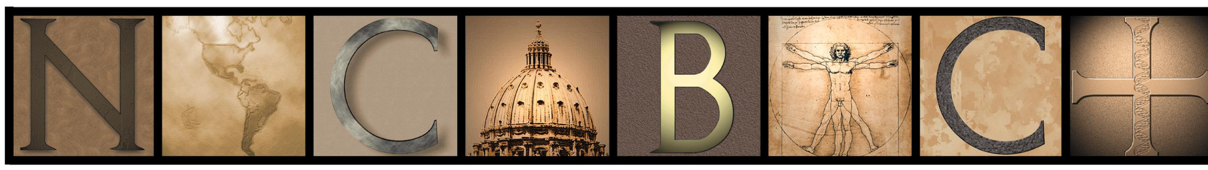

The National Catholic Bioethics Center
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December 4, 2017

Submitted Electronically

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-9940-IFC
P.O. Box 8016
Baltimore, MD 21244-8016

Subj: Religious Exemptions and Accommodations for Coverage of Certain Preventive Services under the Affordable Care Act, RIN 0938-AT20; and Moral Exemptions and Accommodations for Coverage of Certain Preventive Services under the Affordable Care Act, RIN 0938-AT46

Dear Sir or Madam:

I am writing on behalf of The National Catholic Bioethics Center to comment on the "Interim Final Rules"[1] on religious and moral "exemptions" and "accommodations" for certain preventive services under the Affordable Care Act ("ACA"), known as the "Contraceptive Mandate." Specifically, the U.S. Department of Health and Human Services, the U.S. Department of Labor, and the U.S. Internal Revenue Service seek comment on their "Interim Final Rules" regarding mandatory coverage of certain so-called preventive services for women, including contraceptive and abortifacient drugs and devices. The "Interim Final Rules" modify the existing "accommodation" designed for religious ministries such as Catholic charities, universities, and hospitals, as well as closely held for-profit employers, allowing them to choose to remain accommodated or be exempt from the mandate. Furthermore, publically traded for-profit companies with a religious objection may avail themselves of these options, as can non-publicly traded for-profit companies with moral objections. We welcome these expansions and are grateful for them, but seek further relief for those not eligible for the new "exemptions."

[1] 82 FR 47838 (October 13, 2017).

The National Catholic Bioethics Center (NCBC) is a nonprofit 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, many of whom employ and/or serve thousands of person, and thus its collective membership is significant. The Center provides consultation to thousands of institutions and individuals seeking its opinion on the appropriate application of Catholic moral teaching to these ethical issues. The issue of the "Contraceptive Mandate," has had far-reaching negative implications for our membership who regularly seek our ethical advice on the moral quandaries in which it has placed them.

Introductory Summary

The "Final Rules" of July 14, 2015,[2] mandated that virtually all employers provide in their employee benefit packages coverage of certain so-called preventive services for women, including contraceptive and abortifacient drugs and devices. The "Final Rules" did not provide for any new "exemption" to the Contraceptive Mandate. They did expand the definition of "eligible organization" so that "closely held" for-profit organizations with a religious objection qualified for the "accommodation," which was previously limited to religious non-profit organizations. However, the "Final Rules" did not change the limited scope of the "exemption" for most religious organizations. As before, only churches, their integrated auxiliaries, conventions and associations of churches, and the "exclusively religious activities" of religious orders were exempt from the "Contraceptive Mandate." No "exemption" was available for other religious organizations, or even for the caring ministries provided by religious orders themselves. The resulting differentiation of those religious organizations and activities deemed "religious enough," and those deemed "not religious enough," to qualify for the "exemption" is entirely arbitrary and not supported by any legitimate, let alone compelling, government interest. Religion is not limited to worship, and the freedom of religion is not limited to the freedom of worship. Religious freedom must also include the freedom to abide by Church teachings, outside of as well as inside of the four walls of the sanctuary. By limiting the "exemption" predominantly to houses of worship, the "exemption" represented the narrowest protection of conscience in health care anywhere in federal law.

As noted in our prior comments (September 27, 2011; June 18, 2012; April 8, 2013; October 27, 2014), federal conscience protections in the health care context are typically robust. Among such protections is the Church Amendment of 1973, which protects against government coercion of conduct that "would be contrary to [the] religious beliefs

[2] 80 FR 41317.

or moral convictions" of individuals and organizations. Such protections of the right to religious freedom have enjoyed broad bipartisan support, and have been repeated in numerous federal conscience laws over the forty years since its original passage. Historical and legal precedents were being violated by the "Final Rules." Furthermore, religious organizations that were deemed non-exempt based on the redefinition of a religious organization, which include those that contribute most visibly to the common good through the provision of health, educational, and social services, were being unjustly coerced to violate the very tenets that cause them to exist. Even the processes for self-certifying eligibility for an "accommodation" involved these organizations in facilitating coverages for employees that violated the employer's religious freedom.

Cases such as that of the Little Sisters of the Poor,[3] who received a permanent injunction by the US Supreme Court from having to comply with such an "accommodation," have demonstrated that such an "accommodation" does nothing to correct the violations of religious liberty imposed by the Contraceptive Mandate. This conclusion also is borne out by the U.S. Supreme Court's decision in *Burwell v. Hobby Lobby Stores*,[4] as well as lower court decisions, the majority of which have granted some form of injunctive relief to parties with a religious objection to contraceptive coverage. This mandate as presented in the "Final Rules" continued to substantially burden the religious liberty of all persons with religious objections to the mandated coverage. To be eligible for the "accommodation," employers must self-certify their religious objection, either through EBSA Form 700 or through an alternative mechanism by providing to the federal government information that ensures that the very coverage to which the employer objects is extended to its own employees. Thus, an "eligible organization" is still required to facilitate payments and coverage for the contraceptives to which it objects. The "accommodated" organization's own plan becomes a mechanism which ensures that contraceptives are made available to enrollees, preventing the organization from maintaining a plan consonant with its religious or moral beliefs. Thus, self-certification for those seeking an "accommodation" remain problematic; and currently those organizations that are exempt have no such requirement (except to have in their files documentation of the criteria upon which the claim of an "exemption" is supported). Thus, the expanded types of organizations eligible for an "exemption" should not be required to engage in a self-certification process.

Furthermore, claims that the "accommodation" creates a "cost-neutral" plan for the employer, thus exonerating the employer from moral culpability is just not true. Notwithstanding the regulatory prohibition against directly or indirectly charging the employer or employee for contraceptives, the employer still will be contributing to the

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[3] *Zubik v. Burwell*, 578 US _ (2016).
[4] 134 S. Ct. 2751 (2014).

objectionable payments. The former Administration argued that cost reduction will occur by the reduction in maternity care costs. However, there are no reductions in plan premiums. If there are actually reduced maternity claims against the employer's plan as a result of its employees receiving coverage for contraceptives, those cost savings should result in the "accommodated" employers paying a reduced premium in subsequent years. But under the existing regulatory scheme, if claims against the plan are reduced, the employer would not pay a reduced premium for that plan. Instead, the employer's premium would remain as high as it was previously, even though its claims experience should result in a lower premium. And it is precisely that increment of the premium over the actual experience-based cost that would pay for contraceptives, in violation of the religious freedom of the employer.

In the case of insured plans, the Administration claimed in the preamble to its 2013 final rule that the cost of contraceptives could be treated as "an administrative cost that is spread across the issuer's entire risk pool, excluding plans established or maintained by eligible organizations ...."[5] In the case of self-insured plans, funding for contraceptives is purportedly available through a reduction in the exchange user fee, but this assumes that the Third Party Administrator (TPA) will be able to find an insurer willing to make these payments and that the reduction will keep pace with the actual cost of contraceptives. Even if they kept pace, contraceptive payments would not be recovered until months after the payments are made, which raises the question of what source of funds are to be used in the meantime to make such payments. These questions give reasons for concern that the attempted segregation of those contributions from contraceptive payments will likewise turn out to be ineffective. Furthermore, insofar as the insurer/TPA is providing or arranging payments for contraceptives based on an enrollee's participation in the "eligible organization's" group plan, such payments are facilitated by the plan which the religious objector has offered to, and purchased for, its employees. By requiring the "eligible organization's" own health plan to be used as the mechanism or vehicle for ensuring that contraceptive coverage is made to plan enrollees, the government denies this organization the right to establish and maintain a health plan for its employees that is consistent with its religious beliefs and commitments.

In the end, the objecting but "accommodated" employer and any non-exempt employer is prevented from offering its employees a plan that comports with the provider's religious convictions. It is evident that suppression of religious freedom can take at least two forms. It can take the form of making conscientious objectors actively cooperate with what they see as morally forbidden. And it can also take the form of depriving those objectors of the right (a right that others continue to exercise) to do what

[5] 78 FR 39870 (July 2013).

they see as morally required. Objecting employers will lose that right, because any plan they offer will be turned into a conduit for the objectionable coverage.

Finally, the practical outcome for employees and their children is exactly the same: the objectionable coverage is obtained by virtue of their enrollment in the employer-provided health plan. Employees who share the objecting organization's religious tenets are similarly deprived of the freedom to choose an insurance plan organized according to their own values, and are forced to accept coverage for their families to which they have their own religious or moral objection. In this way, the "Contraceptive Mandate" completely fails to acknowledge the religious freedom of both individual and institutional conscientious objectors. Because it is not narrowly tailored to accomplish a compelling government interest, the Contraceptive Mandate violates the Religious Freedom Restoration Act (RFRA), as most courts addressing the issue have either held or found likely in granting some form of injunctive relief.

Current Status

While these "Interim Final Rules" do much to address these violations of religious freedom, and in expanding "exemption" eligibility they are to be lauded and supported, the "Contraceptive Mandate" should be rescinded in its entirety. Specifically, both of these "Interim Final Rules" and the "Final Rules" retain a regulatory scheme in which "preventive" health services are defined to include items that do not prevent disease, but rather are intended to render a woman temporarily or permanently infertile, and may be associated with adverse health outcomes. Designating contraceptives as "preventive services" does not constitute good clinical medicine. An extensive body of evidence shows hormonal contraceptives pose substantial threats to women, including myocardial infarction, cerebrovascular accidents, deep venous thrombosis, pulmonary emboli,[6] as well as breast cancer, cervical cancer, and liver cancer. The relationship between hormonal contraception use and breast cancer—and in particular the disturbing connection between oral contraception use and triple-negative breast cancer (for which oral contraceptives raise the risk by 2.5 to 4.2 times)—should cause caution and concern.[7] Furthermore, it is a scientific fact that contraceptive drugs and devices also are associated with an increased risk of AIDS and sexually transmitted diseases.[8] Designating contraceptives as "preventive services" gives the false impression that these are safe and standard medications. Thus,

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[6] For specific cautions and risks see: "Ortho Tri-Cyclen / Ortho-Cyclen," *RxList: The Internet Drug Index.* Available at http://www.rxlist.com/ortho_tri-cyclen-drug.htm.

[7] Jessica M. Dolle, Janet R. Daling, Emily White, et al., "Risk Factors for Triple-Negative Breast Cancer in Women under the Age of 45 Years," *Cancer Epidemiol Biomarkers Prev*. 2009; 18:1157-1166.

[8] "Hormonal contraception doubles HIV risk, study suggests," *Science Daily*, October 4, 2011, at http://www.sciencedaily.com/releases/2011/10/111003195253.htm.

such contraceptives are not "preventive services," but put the very women they are purported to protect at significant health risk.

Furthermore, as not all employers' religious freedoms are protected, those that are not exempt or accommodated must continue to provide coverage for surgical sterilizations and drugs and devices approved by the United States Food and Drug Administration (FDA) as contraceptives, including drugs and devices that potentially are abortifacients, inappropriately under the guise of "preventive services." Thus, the "Contraceptive Mandate" as presented in the "Interim Final Rules" continues to substantially burden the religious liberty of all employers with moral objections to the mandated coverage, who are not eligible for an "exemption" or "accommodation," for example, if they are employers of publically traded companies. The nature of one's business holdings does not dictate who is eligible for protections of conscience. If a company is not sponsored by a faith-based community but has moral objections consistent with those companies that do have such sponsors, the fact that the company is publicly traded in no way should allow its right to protections under the RFRA to be violated. Identical moral objections to abortifacients can be held by persons of faith, agnostics, and ethicists. Furthermore, whether their company is publicly traded or not should have no bearing on the protections of rights of conscience. The U.S. Supreme Court has made it clear in the *Hobby Lobby* decision, that it is not the role of government to second guess a person's religious beliefs, or what does or does not violate those beliefs. Moral objections are often grounded in religious beliefs. As long as the individual's or organization's religious beliefs are sincerely held, the government may not substitute its judgment for that of the conscientious objector.[9]

Abortifacient Drugs and Devices are Not "Contraception."

The "Interim Final Rules" require non-exempt employer coverage of *abortifacient* drugs and devices. Thus, the "Contraceptive Mandate" departs from a longstanding tradition in federal law of protecting rights of conscience with regard to respect for unborn human life. A number of so-called contraceptives are in fact abortifacients, capable of preventing the implantation of the fertilized human being after fertilization (conception). This is documented by descriptors, provided by the FDA which states publicly concerning *Plan B "*emergency contraception:"

[9] 134 S. Ct. at 2777-79 (discussing *Thomas v. Review Board*, 450 U.S. 707 (1981)).

"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)."[10]

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)."[11] In addition, 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;[12] destroying the capacity of the corpus luteum to produce progesterone for initial support of the implanted embryo;[13] and destroying the endometrial stromal tissues necessary for the survival of the embryo.[14] However, the FDA has taken the position that "conception" only occurs upon implantation in the womb. It claims that these drugs and devices are therefore nothing but "contraceptives." However, biology textbooks are clear that a new member of the human species is alive from the time of fertilization.[15] Just because the American College of Obstetricians and Gynecologists has chosen to redefine the beginning of pregnancy as after implantation of the human embryo has occurred,[16] does not change the status of that human embryo. Furthermore, millions of Americans hold religious and moral convictions about the need to respect and protect human life from its earliest stages.

Thus, the "Contraceptive Mandate" encompasses "abortion," clearly in violation of the "ACA." Specifically, the "ACA" states that "nothing" in title I of "ACA," which includes the provision dealing with preventive services, "shall be construed to require a qualified health

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

[11] Teva Pharmaceuticals, "Plan B, One-Step FAQ" (last accessed October 27, 2014). http://www.planbonestep.com/faqs.aspx.

[12] 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," *Contraception* 58.2 (August 1998): 129.

[13] 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.

[14] 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.

[15] "Development of the embryo begins at Stage 1 when a sperm fertilizes an oocyte and together they form a zygote." [England, Marjorie A. *Life Before Birth*. 2nd ed. England: Mosby-Wolfe, 1996, p.31].

[16] See Christopher M. Gacek, "Conceiving Pregnancy: U.S. Medical Dictionaries and Their Definitions of *Conception* and *Pregnancy*," *National Catholic Bioethics Quarterly* 9.3 (Autumn 2009): 543–557, originally published by Family Research Council.

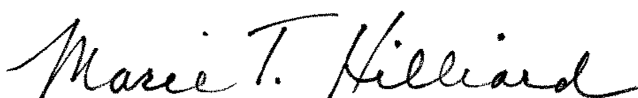
plan to provide coverage of [abortion] services … as part of its essential health benefits for any plan year," and also stating that it is the "issuer" of a plan, not the government, that "shall determine whether or not the plan provides coverage of [abortion] services".[17] Thus, the very law cited as being the foundation of the "Interim Final Rules" is violated by these same rules.

Conclusion

The "Interim Final Rules" continue to retain a regulatory scheme in which "preventive" health services are defined to include items that do not prevent disease, but rather are intended to render a woman temporarily or permanently infertile, and may be associated with adverse health outcomes. The "Contraceptive Mandated" should be rescinded in its entirety. However, the revoking of the artificially and arbitrarily differentiated definitions of the religious community, into those that are deemed "religious enough" for the "exemption" and those that are not, generally excluding those who practice their faith by most visibly serving the common good, is very welcomed and is lauded. Likewise the expansion of organizations that are exempt from the Contraceptive Mandate, to all religiously objecting organizations, is constitutionally sound and welcomed. However, the denial of such rights to a publicly traded for-profit company, that has moral objections to such covered, is a violation of their rights of conscience. Such companies should not lose their constitutional protections merely because they are publicly traded. Lastly, since even the "Final Rules" of 2015 did not require self-certification of those limited religious organizations that were exempt, no such self-certification should be required of those organizations deemed to be exempt by the "Interim Final Rules."

We thank you for considering our prior public comment on this matter of religious freedom, and welcome the changes contained herein. We ask you to consider the more far-reaching provisions that are needed to protect women from a false understanding of what will promote their health and prevent disease, as well as to protect the religious freedom of all organizations and employers.

Sincerely yours,



Marie T. Hilliard, JCL, PhD., RN
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[17] 42 U.S.C. § 18023(b)(1)(A).