



October 27, 2014

Office of Health Plan Standards and Compliance Assistance  
Employee Benefits Security Administration  
Room N-5653  
U.S. Department of Labor  
200 Constitution Avenue, NW  
Washington, DC 20210  
Attention: Preventive Services

*Submitted electronically at [www.regulations.gov](http://www.regulations.gov)*

Subject: IFR: Coverage of Certain Preventive Services Under the Affordable Care Act,  
Docket ID: EBSA-2014-0013-0002

The undersigned organizations write in response to the Interim Final Rules (IFR) on “Coverage of Certain Preventive Services Under the Affordable Care Act,” published in the Federal Register on August 27, 2014 by the Department of the Treasury, Department of Labor (“DOL”), and Department of Health and Human Services (“HHS”) (collectively, “the Departments”). The IFR provides an alternative process by which an entity eligible for the “accommodation” may provide notice of its religious objection to providing insurance coverage of contraception or sterilization. The participants and beneficiaries of the health plans of eligible entities that avail themselves of the accommodation still receive the benefit of the full range of FDA-approved methods of contraception, sterilization, and related education and counseling without cost-sharing, as guaranteed by Section 2713 of the Public Health Service Act and implementing regulations. This alternate process would be available for certain for-profit companies as well, pursuant to the Departments’ proposed rule,<sup>1</sup> and as such, the comments and recommendations included herein are submitted with that in mind.

- I. We support the Departments’ alternative notification process and urge the Departments to adopt additional requirements.

We support the Departments’ alternative notification process in light of the Supreme Court’s order in *Wheaton College*.<sup>2</sup> We support the specific information required by the Departments in this notice, in particular the requirements that the entity identify the contraceptive services to which it objects and that the entity provide the plan name and type (i.e., whether it is a student health insurance plan or an ERISA church plan) and the name and contact information of third party administrators (“TPA”) and/or health insurance issuers and that the entity identify the religion associated with the entity and the reasons

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<sup>1</sup> cite to NPRM.

<sup>2</sup> *Wheaton College v. Burwell*, 134 S. Ct. 2806 (2014).

for its objection. This information is critical to ensuring that the Departments can properly implement the benefit for the women covered by the plan.

This alternative process merely requires the entity to notify the Departments of its objection, so that it does not have to provide coverage of services to which it objects in its group health plan. This process guarantees that the Departments will be able to ensure compliance with the law by issuers and TPAs; it is not intrusive.<sup>3</sup> Requiring notification to a federal agency is common practice when organizations seek an exemption for religious reasons.<sup>4</sup> For example, a church opposed, for religious reasons, to paying Social Security and Medicare taxes under 26 U.S.C. § 3121(w) must file a Form 8274 certificate with the Internal Revenue Service.

However, there are additional requirements the Departments must put into place to provide transparency, eliminate confusion, and ensure the Departments can monitor and enforce the accommodation:

- If an eligible entity chooses the original self-certification process, the issuer or TPA receiving a self-certification must forward a copy of the self-certification to HHS. This step is necessary to ensure that HHS is aware of all of the entities using the accommodation. It will also ensure that the Departments can oversee and enforce the accommodation properly.
- Significantly, the federal regulations do not provide a specific timeline for submission of self-certification, and the IFR does not specify when an employer

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<sup>3</sup> See *Mitchell v. Helms*, 530 U.S. 793, 861-63 (2000) (O'Connor, J., concurring and controlling opinion); *Agostini v. Felton*, 521 U.S. 203, 234 (1997); *Bowen v. Kendrick*, 487 U.S. 589, 615-17 (1988); *Roemer v. Bd. of Public Works*, 426 U.S. 736, 742-43 (1976); see also Presidential Advisory Council on Faith-Based and Neighborhood Partnerships, A New Era of Partnerships: Report of Recommendations to the President 137 & n.52 (March 2010), available at <http://www.whitehouse.gov/sites/default/files/microsites/ofbnp-council-final-report.pdf> (noting that the Supreme Court has held constitutional requirements for religiously affiliated institutions to submit written applications, signed assurances, and written reports, and that even government site visits, including unannounced monthly visits, of religiously affiliated institutions receiving government aid is constitutional).

<sup>4</sup> See, e.g., Dep't of Labor, Office of the Assistant Sec'y for Admin. and Mgmt. Grants—Religious Freedom Restoration Act Guidance, available at <http://www.dol.gov/oasam/grants/RFRA-Guidance.htm> (requiring an organization seeking a religious exemption to submit “a request for exemption to the Assistant Secretary charged with issuing or administering the grant”); Dep't of Justice, Certificate of Exemption, available at <http://www.ojp.usdoj.gov/recovery/pdfs/arrasampleform.pdf>; See also, e.g., Internal Revenue Code Form 4361: Application for Exemption from Self-Employment Tax for Use by Ministers, Members of Religious Orders and Christian Science Practitioners, available at <http://www.irs.gov/pub/irs-pdf/f4361.pdf> (requiring ministers with religious objections to accepting public insurance to certify with the government (1) that the minister is opposed to acceptance of insurance, (2) that the minister has informed the licensing body of the church that he is conscientiously or religiously opposed to acceptance of such insurance, (3) that they have never filed Form 2031 to revoke a previous exemption from social security coverage on earnings as a minister, and (4) request to be exempted from paying self-employment tax on earnings from services as a minister under section 1402(e) of the Internal Revenue Code. The minister must make these declarations “under penalties of perjury.”).

- needs to submit written notice to HHS. At the outset, the Departments must require that the self-certification to the issuer or TPA or notification to HHS be completed annually, in connection with the start of the new plan year. And to ensure the Departments, issuers, and TPAs have sufficient time to arrange for and administer separate payments for contraception, the Departments should clarify that when done annually, it must be within a reasonable time prior to the first day of the plan year to which the accommodation will apply (e.g., 60 days). The Departments must put eligible entities on notice that, if the eligible entity fails to follow the timelines, it may not exclude contraceptive services from the group or student health plan.
- We support the Departments' requirement that eligible entities list the contraceptive services to which they object when using the notification process. However, an entity using the self-certification process does not similarly have to provide this information. We ask the Departments to require this information as part of the self-certification process as well. Additionally, in order to avoid any coverage gaps resulting from inadequate information being provided by the eligible entity, particularly as to the exact description of which methods the entity objects to, we ask that the Departments incorporate into the EBSA Form 700 and the model notification to HHS a checklist of the FDA's list of 20 birth control methods.<sup>5</sup> Because there are many different types of contraceptive services and methods that are currently approved by the FDA and it is unlikely that the person charged with filling out this form will have a medical or pharmaceutical background, including this list will help to eliminate confusion that could result in gaps in the coverage.
  - The Departments should require eligible entities to include in the notification to HHS or certification form to the issuer or TPA the number of workers employed by the entity as well as the total number of beneficiaries covered by the entity's health insurance plan, and should similarly require this information about enrollees and dependents in an accommodated student health plan. This information would better enable the Departments to monitor and enforce the accommodation.
  - HHS must make public the for-profit companies and non-profit organizations availing themselves of the accommodation, so that employees and prospective employees are able to understand the full extent of their employment compensation as well as the source and terms of their employer-based insurance coverage. This also should be done for any entity seeking an accommodation in its student health plan, so that students and prospective students are aware of the complete terms of coverage. HHS should make publicly available the documentation – notifications to HHS, self-certification forms sent to HHS by issuers or TPAs, and back-up supportive documents. At the very least, it should maintain a public list

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<sup>5</sup> FDA Birth Control Guide, *available* at <http://www.fda.gov/downloads/ForConsumers/ByAudience/For%E2%80%A8Women/FreePublications/UCM356451.pdf>. Review or acceptance of the notification or self-certification form by HHS should have no bearing on determinations of whether the issuer or TPA is actually in compliance with the preventive services provision and accompanying regulations and guidance.

of those for-profit companies and non-profit organizations that are using the accommodation. HHS has taken similar steps in relation to organizations that have been relieved of other obligations under the ACA. For example, HHS has previously created a public website that lists all health plans that were granted waivers for complying with the ACA's annual limit requirement to ensure that information is readily available to plan enrollees and beneficiaries.<sup>6</sup>

- II. We call on the Departments to implement policies and procedures to ensure strict oversight and enforcement.

No matter the process by which an eligible entity avails itself of the accommodation, the Departments must ensure that participants and beneficiaries have access to the contraceptive coverage guaranteed to them by law. In order to do so, the Departments must implement strict oversight and enforcement of the accommodation.

We renew our request for a centralized oversight and enforcement entity for the contraceptive coverage accommodation.<sup>7</sup> Creating an oversight and enforcement entity dedicated to the contraceptive coverage accommodation is particularly important because enforcement of the contraceptive coverage requirement will differ based on the source of insurance coverage.<sup>8</sup>

A centralized oversight and enforcement entity will not only ensure that women accessing contraceptive coverage through the accommodation get that coverage as guaranteed by law, but also enable the Departments to easily identify and address any systemic implementation problems. It should include a process by which participants and beneficiaries can file complaints and make appeals when they face adverse action. Such adverse action would include, but is not limited to, a denial or limited authorization of a service; reduction, suspension, or termination of a previously authorized service; partial or total denial of payment for service; failure to provide services in a timely manner; or other obstacles that hinder access to the contraceptive coverage benefit as guaranteed by the law and implementing regulations and guidance. It should also include a process by which participants and beneficiaries who believe that their employer has wrongly claimed status as a religious employer or an organization eligible for the accommodation can file a complaint to trigger the relevant part of the oversight process.

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<sup>6</sup> Annual Limits Policy: Protecting Consumers, Maintaining Options, and Building a Bridge to 2014, [http://cciio.cms.gov/resources/files/approved\\_applications\\_for\\_waiver.html](http://cciio.cms.gov/resources/files/approved_applications_for_waiver.html).

<sup>7</sup> See Letter to Centers for Medicare & Medicaid Services & Department of Health and Human Services, from Advocates for Youth et al., Subject: NPRM Certain Preventive Services Under the Affordable Care Act, CMS-9968-P, Docket ID: CMS-2012-0031-63161 (Apr. 8, 2013).

<sup>8</sup> Depending on whether a health plan is self-insured or fully-insured, it may be governed by ERISA or both ERISA and state insurance regulations. Although states are responsible for enforcing the PHSA, HHS has authority to enforce the PHSA where a state is not substantially enforcing the law. In some cases, plans will be regulated by the Department of Labor, HHS, and/or state insurance regulators. Moreover, the Internal Revenue Service also has authority to penalize plans not complying with the ACA.

A dedicated entity will be able to maintain a file of all entities invoking the exemption or accommodation, conduct audits necessary to ensure that processes are operating as intended under the law, serve as a repository for consumer complaints, and ensure self-certifications and other documentation are publicly available.

Additionally, the oversight and enforcement agency should proactively collaborate with state insurance commissioners, who have a role in enforcing the preventive services provision. The federal oversight and enforcement entity must ensure that state insurance commissioners have a specific contact within the federal agency, with whom they can share information and to whom they can ask questions.

The alternative process allowing eligible entities to notify HHS raises new concerns about enforcement and oversight. Given the range of government agencies and third party entities involved in the alternative process, the following additional requirements should be part of the process:

- Each agency should designate a specific point person at the agency who will be in charge of handling the responsibilities associated with the accommodation.
- There must be a specific process, with clear timelines, by which HHS receives the notification from the employer and in turn notifies the issuer.
- For self-insured plans, there must be a specific process in place with clear timelines to ensure that communication between HHS and DOL happens in a timely manner.

These steps will help to ensure that implementation of the accommodation at the employer, issuer, and agency end does not result in participants and beneficiaries losing their guaranteed, seamless access to the contraceptive coverage benefit.

- III. Deleting the non-interference provision places an obligation on the Departments to prioritize awareness and enforcement of existing laws.

The Departments' interim final regulations deleted the "non-interference provision" codified in the July 2013 final regulations,<sup>9</sup> which prohibited eligible entities that establish or maintain self-insured group health plans from interfering with a TPA's arrangements to provide the contraceptive coverage benefit directly to participants and beneficiaries. The Departments state that the conduct prohibited by the deleted provision – i.e., "bribery, threats, or others forms of economic coercion" – is already "prohibited under other state and federal laws."<sup>10</sup> Because the Departments do not identify specific state and federal laws, it is not clear to which laws the Departments are referring. Though we recognize

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<sup>9</sup> 79 Fed. Reg. at 51,095.

<sup>10</sup> *Id.*

that protections exist,<sup>11</sup> we do not know – without more information from the Departments – whether all states have laws that would prohibit these types of unlawful conduct as well as other forms of interference that might arise.

Regardless, the Departments must not allow eligible entities to block any TPA’s provision of the contraceptive coverage benefit. The Departments should ensure the following:

- That entities seeking to avail themselves of the accommodation are reminded of the existence of these state and federal laws that prohibit such interference;
- That TPAs are aware of the protections against non-interference in state and federal law;
- That TPAs are informed of the enforcement agencies to which they could complain should an eligible entity violate these state or federal laws;
- That participants and beneficiaries of eligible entities are also told of the existence of these laws and what they can do if they suspect a violation of these laws.

The deletion of this provision lends further support to our comments above, concerning the need for strong monitoring, oversight, and enforcement of the accommodation. All parties must comply with their lawful obligations so that participants and beneficiaries receive the coverage to which they are entitled, in a seamless and timely manner. Additionally, if there are obstructions of coverage, the Departments should add language reinforcing the duties of eligible entities and TPAs.

In summary, as the Departments make changes to the accommodation process, it must take the steps outlined above to ensure that the accommodation is seamless for all women and that all eligible women receive the benefits of birth control coverage without cost-sharing or additional barriers, regardless of where they work or study.

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<sup>11</sup> We recognize that there are potential protections available under state and federal laws, such as the Employee Retirement Income Security Act of 1974 (“ERISA”). *See, e.g.*, 29 U.S.C. § 1132 (a)(1)(B) (“A civil action may be brought . . . by a participant or beneficiary . . . to recover benefits due to him under the terms of his plan, or to clarify his rights to future benefits under the terms of the plan.”). This ERISA provision suggests that an aggrieved individual would be able to enforce contractual rights under an employee benefit plan. *See also Weems v. Jefferson-Pilot Life Ins. Co., Inc.*, 663 So.2d 905, 909 (Ala. 1995) (Beneficiaries in an employer-provided medical insurance plan sued the employer and insurer under Alabama state law and ERISA after the employer failed to pay the premiums and notify the beneficiaries, which resulted in termination of coverage. Among other findings, the court held that ERISA preempted the beneficiaries’ state law claims).