NHeLP
NATIONAL HEALTH LAW PROGRAM

1444 I St NW, Suite 1105
Washington, DC 20005
(202) 289-7661
Fax (202) 289-7724

April 8, 2013

VIA ELECTRONIC SUBMISSION

Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
P.O. Box 8013
Baltimore, MD 21244-1850

RE: CMS-9968-P
Coverage of Certain Preventive Services Under the Affordable Care Act

Dear Sir/Madam:

The National Health Law Program ("NHeLP") is pleased to offer these comments on the Notice of Proposed Rulemaking ("NPRM") for Certain Preventive Services Under the Affordable Care Act, from the Department of the Treasury, Department of Labor, and Department of Health and Human Services ("HHS") ("Departments") published in the Federal Register on February 6, 2013.[1] NHeLP protects and advances the health rights of low-income and underserved individuals. The oldest non-profit of its kind, NHeLP advocates, educates and litigates at the federal and state levels. Consistent with this mission, NHeLP works to ensure that all people in the United States—including women—have access to preventive health services. The Patient Protection and Affordable Care Act ("ACA") similarly recognizes that preventive health services are critical to individual and community health, and that cost is often a barrier to accessing needed preventive services. By explicitly requiring that health insurance plans cover women's preventive health services without cost-sharing, the ACA further acknowledges the critical role that a woman's health plays in the health and well-being of her family and her community, as well as her disproportionately lower earnings.[2]

NHeLP continues to strongly support HHS' rule requiring that most new health insurance plans cover women's preventive health services—including contraception—without cost-sharing.[3] We expressed our views on this issue in our June 19, 2012 comments on the Advanced Notice of Proposed Rulemaking ("ANPRM") for Certain Preventive Services Under the Affordable Care Act. HHS' "Women's Preventive Services: Required Health Plan Coverage Guidelines" are a significant triumph for millions of women who are currently insured or who will obtain health insurance through the ACA. Adherence to these guidelines will ensure that most women have access to

[1] Coverage of Certain Preventive Services Under the Affordable Care Act, 78 Fed. Reg. 8,456 (Feb. 6, 2013) (to be codified as 26 C.F.R pt. 54, 29 C.F.R. pt. 2590, 45 C.F.R. pts. 147, 148, 156).
[2] Patient Protection and Affordable Care Act ("ACA"), Pub. L. No. 111-148, 124 Stat. 119 (2010), § 1001, 42 U.S.C. § 300gg-13 (amending § 2713 of the Public Health Services Act ("PHS Act")).
[3] U.S. Dep't of Health and Human Servs., Health Res. & Servs. Admin., *Women's Preventive Services: Required Health Plan Coverage Guidelines*, http://www.hrsa.gov/womensguidelines.

contraception without expensive co-pays, saving some women up to $600 per year.[4] We are therefore very concerned that the Departments are proposing "exemptions" and "accommodations" with regard to compliance with § 2713 of the Public Health Services Act ("PHS Act") for certain "religious employers" and other "eligible organizations."[5] Such an approach will create delays and erect barriers to contraceptive access. It will, moreover, not only undermine the intent of the ACA, but the health and autonomy of affected women as well. We therefore urge the Departments to reject their proposed approach.

1. THE DEPARTMENTS SHOULD FULLY IMPLEMENT § 2713 OF THE PHS ACT.

The Departments' healthcare coverage decisions should be based on accepted standards of medical care recognized by the various professional medical academies. This evidence-based approach is the framework on which the independent Institute of Medicine of the National Academies ("IOM") based its recommendations to HHS regarding the women's preventive health services that most health plans must cover without cost-sharing pursuant to § 2713 of the PHS Act.[6] The IOM's recommendations, which were adopted by the Health Resources and Services Administration ("HRSA") in its "Women's Preventive Services: Required Health Plan Coverage Guidelines," include coverage of all forms of Food and Drug Administration ("FDA")-approved contraceptive drugs and devices.[7] In the final rule on the Preventive Health Services, the Departments stated, "Congress, by amending the [ACA] 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."[8] As the Departments recognized, guaranteeing women coverage of contraception is critical to protecting their health. The NHeLP report, *Health Care Refusals: Undermining Quality Care for Women*, a copy of which is submitted with these comments, provides an extensive analysis of the adverse medical consequences for women when health care decisions are based on ideological beliefs instead of medical standards of care.[9]

Medical guidelines across a range of practice areas firmly document the importance of a woman's ability to prevent pregnancy for many reasons. Women consider a number of

---

[4] *See* James Trussell, et al., *Erratum to Cost-effectiveness of Contraceptives in the United States*, 79 CONTRACEPTION 5 (2009) (estimating cost of different forms of birth control).
[5] Coverage of Certain Preventive Services Under the Affordable Care Act , 78 Fed. Reg. 8,472-75.
[6] Inst. of Medicine of the Nat'l Academies, *Clinical Preventive Services for Women: Closing the Gaps* (2011), www.iom.edu/~/media/Files/Report%20Files/2011/Clinical-Preventive-Services-for-Women-Closing-the- Gaps/preventiveservicesforwomenreportbrief_updated2.pdf.
[7] U.S. Dep't of Health & Human Servs., Health Res. & Servs. Admin., *supra* note 3.
[8] Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services Under the Patient Protection and Affordable Care Act, 77 Fed. Reg. 8,725, 8,727 (Feb. 15, 2012) (codified at 26 C.F.R. pt. 54, 29 C.F.R. pt. 2590, 45 C.F.R. pt. 147).
[9] National Health Law Program, *Health Care Refusals: Undermining Quality Care for Women* (2010) (explaining that standards of care are defined as "practices that are medically necessary and the services that any practitioner under any circumstances should be expected to render"; "[s]tandards of care statements are created to indicate the level of clinical practice endorsed by scientists and clinicians and grounded in evidence from investigations of a particular area of practice").

factors in determining whether to become pregnant, including age, educational goals, economic situation, the presence of a partner and/or other children, medical condition, mental health, and the use of medications that are contra-indicated for pregnancy. Further, millions of women live with chronic conditions such as cardiovascular disease, diabetes, lupus, and epilepsy, which if not properly controlled, can lead to health risks to the pregnant woman or even death during pregnancy. Denying these women access to contraceptive information and services does not comport with medical standards that recommend pregnancy prevention for these medical conditions. For example, according to the guidelines of the American Diabetes Association, planned pregnancies greatly facilitate diabetes care.[10] Their recommendations for women with diabetes of childbearing potential include: (1) use of effective contraception at all times, unless the patient is in good metabolic control and actively trying to conceive; (2) counseling about the risk of fetal impairment associated with unplanned pregnancies and poor metabolic control; and (3) maintenance of blood glucose levels as close to normal as possible for at least two to three months prior to conception.[11]

Women face many barriers to contraceptive use, including cost, notwithstanding the near universal agreement in medical practice guidelines that women should receive information about and access to contraceptives to prevent pregnancy. Unintended pregnancy rates are highest among low-income women, women aged 18-24, cohabiting women, and women of color.[12] Low-income women have higher rates of unintended pregnancy, as compared to higher-income women.[13] While low-income women are the least likely to have the resources to obtain reliable methods of family planning, they are the most likely to be impacted negatively by unintended pregnancy.[14] It is therefore not surprising that poor women's higher rate of unintended pregnancy results in their having higher rates of abortions and unplanned births.[15] Further, unintended pregnancy disproportionally affects women of color: 67% of pregnancies among African American women, 53% of pregnancies among Latina women, and 40% of pregnancies among white women are unintended.[16]

Increased use of longer-acting, reversible contraceptive methods, which have lower failure rates, could further help women reduce unintended pregnancy. These more effective methods of contraception, however, also have the most up-front costs, which

---

[10] Am. Diabetes Ass'n, *Standards of Medical Care in Diabetes-2006*, 29 DIABETES CARE S13, S43 (2006).
[11] *Id.*
[12] Lawrence B. Finer & Stanley K. Henshaw, *Disparities in Rates of Unintended Pregnancy in the United States, 1994 and 2001*, 38(2) PERSPECTIVES ON SEXUAL & REPROD. HEALTH 90, 94 (2006), http://www.guttmacher.org/pubs/psrh/full/3809006.pdf.
[13] *Id.* at 93-94.
[14] *See generally*, Sheila D. Rustgi, Michelle M. Doty & Sara R. Collins, 52 The Commonwealth Fund Publ'n 1262, *Women at Risk: Why Many Women are Forgoing Needed Health Care* (2009) (addressing impact of cost of health care services on women), http://www.commonwealthfund.org/~/media/Files/Publications/Issue%20Brief/2009/May/Women%20at%20Risk/PDF_1262_Rustgi_women_at_risk_issue_brief_Final.pdf.
[15] Lawrence B. Finer & Mia R. Zolna, 84(5) *Unintended Pregnancy in the United States: Incidence and Disparities, 2006*, Contraception 478, 478-85 (2011).
[16] *Id.*

puts them outside of the reach of many women.[17] In 2008, for example, only 5.5% of women using contraception chose the more effective and longer-term methods.[18] As the IOM recognized, the "elimination of cost sharing for contraception . . . could greatly increase its use, including use of the more effective and longer-acting methods, especially among poor and low-income women most at risk for unintended pregnancy."[19] In this regard, the California Kaiser Foundation Health Plan's experience is informative. The California Kaiser Foundation Health Plan eliminated copayments for the most effective contraceptive methods in 2002.[20] Prior to the change, users paid up to $300 for 5 years of use; after elimination of the co-payment, use of these methods increased by 137%.[21]

By improving women's social and economic status, access to contraception promotes equal opportunities far beyond the health care realm. Contraception puts women in control of their fertility, allowing them to decide whether, and when, to become parents. In one study, sixty percent of women reported the ability to better control their lives as a very important reason for using birth control.[22] Indeed, the United States Supreme Court 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."[23] 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.[24] Increased control over reproductive decisions, in turn, provides women with educational and professional opportunities that have increased gender equality over the decades since birth control was introduced. Congress understood that the Women's Health Amendment—including its broadening of access to contraceptives—would be "a huge step forward for justice and equality in our country."[25] It is clear from the debate on this amendment that Congress always intended that the provision would apply to contraception.[26] The significant impact that access to birth control has on women's

---

[17] Inst. of Medicine of the Nat'l Academies, *supra* note 6.
[18] Jennifer J. Frost & Jacqueline E. Darroch, *Factors Associated with Contraceptive Choice and Inconsistent Method Use,* 40(2) PERSPECTIVES ON SEXUAL & REPROD. HEALTH 94, 97 (2008).
[19] Inst. of Medicine of the Nat'l Academies, *supra* note 6.
[20] Kelly Cleland et al., *Family Planning as Cost-Saving Preventive Health Service*, 37(1) New Eng. J. Med. e(37)(2) (April 2011), http://healthpolicyandreform.nejm.org/?p=14266.
[21] *Id.*
[22] 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), http://www.guttmacher.org/pubs/journals/j.contraception.2012.08.012.pdf.
[23] *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).
[24] Jessica Arons & Lindsay Rosenthal, Ctr. for Am. Progress, *The Health Insurance Compensation Gap: How Unequal Health Care Coverage for Women Increases the Gender Wage Gap* (April 16, 2012), \http://www.americanprogress.org/issues/women/report/2012/04/16/11429/the-health-insurance-compensation-gap/.
[25] 155 Cong. Rec. S12,033, S12,052 (daily ed. Dec. 1, 2009) (statement of Sen. Franken).
[26] *See, e.g.,* 155 Cong. Rec. S12,033, S12,052 (daily ed. Dec. 1, 2009) (statement of Sen. Franken) ("[A]ffordable 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

educational and employment opportunities—and the significant impact on women's health that educational and employment achievement have as well—makes access to coverage even more critical.

RECOMMENDATION: Congress enacted § 2713 of the PHS Act to fill a critical gap in health care coverage of women's preventive services—including contraception. The Departments rulemaking should protect this critical coverage.[27] Isolating contraception, through exemptions and accommodations, stigmatizes the service as compared to other types of health care services. Further, exemptions and accommodations create additional barriers to access. We urge the Departments to fully implement § 2713 of the PHS Act, without exemption or accommodation.

2. THE DEPARTMENTS SHOULD WITHDRAW THE EXEMPTION.

The Departments propose to permit group health plans established or maintained by certain religious employers to refuse to provide coverage for contraceptive services, as they would otherwise be required under the law.[28] The religious-employer exemption increases the number of women who will likely go without care because of the out-of-pocket costs. It also perpetuates gender discrimination in health care, and threatens the health of millions of women by making birth control financially inaccessible. The United States Constitution does not require the Departments to create an option to opt-out of the contraceptive coverage requirement.[29] There are no other federal laws requiring the Departments to create this exemption. To the contrary, nothing in the ACA allows for any limitations regarding contraceptive coverage. Indeed, §§ 1557 and 1554 of the ACA prohibit the creation of an exemption. The Departments' exemption strips women and dependents receiving coverage through exempted organizations of contraceptive coverage, and all of its associated benefits.

While we believe that the exemption is unnecessary and unjustified, we herein address questions raised by the Departments' NPRM about the exemption. The NPRM defines a "religious employer" as "an organization that is organized and operates as a nonprofit

---

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.").

[27] In considering the Amendment, Congress expressed its expectation that the HRSA Guidelines would incorporate family planning services. *See, e.g.*, 155 Cong. Rec. S12,027 (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.

[28] *Id.*

[29] *See e.g.*, *Emp't Div., Dep't. of Human Res. of Or. v. Smith*, 494 U.S. 872, 879 (1990) *superseded by statute on other grounds*, 42 U.S.C. § 2000cc*, as recognized in* S*ossamon v. Texas*, 131 S. Ct. 1651, 1655-56 (2011).

entity and is referred to in section 6033(a)(3)(A)(1) or (a)(3)(A)(iii) of the Internal Revenue Code as amended."[30] The NPRM seeks comments on whether this change in the definition of "religious employer" would "unduly expand the universe of employer plans that would qualify for the exemption."[31] As a preliminary matter, we note that the Departments' inquiry should focus on minimizing the number of woman impacted by exemption and ensuring contraceptive coverage for every woman who wants or needs this service. We believe that the change in the definition would have a *de minimus* impact on the number of additional employers (and thereby the number of women deprived of contraceptive coverage) who would qualify for the exemption, as long as the Departments strictly enforce legal standards set forth both in the Internal Revenue Code and in Internal Revenue Service ("IRS") guidance. In the absence of strict enforcement, entities that do qualify as "religious employers" may claim to be, which would increase the number of women losing contraceptive coverage otherwise guaranteed by the ACA.

RECOMMENDATION: We urge the Departments to withdraw the religious employer exemption and fully implement the IOM's recommendations, so that women can make their own decisions about whether to use contraception. If the Departments, however, insist on treating "religious employers" differently than other employers, the Departments should replace the "exemption" with an "accommodation." An accommodation would at least allow women (getting get their insurance through "religious employers" and "eligible organizations") access to contraceptive coverage with no cost-sharing. "Religious employers" would not have to "contract[ ], arrang[e], pay[ ], or refer[ ] for" contraceptive coverage, and employees and their dependents would not be completely stripped of coverage for a critical health care service.[32] An accommodation is therefore preferable to outright exemption.

3. THE DEPARTMENTS SHOULD REQUIRE NON-EXEMPTED ORGANIZATIONS TO PROVIDE CONTRACEPTIVE COVERAGE TO THEIR EMPLOYEES AND STUDENTS.

The proposed accommodation, like the exemption, is unnecessary and unjustified.

RECOMMENDATION: The Departments should require non-exempted organizations to provide contraceptive coverage to their employees and students. Any rule that permits organizations to refuse to cover contraception not only conflicts with the purpose and letter of the ACA (e.g., §§ 1554 and 1557), but it also undermines the health and autonomy of affected women. Therefore, we urge the Departments to reject the proposed accommodation.

Should the Departments decide to adopt an accommodation, despite the adverse health consequences on women's health and well-being, they should do so in a manner that inflicts the least harm on women. To this end, the Departments' rules should delineate clearly (a) the process by which an organization qualifies as an "eligible organization"

[30] Coverage of Certain Preventive Services Under the Affordable Care Act, 78 Fed. Reg. at 8,461, 8,374.
[31] *Id.* at 8,461.
[32] *Id.* at 8,462.

and (b) the process by which Departments will implement and monitor the accommodation. Below, we comment on several aspects of the proposed rule regarding the accommodation.

A. Eligible Organizations

i. The definition of "eligible organization" should include only non-profit entities.

The Departments must adopt a narrow definition of "eligible organization." Only nonprofit organizations should qualify for an accommodation, which would allow them to refuse to contract, arrange, or pay for contraceptive coverage. The purported goal of the accommodation is to protect an institution's exercise of religion while meeting the health care needs of women. In contrast, for-profit organizations exist to sell goods and services, and their objectives are commercial in nature. The Supreme Court has made clear that the Free Exercise Clause of the First Amendment to the U.S. Constitution is not offended when a for-profit enterprise is subject to a neutral law of general applicability.[33] The Court has further recognized,

> [w]hen followers of a particular sect enter into commercial activity as a matter of choice, the limits they accept on their own conduct as a matter of conscience and faith are not to be superimposed on the statutory schemes which are binding on others in that activity.[34]

The Constitution does not require the Departments to create any accommodation. Moreover, permitting a for-profit institution—whose primary purpose is unrelated to religious practice—to opt-out of complying with the law is particularly unjustified. The Departments should therefore exclude for-profit organizations from the definition of "eligible organization." Further, if a nonprofit entity also has a for-profit division, or enters into a for-profit partnership or joint venture, the for-profit division or entity should be required to fully comply with § 2713 of the PHS Act, and should not qualify for the accommodation. Finally, as with for-profit entities, the definition of "eligible organization" should exclude health insurance issuers and third party administrators ("TPAs").

RECOMMENDATION: If the Departments adopt an accommodation, they should strictly limit the definition of "eligible organization" to nonprofit entities.

ii. Every employer in a multi-employer group health plan must independently meet the definition of "eligible organization" or "religious employer" to take advantage of the accommodation or exemption.

[33] *See e.g.*, *Emp't Div. v. Smith*, 494 U.S. 872, 879 (1990).
[34] *United States v. Lee*, 255 U.S. 252, 261 (1982), *abrogated by statute on other grounds,* 42 U.S.C. § 2000bb.

According to the Departments, the proposed definition of "eligible organization" and "religious employer" is intended to strike an appropriate balance between the religious beliefs of nonprofit entities and the health needs of affected women. The Departments are therefore appropriately proposing to make the accommodation or exemption available on an employer-by-employer basis.[35] NHeLP strongly supports the position that for-profit groups should not qualify for the exemption based upon their grouping with an exempted employer. Without such a rule, for-profit or secular non-profit corporations otherwise ineligible for the accommodation or exemption may attempt to use these provisions as a loophole.[36] Any entity that seeks an accommodation or exemption must qualify on an independent basis, regardless of its affiliation with another eligible entity. NHeLP recommends extending the accommodation or exemption to the non-profit religious group only, and not to the for-profit or secular group. The purposes of the regulation would be served by requiring such multiple employer plans to make every effort to distinguish between employees of religious and non-religious groups.

Where, however, a joint venture exists or distinctions are otherwise impossible, NHeLP recommends that the Departments use a variant on the IRS's test for tax exemption to determine whether the entity as a whole merits accommodation. Just as "§ 501(c)(3) confers tax-exempt status only on those organizations that operate *exclusively* in furtherance of exempt purposes," the accommodation should be available *only* to those joint ventures that have a primarily religious purpose.[37]

RECOMMENDATION: The Departments' rules should not allow any for-profit entity to deny women access to preventive health care services, including contraception. The Departments should therefore require each employer in a multiple-group health plan to independently satisfy the requirements of the accommodation or exemption.

iii. Student Health Plans Should Cover Contraception.

The Departments must ensure that college students receive contraceptive services without cost-sharing, even if they attend a college or university that meets the definition of "eligible organization." In March 2012, HHS made clear that "[s]tudent health insurance coverage must include the preventive services specified under PHS Act section 2713 and the implementing regulations (45 CFR § 147.140)."[38] We commend the Departments' decision to require that student health plans provide contraceptive coverage without cost-sharing.[39] The decision reaffirms the critical need for contraceptive coverage. More than one million unintended pregnancies occur to single women in their twenties each year—many of these women are enrolled in a college or university.[40]

---

[35] Coverage of Certain Preventive Services Under the Affordable Care Act, 78 Fed. Reg. at 8,467.
[36] *See*, *e.g.*, *Korte v. Kathleen Sebelius*, No. 12-3841 (7th Cir. filed Dec. 17, 2012).
[37] *St. David's Health Care Sys. v. United States*, 349 F.3d 232, 237 (5th Cir. 2003).
[38] Student Health Insurance Coverage, 77 Fed. Reg. 16,453 (March 21, 2012) (to be codified at 45 C.F.R. pts. 144, 147, and 158).
[39] *Id.* at 16,453.
[40] National Campaign to End Teen and Unplanned Pregnancy, *Unplanned Pregnancy Among 20-Somethings: The Full Story* (2007), http://www.thenationalcampaign.org/resources/20-somethings.aspx.

We strongly oppose any proposal that allows a college or university to refuse to provide contraceptive coverage to its students. As with employer-sponsored health plans, extending the accommodation to religiously-affiliated colleges and universities undermines the health and autonomy of affected students, as well as the promise of the ACA. If the Departments nonetheless decide to extend the accommodation to certain colleges or universities, they must ensure students attending such institutions have the same access to contraceptive coverage, without cost sharing, as students at universities not seeking an accommodation. As discussed further below, the Departments should further ensure that colleges, universities, and health insurance issuers provide students with timely, accurate, and clear information about students' contraceptive coverage without cost-sharing. This is particularly critical since most students likely have had little experience with health insurance, leading to low insurance literacy. Further, the Departments should make clear that students unable to access health care services, including contraceptive services and supplies, from in-network providers are entitled to access to such services through local out-of-network providers without cost-sharing.

RECOMMENDATION: The definition of "eligible organization" should not include religiously-affiliated colleges and universities. If the Departments insist on including these entities in the definition of "eligible organization," despite the adverse health consequences on women's health and well-being, they should do so in a manner that inflicts the least harm affected women.

iv. The Departments should not allow any "eligible organization" to provide coverage for only some forms of contraceptive methods.

We strongly urge the Departments not to bifurcate women's contraceptive coverage. The Departments should not allow "religious organizations" to pick and choose which forms of contraception to cover. Among other things, allowing employers to split contraceptive coverage could confuse plan participants and beneficiaries, consequently leading to gaps in access to and use of the contraceptive method most appropriate for a woman's needs. As many of the comments to the ANPRM pointed out, 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."[41] 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. The medical and scientific community defines abortion as the termination of an established pregnancy (i.e., when a fertilized egg is implanted in the uterus).[42] The established weight of the scientific evidence shows that

[41] *See, e.g., Belmont Abbey Coll. v. Kathleen Sebelius*, No. 1:11-cv-01989, Compl. 12-13 (D. D.C. filed Nov. 10, 2011).
[42] *See* 45 C.F.R. § 46.202(f) (2012) (defining pregnancy as beginning after implantation); Am. Coll. of Obstetricians & Gynecologists, FREQUENTLY ASKED QUESTIONS: INDUCED ABORTIONS (April 8, 2013),

the hormones in emergency contraceptives work primarily, if not exclusively, by inhibiting ovulation, thereby preventing fertilization from occurring.[43] A refusal to provide insurance coverage of certain forms of contraception is at complete odds with the scientific and medical community and should not be accommodated. Moreover, bifurcated coverage is likely to lead to confusion about which contraceptive methods are covered by which plan, leaving a woman unable to easily obtain the method that meets her needs.

RECOMMENDATION: For purposes of the accommodation, the Departments' definition of "eligible organization" should exclude any organization that provides coverage for some, but not all, FDA-approved contraceptives.

v. The Departments Must Strictly Review Whether Organizations Hold Themselves Out as Religious.

The Departments should allow only organizations that meet the legal standard established by the courts for "holding themselves out as religious" to avail themselves of the accommodation. When determining whether an entity is "holding itself out", courts look to how the entity presents itself to the public.[44] The process of determining whether an organization has "held itself out" as something is a fact-intensive inquiry. This analysis requires consideration of the totality of facts and circumstances. It includes assessment of: 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. Courts also consider how the public perceives the organization.

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 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

---

http://www.acog.org/~/media/For%20Patients/faq043.pdf?dmc=1&ts=20120618T1001293688 (defining abortion as a procedure to end a pregnancy).

[43] *See Grote v. Sebelius*, No. 4:12-CV-00134-DML, Amici Curiae Brief of Physicians for Reproductive Health et. al 12-13 (7th Cir. filed March 22, 2013) (internal citations omitted).

[44] *See Arrow Aviation, Inc. v. Moore*, 266 F.2d 488, 490 (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: . . . [including] 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 . . . [including]that the would-be partner has held himself out as a partner . . . . "); Hungerford, Aldrin, Nichols & Carter, SEC No-Action Letter, 1991 WL 290535, at *2 (Dec. 10, 1991) (SEC position that accountant exception is not applicable to an accountant who holds himself out as providing financial planning).

religious statements in the organization's mission statement and articles of incorporation.[45] 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.[46]

RECOMMENDATION: The Departments should identify specific criteria that determine if a nonprofit religious organization qualifies for an accommodation. In addition to setting forth these specific criteria in regulation, the Departments must ensure that only organizations that prominently and consistently hold themselves out to the public as religious take advantage of the accommodation.

vi. The Departments Should Provide Further Guidance Regarding the Process for the Self-Certification.

We urge the Departments to issue rules clearly explaining how the self-certification process will work. These rules should, among other things, 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 transmitted to plan issuers is clear, concise, and uniform.[47] As a preliminary matter, as noted above, we oppose any rule that allows eligible organizations to pick and choose which types of contraceptive methods to over. However, if the Departments proceed with this rulemaking in this regard, the current draft form collects inadequate and insufficient information. As such, it cannot and does not ensure that the issuer or TPA will receive all the information it requires to provide affected women contraceptive coverage, nor does it transmit sufficient information to the Departments, or employees affected by the accommodation. The Departments must accordingly modify the form to ensure all necessary information is collected.

---

[45] *See, e.g.*, *World Vision v. Spencer*, 633 F.3d 723, 738-39 (9th Cir. 2011) (O'Scannlain, J. concurring); *Leboon v. Lancaster Jewish Cmty. Ctr. Ass'n*, 503 F.3d 217, 226-29 (3d Cir. 2007); *Great Falls Univ. v. NLRB*, 278 F.3d 1335, 1343-44 (D.C. Cir. 2002); *Carroll Coll., Inc. v. NLRB*, 558 F.3d 568, 572 (D.C. Cir. 2009).

[46] *See, e.g*., Brian Carroll, "SEC Jurisdiction Over Investment Advice," J. of Accountancy (Aug. 1, 2001), http://www.journalofaccountancy.com/Issues/2001/Aug/SecJurisdictionOverInvestmentAdvice.htm; *Gilbert v. Howard*, 326 P.2d 1085, 1087 (N.M. 1958); Decision & Direction of Election, Univ. of Great Falls, No. 19-RC-13114, slip op. at 6 (NLRB Region 19, Feb. 20, 1996); *d*., 278 F.3d 1335, 1345 (D.C. Cir. 2002); .[1]; *Arrow Aviation, Inc. v. Moore*, 266 F.2d 488, 490 (8th Cir. 1959) (("The holding out may be either by advertising or by actually engaging in the business of carriage for hire."); *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"); *United States v. Conquest*, 148 F. Supp. 62, 68 (E.D. Pa. 1957) (finding showing that motor carrier has advertised in telephone directory, without more, insufficient to establish that company was a common carrier).

[47] Ctrs. for Medicaid & Medicare Servs., CMS Form No.10459, *Certification* (Feb. 1, 2013), http://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS-10459.html

As currently drafted, the form only asks self-certifying organization to provide a list of the contraceptive services it objects to covering. To be effective, the certification form should include a list of all FDA-approved methods of contraception and require the eligible organization to designate which methods it is not covering, and which methods it is covering. If the Departments only ask which methods are *not* covered, some "eligible organizations" that consider certain contraceptive methods to be abortifacients, could fail to list those methods (as not being contraceptives), despite the scientific consensus on the subject. Also, many different types of contraceptive services and methods are currently approved by the FDA. It is unlikely that the person charged with completing the self-certification form will have the medical or pharmaceutical background to provide the information needed to enable an issuer or TPA to provide contraceptive-only coverage.

RECOMMENDATION: The Departments should amend the self-certification form: "***FDA-approved methods of*** contraceptive services for which the organization will not establish, maintain, administer, or fund cover." The Departments' self-certification form should also include a list of all FDA-approved methods of contraception.

4. THE DEPARTMENTS MUST ENSURE THAT THE ACCOMMODATION IS IMPLEMENTED SEAMLESSLY, SO THAT WOMEN HAVE COVERAGE FOR ALL FDA-APPROVED METHODS OF CONTRACEPTION.

Every woman should be able to make her own decisions about whether or when to prevent pregnancy based on her own beliefs and needs, not the beliefs of her employer, college, or university. She should similarly be able to decide, based on accurate and complete information, which method of birth control is most appropriate for her. Indeed, the IOM report recognized that not all contraceptive methods are right for every woman, and that access to the full range of pregnancy prevention options would allow a woman to choose the most effective method for her lifestyle and health status.[48] The IOM accordingly recommended that women have access to the full range of FDA-approved contraceptive methods, sterilization procedures, and patient education and counseling for women with reproductive capacity. In recognition of the importance of contraception to the health and well-being of women and their families, the Departments affirmed that they "aim to maintain the provision of contraceptive coverage without cost sharing to individuals who receive coverage through non-exempt, non-profit religious organizations with religious objections to contraceptive coverage in the simplest way possible."[49] To fulfill this goal, the Departments must ensure that the accommodation is structured to provide affected women seamless access to contraceptive coverage. The Departments must not structure the accommodation as a rider to an eligible employer's or school's health insurance package; nor should the Departments consider the contraceptive-only policy a supplemental policy.

[48] Inst. of Medicine of the Nat'l Academies, *supra* note 6.
[49] Student Health Insurance Coverage, 77 Fed. Reg. at 16,501.

RECOMMENDATION: We urge the Departments to ensure that all women, including women whose employers or schools object to contraception, have seamless access to contraceptive coverage.

A. The Federal Government Must Ensure That The Coverage Is Provided if No Issuers Are Willing To Provide The Coverage.

The Departments must ensure that women have seamless contraceptive coverage. The proposed accommodation will work only if issuers are willing to provide coverage that employers seek to deny their women employees. The Departments' rulemaking must include a contingency plan in the event that insurers refuse to offer coverage to the employees of accommodated entities. For example, the Departments could work with the Office of Personnel Management to require that at least one multi-state plan provides this coverage.

RECOMMENDATION: The Departments' rulemaking must take into consideration the possibility that health insurance issuers will refuse to provide contraceptive-only coverage to accommodate entities' employees, and the employees' dependents. The Departments must accordingly issue rules addressing how affected women would receive contraceptive coverage if issuers refuse to provide contraceptive-only coverage.

i. The Departments' rules should not accommodate any organization if contraceptive coverage is not available to participants and beneficiaries at the start of that plan year.

The Departments should not accommodate an otherwise "eligible organization" for any plan year in which contraceptive coverage is not available to participants and beneficiaries at the start of the plan year.[50] Without such a requirement, employers (and others) could unduly interfere with the women's access to contraception.

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 require that the contraceptive coverage must be in place when this new plan year begins for an employer to get the accommodation. The Departments must continue to ensure that contraceptive-only coverage is in place at the start of each plan year. 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.

RECOMMENDATION: The Departments' accommodation should not be available to any entity unless and until contractive-only coverage is available to affected women.

[50] Coverage of Certain Preventive Services Under the Affordable Care Act, 78 Fed. Reg. at 8,474.

ii. The Departments must require insurers and/or TPAs to provide participants and beneficiaries with a single insurance card for both their employer-sponsored plan and their contraceptive coverage.

A single insurance card will reduce the chance of confusion or of one 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 providing a customer service number that can provide information about the contraceptive coverage to the participants and beneficiaries, and provide customer support to women have difficulty accessing services or with billing questions under their contraceptive coverage. 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.

RECOMMENDATION: To ensure seamless coverage and timely access, the Departments should require insurers and/or TPAs to provide participants and beneficiaries with a single insurance card, which includes all necessary plan information.

5. THE DEPARTMENTS MUST ENSURE THAT WOMEN RECEIVING HEALTH INSURANCE COVERAGE THROUGH EMPLOYERS WITH SELF-INSURED PLANS HAVE TIMELY ACCESS AND SEAMLESS COVERAGE OF CONTRACEPTION WITHOUT COST-SHARING.

The Departments suggest several options for structuring the accommodation in the context of employers with self-insured plans. We urge the Departments to adopt the following principles that apply specifically to self-insured “eligible organizations.” These principles are offered in addition to the general accommodation principles discussed herein.

A. The Departments' Should Require TPAs To Find And Contract With Issuers

The Departments should require any TPA contracting with an "eligible organization" to arrange for an issuer to provide the contraceptive coverage with no cost sharing once the TPA receives a self-certification. Under this approach, TPAs would be compensated by a reasonable charge from the issuer. The Departments cannot guarantee women seamless coverage without adopting such a legal requirement.

RECOMMENDATION: The Departments should require the establishment of a contractual arrangement between TPAs, eligible organizations, and issuers of contraceptive coverage without cost sharing when TPAs receive approved self-certifications from eligible organizations.

B. The Departments Should Not Accommodate Any Self-Insured "Eligible Organization" Without a TPA.

The Departments should not allow a self-insured "eligible organization" without a TPA to avail itself of the accommodation. The entire premise of the accommodation is to make contraception available to affected women through a third-party health insurance issuer. If the "eligible organization" refuses to cover coverage, and refuses or is unable to contract with a third-party, affected women would be left without contraceptive coverage. This is a clear violation of the ACA's contraceptive coverage requirement. Allowing self-insured plans without a TPA to opt-out of the ACA's contraceptive coverage requirement creates a perverse incentive: self-insured plans could simply refuse to contract with a TPA as a means of avoiding the requirements of § 2713 of the PHS Act.

RECOMMENDATION: The Departments' rules should not accommodate any self-insured plan without a TPA. Any other rule would leave countless women without access to contraceptive overage, in violation of the spirit and letter of the law.

C. 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.

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 a 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 TPAs 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. 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.

RECOMMENDATION: The Departments should ensure that the financial integrity and function of the FFEs remains intact to support health insurance coverage for individuals, while arranging appropriate financial support for the contraceptive coverage accommodation.

i. We urge the Departments to identify alternative sources of funding for issuers if Exchange user fees are insufficient.

We expect, given the large number of states using FFEs in 2014, that the user fee adjustment should be 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 a 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.

RECOMMENDATION: The Departments should determine a long-range strategy prior to 2014 to provide a source of funding to address costs of contraceptive coverage issuers that does not include FFE user fees.

6. IF THE DEPARTMENTS ADOPT THE "EXCEPTED BENEFIT" RULE, NOTHWITHSTANDING THAT IT UNJUSTLY SINGLES OUT CONTRACEPTION, THEY MUST ENSURE THAT THE RULE DOES NOT DEPRIVE WOMEN OF TIMELY ACCESS AND SEAMLESS COVERAGE.

The preamble to the proposed rule states "it would be necessary and appropriate to establish a new contraceptive-only excepted benefits category."[51] If the Departments do create a new 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.[52] However, a contraceptive-only benefit is clearly a part of health insurance.

In addition, some categories of excepted benefits are non-coordinated benefits, which means they have no coordination with the group health plan.[53] 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 to ensure proper enrollment and coverage of participants and beneficiaries through COBRA continuation or special enrollment periods, as discussed herein.

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, as discussed herein.

7. THE DEPARTMENTS MUST ENSURE THAT ALL WOMEN HAVE TIMELY ACCESS TO COVERED CONTRACEPTIVES AND RECEIVE TIMELY AND ACCURATE NOTICE OF THEIR RIGHT TO RECEIVE CONTRACEPTIVE COVERAGE WITHOUT COST-SHARING.

The Departments must ensure that employers, schools, and health insurance issuers make women aware that contraceptive coverage is available to them without cost-

[51] *Id.* at 8,467.
[52] 26 C.F.R. § 54.9831-1(c)(2).
[53] 26 C.F.R. § 54.9831-1(c)(4).

sharing. An employer or school seeking to avail itself of the accommodation must adhere to certain notice requirements. To do otherwise would allow employers, schools, and/or insurers to erect new barriers that vastly undermine the promise of the ACA to improve the health of the nation. These notice requirements should include the following:

- Employees and students must receive prominent and conspicuous written notice of contraceptive coverage without cost sharing;
- The notice must be accessible to limited English speakers and for persons with disabilities;
- The notice must contain information about the rights of employees and students to contraceptive coverage, the availability of contraceptive coverage through a third party, as well as contact information for that third party;
- The employer or school should provide written notice in insurance enrollment materials on whether contraceptive coverage is made available by a third party;
- The employer or school must ensure that employees and students have prompt access to this information;
- Health insurers and TPAs should similarly provide such notice on health insurance cards, on separate written notices mailed to beneficiaries, and on their websites;
- The Departments should make clear that an employer, school, and/or insurer does not fulfill its notice requirements by merely providing notice in a Summary Plan Description.

To avoid further confusion, the proposed notice should say:

> "The law says that you and your dependents can get all FDA-approved birth control "methods and supplies" without co-payments or deductibles. However, your employer does not include these contraceptives in your health insurance. So you will get these contraceptives directly from your health plan [insurer?] at no additional charge. [You can use your regular health insurance card from your health plan to get these contraceptives.] Your pharmacist and health care provider cannot make you pay for these contraceptives. If you have any questions, contact . . ."

NHeLP also recommends that HHS contracts with literacy experts to rewrite and focus test the notice before it is final. Plain language is essential to the successful achievement of the legislative and administrative goal of helping individuals better understand their health coverage, the differences in coverage options for meaningful comparison when shopping for a new plan, and terms and concepts commonly used in health coverage.[54]

[54] *See* Cass Sunstein, Memorandum, Office of Mgmt. & Budget, Office of Info. & Regulatory Affairs to Heads of Exec. Dep'ts & Agencies, *Final Guidance on Implementing the Plain Writing Act of 2010* (April 13, 2011), http://www.whitehouse.gov/sites/default/files/omb/memoranda/2011/m11-15.pdf.

As defined in the Plain Writing Act of 2010, plain writing is writing that is clear, concise, and well-organized.[55] By October 13, 2011, agencies must write all new or substantially revised documents in plain language.[56]

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 initially enroll 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 also 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.[57]

Federal guidance should also prohibit the employer or university from providing misleading, inaccurate, or conflicting information to employees and students, including statements suggesting that contraceptive coverage is not available to those individuals. To this end, guidance should make clear that an employer or university is prohibited from stating or implying that an employee or student does not have contraceptive coverage. Under the ACA, all group health plans and health insurance issuers offering group or individual health insurance coverage must provide a Statement of Benefits

---

[55] 5 U.S.C. § 301 (3)(3). *See* Plain Language Action and Information Network, *Federal Plain Language Guidelines* (March 2011, Rev. 1, May 2011), http://www.plainlanguage.gov/howto/guidelines/FederalPLGuidelines/FederalPLGuidelines.pdf. By October 13, 2011, agencies must write all new or substantially revised documents in plain language.

[56] 5 U.S.C. § 301 (4)(b).

[57] 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.

Covered ("SBC") to all applicants, enrollees, and policyholders or certificate holders.[58] The SBC is required by statute to "accurately describ[e] the benefits and coverage under the applicable plan or coverage."[59] To that end, the box, "Services Your Plan Does NOT Cover" should list contraceptive coverage, but there must also be a note in a parenthesis that shows the separate provision of that coverage. 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 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.[60]

RECOMMENDATION: We urge the Departments to ensure that all women, including women whose employers or schools object to contraception, have seamless access to contraceptive coverage and to timely, clear, and accurate information about their health care coverage.

8. THE DEPARTMENTS MUST NOT PERMIT THE EXEMPTION OR ACCOMMODATION TO INFRINGE UPON LEGAL PROTECTIONS THAT WOMEN HAVE AS EMPLOYEES, PLAN PARTICIPANTS, AND BENEFICIARIES.

Currently, federal laws protect women employed by organizations that might qualify as "religious employers" or eligible organizations, including but not limited to ERISA, ACA, HIPAA, Title VII,[61] and Title IX.[62] In addition, women who are not employed by these entities but who are beneficiaries to 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. 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 Administration must make clear that where a third party is standing in for the employer, the employee or an eligible

[58] ACA § 1001.
[59] *Id.*
[60] 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.
[61] 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.).
[62] 20 U.S.C.§ 1681 (1972).

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.

To protect women's legal rights, the rules must clearly and unequivocally provide that employers retain all of legal obligations under existing law. 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. A plan sponsor may contract with a TPA to administer its COBRA for former employees and other qualified beneficiaries. The TPA may be 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.[63]

Ultimately, the legal rights of the 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.
RECOMMENDATION: We strongly support continued legal protections for beneficiaries and enrollees in contraceptive coverage plans, regardless of where the source of potential liability may arise (e.g., among employers, issuers, and/or TPAs).

9. THE CONTRACEPTIVE COVERAGE PLANS MUST COMPLY WITH THE ACA GENERALLY, § 2713 OF THE PHS ACT, AS WELL AS ALL IMPLEMENTING RULES AND GUIDANCE.

The Departments correctly recognize that: "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 § 2713 of the PHS Act. The requirements of § 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."[64] 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.[65]

RECOMMENDATION: Health insurance issuers providing contraceptive coverage to women receiving health insurance coverage through accommodated organizations must comply with all requirements of § 2713 of the PHS Act, its implementing regulations, and other applicable federal and state laws.

---

[63] *See* I. R. C. § 4980B(e)(1)(B) (2012); Treas. Reg. § 54.4980B-2 Q&A 10.
[64] Coverage of Certain Preventive Services Under the Affordable Care Act, 78 Fed. Reg. at 8,463.
[65] Dep't of Labor, *FAQs about Affordable Care Act Implementation* Part XII (Feb. 20, 2013), http://www.dol.gov/ebsa/faqs/faq-aca12.html.

10. IF THE DEPARTMENTS MAKE THE CONTRACEPTIVE COVERAGE POLICIES AN EXCEPTED BENEFIT, WOMEN MUST RETAIN ALL OF THE LEGAL PROTECTIONS THEY HAD WHEN THE COVERAGE WAS PART OF THEIR EMPLOYER'S 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."[66] We reiterate our opposition to treating contraception—a critical health care service for women—differently from all other types of health care services. If the Departments decide to make it an excepted benefit, the rule must include language that protects women's legal rights.

The Departments' should pay particular attention to the protections that must attach to the contraceptive-only coverage plans. In particular, the Departments recognized the importance of the following sections of the Public Health Service Act by proposing that contraceptive-only coverage plans comply with: §§ 2703 (Guaranteed Renewability), 2711 (Annual or Lifetime Dollar Value), 2712 (Rescissions of Coverage), and 2719 (Appeals).[67] These protections should be incorporated in their entirety. The Departments seek comment on what other provisions of the Public Health Service Act, 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:[68]

- Section 1557 of the ACA (*Nondiscrimination* provision): All of the nondiscrimination requirements of the ACA must apply.
- Section 2719A of the PHS Act (*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.[69]
- 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 coverage is not included in the health plan summary plan description (SPD),[70] 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.[71]

[66] Coverage of Certain Preventive Services Under the Affordable Care Act, 78 Fed. Reg. at 8,467.
[67] *Id.* at 8,468.
[68] Given that the final rule is part of the regulations implementing § 2713 of the ACA, all of the other legal protections that apply to § 2713 will apply to these excepted benefits.
[69] ACA § 1001.
[70] ERISA § 102, 29 U.S.C. § 1022.
[71] ERISA § 104(b)(1); 29 U.S.C. § 1024(b)(1).

- Sections 502 and 510 of ERISA (*Civil Enforcement in Court*): 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 plan 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 plan 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 Departments' excepted benefit category must incorporate additional protections into the structure of the accommodation, and guarantee contraceptive coverage to women. These include:

- The Departments must also ensure that contraceptive-only coverage is automatically included in COBRA continuation coverage.[72] If an individual is eligible for and enrolls 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 a health plan receiving an accommodation that apply for coverage through a TPA. An issuer offering a contraceptive-only plan does not need to allow any individual, such as an uninsured individual or individual with a health plan that did not receive an

[72] 29 U.S.C. § 1161.

accommodation, to enroll. However, an issuer offering a contraceptive-only plan should not be allowed to refuse coverage to a group that is otherwise eligible.

RECOMMENDATION: All consumer protection rules should apply to individual health insurance policies providing contraceptive-only coverage. The Departments must maintain all enforcement provisions otherwise available to enforce provisions of federal law applicable to the contraceptive-only coverage.

11. THE DEPARTMENTS SHOULD DESIGNATE AN AGENCY TO ENFORCE AND OVERSEE THE RELIGIOUS EMPLOYER EXEMPTION AND RELIGIOUS ORGANIZATION ACCOMMODATION.

We urge the Departments to create a robust and transparent self-certification process. Such a process is necessary to ensure that women will be fully informed about their health insurance coverage, and to enable the Administration to provide necessary and adequate oversight of the accommodation. Simply maintaining the self-certification in the organization's records is insufficient, both in terms of ensuring transparency and for enforcement purposes. Instead, the Departments should require than any entity availing itself of the exemption or accommodation submits a written certification that the organization satisfies the eligibility criteria and an acknowledgement that it will comply with the notice requirements. The entity should submit this document to an agency designated by the Departments.

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."[73] Filing the form with the Departments facilitates routine enforcement and transparency, and is not intrusive.[74] A filing requirement is a common practice when organizations seek an exemption for religious reasons.[75] For example, an employer whose religious beliefs do not allow it to pay

[73] Coverage of Certain Preventive Services Under the Affordable Care Act, 78 Fed. Reg. at 8,462.
[74] *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 Pub. Works*, 426 U.S. 736, 742-43 (1976); *see also* Presidential Advisory Council on Faith-Based & Neighborhood P'ships, *A New Era of Partnerships: Report of Recommendations to the President* 137 & n.52 (Mar. 2010), 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).
[75] *See, e.g.*, U.S. Dep't of Labor, Office of the Assistant Sec'y for Admin. & Mgmt., *Guidance: The Effect of the Religious Freedom Restoration Act on Recipients of DOL Financial Assistance*, 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"); U.S. Dep't of Justice, *Certificate of Exemption: For Hiring Practices on the Basis of Religion,* http://www.ojp.usdoj.gov/recovery/pdfs/arrasampleform.pdf ; IRS, *Internal Revenue Code Form 4361: Application for Exemption from Self-Employment Tax for Use by Ministers, Members of*

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 the certification. Such verification is routine.[76] 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.[77]

The Departments must also make the self-certification available for public examination, 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 coverage. Similarly, the entity should make the self-certification available for inspection to its employees and/or students. The Departments must ensure that the public is made aware of how to access these self-certifications. The Departments should also make a list of all organizations availing themselves of the accommodation available to the public. Indeed, the Departments have previously created a public website that lists all health plans granted waivers for complying with the ACA's annual limit requirement to ensure that information is readily available to plan enrollees and beneficiaries.[78] In much the same way, the Departments must ensure that enrollees and beneficiaries of plans that take up the accommodation know that their employer-based plans are able to obtain that information about their coverage easily.

Religious Orders and Christian Science Practitioners (Jan. 2011), 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").

[76] *See, e.g.*, U.S. Dep't of Labor, Office of the Assistant Sec'y for Admin. & Mgmt., *supra* note 77 (exemption can be revoked if self-certification was untruthful or if there has been a material change of circumstances); U.S. Dep't of Justice, *supra* note 77(exemption can be revoked if there is "good reason to question the [organization's] truthfulness in completing" self-certification).

[77] *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 to providing contraception coverage 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 Indiana Emp't Sec. Div.*, 450 U.S. 707, 726 (1981).

[78] Ctrs. for Medicaid & Medicare Servs., *Annual Limits Policy: Protecting Consumers, Maintaining Options, and Building a Bridge to 2014*, http://cciio.cms.gov/resources/files/approved_applications_for_waiver.html.

RECOMMENDATION: We strongly support the identification of a federal agency to be responsible for oversight and enforcement of the religious exemption and accommodation process, including verifying the accuracy of organizations that self-certify their eligibility for exemptions and accommodations of the contraceptive coverage requirement.

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

As with the ACA generally, the Departments' proposed accommodation for "eligible organizations" requires close oversight and enforcement to ensure that affected women have seamless access to contraceptive coverage and to timely and accurate information about their health care coverage. The Departments must be vigilant in their oversight and enforcement efforts, particularly during the first few years of implementation of the proposed exemption and accommodation.

To this end, the Departments must maintain an oversight and enforcement entity specifically for the contraceptive coverage exemption and accommodation. The Departments' plan to treat contraceptive coverage differently (than any other health care service) for individuals who receive coverage through a "religious employer" or an "eligible organization" which we strongly oppose as unnecessary and unjustified necessitates an exceptional system of oversight and enforcement. Creating an oversight and enforcement entity dedicated to the contraceptive coverage accommodation is particularly important because enforcement of § 2713 of the PHS Act, which includes the contraceptive coverage requirement, will differ based on the source of insurance coverage.[79]

Among other things, this agency would investigate complaints about, as well as initiate and carry out its own investigations of, any potential violations of the rules governing the religious employer exemption and/or accommodation as well as act on any individual complaints. Women who believe that their employer has wrongly claimed status as an exempted or accommodated entity must have a place to file a complaint. Further, in the section herein discussing self-certification, and in our comments on the ANPRM, 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.

[79] 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 PHS Act, HHS has authority to enforce the PHS Act 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 IRS also has authority to penalize plans not complying with the ACA.

RECOMMENDATION: The Departments must designate a federal agency to enforce and oversee the exemption and accommodation. The Departments should charge this entity not only with ensuring that women accessing contraceptive coverage through the exemption and accommodation seamlessly receive that coverage, but also with overseeing and responding to any systemic implementation problems.

12. SECTION 2713 OF THE PHS ACT SHOULD SET THE FEDERAL MINIMUM

Section 2713 of the PHS Act establishes a federal floor. There is room for states to go *above* this federal minimum standard, but no state can allow health plans to offer less than this federally-defined minimum level of coverage. Twenty-eight states already require employers to provide contraceptive coverage; the ACA seeks to ensure that women across the country will have the same benefits.[80] The Departments appropriately recognize,

> "[T]he 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.[81]

Some state laws, on the other hand, have religious employer exemptions that are broader than the federal contraceptive coverage requirement's exemption, allowing more employers to refuse this critical coverage. The Departments appropriately recognized in the ANPRM that broader religious employer exemptions must be "narrowed to align with that in the final regulations."[82] Such a result is required by the preemption provisions of the ACA, which dictate that state insurance laws that "prevent the application of a requirement" of the ACA are preempted.[83] Allowing more employers to refuse contraceptive coverage would leave more individuals without coverage of this critical service, force them to pay out-of-pocket, and put them at risk for unintended pregnancies, with the concomitant risks of poor maternal and infant health outcomes, particularly for women experiencing health disparities.

RECOMMENDATION: The Departments' rulemaking must make clear that § 2713 of the PHS Act establishes a federally-designated minimum level of coverage. States can go above this federal minimum standard, and provide more expansive coverage. No

---

[80] Student Health Insurance Coverage, 77 Fed. Reg. at 16,508.
[81] Coverage of Certain Preventive Services Under the Affordable Care Act, 78 Fed. Reg. at 8,468.
[82] Student Health Insurance Coverage, 77 Fed. Reg. at 16, 501.
[83] *See* Interim Final Rules for Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services Under the Patient Protection and Affordable Care Act, 75 Fed. Reg. 41,726 41,739 (July 19, 2010) (to be codified at 26 C.F.R. pt. 54, 29 C.F.R. pt. 2590, 45 C.F.R. pt. 147) (referring to "the preemption provisions of § 731 of ERISA and § 2724 of the PHS Act (codified at 29 C.F.R. § 2590.731(a) and 45 C.F.R. § 146.143(a).

state, however, can allow employer or university health plans to offer less than this federally-defined minimum level of coverage.

CONCLUSION

We urge the Departments to consider our recommendations to ensure that all women who are impacted by the NPRM receive seamless coverage for contraception without cost-sharing. If you should have questions about these comments, please contact Susan Berke Fogel at (310) 204-6010 or fogel@healthlaw.org. Thank you for your consideration.

Sincerely,

Emily Spitzer
Executive Director

Attachment: National Health Law Program, *Health Care Refusals: Undermining Quality Care for Women*