Preventive Services Final Rules

Federal agencies released final regulations on the preventive services mandate of the Patient Protection and Affordable Care Act (ACA) that requires non-grandfathered group health plans to provide coverage without cost-sharing for specific preventive services, which for women include contraceptive services.

After pushback from religious employers, interim final regulations, objections from certain employers with religious objections and the subsequent Supreme Court decision in *Burwell v. Hobby Lobby,* proposed regulations, further final regulations, additional interim final regulations, and another set of proposed regulations, the 2015 Final Rules (applicable for plan years beginning on or after September 14, 2015) provide the following:

- Formalizes prior guidance requiring a plan to cover out-of-network services without cost sharing if the plan does not have an in-network provider who can provide a required preventive service.
- Provides for midyear plan changes if a recommended preventive service is downgraded (by task force or advisory body) to a “D” rating or is subject to a safety recall or other significant safety concern.
- Provides contraceptive coverage accommodations for eligible organizations.

Out of Network Coverage

The final regulations clarified that if a plan or issuer does not have a provider in its network that can provide a specific recommended preventive service, then it is required to cover the preventive service performed by an out-of-network provider at no cost to the participant.

Additional Preventive Service Coverage

Plans or issuers may cover preventive services in addition to those required by law. Plans or issuers may impose cost sharing for additional preventive services at its discretion. Treatment that is not a recommended preventive service may be subject to cost sharing, even if it results from a recommended preventive service.

Timing

Plans and issuers must provide coverage for any recommended preventive service on the first day of its plan or policy year through the last day of its plan or policy year, even if the recommendation or guideline is changed or eliminated during the plan or policy year.

The only exception to this rule is when a preventive service is downgraded to a "D" rating by an applicable federal task force, or a preventive service is the subject of a safety recall or other significant safety concern, as designated by a federal agency that has the authority to regulate the item or service. If this happens, there is no requirement for a plan or issuer to cover the item or service through the last day of the plan or policy year.

The list of preventive health services can be found on the healthcare.gov website. Any new recommendations or guidelines will be listed on this page when they become available. Plans and issuers should annually check the list of recommended preventive services, as they will be obligated to cover them in the first plan or policy year beginning on or after the date that is one year after the new recommendation or guideline goes into effect.

Contraception Coverage

The final regulations provide two accommodations for eligible organizations to provide notice of a religious objection to the coverage of contraceptive services. Employers that object to providing contraceptive services will need to determine if they meet the criteria of an eligible organization in order to use one of the two accommodations. An eligible organization is an organization that meets all of the following requirements:

1. Opposes providing coverage for some or all of any contraceptive items or services required to be covered on account of religious objections.
2. Either is organized and operates as a nonprofit entity and holds itself out as a religious organization, or is organized and operates as a closely held for-profit entity, and the organization's highest governing body (such as its board of directors, board of trustees, or owners, if managed directly by its owners) has adopted a resolution or similar action, under the organization's applicable rules of governance and consistent with state law, establishing that it objects to covering some or all of the contraceptive services on account of the owner's sincerely held religious beliefs.
3. If both of the first two requirements are met, the organization must self-certify. The organization must make such self-certification or notice available for examination upon request by the first day of the first plan year to which the accommodation applies. The self-certification or notice must be executed by a person authorized to make the certification or notice on behalf of the organization, and must be maintained in a manner consistent with the record retention requirements under section 107 of ERISA.

A "closely held for-profit entity" is defined in the regulations as an organization that:

- Is not a nonprofit entity;
- Has no publicly traded ownership interests, (for this purpose, a publicly traded ownership interest is any class of common equity securities required to be registered under section 12 of the Securities Exchange Act of 1934); and
- Has more than 50 percent of the value of its ownership interest owned directly or indirectly by five or fewer individuals, or has an ownership structure that is substantially similar thereto, as of the date of the entity's self certification or notice described in the requirements of an "eligible organization."

To determine its ownership interest, the following rules apply:

- Ownership interests owned by a corporation, partnership, estate, or trust are considered owned proportionately by such entity's shareholders, partners, or beneficiaries. Ownership interests owned by a nonprofit entity are considered owned by a single owner.
- An individual is considered to own the ownership interests owned, directly or indirectly, by or for his or her family. Family includes only brothers and sisters (including half-brothers and half-sisters), a spouse, ancestors, and lineal descendants.
- If a person holds an option to purchase ownership interests, he or she is considered to be the owner of those ownership interests.

If an employer is unsure if it meets the requirements as a closely held for-profit entity, it may send a letter describing its ownership structure to the Department of Health and Human Services (HHS). An entity must submit the letter in the manner described by the Department of Health and Human Services. If the entity does not receive a response from the Department of Health and Human Services to a properly submitted letter describing the entity's current ownership structure within 60 calendar days, as long as the entity maintains that structure it will be considered to meet the requirements of being a "closely held for-profit entity."

Accommodations

As discussed, there are two available accommodations or methods for eligible organizations to choose between in order to object to the coverage of contraceptive services:

- The eligible organization may file EBSA Form 700.
- The eligible organization may go through the "alternative process."

The alternative process requires the eligible organization to notify HHS in writing of its objection to covering all or a subset of contraceptive services. The notice must include:

- The name of the eligible organization and the basis on which it qualifies for an accommodation
- A statement that its objection is based on a sincerely held religious belief to covering some or all contraceptive services (if objecting to a subset of services, they must be identified)
- The plan name (and type if it is a student health insurance plan or a church plan)
- The name and contact information for the plan's third party administrator (TPA) and health insurance issuers

There is a model notice available for eligible organizations to review. The content required is considered the minimum information necessary for federal agencies to determine if an entity is covered by the accommodation and to administer the accommodation. Nothing in the process provides for government assessment of the sincerity of religious beliefs.

For self-insured plans subject to ERISA, once they provide proper notice to HHS, the Department of Labor (DOL) and HSS will send a notification to the TPA of the ERISA plan notifying the TPA of the eligible organization's objection. The government notice will list the contraceptive services that are objected to, and will provide the TPA with its obligations and designate the relevant TPA as plan administrators under ERISA for the contraceptive benefits the TPA would otherwise manage.

For fully insured plans (or a student health plan), HHS will send notification to each health insurance issuer of the plan. The notification will inform the issuer or carrier of the eligible organization's objection, and will list the contraceptive services that are objected to. Issuers will be responsible for compliance with statutes and regulations to provide coverage for contraceptive services without cost sharing to participants notwithstanding that the policyholder is objecting.

Participants (employees and their covered spouses and dependents) will still have seamless access to contraceptive services at no cost, but the accommodations will shift the cost burden of the contraceptive services away from an employer that is an eligible organization.

Interim Final Rules Expand Accommodation for Employers who Object to Contraception Coverage

Two tri-agency (Internal Revenue Service, Employee Benefits Security Administration, and Centers for Medicare and Medicaid Services) Interim Final Rules were released and became effective on October 6, 2017, and were published on October 13, 2017, allowing a greater number of employers to opt out of providing contraception to employees at no cost through their employer-sponsored health plan. The expanded exemption encompasses ***all*** non-governmental plan sponsors that object based on sincerely held religious beliefs, and institutions of higher education in their arrangement of student health plans. The exemption also now encompasses employers who object to providing contraception coverage on the basis of sincerely held moral objections and institutions of higher education in their arrangement of student health plans. Furthermore, if an issuer of health coverage (an insurance company) had sincere religious beliefs or moral objections, it would be exempt from having to sell coverage that provides contraception. The exemptions apply to both non-profit and for-profit entities.

The currently-in-place accommodation is also maintained as an optional process for exempt employers and will provide contraceptive availability for persons covered by the plans of entities that use it (a legitimate program purpose). These rules leave in place the government's discretion to continue to require contraceptive and sterilization coverage where no such objection exists. These interim final rules also maintain the existence of an accommodation process, but consistent with expansion of the exemption, the process is optional for eligible organizations. Effectively this removes a prior requirement that an employer be a "closely held for-profit" employer to utilize the exemption.

On November 30, 2017, the Centers for Medicare and Medicaid Services (CMS) released guidance on accommodation revocation notices. Plan participants and beneficiaries must receive written notice if an objecting employer had previously used the accommodation and, under the new exemptions, no longer wishes to use the accommodation process. The Interim Final Rules required the issuer to provide written revocation notice to plan participants and beneficiaries. CMS' recent guidance clarifies that the employer, its group health plan, or its third-party administrator (TPA) may provide written revocation notice instead of the issuer.

CMS' guidance also clarifies the timing of the revocation notice. Under the Interim Final Rules, revocation is effective on the first day of the first plan year that begins on or after 30 days after the revocation date. Alternatively, if the plan or issuer listed the contraceptive benefit in its Summary of Benefits and Coverage (SBC), then the plan or issuer must give at least 60 days prior notice of the accommodation revocation

(SBC notification process). CMS' guidance indicates that, even if the plan or issuer did not list the contraceptive benefit in its SBC, the employer is permitted to use the 60-days advance notice method to revoke the accommodation as long as the revocation is consistent with any other applicable laws and contract provisions regarding benefits modification.

Further, if the employer chooses not to use the SBC notification process to notify plan participants and beneficiaries of the accommodation revocation and if the employer instructs its issuer or TPA not to use the SBC notification process on the employer's behalf, then the employer, its plan, issuer, or TPA must send a separate written revocation notice to plan participants and beneficiaries no later than 30 days before the first day of the first plan year in which the revocation will be effective.

Unlike the SBC notification process which would allow mid-year benefit modification, if an employer uses the 30-day notification process, the modification can only be effective at the beginning of a plan year.

Employers that object to providing contraception on the basis of sincerely held religious beliefs or moral objections, who were previously required to offer contraceptive coverage at no cost, and that wish to remove the benefit from their medical plan are still subject (as applicable) to ERISA, its plan document and SPD requirements, notice requirements, and disclosure requirements relating to a reduction in covered services or benefits. These employers would be obligated to update their plan documents, SBCs, and other reference materials accordingly, and provide notice as required.

Employers are also now permitted to offer group or individual health coverage, separate from the current group health plans, that omits contraception coverage for employees who object to coverage or payment for contraceptive services, if that employee has sincerely held religious beliefs relating to contraception. All other requirements regarding coverage offered to employees would remain in place. Practically speaking, employers should be cautious in issuing individual policies until further guidance is issued, due to other regulations and prohibitions that exist.

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