April 8, 2013

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

Submitted Electronically Via Email
Re. File Code CMS–9968–P

Dear Sir or Madam,

In March 2010 the United States Congress enacted the "Patient Protection and Affordable Care Act" (P.L. 111-148) (PPACA) restructure the provision of healthcare services in the United States. Pursuant to statutory requirements found in PPACA, actions were taken by various agencies of the government and by non-governmental actors that led the Department of Health and Human Services (HHS) to mandate that a substantial majority of American health plans cover prescription contraceptives, sterilization, and related patient education and counseling. These requirements are commonly known as the "HHS mandate" or "the mandate."

The Family Research Council (FRC) submits these comments today to give voice to the large body of Americans who oppose the HHS mandate itself. We also file to express the concerns of those who believe the HHS mandate, including the provisions found in this proposed rule, significantly discriminates against people of faith. FRC believes that the mandate and the related rulemakings have culminated in the creation of a grave threat to religious liberty.

On February 6, 2013 the Department of Health and Human Services (HHS) issued a proposed rulemaking (Proposed Rule) "Coverage of Certain Preventive Services Under the Affordable Care Act" requesting public comments on the proposed changes to the definition of "religious employer" contained originally in the February 10, 2012 "final rules." It also requests comment on a purported "accommodation" originally offered in the March 21 "Advanced Notice of Proposed Rulemaking" which implements the provision mandating coverage of preventive services for women in section 1001 of (PPACA).

The February, 2012 final rule required all insurance plans to cover, with no cost-sharing, the full range of Food and Drug Administration-approved (FDA) contraceptives – including those with abortifacient modes of action. The final rule included only a very

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narrow exemption for houses of worship. The new Proposed Rule makes technical changes to that exemption's criteria but with no expansion of protections for religious organizations other than houses of worship. The Proposed Rule also requests public feedback on how non-exempt organizations that are opposed to certain benefits under the HHS mandate should provide such services to their employees. That is, HHS is seeking suggestions on how religious organizations' health plans would cover these services for free, even if doing so conflicts with their beliefs.

The Proposed Rule does not Protect Religious Non-Profits.

On February 10, 2012, HHS finalized the rule mandating all group and individual health plans to provide all FDA-approved contraceptives, sterilizing agents, and education and counseling services, with no co-pay by August 1, 2012. The HHS regulation provided an exemption only for a narrow category of "religious employers" which would essentially only include churches. The regulation limits "religious employers" to those organizations which a) have the "inculcation of religious values as its purpose," b) primarily employ persons who share its religious tenets, c) primarily serve persons who share its religious tenets, and d) is a non-profit organization that under 26 U.S.C. §§ 6003(a)(1) and 6033(a)(3)(A)(i) or (iii) is exempt from filing annual tax returns.

The new Proposed Rule remains discriminatory despite technical changes to the criteria of what constitutes a "religious employer" in order to qualify for the exemption. The Proposed Rule removes the requirements (a), (b), and (c) above, but leaves in place (d) related to the tax code which applies only to churches or their auxiliaries

Practically, churches and their auxiliaries, associations or religious orders engaged in "exclusively religious activities" are exempt. Other religious institutions, such as religious charities, religious non-profit hospitals and health care providers, universities and colleges are still not exempt. The Proposed Rule remains in direct conflict with the religious freedom protections under current law that otherwise protect such entities from being forced to violate their religious beliefs. The "safe harbor" for such groups ends August 1, 2013, at which point, their religious beliefs will be violated.

The Proposed Rule does not Protect Businesses.

The Proposed Rule does not extend any exemption or even the so-called "accommodation" to businesses (for-profit businesses). Companies such as Hobby Lobby and others must comply with the mandate in their health plans or face steep penalties.

The Proposed Rule does not Protect Individuals.

The Proposed Rule does not protect religious individuals who are required to purchase health insurance (under the "individual mandate"). It does nothing to protect individuals who want to choose health plans without abortifacient and/or contraceptive coverage in the group or individual market.

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The "Accommodation" Does not Protect Religious Groups.

One other slight change under the Proposed Rule concerns self-certification by non-exempt religious employers while guaranteeing their employees receive free coverage of objectionable benefits. The Proposed Rule requires such an employer to file new paperwork and "self-certify" that it opposes coverage of either contraceptives or abortifacients. The employer must send this self-certification to the insurer they pay and contract with for their health coverage. The Proposed Rule mandates the insurance company, upon receipt of such self-certification, "automatically" notifies the employees that their employer does not cover the relevant objectionable services but that the insurer is "contemporaneously" offering free contraceptive coverage to them under a "separate" insurance policy. However, this scheme does nothing to protect the religious freedom of the employer. Under this scheme, the employer remains the legal gateway for contraceptive coverage to its employees. Unlike supplemental dental or eye care insurance, which are separate from an insurance plan but can be added as a rider by the employer, the contraceptive coverage is legally required regardless of the employer's objections.

In the case of self-insured employers, the Third Party Administrator (TPA) handles the processing of benefits claims. The employer is the insurer. Under the Proposed Rule, self-insured objecting employers will still be required to offer the free contraceptive coverage through the TPA, they would have to "arrange" with an insurance company the free objectionable coverage. The Proposed Rule considers the problems raised by comments under the ANPRM. TPAs cannot pay for claims since they are not licensed fiduciaries. TPAs process the claims of benefits for the employer. The Proposed Rule now requires the TPA to work with an insurer to provide the employees the contraceptive coverage. This legally complicated scheme does not protect the religious employer from harm to its religious beliefs in that it must, in some manner left unspecified by the Proposed Rule's operative language, still provide coverage of objectionable services to its employees. This fundamental problem exists for many colleges and universities which are often self-insured.

Religious Employers Face Significant Penalties.

Whether a religious employer has a fully insured plan, or a self-insured plan, it has no choice under the Proposed Rule but to purchase insurance from an insurance company which in turn provides its employees coverage of objectionable services. Failure to comply with the mandate while continuing to offer insurance could lead to massive penalties of $100 per day per employee. Employers choosing instead to drop employer health coverage, in the case of employers with over 50 employees, will face lesser but still significant financial penalties. The Proposed Rule offers no accommodation of religion; it continues discrimination against religious beliefs of many employers through paperwork schemes.

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Students Suffer under the Proposed Rule.

This accounting scheme proposed under the Proposed Rule would also apply to student health insurance. A religious college or university would be required to self-certify to the insurer (in the case of fully insured plans) that it objects to certain services, and the insurer would in turn legally be required to offer and pay for free contraceptives and abortifacients to the students. While self-insured student plans are not captured by the HHS mandate, the Proposed Rule recognizes that most student plans are fully insured and are subject to the mandate. The Proposed Rule discriminates against the sponsoring institution offering such student plans, threatening to eliminate such plans rather than increase health care coverage.

Employers Still Pay for Coverage.

One argument HHS offers argue that the Proposed Rule limited the impact on religious beliefs is to claim that the employer would not have to pay for the actual cost of "free" benefits or services. Accordingly, the Proposed Rule requires the insurance companies to pay for the services. Since insurance companies are likely to shift the cost of the free services on to the employer's premiums, the Proposed Rule analysis states that it prevents the increased costs to be applied to the employer's premiums. However, the Proposed Rule itself provides no prohibition on such practices. As stated in FRC's previous "comment"[1] on the ANPRM, which applies to the Proposed Rule, the contraception mandate will yield little to no cost-savings. In fact, the likelihood is that overall costs of such "free" coverage will increase.

HHS recognizes this real possibility at least in the case of self-insured employers. The Proposed Rule, therefore, offers a new mechanism for insurance companies to defray the costs for drugs and services. It allows insurers providing such free benefits to the employees of religious non-profit organizations and who are on "Federally-Facilitated Exchanges" (FFE) to request from the Federal government a reduction the exchange "user fees."

This user fee proposal raises the question of whether the Proposed Rule exceeds its statutory authority, since Section 1001 of PPACA (Section 2713 of the Public Health Service Act) provides no funding mechanism. Moreover, while Section 1311 of PPACA allows states to require user fees to establish exchanges, it does not authorize such user fees to pay for health insurance coverage. Even if such user fees could be used to pay for coverage, the Proposed Rule only allows insurers providing self-insured employer's contraceptive coverage in FFE.

Even if the Proposed Rule prohibits insurers from shifting the cost back to the employers' premiums for the "free contraceptive coverage," and instead allows them to defray the added cost by obtaining reductions in their user fees, it only applies in states that did not

[1] FRC comment filed June 8, page 10. http://downloads.frc.org/EF/EF12F18.pdf

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establish an exchange. In other words, in states that create a state exchange pursuant to Section 1311 of PPACA, the Proposed Rule does not allow any "accommodation" for self-insured employers such that the insurers' added expenses are mitigated by reducing the user-fees. This means that any additional cost to an insurer for the "free" contraceptive coverage, facilitated by that employer's third party administrator is likely to be passed on to the employers in the form of higher premiums. Insurers will not bear the cost of paying for each and every prescription contraceptive drug or abortifacient, let alone more expensive surgical sterilizations. Even under the theoretical cost-savings model set forth by HHS's ASPE brief,[2] some entity will have to pay for those drugs and services in the short term well before any long term savings kick in due to pregnancy reductions. The insurer is likely to pass on those immediate costs to the employer through higher premiums. In addition, the Proposed Rule acknowledges there may be administrative costs to third party administrators and the insurers.

Regardless of whether the costs can be prevented from being shifted to the religious employer's plans, the fundamental violation still exists. The Proposed Rule does not ameliorate the discriminatory effect on the religious employer from the outset. The employer is still paying for a legal contract with an insurer, or processing claims through a TPA, to cover health benefits, and this contract is the automatic trigger for providing free coverage of objectionable services to its employees.

The Contraceptive Mandate includes Abortifacients.

The HHS mandate includes, and the Proposed Rule continues the inclusion of, drugs that are FDA-approved "contraceptives." As FRC previously commented,[3] such drugs, most notably ella (uliprstal acetate), can function to destroy an embryo prior to implantation, or after implantation.[4] FRC opposes any governmental discrimination against employers on the ground they object to covering abortifacient drugs.

The Proposed Rule Violates Current Hyde-Weldon Anti-Discrimination Law.

The HHS mandate violates the Hyde-Weldon Amendment by mandating the provision of contraceptive drugs that can function as abortifacients even if they are FDA-approved under the category of "emergency contraceptives." The Hyde-Weldon Amendment in current law forbids the government under the Labor, Health and Human Services Act (LHHS Act) from discriminating against an individual on the basis of objections to

[2] HHS ASPE Brief, "The Cost of Covering Contraceptives through Health Insurance," February 9, 2012 (http://aspe.hhs.gov/health/reports/2012/contraceptives/ib.shtml).

[3] FRC Comment, June 8, 2012, page 8.

[4] A new article just published by Mozzanega *et al*. in the Cell Press journal, *Trends in Pharmacological Sciences*, casts significant doubt on the claim that ellaOne prevents pregnancy solely by inhibiting ovulation as an emergency contraceptive (EC). Rather, the evidence shows that ellaOne drug "effects can interfere with embryo implantation and that the high efficacy of ellaOne in EC is probably a result of these endometrial effects, rather than the anti-ovulatory effects." Mozzanega B, Cosmi E, Nardelli GB (2013) Ulipristal acetate in emergency contraception: mechanism of action. *Trends in Pharmacological Sciences* 34, 195-196.

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abortion.[5] Hyde-Weldon specifically states that the federal government, or any state or local government funded under the LHHS Act, may not subject a "health care entity" to "discrimination" on the basis that, among other things, it does not "provide coverage of….abortions."

The Hyde-Weldon Amendment does not require that objections to abortion be based on religious or moral grounds. It categorically prohibits governmental discrimination for those who refuse, for whatever reason, to participate in or cover abortion. Given the fact that some drugs and devices, such as Ella, included in the HHS mandate can function as abortifacients, the HHS mandate violates Hyde-Weldon by requiring entities that do not cover such drugs to do so. The Proposed Rule does not alleviate this legal dilemma.

The Proposed Rule Violates the Religious Freedom Restoration Act.

FRC previously wrote in comments[6] that the HHS mandate violates the Religious Freedom Restoration Act ("RFRA") enacted by Congress in 1993.[7] RFRA requires that the substantial burdening of religion serve a compelling governmental interest, and that the government employ the least restrictive means of achieving its goal.[8] FRC believes that the Proposed Rule does not alleviate this violation for several reasons.

First, the Proposed Rule places a substantial burden on employers and individuals. Many employers to maintain their religious convictions will refuse to comply with the mandate and will be subject to harsh penalties – up to $100 per employee. If they drop coverage altogether, they will face lesser but significant fines. Individuals are placed in the position either of buying health insurance plans in the individual market that cover the provision of drugs and devices that violate their consciences or refusing to purchase health insurance coverage and face fines.

Second, the HHS mandate does not serve a compelling governmental interest. Pregnancy is not a disease to be prevented, and evidence suggests that increased access to contraceptives does not reduce unwanted pregnancies and abortion, or STIs.

Third, the HHS mandate is not the least restrictive means available to increase access to contraceptives. Contraceptive drugs and devices are widely available, are heavily subsidized by the federal government and greater access could have been achieved without burdening religious employers.

[5] "Consolidated Appropriations Act, 2012", PL 112-74, Division F, Title V, Section 507(d)(1). The PL version page number is: 125 STAT. 1111.

[6] FRC Comment June 8, 2012, page 3-7.

[7] 107 Stat. 1488, as amended, 42 U.S.C. § 2000bb et seq.

[8] 42 U.S.C. § 2000bb-1(b).

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The Proposed Rule Discriminates Unlike State Contraceptive Mandate Laws.

The Proposed Rule does nothing to provide religious employers the same types of options they have in states with contraception mandate laws. As FRC stated in its prior comment,[9] under state law, religious employers can generally drop prescription coverage to avoid violating their conscience, or self-insure. Under the Proposed Rule, religious employers have no such options. Taken together, the HHS mandate and the Proposed Rule are far more sweeping in scope than any contraceptive mandate under state law.

Conclusion.

If the accounting gimmicks proposed by the Proposed Rule are sufficient to accommodate religious freedom, why exempt churches? If the exemption for churches is necessary to protect their religious beliefs, why not extend the same exemption to all religiously affiliated employers across the country?

We request that groups not be forced to violate their consciences by being forced to pay for health care plans that provide free coverage of objectionable benefits, whether through an accounting gimmick or not. We ask HHS to rescind its mandate requiring insurance plans to include coverage for all FDA-approved contraceptives and sterilization services. The mandate will still violate the religious liberty protections of millions of Americans.

Sincerely,

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[9] FRC Comment, June 8, 2012, page 9.