The National Catholic Bioethics Center

6399 Drexel Road, Philadelphia, PA 19151 Tel. 215-877-2660 Fax. 215-877-2688 www.ncbcenter.org

April 8, 2013

Submitted Electronically

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

Re: Notice of Proposed Rulemaking on Preventive Services

File Code No. CMS-2012-0031

Submitted Comments, The National Catholic Bioethics Center

Dear Sir or Madam:

I wish to provide comment on behalf of The National Catholic Bioethics Center (Center) concerning the Notice of Proposed Rulemaking ("NPRM") titled *Coverage of Certain Preventive Services Under the Affordable Care Act* (hereafter "Proposed Rule"), 78 Fed. Reg. 8456 (February 6, 2013). The Center is a non-profit research and educational institute committed to applying the moral teachings of the Catholic Church to ethical issues arising in health care and the life sciences. The Center has 2500 members throughout the United States, and provides consultations to hundreds of institutions and individuals seeking its opinion on the appropriate application of Catholic moral teaching to these ethical issues.

On February 10, 2012, the Department of Health and Human Services (HHS) promulgated the Final Rule (Final Rule),[1] purportedly implementing coverage of certain preventive services pursuant to the *Patient Protection and Affordable Care Act.*[2] The Final

[1] 77 Fed. Reg. 8725, 8728 (Feb. 15, 2012).
[2] Pub.L. 111–148, 124 Stat. 119, to be codified as amended at scattered sections of the Internal Revenue Code and in 42 U.S.C.

Rule left unchanged the requirements of the Interim Final Rule of August 1, 2011.[3] The Final Rule requires that all group health plans (including student health insurance plans) and health insurance issuers provide the full range of US Food and Drug Administration (FDA)-approved contraceptive methods, as "preventive services" for women, as mandated under the PPACA.[4] These FDA-approved contraceptives include potential abortifacients such as so-called emergency contraception and Intra Uterine Devices (IUDs), as well as surgical sterilizations. Furthermore, no co-pays are to be charged to beneficiaries.

The Final Rule narrowly defines the religious employer exempt from providing this coverage in the following manner:

> (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 described in section 6033(a)(1) and section 6033(a)(3)(A)(i) or (iii) of the Code.[5]

The NPRM seeks public comment on the Proposed Rule, the "Summary" of which states:

> The proposed rules would amend the authorization to exempt group health plans established or maintained by certain religious employers (and group health insurance coverage provided in connection with such plans) with respect to the requirement to cover contraceptive services. The proposed rules would also establish accommodations for group health plans established or maintained by eligible organizations (and group health insurance coverage offered in connection with such plans), including student health insurance coverage arranged by eligible organizations that are religious institutions of higher education.[6]

In fact, the Proposed Rule itself asserts that "The Departments believe that this Proposed Rule would not expand the universe of employer plans that would qualify for the exemption beyond that which was intended in the 2012 final rules."[7] Thus, pursuant to this Proposed Rule, most, if not all, of our membership will not be exempt and will be subject to the violations of their religious freedom and their conscientious objections to these methods by the mandates contained in the Proposed Rule.

---

[3] 76 Fed. Reg. 46621 (Aug. 3, 2011).
[4] *http://www.ofr.gov/OFRUpload/OFRData/2011-19684_PI.pdf*.
[5] 77 Fed. Reg. at 16502.
[6] 78 Fed. Reg. 8456-8476 (February 6, 2013), at 8456-8457.
[7] Ibid, 8461.

The Center wishes to comment on the following concerns pertaining to the Proposed Rule in the NPRM:

1. The Proposed Rule continues to create new law by narrowly defining which organizations the federal government arbitrarily will recognize as exempt: "Religious employers," which basically include only "churches, their integrated auxiliaries, and conventions or associations of churches," or "the exclusively religious activities of any religious order."[8]

The Proposed Rule violates the *Establishment Clause* of the *First Amendment*[9] of the U.S. Constitution in that *de facto* the Proposed Rule is establishing what the administration considers to be a religious organization. It is creating an arbitrary definition and legal recognition of some religious organizations, inconsistent with federal law, deeming some, but not others, to have an equal protection under the *First Amendment* of the U.S. Constitution and the *Religious Freedom Restoration Act.*[10] Specifically, despite the fact that thousands of other religious organizations are recognized under a federal Group Ruling[11] as being organized and operating as non-profit religious organizations, they are being deemed, under this legally inaccurate and arbitrary delineation, as not religious enough to be exempt from the mandated coverage.

The Proposed Rule restricts religious freedom by using a category in tax law that relates to whether an organization files its own 990 tax form, which has no relationship to conscience as protected under the *First Amendment* of the U.S. Constitution. Furthermore, even when citing the tax code section, not all subparts are included as exempt. Specifically omitted is subpart (ii) which includes other non-profits and not just "churches, their integrated auxiliaries, and conventions or associations of churches," or "the exclusively religious activities of any religious order."[12] This represents an arbitrary citing of existing law defining what is to be considered under the law as a religious organization.

As stated in the NPRM itself, there is expected to be no effective increase in the number of organizations to be exempted from the mandate that contraceptive and abortifacient insurance coverage be included in employee health plans. The exempt organization is defined much more narrowly than in existing federal laws which provide for conscience exemptions. The mandated contraceptive and abortifacient insurance coverage violates constitutional and

---

[8] Internal Revenue Code section 6033(a)(3)(A)(i) and (iii), as cited in 78 Fed. Reg. 8458.
[9] U.S. Constitution: First Amendment.
[10] 42 U.S.C. § 2000bb through 42 U.S.C. § 2000bb-4.
[11] In 1946 the Internal Revenue Service (IRS) issued to the United States Conference of Catholic Bishops and its predecessor organization, a group tax exemption ruling to Catholic organizations listed in The Official Catholic Directory (OCD). This is updated annually. The Group Ruling establishes (1) that organizations included in the OCD are exempt from federal income tax under section 501(c)(3) of the Code and from federal unemployment tax; and (2) that contributions to such organizations are deductible for federal income, gift, and estate tax purposes. See: http://www.usccb.org/about/general-counsel/upload/group-ruling-memo.pdf.
[12] Internal Revenue Code section 6033(a)(3)(A)(i) and (iii), as cited in 78 Fed. Reg. 8458.

statutory protections of religious freedom and conscience, as well as the constitutionally protected right of private enterprise.

2. The Proposed Rule, despite existing federal law, not only creates two categories of "religious" organization, but then treats those within each category differently: those limited few which are exempted, and a new category, not identified in existing federal law, who will be "accommodated." However, the accommodation is false. So called "accommodated" religious organizations, in fact, are being subjected to a violation of the statutorily and constitutionally-protected right to religious freedom.

The *Patient Protection and Affordable Care Act* requires, as of January 2014, that virtually all organizations with 50 or more full-time employees provide health insurance coverage or be fined,[13] and that coverage will be the trigger for the mandated objectionable items of coverage for their employees. Furthermore, any organization, regardless of the number of employees, choosing to provide employees with health insurance will be severely fined for not including the contraceptive and abortifacient insurance coverage.[14] The number of exempted religious organizations is negligible.

However, the *Religious Freedom Restoration Act* requires the federal government to exempt any religious objector from rules such as the Proposed Rule. It prohibits the federal government from "substantially burden[ing] a person's exercise of religion," unless "it demonstrates that application of the burden to the person (1) is in furtherance of a compelling governmental interest; and (2) is the least restrictive means of furthering that compelling governmental interest."[15] Thus, it prohibits the federal government from imposing a substantial burden on religious beliefs without a compelling governmental interest, while employing the least restrictive means of so doing. There is no absence of availability of contraceptives and abortifacients at little or no cost to women. Thus, there is no prevailing state interest to impose this restriction on the free exercise of religion, especially since there are a myriad of ways in which the federal government could accomplish its goal of universal contraceptive coverage. Most notably, the *Patient Protection and Affordable Care Act* has "grandfathered" tens of millions of other Americans, exempting them for nonreligious reasons from providing the mandated insurance coverage. However, *the Religious Freedom Restoration Act* mandates that all burdens on free exercise of religion be applied equally. Yet the government refuses to exempt most objecting individuals and organizations, whose objections are based upon their deeply held religious beliefs. This is clearly religious discrimination, and a violation of the *Religious Freedom Restoration Act.*

[13] 26 U.S.C. § 4980H(c)(1) and (c)(2)(D)(i). As we understand it, employees must be eligible to receive a subsidy to their premium by the federal government for the penalty to be invoked.
[14] 26 U.S.C. § 4980D (b)(1).
[15] 42 U.S.C. 2000bb-1(c).

Furthermore, HHS claimed in the Final Rule that the definition of "religious employer" (which has not changed in this Proposed Rule) is not "intended to set a precedent for any other purpose."[16] Clearly, this demonstrates the arbitrary and discriminatory nature of the narrow "accommodation," inconsistent with any federal law. There are numerous and historical federal statutory provisions to respect religious freedom, most notably, the statutory prohibition in the *Patient Protection and Affordable Care Act* against mandating that health care providers participate in assisted suicide[17] or abortion.[18] There is no reason why such rights of religious freedom, intended to be protected by our United States Constitution, should be selectively applied to some situations, and not to others. In fact, such selective application of the Free Exercise Clause of the United States Constitution reflects a discriminatory bias against the largest non-governmental provider of health care, social services and education in this country,[19] which has clearly and consistently indicated that contraceptive methods and abortifacients are inconsistent with its tenets: the Catholic Church.

The NPRM claims that it has addressed the right to religious freedom of those religious organizations which the federal government intends to "accommodate." However, despite the religiously based objections of thousands of employers the mechanism to be used to provide the contraceptive and abortifacient insurance coverage is through the religious organization's own insurer or plan administrator. Thus, the Proposed Rule coerces the religious organization's cooperation in an act to which the organization objects on religious grounds. Specifically, the morally objectionable coverage will come from the same insurers or plan administrators paid by the religious organization. The NPRM erroneously is dictating a moral judgment that the "accommodation" frees objecting entities from culpability for coverage of objectionable items. Religious organizations are not allowed to disagree with the government's moral judgment. Several facts, critical to the moral analysis, indicate that the government is in error. Furthermore, the government has no right to dictate how a religious organization comes to its moral conclusions concerning what constitutes cooperation in evil.

Clearly, it will be the premiums of objecting employers that trigger the morally objectionable coverage, despite claims by the NPRM that the religious organization will not be paying for such coverage. There will be no coverage without the contract, and there will be no contract without the payment of premiums. Religious organizations clearly are forced to subsidize, through premiums, the items they consider morally reprehensible. Specifically, the "accommodated" organization must sign a certification asserting that it is organized and

---

[16] 77 Fed. Reg. at 16502.
[17] *Patient Protection and Affordable Care Act*, §1553. http://www.gpo.gov/fdsys/pkg/PLAW-111publ148/html/PLAW-111publ148.htm.
[18] *Patient Protection and Affordable Care Act*, §1303. http://www.gpo.gov/fdsys/pkg/PLAW-111publ148/html/PLAW-111publ148.htm.
[19] USCCB, "A Place at the Table," USCCB (November 2012). http://www.usccb.org/issues-and-action/human-life-and-dignity/poverty/place-at-the-table.cfm.

operating as non-profit religious organizations. It must retain a record of the certification "for examination upon request so that regulators, issuers, third party administrators, and plan participants and beneficiaries,"[20] and provide the certification to the insurance issuer(s) and/or its self-insurance plan administrator(s). These same insurance providers/administrators are paid for their ordinary services to the religious organization, thus, requiring the religious organization to cooperate in what is morally objectionable. Under the accommodation, once the religious group's insurer or administrator receives that certification, the insurer or administrator is required to "automatically" provide the religious organization's employees and plan beneficiaries with the morally objectionable insurance coverage. Despite the fact that the NPRM states that this insurance plan will be "separate" and will not be charged to the religious organization, the NPRM also identifies that there are up-front costs to the items.[21]

Furthermore, the Proposed Rule makes no provision for the protection of the *First Amendment* right to free speech, since the Proposed Rule will require counseling and information[22] concerning the very products to which religious organizations object. Clearly, the rights of the religious organization as to the free exercise of religion and to free speech are being violated. Furthermore, conscientious objectors are left with no legal options, whatsoever. They must either violate deeply held moral convictions, or unjustly be forced to discontinue health care coverage for employees, or pay huge fines that will effectively cause them to cease serving the poor, the sick and other ministry beneficiaries.

3. The Proposed Rule requires employees to receive the contraceptive and abortifacient insurance coverage automatically. Thus, the employees could not opt out of the coverage for themselves or their female family members, including their minor children.

Virtually all Americans who purchase a health plan will ultimately be required to have an insurance plan that provides for contraceptive and abortifacient coverage for themselves and their dependents, whether they want such coverage or not. There is neither an exemption nor a feigned accommodation provided under the Proposed Rule for employees of secular or religious organizations who do not want contraceptive and abortifacient insurance coverage for themselves, their spouses, or their children. This is a significant violation of the rights of families to determine, not only the insurance coverage to which they consent, but also parental rights over the welfare of their minor children. Furthermore, under the *Patient Protection and Affordable Care Act* adult children under the age of 26 years can receive insurance coverage

[20] Re "Self-insured" plans: "Under each of these approaches, a health insurance issuer that provides individual health insurance policies for contraceptive coverage for plan participants and beneficiaries at no additional cost would be able to offset the costs of providing such coverage by claiming an adjustment in Federally-facilitated Exchange (FFE) user fees that would reduce the amount of such fees for the issuer (or an affiliated issuer), as discussed later in this section." 78 Fed. Reg. at 8463.
[21] 78 Fed. Reg. at 8462.
[22] 78 Fed. Reg. at 8460.

through their parents' insurance. Thus, despite a plan enrollee not wishing to be the means for providing other family members with what the enrollee deems is morally objectionable, the enrollee is forced to cooperate in a violation of his or her conscience. This also is a violation of the *Religious Freedom Restoration Act.* It is obvious that the issue of individual "choice" is being administered in a discriminatory manner. Parents will have no freedom to determine the wellbeing of their own minor children, pertaining not only to what contraceptive and abortifacient methods they are obtaining, but also as to what counseling concerning these methods that their minor children are receiving. This is true not only for employees of non-faith-based organizations, but also "accommodated" religious organizations.

In addition, employees who themselves have a religious objection to contraceptive and abortifacient insurance coverage will be contributing to a pool of funds from which the insurer will draw to pay claims for these methods to be used by others. Thus, those employees will ultimately be paying for other people's contraceptive and abortifacient methods, even if they themselves and their dependents do not use such methods. It is obvious the Proposed Rule coerces cooperation with immoral actions by persons with religious objections that violates not only the *Religious Freedom Restoration Act*, but also the Free Exercise Clause of the *First Amendment.*

4. NPRM proposes to require that self-insured "accommodated" religious organizations use a plan administrator (even if it does not currently have one) to accomplish the federal government's goal of universal contraceptive and abortifacient insurance coverage.

The Proposed Rule creates an approach in which the self-insured plan "accommodated" sponsor (religious organization/employer) must contract with a plan administrator, who would act as the plan fiduciary. This creates significant conflicts of interest between the plan administrator and the religious organization, as well as additional legal liabilities and administrative costs. These costs clearly will be assumed by the religious organization forced to contract with the plan administrator. Thus, the religious organization is forced to cooperate in providing to employees the contraceptive and abortifacient insurance coverage, to which the religious organization objects, violating its religious freedom. In addition, the Proposed Rule provides no respect for the religious objections of the plan administrators and/or insurers unless they only serve religious organizations.

The religious organization must issue a certification to the plan administrator that triggers the morally objectionable coverage to employees. The plan administrator, under contract with the religious organization, is responsible for finding an external insurance company to directly provide insurance coverage of morally objectionable items to the religious organization's employees. The NPRM proposes that the costs of the objectionable items will be offset by rebates that the federal government will offer those insurers in the health "exchanges" to be set up pursuant to the *Patient Protection and Affordable Care Act*.

However, despite the religious organization's objections, the very mechanism to be used to trigger the provision of the contraceptive and abortifacient insurance coverage is provided by the employing religious organization. Furthermore, the very fact that the services of the plan administrator are paid for by the religious organization, constitutes cooperation by the objecting religious organization.

5. The Proposed Rule offers no accommodation options whatsoever to protect the rights of conscience or the religious freedom of individuals, owners or sponsors of non-faith-based organizations or even faith-based for-profit organizations.

The overwhelming majority of employers and insurers are offered no exemption or accommodation under the Proposed Rule. It is incongruous that there is no recognition of the sacrosanct right to religious freedom by individuals if they sponsor a non-religious organization. The rights to religious freedom guaranteed by the *First Amendment* of the U.S. Constitution, as well as by the *Religious Freedom Restoration Act*, do not discriminate against individuals whose employment or business is not religious. Respect for their religious freedom demands robust protection from all violations; but under the Proposed Rule such individuals and organizations have none. Even current court decisions have recognized that the mandated insurance coverage of contraceptive methods and abortifacients violates religious freedom. To date 25 lawsuits by non-exempt, non-accommodated for-profit organizations have been filed over these HHS mandates. To date, of the 22 for-profit plaintiffs that have obtained rulings touching on the merits of their claims against the Mandate, and 17 have secured injunctive relief against it.[23] Clearly, judicial review is drawing into question the constitutionality of the coercion contained in the Proposed Rule.

Conscientious objection is a respected mode of claiming one's legal right to the protections guaranteed by the *First Amendment* of the U.S. Constitution, as well as by the *Religious Freedom Restoration Act*. Even under the military conscription (draft) policies, there was recognition of these rights to religious freedom and freedom of conscience. Laws legalizing assisted suicide and those pertaining to medical cooperation in capital punishment, all provide for these protections. As stated earlier, even the *Patient Protection and Affordable Care Act* references these protections in terms of physician-assisted suicide and abortion. Yet the Proposed Rule does not recognize or respect such legally enshrined rights.

6. The Proposed Rule violates the Weldon Amendment,[24] passed by Congress on a bipartisan basis, which bans the federal government from requiring abortion coverage, by including drugs and devices that are abortifacient. This has particular

[23] The Becket Fund, "Current Scorecard for For-Profit Cases" (April 5, 2013). http://www.becketfund.org/hhsinformationcentral/.

[24] For the text of the Weldon Amendment, see Consolidated Appropriations Act, 2012, Pub. L. No. 112-74, Div. F, § 507(d) (2012).

relevancy for those who object to the abortifacient but not the contraceptive nature of the mandated methods under the Proposed Rule.

The Proposed Rule requires coverage of abortifacient drugs and devices, in particular, intra uterine devices[25] and "emergency contraception". As stated earlier, the *Patient Protection and Affordable Care Act* purports to protect the rights of conscience of those impacted by that Act. Furthermore, federal law (the Weldon Amendment) forbids government discrimination against health plans that do not offer abortion, and the Administration's own Executive Order[26] provides assurances that the *Patient Protection and Affordable Care Act* does not require abortion coverage. The Proposed Rule contradicts these provisions, as well as the already referenced *First Amendment* of the U.S. Constitution and the *Religious Freedom Restoration Act.*

A number of so-called contraceptives are in fact abortifacients, capable of preventing the implantation of the fertilized human being after conception, based on the descriptors provided by the U.S. Federal Drug Administration. Specifically, the U.S. Food and Drug Administration (FDA) states publicly concerning *Plan B "*emergency contraception":

> "Plan B One-Step is believed to act as an emergency contraceptive principally by preventing ovulation or fertilization (by altering tubal transport of sperm and/or ova). In addition, it may inhibit implantation (by altering the endometrium)."[27]

The FDA did not arrive at this conclusion because there is no credible evidence that this drug prevents implantation; it arrived at this conclusion from an analysis of the relevant scientific data. Likewise, the manufacturer of Plan B, Teva Pharmaceuticals, states that Plan B may work "by preventing attachment (implantation) to the uterus (womb)."[28] In fact, another FDA-approved emergency contraceptive is even capable of dislodging the embryo after implantation. Specifically, ulipristal (*ellaOne*) may prevent ovulation but is clearly abortifacient. Its chemical structure is similar to that of mifepristone (RU-486), which blocks natural progesterone receptors in three critical areas: destroying receptivity of the endometrial glands to embryo implantation;[29] destroying the capacity of the corpus luteum to produce

---

[25] Women's Health LLC, "Proposed Prescribing Information: ParaGard®T 380A Intrauterine Copper Contraceptive" (Updated Sept 2005; Accessed April 5, 2013). http://www.accessdata.fda.gov/drugsatfda_docs/label/2005/018680s060lbl.pdf.

[26] See Executive Order 13535, "Ensuring Enforcement and Implementation of Abortion Restrictions in the Patient Protection and Affordable Care Act," 75 Fed. Reg. 15599 (Mar. 24, 2010).

[27] U.S. Food and Drug Administration, "Labeling Information" (07/10/2009). http://www.accessdata.fda.gov/drugsatfda_docs/label/2009/021998lbl.pdf.

[28] Teva Pharmaceuticals, "Plan B, One-Step FAQ" (last accessed April 5, 2013). http://www.planbonestep.com/faqs.aspx.

[29] Jerry R. Reel, Sheri Hild-Petito, and Richard P. Blye, "Antiovulatory and Postcoital Antifertility Activity of the Antiprogestin CDB-2914 When Administered as Single, Multiple, or Continuous Doses to Rats," Contraceptive 58.2 (August 1998): 129.

progesterone for initial support of the implanted embryo;[30] and destroying the endometrial stromal tissues necessary for the survival of the embryo.[31] Thus, for those whose objections to the Proposed Rule are based on the abortifacient nature of some "contraceptive" methods, they have the right under the *First Amendment* of the U.S. Constitution and the *Religious Freedom Restoration Act* to object to some, even if not opposed to all, the contraceptive and abortifacient methods mandated by the Proposed Rule.

Conclusion

Clearly, the mandates contained in the Proposed Rule constitute a violation of the *First Amendment* to the United States Constitution and the *Religious Freedom Restoration Act.* The Proposed Rule creates a discriminatory bifurcated definition of a religious organization, illegally restricting the religious freedom of most of them, with no statutory authority to do so. The attempt in the NPRM to create alternative compliance mechanisms, for persons who hold religious objections to these mandates, results in an identical outcome for both self-insured and contracted plans: insurers, employers, colleges and universities, and beneficiaries are required to concede their right to religious freedom.

None of the faux mechanisms to protect religious freedom in the NPRM accomplish the stated intent. The NPRM even suggests that the federal government has the legal right to determine which type of religious objection is to be respected, based on the type of contraceptive found to be morally objectionable.

The NPRM violates the robust religious freedom protections in existing federal laws. It completely ignores the religious freedom rights of non-faith based organizations and their sponsors/owners. Lastly, the entire proposal is destructive not only to religious and non-religious organizations and their sponsors, but also to all of the purported beneficiaries who supposedly are to be protected by these "preventive services." In fact, these "beneficiaries" are not only being denied "choice" not to be a party to such an expansive violation of religious freedom, but also are being forced to cooperate in it by premiums they are obliged to pay to support insurance plans that provide the morally objectionable coverage.

What is needed is a rescinding of the Final Rule in its entirety. At a minimum, the legal obligation of the government to protect religious freedom requires that there be a robust, non-discretionary exemption from the mandate for any employer, insurance company, college or university, payer, individual, or entity who in his/her or its own determination has any religious objection to providing, issuing, enrolling in, participating in, paying for, or otherwise facilitating

[30] Catherine A. VandeVoort et al., "Effects of Progesterone Receptor Blockers on Human Granulosa-Luteal Cell Culture Secretion of Progesterone, Estradiol, and Relaxin," *Biology of Reproduction* 62.1 (January 2000): 200.
[31] Sheri Ann Hild et al., "CDB-2914: Anti-progestational/Anti-glucocorticoid Profile and Postcoital Anti-fertility Activity in Rats and Rabbits," *Human Reproduction* 15.4 (April 2000): 824.

or cooperating in coverage of any required practice or of any required provision of information which violates their moral beliefs.

The Center thanks you for the opportunity to provide input on this most fundamental matter of religious freedom.

Sincerely yours,

Marie T. Hilliard, MS (Maternal Child Health Nursing), PhD, RN
Director of Bioethics and Public Policy
The National Catholic Bioethics Center