April 8, 2013

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-9968-P
P.O. Box 8013
Baltimore, MD 21244-1850

Submitted electronically at www.regulations.gov

Subject: NPRM: Certain Preventive Services Under the Affordable Care Act, CMS-9968-P, Docket ID: CMS-2012-0031-63161

The undersigned organizations write in response to the Notice of Proposed Rulemaking (NPRM) on "Certain Preventive Services Under the Affordable Care Act," published in the Federal Register on February 6, 2013. The NPRM announces the intention of the Departments of the Treasury, Labor, and Health and Human Services (the Departments) to change the definition of "religious employer" that will be exempted from coverage of contraceptive services without cost sharing as required by the Patient Protection and Affordable Care Act (ACA).[1] In addition, it proposes an accommodation to "eligible organizations" that object to providing this coverage for religious reasons.

We applaud the Departments' goal of "secur[ing] the protections under section 2713 of the [Public Health Service Act] that are designed to enhance coverage of important preventive services for women without cost sharing."[2] However, we oppose the Departments' decision to create an exception for certain "religious employers." This provision undermines women's ability to access contraceptive coverage without cost sharing. Nothing in the ACA allows for any limitations regarding contraceptive coverage. Moreover, Sections 1554 and 1557 of the ACA actually prohibit the exemption of "religious employers" from covering contraceptives.

The accommodation is unnecessary under the law. However, if the Departments move forward with creating the accommodation, it must provide seamless contraceptive coverage with no cost sharing for women. In order to reach that goal, the Departments must provide greater detail as to how the accommodation will actually work. To that end, we provide the following comments on the specific questions raised in the NPRM.

Summary of Comments

To aid the Departments in their review of our comments, we have included this summary of the key points:

[1] Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (codified as amended in scattered sections of 21 U.S.C., 25 U.S.C., 26 U.S.C., 29 U.S.C., and 42 U.S.C.).
[2] Coverage of Certain Preventive Services Under the Affordable Care Act, 78 Fed. Reg. 8456, 8460 (proposed Feb. 6, 2013) (to be codified at 26 C.F.R. pt. 54, 29 C.F.R. pt. 2590, and 45 C.F.R. pts. 147, 148, and 156).

- In order to meet the promise of the preventive services provision of the ACA, women must have seamless access to no-cost contraceptive coverage under the final rule.

- Women in plans that are exempted or accommodated must retain all existing legal protections such as those under the civil rights, employee benefit, and health care laws.

- We strongly urge the Departments to replace the exemption with the accommodation, which would allow the women who receive health insurance through "religious employers" to get contraceptive coverage. Also, the Departments' change to the test to be a "religious employer" should only have a de minimis impact on the number of employers who take the exemption if the applicable laws are strongly enforced.

- The Departments must address the following concerns with the accommodation:

    - The test to become an "eligible organization" for the accommodation must be narrowly applied and fully enforced, so that as few women as possible are affected by it.
        - We strongly support the Departments' decision to limit the accommodation to non-profits.
        - We strongly oppose the Departments' decision to offer the accommodation to organizations that refuse to cover only some contraceptives.
        - The Departments must ensure that only organizations that prominently and consistently hold themselves out to the public, their employees, and students as religious may take advantage of the accommodation.
        - The Departments must ensure that the self-certification process is robust and transparent, including a requirement that "eligible organizations" file their self-certifications with the Departments.

    - The Departments must implement the accommodation so that women receive seamless access to contraceptive coverage.
        - The Departments must clearly state that if the contraceptive coverage is not in place at the start of the plan year, the "eligible organization" will not be accommodated that year.
        - The Departments must ensure that participants and beneficiaries subject to the accommodation receive timely, accurate, and clear notice about their contraceptive coverage without cost-sharing.
        - The Departments must require that insurers and TPAs provide participants and beneficiaries with a single insurance card for both their employer-sponsored plan and their contraceptive coverage.

    - In creating the mechanism through which self-insured employers will be accommodated, women's access to coverage must be assured.
        - The Departments must state that it is a legal requirement that third-party administrators (TPAs) find issuers of the contraceptive coverage for "eligible organizations" with which they contract.

- The Departments must state that where an "eligible organization" shifts its legal responsibility to provide contraceptive coverage to TPAs and issuers, the TPAs and issuers get the legal obligations of the employers as well.
- The Departments must clearly state that if an "eligible organization" does not have a third-party to provide coverage to its employees, it cannot be accommodated.
- If the Departments proceed with their plan of adjusting the Federally-facilitated exchange user fees for issuers, we strongly urge that the Departments do so in a way that does not undermine any aspect of the exchanges.

- We strongly support the Departments' statement that these rules allow states to enact "stronger consumer protections than these minimum standards."[3] The Departments must also clarify that other existing legal obligations specifically requiring contraceptive coverage continue to apply to those organizations that are exempted or accommodated.

- The Departments must provide enforcement and oversight of the preventive services requirement overall, and of the "religious employer" exemption and the accommodation in particular.

I. Women Must Receive The Seamless Contraceptive Coverage Guaranteed by the ACA.

The Departments' first priority must be that women – regardless of where they work – have access to the affordable and comprehensive contraceptive coverage they need, deserve, and are guaranteed by law. Any impediments created by the rule must not be borne by participants or beneficiaries.

As the Departments have recognized, access to contraception without cost sharing is a critical component of preventive care that has demonstrable benefits for the health of women and children. In the final rule on the preventive health services, the Departments stated, "Congress, by amending the Affordable Care Act during the Senate debate to ensure that recommended preventive services for women . . . recognized that women have unique health care needs and burdens. Such needs include contraceptive services."[4]

[3] *Id*. at 8468.

[4] Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services Under the Patient Protection and Affordable Care Act, 77 Fed. Reg. 8725, 8727 (Feb. 15, 2012). The Departments specifically noted: "In addition, there are significant cost savings to employers from the coverage of contraceptives. A 2000 study estimated that it would cost employers 15 to17 percent more not to provide contraceptive coverage in employee health plans than to provide such coverage, after accounting for both the direct medical costs of pregnancy and the indirect costs such as employee absence and reduced productivity. In fact, when contraceptive coverage was added to the Federal Employees Health Benefits Program, premiums did not increase because there was no resulting health care cost increase. Further, the cost savings of covering contraceptive services have already been recognized by States and also within the health insurance industry. Twenty-eight States now have laws requiring health insurance issuers to cover contraceptives. A 2002 study found that more than 89 percent of insured plans cover contraceptives. A 2010 survey of employers revealed that 85 percent of large employers and 62 percent of small employers offered coverage of FDA approved contraceptives." *Id.* at 8727-28 (internal citations omitted).

Unfortunately, costs remain a barrier to women being able to use birth control effectively.[5] Studies also show that eliminating cost barriers to contraception can greatly reduce the incidence of unintended pregnancy. Congress, by amending the ACA with the women's preventive health services, intended to eliminate those barriers by providing coverage with no cost sharing.[6] It is clear from the debate on this amendment that Congress always intended that the provision would apply to contraception.[7]

In addition, comprehensive reproductive health care – including contraception – is a vital part of women's health care and is essential in ensuring that women and families are able to lead healthy, productive lives. Contraceptive services should not be stigmatized by isolating them from other coverage or services, nor should barriers be created to make securing access to this care more difficult.

Access to contraception promotes equal opportunities far beyond the health care realm by improving women's social and economic status. Contraception puts women in control of their fertility, allowing them to decide whether, and when, to become parents. In one study, 60% of women reported the ability to better control their lives as a very important reason for using birth control.[8] Indeed, the U.S. Supreme Court has found that "[t]he ability of women to participate equally in the economic and social life of the Nation has been facilitated by their ability to control their reproductive lives."[9] In addition, the disparate out-of-pocket health care costs for men and women – a disparity that is exacerbated by women's costs for contraception – increases the wage gap.[10] Increased control over reproductive decisions, in turn, provides women with educational and professional opportunities that have increased gender equality over the decades

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[5] *See, e.g.*, Guttmacher Inst., A Real-time Look at the Impact of the Recession on Women's Family Planning and Pregnancy Decisions 5 (2009), *available at* http://www.guttmacher.org/pubs/ RecessionFP.pdf (finding that, in order to save money, women forewent contraception, skipped birth control pills, delayed filling prescriptions, went off the pill for at least a month, or purchased fewer birth control packs at once).

[6] Patient Protection and Affordable Care Act of 2010, Pub. L. No. 111-148, § 1001, 124 Stat. 119, 131 (2010) (to be codified at 42 U.S.C. § 300gg-13).

[7] In considering the women's preventive health services, Congress expressed its expectation that the Health Resources and Services Administration Guidelines would incorporate family planning services. *See, e.g.*, 155 Cong. Rec. S12,027 (daily ed. Dec. 9, 2009) (statement of Sen. Gillibrand) ("With Senator Mikulski's amendment, even more preventive screening will be covered, including…family planning."); 155 Cong. Rec. S12,033, S12,052 (daily ed. Dec. 1, 2009) (statement of Sen. Franken) ("I believe that affordable family planning services must be accessible to all women in our reformed health care system."); 155 Cong. Rec. S12,106, S12,114 (daily ed. Dec. 2, 2009) (statement of Sen. Feinstein) ("[The amendment] will require insurance plans to cover at no cost basic preventive services and screenings for women. This may include mammograms, Pap smears, family planning, screenings to detect postpartum depression, and other annual women's health screenings."). Following three days of debates, the Senate adopted the Women's Health Amendment by a vote of 61 to 39.

[8] Jennifer J. Frost & Laura Duberstein Lindberg, Guttmacher Inst., Reasons for Using Contraception: Perspectives of US Women Seeking Care at Specialized Family Planning Clinics 9 (2012), *available at* http://www.guttmacher.org/pubs/journals/j.contraception.2012.08.012.pdf .

[9] *Planned Parenthood of Se. Pa.* v. *Casey*, 505 U.S. 833, 856 (1992); *see also Erickson* v. *Bartell Drug Co.*, 141 F. Supp. 2d 1266, 1273 (W.D. Wash. 2001) ("[T]he adverse economic and social consequences of unintended pregnancies fall most harshly on women and interfere with their choice to participate fully and equally in the marketplace and the world of ideas.") (internal quotations omitted).

[10] Jessica Arons & Lindsay Rosenthal, Ctr. for American Progress, The Health Insurance Compensation Gap: How Unequal Health Care Coverage for Women Increases the Gender Wage Gap (April 16, 2012), *available at* http://www.americanprogress.org/issues/women/report/2012/04/16/11429/the-health-insurance-compensation-gap/.

since birth control was introduced.[11] Congress understood that the women's preventive health services—including its broadening of access to contraceptives—would be "a huge step forward for justice and equality in our country."[12]

Given that the preventive health services were enacted to fill a critical gap in health care coverage – including birth control – that threatened women's health, it is imperative that any rule that the Departments finalize protect this critical coverage. In addition, the significant impact that access to birth control has on women's educational and employment opportunities – and the significant impact on women's health that educational and employment achievement have as well – makes access to this coverage even more critical.

II. The Final Rule Must Not Infringe on Existing Legal Protections for Women

In crafting the final rule on the accommodation, a second important priority is that all of the legal rights that women currently have are not limited in any way by the exemption or accommodation.

A. Legal Protections That Women Have As Employees, Plan Participants, and Beneficiaries Cannot and Must Not Be Infringed Upon.

The women whose employers might qualify as "religious employers" or "eligible organizations" are currently protected by many federal laws, including but not limited to Employee Retirement Income Security Act of 1974 ("ERISA"),[13] ACA, Health Insurance Portability and Accountability Act of 1996 (HIPAA),[14] Title VII of the Civil Rights Act of 1964,[15] and Title IX of the Education Amendments of 1972.[16] In addition, women who are not employed by these entities but who are beneficiaries of health insurance plans that the entities sponsor also have legal protections. The fact that the Departments have opted to create the exemption and accommodation – even though there is no constitutional or statutory requirement that these steps be taken – cannot and must not be allowed to infringe on these legal protections in any way.

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[11] A number of analyses have connected the advent of oral contraception to significant augmentation of women's wages. One study found that "the Pill-induced effects on wages amount to roughly one-third of the total wage gains for women in their forties born from the mid-1940s to early 1950s." Bailey et al., The Opt-In Revolution? Contraception and the Gender Gap in Wages 26-7 (2012), available at http://www-personal.umich.edu/~baileymj/Opt_In_Revolution.pdf. That same study estimates that approximately 10% of the narrowing of the wage gap during the 1980s and 31 percent during the 1990s can be attributed to access to oral contraceptives prior to age 21. *Id*. Another study concludes that the advent of oral contraceptives contributed to an increase in the number of women employed in professional occupations, including as doctors and lawyers. Goldin & Katz, The Power of the Pill: Oral Contraceptives and Women's Career and Marriage Decisions, 110 J. Pol. Econ. 730, 759-62 (2002).

[12] 155 Cong. Rec. S12,033, S12,052 (daily ed. Dec. 1, 2009) (statement of Sen. Franken).

[13] Employee Retirement Income Security Act of 1974, Pub. L. No. 93-406, 88 Stat. 829 (codified as amended in scattered sections of 29 U.S.C.).

[14] Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936 (codified as amended in scattered sections of 18 U.S.C., 26 U.S.C., 29 U.S.C., and 42 U.S.C.).

[15] Civil Rights Act of 1964, Pub. L. No. 88-352, 78 Stat. 241 (codified as amended in scattered sections of 2 U.S.C., 28 U.S.C., & 42 U.S.C.).

[16] 20 U.S.C. 1681 (1972).

For example, a health plan that is provided by an employer to an employee as part of that employee's benefits package is protected by ERISA. The fact that the Departments are allowing employers to shift their obligation to provide contraceptive coverage with no cost sharing must not mean that employees and their eligible dependents lose this legal protection. The Departments must make clear that where a third party is standing in for the employer, the employee or an eligible dependent retains all of the legal rights that she had when the benefit was being offered by the employer. This must be true as to all of her other legal rights as well.

The rule must also be clear that employers retain all of their legal obligations under existing law. In addition, to the extent that the proposed rule requires employers, issuers, and TPAs to fulfill various aspects of providing the coverage, employees and their eligible dependents must be able to exert their legal rights as participants and beneficiaries against all three parties to the extent that they are responsible. In other words, where the accommodation allows an employer to shift its responsibility to an issuer or TPA, they assume that employer's legal obligations. This shift in legal liability is not unprecedented and an analogous situation occurs under COBRA.[17] A plan sponsor may contract with a TPA to administer its COBRA for former employees and other qualified beneficiaries. The TPA can be held responsible for the excise taxes and other penalties associated with its errors if it assumed (in a written contract) the obligation associated with the COBRA failure.[18]

Ultimately, the legal rights of women must be kept whole. Any other result would create a loophole in the critical network of federal and state laws that have been enacted to protect women. That would be an unacceptable result.

B. If The Departments Make The Contraceptive-Only Coverage An Excepted Benefit, Women Must Retain All Of The Legal Protections They Had When The Coverage Was Part Of An Employer-Based Group Health Plan.

The preamble to the proposed rule states "it would be necessary and appropriate to establish a new contraceptive-only excepted benefits category."[19] It may be necessary, for logistical reasons, for the contraceptive-only coverage to be an excepted benefit in order for women to receive coverage of services without cost sharing under an accommodation. If the Departments decide to make it an excepted benefit, the rule must include language that protects women's legal rights.

We support the Departments' decision to pay particular attention to the protections that must attach to the contraceptive-only coverage. In particular, the Departments recognized the importance of the following sections of the Public Health Service Act (PHSA) by proposing that contraceptive-only coverage comply with: §§ 2703 (Guaranteed Renewability), 2711 (Annual or Lifetime Dollar Value), 2712 (Rescissions of Coverage), and 2719 (Appeals).[20] These protections should be incorporated in their entirety.

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[17] 29 U.S.C. § 1161.
[18] *See* I.R.C. § 4980B(e)(1)(B) (2013); Treas. Reg. § 54.4980B-2 Q&A 10 (2013).
[19] Coverage of Certain Preventive Services Under the Affordable Care Act, 78 Fed. Reg. 8467.
[20] *Id*. at 8468.

The Departments seek comment on what other provisions of the PHSA, ERISA, and the Internal Revenue Code should apply. The following is a non-exhaustive list of provisions with which the contraceptive-only coverage should comply:[21]

- Section 2719A of the PHSA (*Direct Access to OB-GYN providers*): Women seeking contraception services must be allowed direct access to any primary care provider in the network as required by Section 2719A, including any OB-GYN provider, and without a referral.[22]
- Section 101 *et seq.* of ERISA (*Reporting and Disclosure Requirements)*: Participants and beneficiaries must have rights to plan documents and be protected by the required reporting and disclosure requirements of Sections 101 through 111 of ERISA. If information on the contraceptive-only coverage is not included in the health plan summary plan description (SPD,)[23] then the issuer or TPA must be required to provide a separate SPD that is required to have all appropriate information that would apply to the contraceptive coverage. The issuer or TPA must be required to provide any summaries of material modification.[24]
- Sections 502 and 510 of ERISA (*Civil Enforcement in Court*):[25] Participants and beneficiaries must have the right to bring claims for benefits and claims for interference with protected rights.
- HIPAA Nondiscrimination: All of the nondiscrimination requirements of HIPAA must apply.
- HIPAA Privacy and Disclosure: The privacy and disclosure requirements of HIPAA must apply to both the TPA and the issuer of the contraceptive-only coverage. Because the employer has chosen to have an accommodation, the HIPAA privacy and security requirements should preclude the sharing of any protected health information (PHI) with the employer or employer-sponsored plan, since neither would need information about contraceptive use. In the event that a participant or beneficiary has a complication from the result of a service or medication covered by the contraceptive-only coverage and the health plan covers the services associated with the complication, there is still no need for the TPA or issuer of the contraceptive-only coverage to share PHI. Any information the plan needs for coverage of such services would be available in a claim or, in the event of an initial denial, information provided during an appeal process.

In addition to these requirements, the excepted benefit category needs to be designed in a way that incorporates additional protections into the structure of the accommodation. These include:

- The Departments must also ensure that contraceptive-only coverage is automatically included in COBRA continuation coverage.[26] If an individual is eligible for and enrolls

[21] Given that the final rule is part of the regulations implementing Section 2713 of the PHSA, as amended by the ACA, all of the other legal protections that apply to Section 2713 will apply to these excepted benefits.
[22] Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 1001 (2010), *amended by* Health Care and Education Affordability and Reconciliation Act, Pub. L. No. 111-152 (2010) (to be codified at 40 U.S.C. § 300gg-19a).
[23] Employee Retirement Income Security Act of 1974 § 102, 29 U.S.C. § 1022 (2013).
[24] Employee Retirement Income Security Act of 1974 § 104(b)(1), 29 U.S.C. § 1024(b)(1) (2013).
[25] 29 U.S.C. §§ 1132 & 1140 (2013).
[26] 29 U.S.C. § 1161 (2013).

in continuation coverage, then that coverage must include the identical contraceptive coverage provided to current employees. Therefore, if an employer has an accommodation, the contraceptive coverage would continue to be provided through the same contraceptive-only issuer and would include the same benefit coverage. There should be no additional steps required, including no requirement to actively choose to have contraceptive coverage included, and no additional premium. The TPA should arrange the COBRA continuation coverage so that the coverage is seamless for any participant or beneficiary that enrolls.

- HIPAA special enrollment rights for the contraceptive-only coverage should be tied to the underlying health plan, similar to our recommendation for COBRA continuation coverage. Participants and beneficiaries that enroll in a plan that has an accommodation during a special enrollment period should seamlessly be enrolled in the contraceptive-only coverage.
- There must be guaranteed availability of coverage to any group of individuals that are participants and beneficiaries in an accommodated plan that applies for coverage through a TPA. An issuer offering contraceptive-only coverage does not need to allow any individual, such as an uninsured individual or individual with a health plan that did not receive an accommodation, to enroll. However, the issuer offering a contraceptive-only plan must not refuse coverage to a group that is otherwise eligible.

In summary, the Departments must maintain all enforcement provisions that would be available for use to enforce provisions of the ACA or other insurance or employee health benefit requirements that apply to the contraceptive-only coverage.

C. The Departments Correctly State That The Contraceptive-Only Coverage Must Comply With All The Requirements Of The ACA, Including The Most Recent Guidance Addressing The Preventive Services Coverage Requirement.

We commend the Departments for their statement in the preamble to the proposed rule recognizing these requirements: "The issuer would provide benefits for such contraceptive services without the imposition of any cost sharing requirement (such as a copayment, coinsurance, or a deductible), premium, fee, or other charge, consistent with section 2713 of the PHS Act. The requirements of section 2713 of the PHS Act, its implementing regulations, and other applicable federal and state law (as well as their enforcement mechanisms) would continue to apply with respect to such coverage."[27] This is particularly important for women's ability to access the full range of FDA-approved contraceptive methods from an out-of-network provider at no cost sharing when no in-network provider is available to perform the preventive services.[28]

III. The Exemption Is An Unnecessary Barrier to Women Receiving Contraceptive Coverage With No Cost Sharing

In the proposed rule, the Departments state that they are changing the test for which organizations qualify as "religious employers" for the exemption. The change in the test should

[27] Coverage of Certain Preventive Services Under the Affordable Care Act, 78 Fed. Reg. at 8463.
[28] Dep't of Labor, FAQs about Affordable Care Act Implementation Part XII (Feb. 20, 2013), *available at* http://www.dol.gov/ebsa/faqs/faq-aca12.html.

only have a de minimis impact on the number of employers who take the exemption if the applicable laws are strongly enforced. Additionally, we urge the Department to replace the exemption with the accommodation so that all women will have access to contraceptive coverage with no cost sharing.

A. Depending On Proper Enforcement, The Change In The Test For "Religious Employers" Need Not Unduly Expand The Number Of Employers Who Will Qualify.

The Departments ask whether the change in the test for the exemption "unduly expand[s] the universe of employer plans that would qualify for the exemption."[29] Under the legal standards set forth both in the Internal Revenue Code (IRC) and in Internal Revenue Service (IRS) guidance, we believe that the change in the number of additional employers who would qualify for the exemption should be de minimis as long as the Departments strictly enforce IRS and IRC standards. Otherwise, organizations that do not actually qualify as "religious employers" may claim to be, which would impact the number of women losing the contraceptive coverage guaranteed by the ACA.

B. Eliminating The Exemption And Replacing It With The Accommodation Would Ensure that More Women Have Access to This Critical Health Service.

We oppose the exemption that allows certain "religious employers" to exclude contraceptive services from their employees' health plans. Nothing in the ACA allows for any limitations regarding contraceptive coverage. In fact, Sections 1557 and 1554 of the ACA prohibit the creation of the exemption. In addition, there are no laws requiring that the Departments create this exemption. Ultimately, this exemption means that women and their dependents who receive health coverage through these organizations will completely lose the contraceptive coverage and all of its concomitant benefits.

If the Departments do move forward in treating "religious employers" differently than other employers, the Departments should replace the exemption with the accommodation. This would allow all women (those that get their insurance through "religious employers," "eligible organizations," and other employers) to have access to contraceptive coverage with no cost sharing. The result still would be that the "religious employers" would not "contract[], arrang[e], pay[], or refer[] for" the contraceptive coverage, while employees and their dependents would not completely lose this important coverage.[30]

In addition, and in keeping with other laws, "religious employers" must have notice and filing obligations to ensure that employees have complete information relating to their health plan coverage. Please see pages 12 and 16 below for further discussion.

[29] Coverage of Certain Preventive Services Under the Affordable Care Act, 78 Fed. Reg. at 8461.
[30] *Id*. at 8462.

IV. The Accommodation Must Be Implemented In a Manner That Provides Women With Seamless Coverage of Contraception With No Cost Sharing.

Although the accommodation is legally unnecessary, we agree with the Departments' decision to make women's access to contraceptive coverage with no cost sharing a priority. In order for this to become a reality, however, the rule must include more clarity and detail about how an organization qualifies as an "eligible organization" and how the accommodation will actually work.

A. "Eligible Organizations"

1. We strongly support the Departments' decision to limit the accommodation to non-profits and exclude for-profit businesses.

We strongly support the Departments' decision to limit the accommodation to non-profits and to exclude for-profit businesses. For-profit businesses exist to make money through commercial activity, not to exercise religion. Accordingly, the decision to limit the accommodation not only ensures that the impact of the accommodation reaches fewer women, but also ensures that women who work for these companies – and not their bosses – will be able to make their own personal health care decisions.

2. We urge the Departments to not allow organizations that only oppose some methods of contraception to be eligible for the accommodation.

The Departments' decision to allow an accommodation for organizations that only refuse to cover some of the FDA-approved contraceptive methods is very problematic. Organizations that refuse to provide insurance coverage of some specific methods (like emergency contraception) often do so because they incorrectly claim that those methods are "abortifacients."[31] The Departments' decision must be based on medical science, rather than on employers' religious beliefs that may conflict with the women's own beliefs. In addition, this inaccurate characterization could create confusion and practical difficulties with implementation.

As the medical and scientific communities recognize, FDA-approved methods of contraception, including IUDs and emergency contraception, do not impact an established pregnancy.[32] A refusal to provide insurance coverage of certain forms of contraception is at complete odds with the medical and scientific communities and should not be accommodated. Allowing organizations to bifurcate coverage inaccurately characterizes certain contraceptives as "abortifacients" – notwithstanding the fact that the medical community, scientific community, and the FDA all have recognized such items as contraceptives.

The Departments seek comment on the efficiencies of allowing the separate contraceptive coverage plans to cover some or all of the FDA recommended contraceptive services.[33] If the

[31] *See, e.g.*, Complaint at 12-13, *Belmont Abbey College v. Sebelius*, 1:11-cv-01989 (D. D.C. filed Nov. 10, 2011).
[32] *See, e.g.*, Amicus Curiae Brief of Physicians for Reproductive Health et. al at 12-13, *Grote v. Sebelius*, No. 4:12-CV-00134-DML (7th Cir. filed March 22, 2013) (internal citations omitted).
[33] Coverage of Certain Preventive Services Under the Affordable Care Act, 78 Fed. Reg. at 8464.

Departments do allow employers that object to some contraception to be eligible for the accommodation, we strongly urge the Departments to work with issuers to determine the most efficient way to provide this coverage so that women who are covered are able to access it with no additional barriers.

3. We urge the Departments to strictly review whether organizations hold themselves out as religious.

We recommend that the Departments include in the final rule a statement that only organizations that meet the legal standard established by the courts for "holding themselves out as religious" are deemed eligible for the accommodation. "Holding oneself out" is a concept in many areas of the law, and the central question in any analysis of this issue focuses on the manner in which someone presents himself or herself to the public.[34]

The determination of whether an organization has "held itself out" as something is a factually intensive inquiry that reviews many issues, including but not limited to: what the organization has done to characterize itself to the public; how regularly and how often it characterizes itself this way; how conspicuously it has done so; and, whether it has done so in its mission statement, publications, signage, and other locations that the public commonly use to understand the nature of an organization. In addition, courts consider how the public perceives the organization. What is clear from these inquiries is that courts look at the totality of the facts and circumstances and that the showing must be significant.[35]

Whether an organization "holds itself out" as religious requires an organization to consistently identify itself as religious to the public and to its current and prospective employees and students in multiple ways. In other contexts, courts have looked at physical manifestations of religiosity (e.g., prominently displayed crosses, mezuzahs, biblical or religious writings), whether the religious character of the institution was evident to prospective and current employees or

[34] *See Arrow Aviation, Inc. v. Moore*, 266 F.2d 488 (8th Cir. 1959) ("A carrier is a common carrier if it holds itself out to the public as willing to carry all passengers for hire indiscriminately."); *Claveria's Estate v. Claveria*, 615 S.W.2d 164, 166 (Tex. 1981) ("A valid common-law marriage consists of three elements: … (3) holding each other out to the public as such."); *Andrews v. Elwell*, 367 F. Supp. 2d 35, 41-42 (D. Mass. 2005) ("The party seeking to invoke [partnership-in-fact] must prove four elements: (1) that the would-be partner has held himself out as a partner…"); Hungerford, Aldrin, Nichols & Carter, SEC No-Action Letter, 1991 WL 290535 (Dec. 10, 1991) (SEC position that accountant exception is not applicable to an accountant who holds himself out as providing financial planning).

[35] *See, e.g.*, Brian Carroll, "SEC Jurisdiction Over Investment Advice," Journal of Accountancy (Aug. 1, 2001), *available at* http://www.journalofaccountancy.com/Issues/2001/Aug/SecJurisdictionOverInvestmentAdvice.htm; *Gilbert v. Howard*, 326 P.2d 1085, 1087 (N.M. 1958). Decision and Direction of Election, University of Great Falls, Case 19-RC-13114, slip op. at 6 (NLRB Region 19, Feb. 20, 1996). *Id*. 278 F.3d 1335 (D.C. Cir. 2002) at 1345. "The holding out may be either by advertising or by actually engaging in the business of carriage for hire." *Arrow Aviation, Inc. v. Moore*, 266 F.2d 488, 490 (8th Cir. 1959); *see also Vincent v. United States*, 58 A.2d 829, 831 (D.C. Apr. 30, 1948) ("[T]hat the carrier in some way makes known to its prospective patrons the fact that its services are available. This may be done in various ways, as by advertising, solicitation, or the establishment in a community of a known place of business where requests for service will be received. However the result may be accomplished, the essential thing is that there shall be a public offering of the service, or, in other words, a communication of the fact that service is available to those who may wish to use it"); *U.S. v. Conquest*, 148 F. Supp. 62, 68 (E.D. Pa. 1957) (mere showing that motor carrier has advertised in telephone directory, without more, was insufficient to show that company was a common carrier).

students (e.g., prominent religious statements in employee handbooks and course catalogues, on the institution's website, in its external communications and public documents), and the prominent presence of religious statements in the organization's mission statement and articles of incorporation.[36]

The Departments must ensure that only organizations that prominently and consistently hold themselves out to the public as religious may take advantage of the accommodation.

4. The self-certification process must be robust and transparent.

We urge the Departments to create a more robust and transparent self-certification process. This is necessary to ensure that women will be fully informed about the coverage that they will be receiving and so that the Departments can provide adequate oversight.

a. We urge the Departments to require "eligible organizations" to file certification of eligibility with the Departments.

The proposed rule states that an "eligible organization" will self-certify that it meets the necessary criteria for the accommodation, and will maintain the self-certification in its records.[37] The Departments suggest that this will allow for examination upon request "while avoiding any inquiry into the organization's character, mission, or practices."[38] Simply maintaining the self-certification in the organization's records, however, would be insufficient both in terms of ensuring transparency and for enforcement purposes. Accordingly, we urge the Departments to require an eligible organization seeking to take advantage of the accommodation to file the appropriate form with the Departments to allow for appropriate oversight and enforcement. In addition, employer certifications filed with the Departments must be publicly available so that employees and perspective employees are able to understand the full extent of their employment compensation as well as the source and terms of their coverage.

A filing requirement is fully in line with the Departments' goal of ensuring coverage requirements are met without undue inquiries into an organization's character. Asking an authorized organizational representative to sign and submit a form that simply states the organization meets the eligibility definition is in no way an "inquiry into the organization's character, mission, or practices."[39] Filing the form with the Departments merely facilitates routine enforcement and transparency, and is not intrusive.[40] This is common practice when

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[36] *See, e.g.*, *World Vision v. Spencer*, 633 F.3d 723, 738-39 (9th Cir. 2011) (O'Scannlain, J. concurring); *Leboon v. Lancaster Jewish Community Center Ass'n*, 503 F.3d 217, 226-29 (3d Cir. 2007); *Great Falls University v. NLRB*, 278 F.3d 1335 (D.C. Cir. 2002); *Carroll College, Inc. v. NLRB*, 558 F.3d 568 (D.C. Cir. 2009).

[37] Coverage of Certain Preventive Services Under the Affordable Care Act, 78 Fed. Reg. at 8462.

[38] *Id.*

[39] *Id.*

[40] *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

organizations seek an exemption for religious reasons.[41] For example, a church whose religious beliefs do not allow it to pay Social Security and Medicare taxes under 26 U.S.C. § 3121(w) must file an Internal Revenue Service Form 8274 certificate.

In addition, if a question arises regarding a certification, the Departments should take action to verify it. Such verification is routine.[42] Because the test to become an "eligible organization" is based on objective criteria, this inquiry would not require the government to ask intrusive questions and thus would not lead to any impermissible inquiries into the beliefs or practices of the organization.[43]

The Departments should maintain these records in a manner that allows the public to review them. This would not be an unprecedented action for the Departments to take in relation to organizations which have been relieved of an obligation under the ACA. The Departments have 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.[44] In much the same way, the Departments must ensure that enrollees and beneficiaries of plans that take up the accommodation are able to obtain that information about their coverage easily.

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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).

[41] *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.").

[42] *See, e.g.*, Dep't of Labor form (exemption can be revoked if self-certification was untruthful or if there has been a material change of circumstances); Dep't of Justice form (exemption can be revoked if there is "good reason to question the [organization's] truthfulness in completing" self-certification).

[43] *See, e.g. World Vision v. Spencer*, 633 F.3d 723, 734 (9th Cir. 2011) (O'Scannlain, J. concurring) (whether an organization "holds itself out as religious" is a "neutral factor"); *Carroll College, Inc. v. NLRB*, 558 F.3d 568 (D.C. Cir. 2009) (whether an organization "holds itself out" as religious is one element of a "bright-line test" which can be "easily answered with objective criteria"). Furthermore, the government "violates no constitutional rights by merely investigating the circumstances" of a claim. *See Ohio Civil Rights Comm'n v. Dayton Christian Sch., Inc.*, 477 U.S. 619, 628 (1986). Determining whether an organization's objection is religious and sincerely held is a well-established and routine inquiry. "[T]he truth of a belief is not open to question"; rather, the "question [is] whether it is 'truly held' and this 'threshold question . . . must be resolved in every case." *United States v. Seeger*, 380 U.S. 163, 185 (1965). *See also Gonzales v. O Centro Espirita Beneficente Uniao do Vegetal*, 546 U.S. 418, 428 (2006); *Cutter v. Wilkinson*, 544 U.S. 709, 725 n.13 (2005); *Thomas v. Review Bd. of Ind. Emp't Sec. Div*., 450 U.S. 707, 726 (1981).

[44] Annual Limits Policy: Protecting Consumers, Maintaining Options, and Building a Bridge to 2014, http://cciio.cms.gov/resources/files/approved_applications_for_waiver.html.

b. The Departments should provide further guidance regarding the process for the self-certification.

The Department provides very little detail about how the self-certification process would work. We urge the Department to provide more guidance in the final rule about this. For example, we recommend that the Departments require that the self-certification be required annually, in connection with the start of the new plan year.

In addition, the Departments should modify the proposed self-certification form to ensure that the information transferred to plan issuers is clear, concise, and uniform.[45] As currently drafted, the form asks self-certifying organizations to provide a list of the contraceptive services that it has religious objections to covering. This part of the form is drafted in such a way that it is not certain that the issuer or TPA will receive all the information it requires to provide the contraceptive coverage. It will also provide inadequate information to the Departments and to employees. The Departments must make changes to this part of the form to ensure all necessary information is provided:

- The Departments should change the question on the form to ask which "FDA-approved contraceptive services" will not be covered. As noted above, some "eligible organizations" may consider certain contraceptive methods to be abortifacients, despite the scientific consensus on the subject. We are concerned that organizations espousing those beliefs would fail to list those methods as the question is now phrased. Instead, it must be clear that if a method of contraception that has been approved by the FDA as such is not going to be covered, it must be listed. Therefore, we recommend amending the proposed language (additional language in italics):

  "*FDA-approved* contraceptive services for which the organization will not establish, maintain, administer, or fund cover."

- In order to avoid any coverage gaps resulting from inadequate information being provided by the "eligible organization," the form should include a list of FDA approved methods of contraception. There are many different types of contraceptive services and methods that are currently approved by the FDA. It is unlikely that the person who is charged with filling out this form will have the medical or pharmaceutical background to provide the accurate information that is needed so that the issuer or TPA can provide the right coverage. Without a way for the "eligible organization" to provide clear information, confusion may arise that could result in gaps in the coverage.

[45] CMS-10459, Certification (Feb. 1, 2013), *available at* http://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS-10459.html

B. The Final Rule Should Include Greater Clarity And Detail About The Structure Of The Accommodation To Ensure That Women Receive Seamless Contraceptive Coverage.

In the proposed rule, although the Departments set forth the concept for the accommodation, they provide very little guidance as to how it would work as a practical matter. In order to ensure that women will in fact receive contraceptive coverage with no cost sharing seamlessly, we urge the Departments to clarify the steps that must be met in order for employers, issuers and TPAs to meet their obligations to participants and beneficiaries. As discussed above, any burdens created by this accommodation should not be borne by participants or beneficiaries nor should there be a barrier to accessing coverage of contraceptives. Coverage of contraceptives provided through this accommodation must be seamless for every woman.

1. <u>The Departments should clearly state in the final rule that the "eligible organization" will not be accommodated for a plan year if the contraceptive coverage is not available to participants and beneficiaries at the start of that plan year.</u>

There is very little clarity in the proposed rule about the steps that an "eligible organization" must take to be accommodated. The Departments must state in the final rule that, if contraceptive coverage is not available to participants and beneficiaries at the start of the plan year, that the "eligible organization" will not be accommodated for that plan year. Any other standard would allow employers and others to interfere with the coverage by slowing down the process or by never completing the steps.

In addition, the proposed rule sets no time limits on when employers, issuers and TPAs must make the contraceptive coverage available. The safe harbor ends when the next plan year starts after August 1, 2013. We urge the Departments to state that the contraceptive coverage must be in place when this new plan year begins for an employer to get the accommodation. And, in the future, it must be in place at the start of each subsequent plan year as well. To that end, employers, issuers, and TPAs must make all arrangements for coverage in time to meet that deadline, e.g., the self-certification must be given to the issuer or TPA, TPAs must contract with issuers, etc. at a time that allows the issuer to ensure that the contraceptive coverage is in place at the start of the plan year.

2. <u>The Departments must require that insurers and/or TPAs provide participants and beneficiaries with a single insurance card for both their employer-sponsored plan and their contraceptive coverage.</u>

A single insurance card will reduce the chance of confusion and the risk of the cards being lost. For individuals enrolled in a fully-insured plan, the same insurer will provide the employer-sponsored plan and the contraceptive coverage plan. The insurer would use its internal claims system to process claims under the appropriate plan, either the employer-sponsored plan or the contraceptive coverage plan.

A single insurance card should also be provided by TPAs where the "eligible organization" is self-insured. If the TPA is a health insurer that will also be providing the contraceptive services, then the issuance of the one card should be no different than in the fully-insured plan example discussed above. In other instances, a TPA can print one card that has both information on the self-funded plan and the additional contraceptive coverage plan. This is current practice in the industry when someone has a medical plan but a separate pharmacy plan.

The single insurance card must include all the information that would normally be provided on an insurance card to allow a provider to process a claim, including the plan number, group number, phone number, and claims address, in addition to a customer service number that can provide information about the contraceptive coverage to the participants and beneficiaries. Having one card would reduce complications for health care providers and women receiving contraceptive coverage through the accommodation, thus helping to ensure seamless access to this critical benefit.

C. We Urge The Departments To Require Organizations To Provide Their Employees With Notice That The Organization Is Using The Accommodation Or Exemption.

We urge the Departments to require that both "religious employers" taking the exemption and "eligible organizations" utilizing the accommodation provide notice directly to their employees. The proposed rule's requirement that the issuers provide notice to the employees, while necessary, is not sufficient. Without notice from the employer organization, it is possible that employees may never know the status of their coverage or that such knowledge will be delayed.

Employers are regularly required to provide employees notice of their rights and opportunities under other laws.[46] Indeed, the proposed notice requirement is similar to the requirement that the Departments put in place for organizations seeking to utilize the safe harbor.[47] Providing factual information about the process the Departments have set up to exempt or accommodate these employers is merely the statement of an objective fact and thus is not intrusive.

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[46] *See, e.g.*, U.S. Dep't of Labor, Compliance Assistance, *available at* http://www.dol.gov/compliance/topics/posters.htm (employers are required to display posters explaining workers' rights and protections). 42 U.S.C. § 2000e-10 (2013) (requiring employers covered by Title VII to post and keep posted in conspicuous places upon the premises, a notice stating the pertinent information of the Act as well as information on how to file a complaint under the Act); 42 USCS § 12115 (2013) (requiring employers covered by the ADA to post a notice in an accessible format to applicants, employees and members of labor organizations, describing the provisions of the Act); 29 C.F.R. § 1903.2 (2013) (requiring employers covered by the Occupational Safety and Health Act to place posters for employees) (29 C.F.R. § 1975.4(c)(1) (2013) ("Churches or religious organizations, like charitable and nonprofit organizations, are considered employers under [OSHA] where they employ one or more persons in secular activities."); Haw. Rev. Stat. § 431:10A-116.7(c)(1), (2) (requiring employers utilizing the contraceptive equity law's religious exemption to provide notice to their employees and "written information describing how an enrollee may directly access contraceptive services and supplies in an expeditious manner").

[47] *See* Ctr. for Consumer Info. and Ins. Oversight (CCIIO), Ctrs. for Medicare & Medicaid Servs. (CMS), Guidance on the Temporary Enforcement Safe Harbor for Certain Employers, Group Health Plans and Group Health Insurance Issuers with Respect to the Requirement to Cover Contraceptive Services Without Cost Sharing Under Section 2713 of the Public Health Service Act, Section 715(a)(1) of the Employee Retirement Income Security Act, and Section 9815(a)(1) of the Internal Revenue Code (Aug. 15, 2012), *available at* http://cciio.cms.gov/resources/files/prev-services-guidance-08152012.pdf.

In fact, in the states that have enacted contraceptive coverage requirements that include religious exemptions, requirements that these employers notify their employees are standard.[48] Thus, the Departments must require that employees of organizations utilizing the exemption or the accommodation are provided notice that their health plan will exclude contraceptive coverage, including the specific list of services, drugs, and devices excluded, and for what purpose. Employees at accommodated institutions should also be given information on how they can otherwise obtain contraceptive coverage.

1. We urge the Departments to require that accommodation notice be provided through a standard form that contains accurate and timely information and in a manner that makes it most accessible to participants and beneficiaries.

The purpose of providing notice to plan participants and beneficiaries is so that they have the information they need in order to access the contraceptive coverage. To that end, we recommend that the Departments provide a standard notice form that issuers, employers, plan sponsors, and TPAs must use. Without standard language, there is a risk that inaccurate or incomplete information may be provided to some women, and that they would be unable to access the coverage.

The Departments included a notice form containing standard language with the proposed rule.[49] We urge the Departments to use the standard language as amended below which will more clearly reflect that the participants and beneficiaries will receive coverage through a third party. The Department should amend the model language to read as follows (new language in italics, language to delete in strikethrough):

> The organization that establishes and maintains, or arranges, your health coverage ["the organization"] has certified that your [group health plan/student health insurance coverage] qualifies for an accommodation with respect to the federal requirement to cover all Food and Drug Administration-approved contraceptive services for women, as prescribed by a health care provider, without cost sharing. ***As a result, you and any covered dependents will be enrolled in a separate individual health insurance policy that provides contraceptive coverage at no additional cost to you.*** *The separate policy will be arranged by [if fully insured insert name of issuer; if self-insured insert name of TPA]*. ~~This means that y~~Your health coverage *provided by the organization* will not cover the following contraceptive services: [contraceptive services specified in self-certification]. Instead, these contraceptive services will be covered through ~~a~~ *the* separate individual health insurance policy, which is not administered or funded by, or connected in any way to, your health coverage *provided by the organization*. ~~You~~

[48] *See* Ariz. Rev. Stat. Ann. § 20-1402 (M); Cal. Ins. Code **§** 10123.196(d)(2); Conn. Gen Stat. Ann. § 38a-530e(c); Del. Code Ann. tit 18, § 3559(d) (2010); Haw. Rev. Stat. § 431:10A-116.7(c)(1); Me. Rev. Stat. Ann. tit. 24, § 2847-G(2); Md. Code Ann., Ins. § 15-826(c)(2) (West 2010); Nev. Rev. Stat. Ann. § 689B.0376(5) (West 2010); N.J. Stat. Ann. § 17B:27-46.1ee; N.Y. Ins. Law § 3221(1)(16)(A)(2); N.C. Gen. Stat. Ann. § 58-3-178(e); R.I. Gen. Laws § 27-18-57(e) (2009); W. Va. Code Ann. § 33-16E-7(c).

[49] CMS-10459, Notice of Availability of Contraceptive Coverage (Feb. 1, 2013), *available at* http://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS-10459.html.

~~and any covered dependents will be enrolled in this separate individual health insurance policy at no additional cost to you.~~ If you have any questions about this notice, contact [contact information for health insurance issuer] or *visit the [issuer or TPS's] website at www.____.com.*

In addition, the Departments should not allow employers to use language "substantially similar" to the model language, as the proposed form states. That would simply make the omission of relevant information more likely.

The Departments should require that "eligible organizations" provide notice of the accommodation to their employees whenever and however they provide other insurance information to them, including both when they first become enrolled in the plan at the start of their employment and prior to each plan year.

The Departments should require health insurance issuers and TPAs to use multiple methods of notification so that every participant and beneficiary receives notice. For example, in addition to the notice proposed in the NPRM, the health insurance issuer or TPA can provide notice when it provides an insurance card to the participants and beneficiaries after they enroll. Health insurance issuers and TPAs should also provide information on contraceptive coverage to participants and beneficiaries through their websites.

The Departments must require plan issuers to provide direct notice of the contraceptive coverage accommodation to every participant and beneficiary. Some women may prefer that the plan participant not know of the beneficiary's contraceptive use, like adolescents, women up to age 26 who hold coverage through a parent's insurance plan, and women who are victims of domestic violence. These plan beneficiaries should not have to rely on the plan participant's willingness or ability to relay notice of contraceptive coverage to the woman. Notice must be directly provided to plan beneficiaries in addition to plan participants.[50]

A related issue is the manner in which the accommodation will be reflected in a plan's summary of benefits and coverage (SBC). Under the ACA, all group health plans and health insurance issuers offering group or individual health insurance coverage must provide an SBC to all applicants, enrollees, and policyholders or certificate holders.[51] The SBC is required by statute to "accurately describ[e] the benefits and coverage under the applicable plan or coverage."[52] To that end, contraceptive coverage *should* be listed in the box "Services Your Plan Does NOT Cover" but there must also be a note in a parenthesis that states that the coverage is provided separately. Specifically, it should be listed as: "Contraceptive coverage (You will receive coverage for these services arranged by *issuer/TPA* according to federal law)." Additionally, the Departments should make clear in this rulemaking, or through future guidance, that contraceptive

[50] We note that in the context of the Summary of Benefits and Coverage (SBC), the Department of Health and Human Services determined that the SBC only needs to be sent to the plan participant and should only be sent to a plan beneficiary if the beneficiary has a different address than the participant. This process of notice would not meet the needs of women in the context of a contraceptive coverage plan under the accommodation.

[51] Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 1001 (2010), *amended by* Health Care and Education Affordability and Reconciliation Act, Pub. L. No. 111-152 (2010) (to be codified at 40 U.S.C. § 300gg-15).

[52] *Id.*

coverage without cost sharing provided by health insurance issuers or TPAs in accordance with the accommodation does not necessitate providing an additional SBC reflecting that coverage.[53]

D. We Support the Departments' Decision to Require Each Employer in a Multiple Employer Group Health Plan to Separately Satisfy the Exemption or Accommodation Definition.

We strongly support the Departments' decision to require that each employer in such plans independently satisfy the requirements of the accommodation or exemption to qualify. A contrary decision would have allowed a non-exempt entity to "piggyback" on a "religious employer's" exemption status by sharing a group health insurance plan that covers multiple employers. The language in the proposed rule will help ensure that both the accommodation and exemption are applied as narrowly as possible.

E. The Departments Should Ensure That Students with Accommodated Plans Receive Seamless Access to Contraceptive Coverage.

Because the Departments are moving forward with their proposal to extend the accommodation to student health insurance plans – which we oppose because students have individual insurance plans – we strongly urge the Departments to ensure that these students receive the same seamless coverage as students attending universities that do not have the accommodation. Most students likely have had little experience with health insurance, leading to low insurance literacy. Accordingly, it is critical that the Departments require issuers to provide students with timely, accurate, and clear information about the contraceptive coverage without cost sharing.

V. The Questions that the Departments Raise in the Proposed Rule Regarding the Accommodation for Self-Insured Employers Must be Resolved in a Manner that Ensures Seamless Coverage of Contraception with No Co-Pay.

The Departments suggest several options for how the accommodation could be structured for employers with self-insured plans. We urge the Departments to adopt the following principles that apply specifically to "eligible organizations" that are self-insured. These are offered in addition to the general accommodation principles discussed above, such as an "eligible organization" not being accommodated if the contraceptive coverage is not available at the start of the plan year.

A. TPAs Must Be Legally Required To Find And Contract With An Issuer

In the proposed rule, the Departments contemplate several different approaches for how the accommodation for self-insured "eligible organizations" would work. These approaches include

[53] The final rule on the SBC was not drafted with the proposed accommodation in mind. As a result, a misinterpretation of the final rule could result in participants and beneficiaries receiving two SBCs, one reflecting coverage under the employer or university plan and one reflecting contraceptive coverage provided by the health insurance issuer. Receiving two SBCs would clearly thwart the statutory and regulatory intent of the SBC to allow consumers to understand their coverage and compare coverage options, and would perpetuate the problem of non-uniform disclosure documents by necessitating two documents to convey the full scope of coverage rather than one simple document.

two in which the TPA is required to contract with an issuer and one in which the TPA volunteers. We urge the Departments to adopt a rule that states that, if a TPA chooses to contract with an "eligible organization," it is legally required to arrange for an issuer to provide the contraceptive coverage with no cost sharing once the TPA receives a self-certification. Under this plan, TPAs would be compensated by a reasonable charge from the issuer. If TPAs are not legally required to do this, seamless coverage cannot be guaranteed.

B. Self-Insured "Eligible Organizations" Without A TPA Cannot Be Accommodated.

The Departments seek comment as to whether self-insured plans that do not have TPAs should be accommodated and how to ensure that "participants and beneficiaries in such plans receive separate contraceptive coverage without cost sharing."[54] The answer must be that if a self-insured "eligible organization" does not have a TPA, the organization cannot be accommodated. The accommodation is premised on the idea that a third-party will contract for the contraceptive coverage for self-insured "eligible organization's" participants and beneficiaries. If there is no third party, and the "eligible organization" is unwilling to contract for the coverage itself, the result would be that there would be no contraceptive coverage. This is a violation of the ACA's contraceptive coverage requirement. In addition, if the Departments were to decide that self-insured plans that do not have a TPA are not subject to the ACA's contraceptive coverage requirement, the Departments would be creating a perverse incentive that could result in self-insured plans not getting TPA's in order to be released from the law's requirements.

C. If No Issuers Are Willing To Provide The Coverage, The Federal Government Must Ensure That The Coverage Is Provided.

The proposed accommodation will only work if issuers are willing to provide this benefit. Although we expect that issuers will be willing to do so, the proposed rule must include a "back-up plan" to ensure that the accommodation will work. Otherwise, the accommodation will not work. To that end, we urge the Departments to work on a plan for such a situation – for example, the Departments could work with the Office of Personnel Management to require that at least one multi-state plan will be available to provide this coverage.

VI. If the Departments Proceed with Their Plan of Adjusting the Federally-Facilitated Exchange User Fees for Issuers, We Strongly Urge that the Departments Do So in a Way that Does Not Undermine Any Aspect of the Exchanges.

The Departments have proposed adjusting the Federally-facilitated exchange (FFE) user fees to take into account issuers that provide the contraceptive coverage-only plans to participants and beneficiaries of self-insured plans receiving an accommodation. As a matter of principle, taking money that has been assessed for the specific purpose of ensuring that millions of Americans have access to health care coverage and using it instead to underwrite the religious beliefs of the "eligible organizations" is problematic. However, as the Departments finalize the details of such an adjustment, we strongly urge the Departments to carefully consider the overall impact on the FFEs.

[54] Coverage of Certain Preventive Services Under the Affordable Care Act, 78 Fed. Reg. at 8464.

Women have much at stake in the successful operation of exchanges. By 2019, roughly 14 million women will purchase their health coverage through an exchange, with over half of them previously uninsured. Many of these women will be receiving health coverage through an FFE. It is therefore critical that the FFE fee adjustment for the accommodation does not undermine any aspect of the FFE or women's access to affordable coverage through the FFE.

While we do not have expertise on how the adjustments should be calculated, we urge the Departments to ensure the adjustments are adequate to cover the administrative costs and to provide the financial incentives necessary to ensure TPAs and issuers provide the services necessary to ensure women receive contraceptive coverage under the accommodation. In addition, because the TPA's and issuers will not be covering the full array of woman's health care needs, they will not capture the savings that usually come with contraceptive coverage.[55] Thus, the adjustments will also have to compensate them for the costs of covering the birth control itself. The Departments should consult with actuaries, TPAs, and issuers to help determine the necessary adjustment.

VII. We Urge the Departments to Identify Alternative Sources of Funding for Issuers in the Event that the Exchange User Fees Become an Inadequate Source.

We expect, given the large number of states using FFEs in 2014, that the user fee adjustment should be a sufficient to cover the costs of issuers providing the contraceptive coverage. However, over time, the FFE user fees may not be a feasible source of adjustments as more states transition to a state based exchange. If there is a significant reduction in the number FFEs, there may not be sufficient user fees for an adjustment. Moreover, in some states, it is possible that none of the issuers participating in an FFE will provide the contraceptive coverage product. Therefore, we strongly urge the Departments to consider alternative sources of funding, should the FFE user fee source become inadequate.

VIII. Although The Excepted Benefit Unjustly Singles Out Contraceptive Coverage, If The Departments Include It In The Final Rule, It Must Be Constructed To Protect Women.

The preamble to the proposed rule states "it would be necessary and appropriate to establish a new contraceptive-only excepted benefits category."[56] If the Departments do create a new

[55] As the Departments stated in the final rule on the preventive services, "there are significant cost savings to employers from the coverage of contraceptives. A 2000 study estimated that it would cost employers 15 to17 percent more not to provide contraceptive coverage an employee health plans than to provide such coverage, after accounting for both the direct medical costs of pregnancy and the indirect costs such as employee absence and reduced productivity. In fact, when contraceptive coverage was added to the Federal Employees Health Benefits Program, premiums did not increase because there was no resulting health care cost increase. Further, the cost savings of covering contraceptive services have already been recognized by States and also within the health insurance industry. Twenty-eight States now have laws requiring health insurance issuers to cover contraceptives. A 2002 study found that more than 89 percent of insured plans cover contraceptives. A 2010 survey of employers revealed that 85 percent of large employers and 62 percent of small employers offered coverage of FDA approved contraceptives." Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services Under the Patient Protection and Affordable Care Act, 77 Fed. Reg. 8725, 8727-28 (Feb. 15, 2012), at 8727-8728 (internal citations omitted).

[56] Coverage of Certain Preventive Services Under the Affordable Care Act, 78 Fed. Reg. at 8467.

contraceptive coverage-only excepted benefit, the benefit must be structured to avert any adverse impact from singling out this reproductive health service.

The Departments will be creating a new category of excepted benefits and it must be clear that this category is different from existing categories. Some categories of excepted benefits are benefits that are not health insurance. For example, HIPAA excepted benefits include disability income insurance, liability insurance, and credit-only insurance.[57] However, a contraceptive-only benefit is clearly a part of health insurance.

In addition, some categories of excepted benefits are non-coordinated benefits, which mean they have no coordination with the group health plan.[58] If not constructed properly, the creation of a new excepted benefits category could suggest that contraceptive-only plans may be offered to individuals without other health coverage or offered as a voluntary benefit. However, a contraceptive-only benefit must have coordination through the TPA so that participants and beneficiaries are properly enrolled and receive coverage through COBRA continuation or special enrollment periods, as discussed above.[59]

The regulations must therefore make clear that this new excepted benefits category:

- Is created only for the purpose of the accommodation;
- Can only be provided to participants and beneficiaries that are enrolled in a health plan that has self-certified for the accommodation;
- Is a part of health insurance and covers benefits that are for services considered health services; and,
- Provides all the same protections and benefits participants and beneficiaries would receive if the benefits were provided as a part of their health plan.[60]

IX. The Departments Must Be Vigilant In Overseeing And Enforcing The Exemption And Accommodation For "Eligible Organizations."

As with the entire ACA, the proposed accommodation for "eligible organizations" requires close oversight and enforcement by the Departments to ensure that plans and employers comply with the changes resulting from the final rule. The NPRM, the Advanced Notice of Proposed Rulemaking, the "religious employer" final regulations, and the preventive services requirement regulations overall are silent as to oversight and enforcement.[61] Insurers and employers are facing a myriad of changes to insurance regulations that impact the coverage they provide to enrollees and beneficiaries. The Departments must ensure that employers, TPAs, and issuers meet the requirements of both the exception and accommodation so that women have full access to the coverage guaranteed to them under the women's preventive health services coverage requirement. We urge the Departments to be vigilant in their oversight and enforcement efforts,

[57] 26 C.F.R. § 54.9831-1(c)(2).
[58] 26 C.F.R. § 54.9831-1(c)(4).
[59] See discussion on p.7-8 above.
[60] This is discussed in-depth on p. 6-8 supra.
[61] The ACA refers to the enforcement provisions of ERISA, PHSA, and HIPAA.

particularly for the proposed accommodation and, for the ACA more broadly, in the first few years as plans transition to provide coverage compliant with the ACA.

The Departments must maintain an oversight and enforcement entity specifically for the contraceptive coverage exemption and accommodation. While we disagree with the Departments' decision to treat contraceptive coverage differently for individuals who receive coverage through a "religious employer" or an "eligible organization," this exceptional treatment of contraceptive coverage necessitates that the Departments create an exceptional system of oversight and enforcement to ensure the accommodation functions properly. It is also important that women who believe that their employer has wrongly claimed status as a "religious employer" or an "eligible organization" in order to be exempted or accommodated from the requirement have a place to file a complaint. The Departments must ensure that they provide adequate oversight and enforcement of every requirement that is part of the exemption and accommodation, from an organization's self-certification that it can take up the accommodation to the issuer's implementation of a contraceptive coverage plan.

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.[62] This fragmented system is not well-equipped to deal with the oversight and enforcement needs the proposed accommodation creates.

In the section discussing self-certification, we encouraged the Departments to require that any entity seeking to avail itself of the exemption or accommodation send a written statement certifying its eligibility to an appropriately designated enforcement body. The enforcement body should maintain a file of all entities invoking the exemption or accommodation and make that information available to the public. As noted above, these procedural requirements would formalize the process and provide transparency to the public about which entities have invoked the exemption or accommodation.

A centralized oversight and enforcement entity for the contraceptive coverage exemption and accommodation will not only ensure that women accessing contraceptive coverage through the exemption and accommodation get that coverage, but also enable the Departments to easily see and address any systemic implementation problems.

X. We Support The Departments' Affirmation That The Federal Contraceptive Coverage Rule Provides A Floor And That States Can Establish Stronger Consumer Protections.

We strongly support the Departments' statement that:

[62] 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.

> "the provisions of these proposed rules would not prevent states from enacting stronger consumer protections than these minimum standards. Federal health insurance regulation generally establishes a federal floor to ensure that individuals in every state have certain basic protections. State health insurance laws requiring coverage for contraceptive services that provide more access to contraceptive coverage than the federal standards would therefore continue under the proposed rules."[63]

As the Departments recognized in the ANPRM, twenty-eight states have existing legal requirements mandating coverage of contraception in health insurance plans.[64] Like the women's preventive health services required by the ACA, these state laws were enacted to remedy disparities in women's access to critical health care. These laws have gone a long way toward meeting women's unique health care needs and ensuring health benefits for both women and infants. Now, the federal contraceptive coverage requirement will help to fill in gaps in coverage and further reduce disparities by providing women broad access to contraceptive coverage without cost sharing.

Some of the state contraceptive coverage laws have "religious employer" exemptions that are broader than the exemption in the federal contraceptive coverage requirement. In the ANPRM, the Departments appropriately recognized that broader "religious employer" exemptions must be "narrowed to align with that in the final regulations."[65] All of these requirements are in keeping with the ACA's preemption provision in Title I.[66]

XI. We Support The Departments' Statement That The Exemption And Accommodation Definitions Have No Precedential Value And Urge The Departments To State The Principle In The Text Of The Final Rule.

We strongly support the Departments' statement in the preamble that "[t]he religious employer exemption and accommodations in these proposed rules are intended to have meaning solely with respect to the contraceptive coverage requirement under section 2713 of the PHS Act and the companion provisions of ERISA and the Internal Revenue Code."[67] As noted above, an accommodation is not legally required and is not necessary; therefore the definition should not be used for any other purpose. We also support the specification that, "[t]he definition of religious employer or eligible organization in those proposed rules is not being proposed to apply with respect to, or relied upon for the interpretation of, any other provision of the PHS Act, ERISA, the [Internal Revenue] Code, or any other provision of federal law, nor it is intended to set a precedent for any other purpose."[68] In addition, the Departments should clarify that other existing legal obligations specifically requiring contraceptive coverage, such as those arising from Title VII of the Civil Rights Act of 1964 or Title IX of the Education Amendments of 1972,

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[63] Coverage of Certain Preventive Services Under the Affordable Care Act, 78 Fed. Reg. at 8468.
[64] Certain Preventative Services Under the Affordable Care Act, 77 Fed. Reg. 16,501, 16,507-08 (proposed Mar. 21, 2012) (to be codified at 45 C.F.R. pt. 147).
[65] *Id*. at 16,508.
[66] Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 1321(d) (2010), *amended by* Health Care and Education Affordability and Reconciliation Act, Pub. L. No. 111-152 (2010) (to be codified at 42 U.S.C. § 18041). In addition, it is worth noting that plans that are grandfathered under the ACA are still subject to state laws.
[67] Coverage of Certain Preventive Services Under the Affordable Care Act, 78 Fed. Reg. at 8468.
[68] *Id*.

continue to apply to those organizations that are exempted or accommodated. We appreciate the Departments' position that the definition will not be used to interpret any other statute or regulation, and urge the Departments to repeat the statement in the final rule establishing the exemption and accommodation.

In summary, in order to fulfill the promise of the preventive services provision of the health care law, women receiving coverage through accommodated plans must have the same seamless no-cost contraceptive coverage as women receiving coverage from other organizations.

Respectfully Submitted,

Advocates for Youth
American Association of University Women (AAUW)
Asian American Justice Center, Member of Asian American Center for Advancing Justice
Asian Pacific American Legal Center, Member of Asian American Center for Advancing Justice
Association of Reproductive Health Professionals (ARHP)
American Society for Reproductive Medicine
Catholics for Choice
Center for American Progress Action Fund
Center for Reproductive Rights
Disciples Justice Action Network
Hadassah, The Women's Zionist Organization of America, Inc.
League of Women Voters of the U.S.
MergerWatch
NARAL Pro-Choice America
National Abortion Federation
National Council of Jewish Women
National Family Planning & Reproductive Health Association
National Health Law Program
National Latina Institute for Reproductive Health
National Partnership for Women & Families
National Women's Law Center
Planned Parenthood Federation of America
Population Connection
Population Institute
Raising Women's Voices for the Health Care We Need
Reproductive Health Technologies Project
The United Methodist Church, General Board of Church & Society