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Government Issues New Rules for Religious Employers, But Health Plans, TPAs, and PBMs are still on the Hook to Provide Contraceptive Coverage

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The Affordable Care Act ("ACA") requires that non-grandfathered health plans make preventive care and screenings available to their members at no cost (i.e. no deductibles, coinsurance, or co-payments). The **Department of Health and Human Services ("HHS")** determined that contraceptive services, including all **Food and Drug Administration ("FDA")**-approved contraceptives, are part of the essential preventive care that must be made available to women.

This requirement was met with protests from religious employers who believe that forcing them to offer and pay for contraceptive services violates their first amendment right to religious freedom. To address these concerns, the **Department of Labor ("DOL")** and HHS promulgated regulations creating an exception to the contraceptive coverage mandate for religious employers that qualify as an "eligible organization." An "eligible organization" is one that self-certifies that it is an "eligible organization" and therefore is not required to contract, arrange, pay or refer for coverage of contraceptive services for its plan members. These regulations, discussed on our blog in greater detail **here**, result in a system where health plans and third party administrators (which include pharmacy benefit managers ("PBMs") for the purpose of this regulation), must pay for these contraceptive services and then receive reimbursement for the services more than a year later, if at all.

Religious employers, both non-profit and closely-held for-profit entities, were not satisfied with this approach and looked to the court system for relief. Earlier this summer in the much anticipated *Burwell v. Hobby Lobby* case, **the Supreme Court held** that the requirement to provide contraceptive products substantially burdened the exercise of religious freedom by closely-held corporations and was not the least restrictive means to ensure that women have access to these contraceptives. The Supreme Court also stated that a possible solution might be to expand the definition of "eligible organization" to include closely-held corporations.

Then, only three days later, the court granted an injunction to Wheaton College, a religious employer arguing that the "religious exemption" regulations effectively require an eligible organization to "sanction" contraceptive services. The Supreme Court held that, pending final appellate review, HHS cannot enforce the challenged provisions if the organization informs the HHS Secretary in writing that it is a non-profit organization that holds itself out as religious and has religious objections to providing coverage for contraceptive services. In short, to meet this condition for injunction, the religious organization need not use the form designated by HHS/DOL and need not send copies to health plans, third-party administrators, or PBMs.

In response to this injunction and the growing federal circuit split on whether the process for obtaining a religious exemption to the contraception mandate is overly burdensome, HHS and DOL issued an interim final rule ("IFR") on August 22nd. The new rules establish a second mechanism for eligible organizations to take advantage of the religious exemption from providing coverage for contraceptive services. Now, eligible organizations can use the process set out in the 2013 rules, or, simply notify HHS in writing of its religious objection. In turn, HHS or DOL will notify the health plan, third party administrator, or PBM responsible for providing enrollees in the health plan with contraceptive services at no cost for as long as they remain enrolled in the health plan.

What Does This Mean for Health Plans, TPA, and PBMS?

HHS clearly states in its **fact sheet** that regardless of whether the eligible organization self-certifies in accordance with the July 2013 final rules, or provides notice to HHS in accordance with the August 2014 IFR, the obligations of health plans, third party administrators, and PBMs to provide or arrange separate payments for contraceptive services are the same.

Between the *Hobby Lobby* decision, the injunction, and subsequent new rules, entities are able to take advantage of the religious exemption with very little proof or demonstration that they are a religious organization. As a result, health plans, third party administrators, and PBMs stand to be increasingly put on the spot to pay for contraceptive services.

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Theresa advises clients on all aspects of the pharmaceutical supply chain, including counseling industry stakeholders on a range of business, legal, transactional, and compliance matters. She provides clients with strategic counseling and creative business modeling that considers legal restrictions and regulatory risk in light of innovation and business goals.