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# Departments Issue Final Regulations on Preventive Services

Final regulations addressing the Affordable Care Act's preventive services mandate have been issued. These regulations confirm various directives on preventive care services generally, including the need to look to the "primary" purpose of the visit when a preventive service is billed together with an office visit. Additionally, the regulations set forth accommodations for employers that have religious objections to covering FDA-approved contraceptive services under the preventive service mandate — a hotly litigated issue under the ACA.

## Background

Under what is known as the preventive services mandate, the Affordable Care Act (ACA) requires non-grandfathered group health plans to cover certain preventive care services without cost-sharing. These include services in the following categories:

- Evidence-based items or services that have a rating of "A" or "B" in the current recommendations of the United States Preventive Services Task Force (USPSTF)
- Immunizations for routine use in children, adolescents and adults that have a recommendation from the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention
- Evidence-informed preventive care and screenings for infants, children and adolescents provided in comprehensive guidelines supported by the Health Resources and Services Administration (HRSA)
- 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 for women

In July 2010, the Departments of Labor, Treasury, and Health & Human Services (departments) issued interim final regulations addressing this mandate. (See our July 20, 2010 *For Your Information*.) Following those regulations, the departments issued a series of FAQs clarifying specific aspects of the requirement. (For more information, see our March 15, 2013, June 10, 2014 and May 28, 2015 editions of *For Your Information*.)

The inclusion of FDA-approved contraceptive services in the list of required preventive care services has proven to be controversial in ACA implementation because of some employers' religious objections to covering these services. In 2013, the departments issued regulations that exempted plans maintained by certain "religious organizations" (generally churches and conventions or associations of churches) from the mandate and provided an "accommodation" for other entities with religious objections. Under this accommodation, nonprofit entities that hold themselves out as religious organizations, have religious objections to the mandate, and self-certify that they meet these criteria are not required to contract, arrange, pay or refer for contraceptive coverage. If the organization's plan is insured, the insurer assumes responsibility for providing separate payments for contraceptive services directly to participants and beneficiaries — without charge or cost-sharing to them, the organization or the organization's plan. If the organization's plan is self-insured, the plan's third party administrator assumes responsibility for this. The regulations provided that to take advantage of this accommodation, a nonprofit religious entity was required to sign EBSA Form 700 and provide that form to an insurer or TPA. (See our October 18, 2013 *For Your Information*.)

In August 2014, following claims by numerous nonprofit entities that signing EBSA Form 700 would violate their religious beliefs, the departments issued interim final regulations providing an alternate process whereby an organization can simply notify HHS in writing of its objection. (See our September 9, 2014 *For Your Information*.) At the same time, reacting to the Supreme Court's decision in *Burwell v. Hobby Lobby* striking down the contraceptive coverage mandate as applied to closely held, for-profit corporations with religious objections, the departments issued proposed regulations that would explain what entities fall into this category and extend the nonprofit accommodation to those entities. (See our June 30, 2014 *FYI Alert* and September 9, 2014 *For Your Information* publications.)

**Comment.** The *Hobby Lobby* decision did not define the term "closely held, for-profit corporation."

## Final Regulations

The departments recently issued final regulations that address both the general preventive services coverage requirements and the accommodations for employers with religious objections to covering contraceptive services. The final regulations generally track the 2010 and 2014 interim final regulations, as well as the 2014 proposed regulations.

### Preventive Services Coverage Requirements

The final regulations confirm that:

- When a preventive service is billed together with an office visit, a plan must look to the "primary" purpose of the visit when determining whether it may impose cost-sharing with respect to the office visit.

  **Comment**. This rule can be difficult to apply in situations where an office visit has a preventive as well as a diagnostic or treatment component.

- For plans that maintain a network of providers, a plan lacking an in-network provider who can offer a particular recommended preventive service must nevertheless cover that service without cost-sharing when performed by an out-of-network provider.

- If a recommendation or guideline for a preventive service does not specify the frequency, method, treatment or setting for the provision of that service, the plan may use reasonable medical management techniques to determine any coverage limitations — and may rely on the relevant evidence base and established reasonable medical management techniques to do so.

  **Comment**. The final regulations do not require plans to document the evidence base underlying a reasonable medical management technique, but such documentation can be critical should a participant file a benefit claim and generally must be provided upon request as part of ERISA claims and appeals procedures.

- A plan may impose cost-sharing at its discretion, consistent with applicable law, for preventive services not on the list of recommended preventive services.

- When a plan is required to provide coverage for a preventive service on the first day of a plan year, it generally must provide coverage for that service for the entire plan year even if the recommendation or guideline for that service changes or is eliminated during the plan year. However, if, during a plan year, the USPSTF downgrades an "A" or "B" recommendation or guideline to a "D" rating (meaning that the USPSTF has determined there is strong evidence of no net benefit, or that the harm outweighs the benefits), or if any item or service is the subject of a safety recall or is otherwise determined to pose a significant safety concern, a plan need not cover the service or item through the end of the plan year.

  **Comment.** Should such circumstances arise, the departments expect to issue specific guidance on the item or service.

**Recommendations and Guidelines**

Plan sponsors should check the complete **list** of preventive services recommendations and guidelines once each year to determine which services to cover without cost-sharing for the plan year.

- A plan must cover a new recommendation or guideline beginning with the first plan year that starts on or after the date that is one year after the new recommendation or guideline goes into effect. For example, if the USPSTF adopts a new preventive service coverage recommendation on August 1, 2015, a calendar year plan must begin covering this service on January 1, 2017.

### Accommodations for Employers with Religious Objections to Providing Contraceptive Coverage

The final regulations also address issues related to the accommodations for employers that object to providing coverage for contraceptive services for religious reasons. The regulations:

- Continue to allow eligible nonprofit organizations to choose between using EBSA Form 700 or the alternative process of notifying HHS in writing of a religious objection to covering all or a subset of contraceptive services. A model notice is available for this purpose.
- Extend the nonprofit accommodations to closely held, for-profit entities that are not publicly traded, are majority-owned by a relatively small number of individuals, and object to providing contraceptive coverage based on its owners' religious beliefs. Specifically, such an entity must be more than 50% owned directly or indirectly by five or fewer individuals, or have an ownership structure that is "substantially similar."

- Provide that the closely held, for-profit organization's highest governing body (e.g., board of directors) must adopt a resolution (or take other similar action) establishing that the organization objects to covering some or all of the contraceptive services due to its owners' sincerely held religious beliefs. The organization need not provide the federal government with this resolution although it must furnish notice of its decision under the same process that must be followed by nonprofits.

  **Comment**. Under the "substantially similar" standard, a closely held, for-profit entity that is 49% owned directly by six individuals could also qualify for the accommodation. If an entity is unsure if its structure meets the requirements for the accommodation, it may send a description of its ownership structure to HHS at accommodation@cms.hhs.gov. If HHS does not respond within 60 calendar days, the entity will be considered to meet the requirement as long as it maintains that structure. However, an entity is not required to use this process to qualify as a closely held, for-profit entity.

**To Determine Ownership**

- Ownership interests of a corporation, partnership, estate or trust are considered owned proportionately by the entity's shareholders, partners or beneficiaries
- An individual is considered to own the ownership interests of his or her family (including brothers, sisters, spouse, ancestors and lineal descendants)
- A person who holds an option to purchase ownership interests is considered the owner of those interests

## Effective Date

The final regulations are effective beginning on the first day of the first plan year that begins on or after September 14, 2015.

## In Closing

On preventive care services generally, the final regulations largely confirm previous guidance. They also provide clarity on which entities may qualify for a contraceptive coverage mandate accommodation. The departments crafted the regulations' definition of "closely held, for-profit entity" to include all for-profit entities that have challenged the contraceptive coverage mandate to date. However, it is not clear if the accommodation for nonprofit organizations will satisfy the nonprofit entities nationwide that are currently challenging the contraceptive coverage requirement aspect of the preventive services mandate; such cases are expected to continue winding their way through the federal courts.

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**Authors**
Kimberley Mitchell, JD
Julia Zuckerman, JD

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