September 30, 2011

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Submitted electronically at www.regulations.gov

RE: Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services Under the Patient Protection and Affordable Care Act; CMS-9992-IFC2

The National Women’s Law Center is a non-profit organization dedicated to expanding the possibilities for women and girls. Since its founding in 1972, the Center has sought to address the discrimination and barriers women experience in the health care system. We are writing in response to your request for comments regarding the coverage of preventive services under the Patient Protection and Affordable Care Act (hereinafter ACA) in the Interim Final Rule published August 3, 2011.¹

Specifically, the following comments address the importance of the inclusion of contraception in preventive care to be provided without co-pays. These comments also describe the serious problems resulting from the exemption from providing contraceptives that has been proposed for certain religious employers and oppose the inclusion of this exemption or any expansion thereof.

I. The Preventive Services Provision and the Women’s Health Amendment

The National Women’s Law Center was proud to support ACA, especially because of its promise to address the many challenges women encounter in seeking preventive health care for themselves and their families.² One of the law’s key protections in fulfilling this promise was the guarantee that all new insurance plans will cover preventive services, including counseling,
screenings, and interventions that have received either “A” or “B” recommendations from the United States Preventive Services Task Force.3

The Women’s Health Amendment was enacted because Congress recognized that these recommendations left some important gaps in preventive care for women.4 Women are especially vulnerable to the financial hardships imposed by health care costs, forgoing other basic necessities to pay for health care or not obtaining needed care at all.5 Evidence suggests that even moderate co-payments can cause individuals to forgo needed preventive care, particularly those with low and moderate incomes.6

The Women’s Health Amendment required the Department of Health and Human Services (HHS) to identify additional preventive health services for women that should be covered and provided to patients at no cost. HHS asked the Institute of Medicine (IOM), an organization that provides authoritative, unbiased advice to decision makers on health and medical issues, to review the available evidence and recommend additional women’s preventive health services that should be included in the required coverage of preventive health services without cost-sharing.

The Center testified before the IOM panel seeking input on the coverage of specific services, submitting evidence on the impact of health care costs borne by women, and how these costs have a negative impact on their health and financial status.7 The IOM released its findings on July 19th, 2011, recommending no cost-sharing for a range of women’s preventive health services including screening for cervical cancer, and counseling for sexually transmitted infections; critical health services for pregnant women, including breastfeeding support; a minimum of one well-woman visit, an essential component of identifying and treatment chronic health conditions such as heart disease and diabetes; screening for intimate partner violence; and all FDA-approved forms of contraception.8 HHS took the important and commendable step of adopting the IOM’s recommendations on August 1st. The Center strongly supports HHS’s adoption of the IOM recommendations in their entirety, and believes that women and their families will benefit from improved health as a direct result of HHS’s actions.

II. Barriers to Contraceptive Access and Impact on Women’s Health

The inclusion of contraception as a service that is required to be covered with no cost-sharing presents a tremendous step forward in improving the health status of women and their families. Contraceptive care and counseling allow women to control the timing, number, and spacing of births, leading to improved health and mortality outcomes for themselves and their children. Planned pregnancies—which for most women require contraception—improve women’s health. The ability to determine the timing of a pregnancy can prevent a range of pregnancy complications that can endanger a woman’s health, including gestational diabetes, high blood pressure, and placental problems, among others.9 In addition, an unintended pregnancy may have significant implications for a woman’s health. A preexisting health condition such as diabetes, hypertension, or coronary artery disease may be worsened by a pregnancy.10 A planned pregnancy allows a woman to take steps so she is sufficiently healthy to undergo pregnancy and childbirth.11

Planned pregnancies not only improve women’s health, but improve the health of their children. Women who wait for some time after delivery before conceiving their next child lower the risk of adverse perinatal outcomes, including low birth weight, preterm birth, and small-for-size gestational age.12 And a planned pregnancy affords women an opportunity to make behavioral changes that lead to better birth outcomes.13

III. The Cost of Contraception, Including Co-Pays and its Effect on Use and Selection

In general, cost plays a major role in a woman’s ability to secure access to contraception and to choose the contraceptive method that is right for her. A 2009 survey by the Guttmacher Institute found that because of the economic recession, 23% of women report having difficulty paying for birth control and 24% have put off a gynecology or birth control visit because of cost.14 There is evidence that cost and lack of insurance coverage pose barriers to obtaining a postpartum tubal ligation among women who express a desire for the procedure.15

High costs can also lead women to use contraception inconsistently or incorrectly. The same survey by the Guttmacher Institute found that among women using the Pill, 18% report inconsistent use as a means of saving money. Pill users reported skipping pills (4%), delaying getting a prescription filled (12%), going off the Pill for at least a month (11%) and obtaining

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11 Id.
13 For example, a woman whose pregnancy is unplanned is less likely to seek prenatal care in the first trimester and more likely not to obtain prenatal care at all, less likely to breastfeed, and more likely to expose the fetus to harmful substances, such as tobacco or alcohol. Id. at 9-5.
15 Andrea Ries Thurman & Torri Janecek, One-Year Follow-up of Women with Unfulfilled Postpartum Sterilization Requests, 116 Obstetrics & Gynecology 1071 (2010).
fewer Pill packs at one time (8%). This is even more common among women struggling financially, a quarter of whom report inconsistent use.16

Though there is a range of contraceptive products available for women to choose among, many of them—particularly the most effective—are expensive. Oral contraceptives, the most commonly used contraceptive in the U.S., cost an average of $2,630 over 5 years.17 Other hormonal contraceptives, including injectable contraceptives, the transdermal patch, and the vaginal ring, are also expensive; over five years, these methods cost $2,341, $2,774, and $2,467 respectively.18 Long-acting reversible contraceptives, including intrauterine contraception (IUC) and subdermal implants, although they cost less in the long run than oral contraceptives, with an IUD costing about $600 over 5 years and an implant costing just over $1,500, a much larger portion of the cost must be paid up front.19 Similarly, permanent contraception, though cost-effective, also has high up-front costs; a tubal ligation costs approximately $2,866.20 Notably, the costs associated with many contraceptives include not only the costs of the products themselves, but the costs of physician visits, fittings and removals, and other related care. An office visit can cost from $35 to $250.21

It is not only the actual total cost of contraception that shapes women’s choices, but cost-sharing requirements as well. Women’s contraceptive practices, in both selection and ability to use contraceptives correctly and consistently, are affected when women are required to pay even a portion of the costs. A 1983 study of California family planning clinics found that after implementing sliding scale co-payments, 22% of clinics saw a decline in the use of contraceptive services.22 More recent studies also support this conclusion. A 2004 study in the Journal of the American Women’s Medical Association found that along with dispensing restrictions, cost-sharing and other out-of-pocket costs are a barrier to consistent use of oral contraceptives.23 While long acting reversible forms of contraception are the most effective non-permanent method, the co-payments for these methods are often equivalent to paying for multiple years of oral contraceptives at once, costing women several hundred dollars up front.24 These high up-front costs contribute, in part, to the low number of women using these methods. Compared to the 17.3% of women using oral contraceptives, only 3.4% use IUDs and less than 1% use implants.25 A national survey from 2004 of women 18–44 who were using reversible

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16 Guttmacher Institute, supra note 14.
18 Id.
19 Id.
20 Id.
contraception found that one-third of them would switch methods if they did not have to worry about cost. Women citing cost concerns were twice as likely as other women to rely on condoms or less effective methods like withdrawal or periodic abstinence.26

The impact of cost-sharing on contraceptive choice has also been seen in practice. In 2002, the Kaiser Foundation Health Plan in California eliminated cost-sharing for contraceptive shots and IUDs. After the change, the percentage of women choosing those methods increased by 32 and 137 percent respectively.27 Similarly, a study involving 10,000 women in the St. Louis area were offered the choice of any contraceptive method, including long-acting reversible methods of contraception such as the IUD and implant, at no cost. Two-thirds of the women chose long-acting methods, a level far higher than in the general population.28

IV. There Neither Should Be, Nor Does the ACA Allow, a Religious Exemption to Coverage of Preventive Care Without Cost-Sharing

Unfortunately, HHS has included in its Interim Final Rules (IFR) a provision that would allow certain religious employers to exclude contraceptive services from their employees’ health plans.29 Such an exemption would undermine the above-described intention of both the ACA and the Women’s Health Amendment. Rather than giving all women no-cost contraceptive access to which they would be entitled pursuant to the ACA and the Women’s Health Amendment, the exemption arbitrarily precludes certain women from receiving needed preventive care. Women who work for employers who are permitted to and then do invoke the exemption will not receive the intended benefits, and will be required to pay for what the IOM, and HHS itself have determined should be available at no cost.

Nothing in the ACA, its language or legislative history, allows for any limitations regarding contraceptive coverage.30 Moreover, Sections 1554 and 1557 of the ACA actually prohibit the exemption of religious employers from covering preventive services.

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27 Postlethwaite et al., supra note 24 at 360-65.
29 Specifically, the Interim Final Rules define an employer that can invoke the exemption as one that:
   (1) Has the inculcation of religious values as its purpose;
   (2) primarily employs persons who share its religious tenets;
   (3) primarily serves persons who share its religious tenets; and
   (4) is a non-profit organization under section 6033(a)(1) and section 6033(a)(3)(A)(i) or (iii) of the Code. Section 6033(a)(3)(A)(i) and (iii) refer to churches, their integrated auxiliaries, and conventions or associations of churches, as well as to the exclusively religious activities of any religious order.
30 The Department cites §2792 of the ACA, as well as its general authority to issue regulations and promulgate interim final rules, but such authority does not allow for the creation of regulations or rules without basis in the ACA and there is no specific authority in the preventive services provision, §2713 of the Public Health Act as amended by the ACA, to exempt certain employers from its requirements.
A. The Exemption is Inconsistent with Section 1554 of the Affordable Care Act

Section 1554 of the ACA, entitled Access to Therapies, prohibits the Secretary from promulgating the religious exemption proposed in the IFR. Section 1554 states in relevant part:

Notwithstanding any other provision of this Act, the Secretary of Health and Human Services shall not promulgate any regulation that—
(1) creates any unreasonable barriers to the ability of individuals to obtain appropriate medical care;
(2) impedes timely access to health care services;

The IOM found that contraceptive services are “appropriate medical care” for women of childbearing age, citing the high prevalence of unintended pregnancies, the public health consequences for both women and their children, and the effectiveness of contraceptive counseling and services. HHS accepted that analysis when it adopted the IOM recommendations.

As noted above and also by the IOM, women face significant barriers resulting from the cost of contraceptive services, including the cost of co-pays. These barriers, the IOM determined, result in delays in access to contraceptive counseling and services, inconsistent contraceptive use, or use of less effective methods. Rather than receiving the full benefit of the ACA’s provision requiring access to preventive care without cost-sharing, a woman who works for an employer that invokes the religious exemption would be presented with unreasonable barriers to access, which contravenes §1554(1). These barriers impede timely access to care, and should be prohibited by §1554(2).

For example, a woman who works for a religious employer invoking the exemption may go to her doctor for her well woman visit, which includes contraceptive counseling and services. Her doctor’s office then would typically submit the claim to her insurance company, which would pay the costs of the well woman visit, but exclude payment of the contraceptive counseling and services. The woman would then receive a bill from her doctor requesting payment for those excluded services. In the alternative, a provider might request full payment when all services are rendered. When she then seeks reimbursement from her insurance company for the full amount, she will not be reimbursed for the contraceptive counseling and services.

Whatever the sequence of events, the religious exemption subjects women to precisely the types of financial burdens the Women’s Health Amendment sought to address in identifying additional preventive services that should be available without cost-sharing. These barriers are also impediments to timely access to care, as is prohibited by §1554(2). A woman may visit her doctor less frequently than medically recommended for pap smears or breast exams until she can afford to cover the up-front cost of the contraceptive services she also needs during the visit, or she may forgo the contraceptive services she needs altogether.

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31 Closing the Gaps, supra note 8 at 89-91.
B. Section 1557 of the Act, and Title VII of the Civil Rights Act of 1964 Prohibit the Religious Exemption

Section 1557(a) of the ACA states that except as otherwise provided, no individual shall on the basis of sex “be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health program or activity, any part of which is receiving Federal financial assistance, including credits, subsidies, or contracts of insurance, or under any program or activity that is administered by an Executive Agency or any entity established under this title (or amendments).” Furthermore, §1557(b) of the ACA states: “Nothing in this title (or an amendment made by this title) shall be construed to invalidate or limit the rights, remedies, procedures, or legal standards available to individuals aggrieved under . . . Title VII of the Civil Rights Act of 1964 (42 U.S.C. §2000e et seq.), . . . .” These provisions, together and separately, explicitly prohibit a broad range of entities from discriminating on the basis of sex in the provision of health care programs, and there is no exception to the protection against sex discrimination applicable to contraception in the ACA.

Longstanding EEOC guidance has made clear that a refusal to provide contraception for women constitutes sex discrimination. In December 2000, the EEOC issued a Commission Ruling stating that it is sex discrimination for employer-sponsored health insurance plans to provide coverage of other prescription drugs and preventive services but fail to provide coverage of contraceptives. As recognized by the EEOC (and spelled out in far more detail by the IOM recommendations as adopted by HHS) the failure to cover contraceptives exposes women to the physical consequences of unintended pregnancy and can cause substantial harm to women’s health. Therefore, under Title VII, all covered employers (those with 15 or more employees) must provide such coverage if they otherwise provide preventive and prescription drug services. Erickson v. Bartell Drug Co., the first federal court to consider the issue, ruled that an employer offering otherwise comprehensive health insurance to its employees, but failing to cover prescription contraceptives, was in violation of Title VII. There has been limited case law ever since.

32 The Pregnancy Discrimination Act of 1978 explicitly protects women from employment discrimination, including discrimination in the provision of benefits, on the basis of pregnancy or the capacity to become pregnant. 42 U.S.C. §2000e(k) states:

The terms “because of sex” or “on the basis of sex” include, but are not limited to, because of or on the basis of pregnancy, childbirth, or related medical conditions; and women affected by pregnancy, childbirth, or related medical conditions shall be treated the same for all employment-related purposes, including receipt of benefits under fringe benefit programs, as other persons not so affected but similar in their ability or inability to work, and nothing in section 703(h) of this title shall be interpreted to permit otherwise.


34 Erickson v. Bartell Drug Co., 141 F. Supp.2d 1266, 1273 (W.D. Wash. 2001) (women disproportionately bear the “adverse economic and social consequences of unintended pregnancies,” rendering the defendant’s exclusion of prescription contraceptives from the health plan while including a range of other preventive drugs discrimination under the Pregnancy Discrimination Act). See also Cooley v. DaimlerChrysler Corp., 281 F. Supp.2d 979 (E.D. Mo. 2003) (exclusion of prescription contraceptives from the employee insurance plan, while “seemingly neutral” placed a burden on women since only they have the capacity to become pregnant and the only prescription contraceptives
The ACA provides no basis for the denial of contraceptive benefits to women working for religious employers, and neither does Title VII. Title VII does not allow religious organizations to discriminate on the basis of race, sex (including pregnancy-related conditions), national origin or religion in the provision of pay or benefits to their employees. The EEOC has addressed the issue squarely in the context of fringe benefits. It has determined that it is sex discrimination for a religious organization to deny benefits to women or to pay women less based on a religious belief, for example, that only men can be the head of a household. Furthermore, the Title VII Bona Fide Occupational Qualification exemption applicable to religious employers is explicitly limited to hiring and employment only, and does not allow religious employers to discriminate in pay or benefits once an employee is hired.

Therefore, the proposed religious exemption directly conflicts with §1557 both by allowing discrimination on the basis of sex in any health program or activity receiving federal funds, as expressly prohibited by §1557, and by limiting the current rights, remedies, procedures, and legal standards established under Title VII, as expressly prohibited by §1557.

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available were for women); Mauldin v. Wal-Mart, 89 Fair Empl. Prac. Cas. (BNA) 1600, 2002 WL 2022334 (N.D. Ga. 2002) (certifying plaintiff class of women who use contraceptives and citing Erickson favorably; the case ultimately settled with the provision of contraceptives to Wal-Mart employees). While in EEOC v. United Parcel Service, Inc., 141 F.Supp.2d 1216 (D. Minn. 2001), the Court did not consider the applicability of the Pregnancy Discrimination Act because the plaintiff was not taking contraceptives to prevent pregnancy, the Court found that the denial of insurance coverage for contraceptives to treat a hormonal disorder resulted in disparate impact discrimination under Title VII when drugs used to treat male hormonal disorders were covered. But see, In re Union Pacific R.R. Emp’t Practices Litig., 479 F.3d 936, 943 (8th Cir. 2007). In Union Pacific, the Court did not read the PDA as encompassing contraceptives per se, and regarding sex discrimination held that the EEOC decision did not present a persuasive basis for comparing contraception to the broad spectrum of other preventive treatments and services – precisely what the IOM did, as adopted by HHS. Moreover, the exceptions to coverage permitted in the Union Pacific health care plan are not relevant post ACA. See also Stocking v. AT&T, No. 03-0421, 2007 WL 3071825 (W.D. Mo. 2007) (controlled by Union Pacific), and Cummins v. Illinois, No. 02-4201, slip op. at 16 (S.D. Ill 2005).


36 Title VII’s BFOQ exemption, 42 U.S.C. §2000e-2(e)(1) states in relevant part:

[I]t shall not be an unlawful employment practice for an employer to hire and employ employees, … on the basis of his religion, sex, or national origin in those certain instances where religion, sex, or national origin is a bona fide occupational qualification reasonably necessary to the normal operation of that particular business or enterprise,… See, e.g., EEOC v. Fremont Christian Sch., 781 F.2d 1362, 1367 (9th Cir. 1986) (church owned and operated school held religious belief that only single persons and men could be the “head of household” eligible for the employee health insurance plan; court held “BFOQ exception does not apply to the discriminatory provision of benefits involved here”).

37 Additionally, the preamble to the Interim Final Rule notes, “The change in policy effected [sic] by this amendment to these interim final rules is intended solely for purposes of PHS Act section 2713 and the companion provisions of ERISA and the Internal Revenue Code.” Interim Final Rules, supra note 1 at 46,623. This is further indication that the religious exemption cannot usurp Title VII protections.
C. Any Expansion of the Religious Exemption Would Serve to Even Further Undermine the Purpose of and Conflict With the ACA and the Women’s Health Amendment

Some organizations and individuals are calling upon HHS to even further expand the scope of the religious exemption to include many large religiously-affiliated employers, including universities and hospitals. 38  Since the Center urges HHS to eliminate the exemption altogether, it obviously opposes any expansion of it. For the reasons described above, the proposed exemption contravenes the legislative intent of the ACA, the Women’s Health Amendment, and constitutes impermissible sex discrimination under §1557 and Title VII.

Any expanded religious exemption would not only further undermine the important legislative goals of the ACA and the Women’s Health Amendment, but would encourage institutions that provide such coverage to drop it. In fact, many religiously-affiliated entities seeking to be included in the exemption actually do, in fact, provide contraceptive coverage in their employees’ health benefits plans.39  And all federal employees can not only buy insurance that includes contraception, but no insurance plan currently offered to federal employees excludes coverage for such services.40

Conclusion

The National Women’s Law Center urges HHS to ensure that the Patient Protection and Affordable Care Act is implemented in the way that Congress not only intended, but required. This groundbreaking law does not allow the continuation of discriminatory health care policies and practices that place an unfair burden on women, including those who work for religious employers.

Respectfully Submitted,

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Co-President      Vice President, Health and Reproductive Rights

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38 Letter from Sr. Carol Keehan, President and CEO, Catholic Health Association of the United States, to Centers for Medicare & Medicaid Services, Department of Health and Human Services (Sept. 22, 2011) available at http://chausa.org/WorkArea/DownloadAsset.aspx?id=4294969669. As the IOM made clear, access to contraception is an important public health measure, so any exemptions to coverage undermine the stated governmental objectives of the ACA to prevent chronic conditions and reduce health disparities resulting from lack of access to preventive care.

39 The National Women’s Law Center, in 2010, reviewed fifteen employee plans from Catholic-affiliated universities. It identified eight plans that generally provided coverage, two additional plans that provided coverage when contraceptives were “medically necessary.” Two others, while not providing coverage, allowed employees to be reimbursed for contraceptives with flexible spending account funds. Only three of the fifteen plans reviewed excluded all assistance for contraceptives. On file with the National Women’s Law Center.

40 The National Women’s Law Center, in 2010, reviewed all plans available to Federal employees, and found that every plan included contraceptive coverage. On file with the National Women’s Law Center.