHS) issued a press release in response to the executive order stating their intent to take action as a result. According to President Trump and HHS, these actions are intended to safeguard the deeply held religious beliefs of employers who provide health insurance to their employees.

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