

CMS Publishes Final Rule on Coverage for Contraceptive Items and Services

Background

On July 14, 2015, the Centers for Medicare and Medicaid Services (CMS), the Internal Revenue Service (IRS) and Employee Benefits Security Administration (EBSA) jointly published a [final regulation](#) regarding coverage of certain preventive and screening services, including contraceptive items and services, by non-grandfathered group health plans and health insurance coverage for individuals.¹ The regulation responds to more than 75,000 public comments on prior proposals and interim final rules, as well as the [decision](#) of the Supreme Court in the *Hobby Lobby* case.²

Under the Affordable Care Act (ACA) most insurers are required to cover, without cost sharing, all FDA approved contraceptives, sterilization procedures, and patient education and counseling for women with reproductive capacity, as prescribed by a health care provider.³

Objections to covering contraceptive items and services have been raised by non-profit religious organizations and for-profit closely held organizations with religious objections to providing such coverage. A regulatory mechanism had been put in place to accommodate the non-profit religious organizations, but not the for-profit organizations. The Supreme Court held, in the *Hobby Lobby* case that closely held for-profit organizations with religious objections should also be exempted from the requirement to provide coverage for contraceptive items and services.

Provisions of the Final Regulation

Under the final regulation, a non-profit religious organization or closely held for-profit organization with religious objections to providing coverage for some or all of the contraceptive items and services otherwise required to be covered would be exempt from providing such coverage as long as the organization meets eligibility criteria.

Eligibility criteria include:

- The opposition to providing such coverage is based on a religious objection.
- The organization is organized and operated as a non-profit entity and holds itself out as a religious organization, or is organized and operated as a closely held for-profit entity and its highest governing body has adopted a resolution or similar action under the organization's applicable rules of governance and

¹ See: <http://www.gpo.gov/fdsys/pkg/FR-2015-07-14/pdf/2015-17076.pdf>

² See: http://www.supremecourt.gov/opinions/13pdf/13-354_olp1.pdf

³ See: <http://www.hrsa.gov/womensguidelines/>

consistent with state law, establishing that it objects to covering all or some of the contraceptive services on account of the owner's sincerely held religious beliefs.

- The organization self-certifies to its third party administrators or provides notice to HHS regarding its objection. This certification or notice must include specified information that will allow the third party administrator or HHS to identify the affected plan and beneficiaries.
 - Notably, a number of religious organizations have objected to the requirement that they provide such notice and have brought suit over that issue. Thus far, five circuit court decisions have concluded that the requirement to submit a notice to the government regarding the religious objection does not impose a substantial burden on religious freedom and must be complied with by the plaintiffs. Whether this issue is taken up by the Supreme Court is yet to be seen.

A closely held, for-profit entity must have more than 50 percent of the value of its ownership interests owned directly or indirectly by five or fewer individuals, or must have an ownership structure that is *substantially similar*. An individual is considered to own the ownership interests owned, directly or indirectly, by or for his or her family. Accordingly, the family members count as a single owner for purposes of these final regulations.

A personal services corporation (such as an accounting firm, architectural firm or law firm) may qualify as a closely held for-profit entity under these final regulations, provided it satisfies the other criteria.

Publicly traded companies may not qualify for the exception to providing coverage for contraceptive items and services.

Coverage Mechanism

Upon receipt of an organizations certification, or notice from HHS that the Department has received notice of an objection to covering contraceptive services, third party administrators must then provide coverage for contraceptive services for affected plan beneficiaries, without cost sharing of any sort and without imposing any costs for such coverage on the organization objecting to providing such coverage. Costs to the third party administrator of providing the coverage will be reimbursed through a reduction in an otherwise applicable fee that insurers are required to pay to support the federally facilitated exchange.

Third party administrator must provide written notice of the availability of separate payments for these services contemporaneous with (to the extent possible), but separate from, any application materials distributed in connection with enrollment or reenrollment in health coverage.

Billing

If contraceptive items and services can be billed separately from an office visit, cost sharing can be imposed for the office visit. However, if the item or service is not tracked

or billed separately from the office visit and the primary purpose of the office visit is to obtain the item or service, no cost sharing may be imposed for the office visit.

In-Network vs. Out-of-Network Coverage

If a plan or issuer does not have in its network a provider who can provide a particular recommended service, then the plan or issuer must cover, without cost sharing, the item or service when performed by an out-of-network provider.

Medical Management

The final regulations stipulate that to the extent not specified in a recommendation or guideline, a plan or issuer may rely on the relevant evidence base and established reasonable medical management techniques to determine the frequency, method, treatment, or setting for the provision of a recommended contraceptive service.

Timing of Coverage

The final regulations state that a plan or issuer that is required to provide coverage for any recommended preventive service on the first day of a plan or policy year under a particular recommendation or guideline must generally provide that coverage through the last day of the plan or policy year, even if the recommendation or guideline changes or is eliminated during the plan or policy year. However, there are limited circumstances under which it may be inadvisable for a plan or issuer to continue to cover such preventive items or services, for example, due to safety concerns.

Plans and issuers need not make changes to coverage and cost-sharing requirements based on a new recommendation or guideline until the first plan year (in the individual market, policy year) beginning on or after the date that is one year after the new recommendation or guideline goes into effect.

Impact

The number of women actually impacted by the exception made available through the final regulation is likely to be relatively small. Based on litigation and communications received by HHS, the Departments estimate that the exemption will be utilized by 87 closely held for-profit organizations and 122 non-profit eligible organizations.