



# THE NATIONAL CATHOLIC BIOETHICS CENTER

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September 27, 2011

Ms. Kathleen Sebelius, Secretary  
Department of Health and Human Services  
200 Independence Avenue, S.W.  
Washington, D.C. 20201

CMS-9992-IFC2  
45 CFR Part 147  
RIN 0938-AQ07

## **Re: Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services under the Patient Protection and Affordable Care Act**

Dear Secretary Sebelius:

On August 1, 2011 the Department of Health and Human Services (HHS) issued and implemented amendments to the Interim Final Rule (Rule) for group health plans and health insurance issuers, relating to coverage of preventive services under the Patient Protection and Affordable Care Act of 2010 (PPACA).<sup>1</sup> HHS invited comments on the regulation to be submitted on or before September 30, 2011. The National Catholic Bioethics Center (Center) wishes to take this opportunity to provide comment on the provisions of this Rule.

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.

The mandates contained in the Rule require that all group health 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. 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. We will provide comment on the following implications of such a mandate.

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<sup>1</sup> [http://www.ofr.gov/OFRUpload/OFRData/2011-19684\\_PI.pdf](http://www.ofr.gov/OFRUpload/OFRData/2011-19684_PI.pdf).

**1. The legislative history of PPACA indicates the intent to cover screening and prevention of pathological conditions of women. Yet a broad and unfounded interpretation which mandates contraceptives and abortifacients has occurred.**

In a review of the PPACA, specifically, Section 2713(a)(4), it is clear that the PPACA never stipulates the intent to mandate the inclusion of contraceptives, abortifacients, or sterilizations, with no co-pay, within “preventive care and screenings” for women. Furthermore, the Senate floor debate over the addition of Section 2713(a)(4) to the Act indicated no intent to include abortion. Section 2713(a)(4), which requires private insurance plans to cover certain preventive services for women, was added to the PPACA in an amendment offered by Senator Barbara Mikulski (D-MD) who issued a press release describing that amendment as follows:

Services that would be covered under the Mikulski Amendment are likely to include cervical cancer screenings for a broad group of women; annual mammograms for women under 50; pregnancy and postpartum depression screenings; screenings for domestic violence; and annual women’s health screenings, which would include testing for diseases that are leading causes of death for women such as heart disease and diabetes.<sup>2</sup>

In her prepared floor statement, Senator Mikulski concluded:

Often health care doesn’t cover basic women’s health care like mammograms and cervical cancer screenings. My amendment is about saving lives and saving money to give women access to comprehensive preventive services that are affordable and life saving.<sup>3</sup>

She stated further, in terms of abortion:

This amendment does not cover abortion. Abortion has never been defined as a preventive service. This amendment is strictly concerned with ensuring that women get the kind of preventive screenings and treatments they may need to prevent diseases particular to women such as breast cancer and cervical cancer. There is neither legislative intent nor legislative language that would cover abortion under this amendment, nor would abortion coverage be mandated in any way by the Secretary of HHS.<sup>4</sup>

It is evident that the legislative intent of Section 2713(a)(4) was to screen for and prevent pathological conditions of women, and not to include abortion. Despite this fact, the Institute of Medicine’s report and recommendations specify as “preventive services” the “well-women preventive visits,” described as including prenatal screening for “genetic or

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<sup>2</sup> <http://mikulski.senate.gov/Newsroom/PressReleases/record.cfm?id=320304>.

<sup>3</sup> <http://mikulski.senate.gov/Newsroom/PressReleases/record.cfm?id=320304>.

<sup>4</sup> December 3, 2009 <http://thomas.loc.gov/cgi-bin/query/F?r111:2:./temp/~r111ulsMjy:e77041>. On December 1, 2009, Senator Mikulski stated: “There are no abortion services included in the Mikulski amendment. It is screening for diseases that are the biggest killers for women—the silent killers of women. It also provides family planning—but family planning as recognized by other acts.” <http://thomas.loc.gov/cgi-bin/query/F?r111:1:./temp/~r111ulsMjy:e58173>.

developmental conditions.”<sup>5</sup> Clearly, such testing will not prevent genetic abnormalities already identified by such testing on the fetus, unless the intent is to “prevent” the fetus from being born through abortion. Furthermore, a number FDA-approved contraceptives mandated to be covered by insurers under the Rule are abortifacients, either by preventing implantation of the conceived human being, or with the potential, as with *ulipristal acetate [ella]*, of inducing an expulsion of the human being from the uterus. Moreover, IUDs are listed as contraceptives by the FDA. Prescribing information indicates that they can prevent implantation of the conceived human being.<sup>6</sup> Also, the FDA acknowledges, concerning Levonorgestrel [*Plan B*], another so-called “emergency contraceptive,” that “If fertilization does occur, Plan B may prevent a fertilized egg from attaching to the womb (implantation).”<sup>7</sup> Furthermore, the FDA is allowing *ulipristal acetate [ella]* to be marketed as an “emergency contraceptive.” FDA’s prescribing instructions for the drug admit that it may prevent implantation; and the FDA states that this drug is contraindicated in an existing pregnancy.<sup>8</sup> The FDA notes, one reason for the effectiveness of *ulipristal acetate [ella]* is that it “may also work by preventing attachment (implantation) to the uterus.”<sup>9</sup> This means *ulipristal acetate [ella]* does more than prevent conception; *ulipristal acetate [ella]* can kill the conceived human embryo. Furthermore, *ulipristal acetate [ella]* may kill an embryo even after implantation, as it has a similar chemical make-up to the abortion drug mifepristone (RU-486), which blocks natural progesterone receptors in three critical areas: destroying receptivity of the endometrial glands to embryo implantation;<sup>10</sup> destroying the capacity of the corpus luteum to produce progesterone for initial support of the implanted embryo;<sup>11</sup> and destroying the endometrial stromal tissues necessary for the survival of the embryo.<sup>12</sup> In approving *ulipristal acetate [ella]*, the FDA contraindicates *ulipristal acetate [ella]* for “existing or suspected” pregnancy. The FDA admits, “There are no adequate and well controlled studies in pregnant women.” It cites studies in animals with high rates of pregnancy loss, and it acknowledges that the effects on a fetus that survives *ulipristal acetate [ella]* are unknown. Furthermore, in animal studies 40% of first trimester fetuses aborted after exposure to high doses of this drug.<sup>13</sup> Clearly, *ulipristal acetate [ella]* and any other form of “emergency contraception” that may cause abortions, like surgical and other chemical abortions, should not be included as mandated “preventive services” under Section 2713(a)(4).

Most importantly, the Rule is creating new law in terms of mandating contraceptive, abortifacient, and sterilization coverage with no co-pay by the enrollees. This is well beyond

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<sup>5</sup> Committee on Preventive Services for Women; Institute of Medicine, *Clinical Preventive Services for Women: Closing the Gaps*, Institute of Medicine (Washington, DC: The National Academies Press, July 20, 2011), p. 112.

<sup>6</sup> *PRESCRIBING INFORMATION: ParaGard® T 380A Intrauterine Copper Contraceptive*. Accessible at , <http://www.drugs.com/pro/paragard.html>.

<sup>7</sup> U.S. Food and Drug Administration, “FDA’s Decision Regarding Plan B: Questions and Answers.” Available at <http://www.fda.gov/drugs/drugsafety/postmarketdrugsafetyinformationforpatientsandproviders/ucm109795.htm>

<sup>8</sup> [http://www.accessdata.fda.gov/drugsatfda\\_docs/label/2010/022474s000lbl.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/label/2010/022474s000lbl.pdf).

<sup>9</sup> *Ibid.*

<sup>10</sup> Jerry R. Reel, Sheri Hild-Petito, and Richard P. Blye, “Antiovaratory 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.

<sup>11</sup> 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.

<sup>12</sup> 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.

<sup>13</sup> [http://www.accessdata.fda.gov/drugsatfda\\_docs/label/2010/022474s000lbl.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/label/2010/022474s000lbl.pdf).

the provisions of the PPACA, and the statutory intent at the time of its adoption. On December 1, 2009, Senator Mikulski clearly stated: “There are no abortion services included in the Mikulski amendment. It is screening for diseases that are the biggest killers for women—the silent killers of women. It also provides family planning—*but family planning as recognized by other acts.*”<sup>14</sup> [Emphasis added.] No other federal act mandates the provision of contraceptives, abortifacients, and surgical sterilizations, with no co-pay, with so limited a religious exemption that it is virtually meaningless, as addressed in section 3., below.

## 2. Evidence supports that increased access to contraception does not prevent pregnancy.

Despite the fact that 35 states have some form of contraceptive mandate,<sup>15</sup> and many have had such mandates for over a decade, evidence increasingly is demonstrating that contraceptive use does not promote sexual responsibility and results in more unplanned pregnancies. In 2006, nearly half (49%) of pregnancies were unintended, up slightly from 2001 (48%). The unintended pregnancy rate increased to 52 per 1000 women aged 15–44 years in 2006, from 50 in 2001.<sup>16</sup> Over this same period of time, Planned Parenthood’s governmental grants and contracts increased from \$240.9 million to \$305.3 million.<sup>17</sup> During that period dramatic increases in unintended pregnancies were demonstrated among poor women—the very group that Planned Parenthood claims to help the most. Specifically, the number of poor women experiencing an unintended pregnancy per 1,000 women of childbearing age went from 120 unintended pregnancies in 2001 to 132 in 2006.<sup>18</sup> The Rule specifically identifies the supposed need to provide free coverage of college students as soon as possible. College students already have virtually universal access to free or low cost contraception,<sup>19</sup> yet statistics demonstrate that the unintended birth rate increased the most for women aged 18–24 years during this period. Rates for women aged 18–24 years were more than twice the national rate.<sup>20</sup> Thus, it is abundantly clear that providing contraceptive coverage, even with little or no cost (as the Rule mandates) does not decrease unintended pregnancies, and in fact provides false assurances that foster less sexual responsibility.

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<sup>14</sup> <http://thomas.loc.gov/cgi-bin/query/F?r111:1:./temp/~r111ulsMjy:e58173:>

<sup>15</sup> 28 states require insurers that cover prescription drugs in general to provide coverage of the full range of FDA-approved contraceptive drugs and devices; 7 states have mandates that only apply to a segment of the insurance market. See Guttmacher Institute, “Policies in Brief: Insurance Coverage of Contraceptives (Sept. 1, 2011). Accessible at <http://www.guttmacher.org/sections/contraception.php>.

<sup>16</sup> Lawrence B. Finer,\* Mia R. Zolna, *Unintended pregnancy in the United States: incidence and disparities* (Guttmacher Institute, 2006), p. 2.

<sup>17</sup> Planned Parenthood Federation of America, Inc., *Annual Report*, July 2001–2002, and 2005–2006. Accessible at <http://www.stopp.org/PPFARports/>.

<sup>18</sup> Finer and Zolna, Table 2.

<sup>19</sup> 80% of college students are covered by health insurance. See: Government Accounting Office, *Report to the Committee on Health, Education, Labor, and Pensions, U.S. Senate: Most College Students Are Covered through Employer-Sponsored Plans, and Some Colleges a States Are Taking Steps to Increase Coverage* (Washington, DC: GAO, March 2008), p.1. Accessible at <https://docs.google.com/viewer?url=http%3A%2F%2Fwww.gao.gov%2Fnew.items%2Fd08389.pdf>.

<sup>20</sup> Finer and Zolna, p. 9.

### 3. The Religious Exemption is not consistent with state laws.

HHS' discussion of the religious exemption<sup>21</sup> is both misleading and incorrect. We note first that HHS is not in fact providing for a religious accommodation; they are merely giving HRSA discretion to include such exemption in its binding guidelines if it wishes.<sup>22</sup> Specifically, amended Section 147.130(a)(1)(iv)(A) provides that HRSA "may establish"<sup>23</sup> exemptions for religious employers with respect to any requirement to cover contraceptive services.

We further note that, though claiming "to accommodate, in a balanced way,"<sup>24</sup> the religious freedom of covered employers, HHS offers the most limiting exemption possible. The proposal incorporates the language in Section 6033 of Title XXVI, exempting certain religious organizations from filing requirements under the Internal Revenue Code.<sup>25</sup> Designed to avoid excessive entanglement between church and state, Section 6033 is of doubtful relevance where accommodating religious freedom is the issue.

Nevertheless, as so restricted, only "churches, their integrated auxiliaries, and conventions or associations of churches, as well as . . . the exclusively religious activities of any religious order[.]" are eligible for HHS' proposed exemption. Consequently, Catholic hospitals and schools and universities and social service ministries must offer their employees sterilization coverage, while being allowed the right to religious freedom in not providing the same procedures for their patients, students, and clients on religious grounds. Parochial schools may not deny teachers contraceptive coverage, while, at the same time, their students are taught that contracepting violates natural moral law.<sup>26</sup> This is exactly the outcome HHS has constructed, restricting their exemption to "the unique relationship between a house of worship and its employees in ministerial positions."<sup>27</sup>

HHS correctly observes that a majority of states that require contraceptive coverage "simultaneously provide for a religious accommodation."<sup>28</sup> To contend further, however, that their proposed accommodation is "[c]onsistent with most States that have such exemptions"<sup>29</sup> is demonstrably false. Only three such states -- California,<sup>30</sup> Oregon,<sup>31</sup> and New York<sup>32</sup>-- have

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<sup>21</sup> See Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services Under the Patient Protection and Affordable Care Act, 76 *Fed. Reg.* 46621-01, 46623-24 (Aug. 3, 2011) (to be codified at 26 C.F.R. pt. 54).

<sup>22</sup> See, e.g., *id.* at 46623 ("The amendment to the interim final rules provides HRSA with the discretion to establish this exemption.").

<sup>23</sup> *Id.* at 46626.

<sup>24</sup> *Id.* at 46624.

<sup>25</sup> See 45 C.F.R. § 147.130(a)(1)(iv)(B)(4) (2011); 76 *Fed. Reg.* 46621-01 (Aug. 3, 2011) (to be codified at 26 C.F.R. pt. 54) (incorporating by reference 26 U.S.C. §§ 6033(a)(1), (3)(A)(i), (iii) (2011)).

<sup>26</sup> Most Catholic hospitals and some Catholic schools would also not qualify for the exemption since they do not employ or do not serve primarily "persons who share . . . [their] religious tenets[.]" 45 C.F.R. §§ 147.130(a)(1)(iv)(B)(2), (3)(2011); 76 *Fed. Reg.* 46621-01 (Aug. 3, 2011) (to be codified at 26 C.F.R. pt. 54).

<sup>27</sup> *Id.* at 46623.

<sup>28</sup> *Id.* See National Conference of State Legislatures, "Insurance Coverage for Contraception State Laws," available at <http://www.ncsl.org/default.aspx?tabid=14384#m> (accessed Sept. 3, 2011).

<sup>29</sup> 76 *Fed. Reg.* 46623 (Aug. 3, 2011) (to be codified at 26 C.F.R. pt. 54) ("The definition of religious employer, as set forth in the amended regulations, is based on existing definitions used by most States that exempt certain religious employers from having to comply with State law requirements to cover contraceptive services.").

<sup>30</sup> See CAL. HEALTH & SAFETY CODE § 1367.25(b) (West 2003); CAL. INS. CODE § 10123.196(d) (West 2000).

<sup>31</sup> See OR. REV. STAT. ANN. § 743A.066 (4) (West 2011).

<sup>32</sup> See N.Y. INS. LAW §§ 3221(l)(16)(A)(1), 4303(cc)(1)(A) (McKinney 2011).

exemptions nearly identical to what HHS proposes. Only these three, along with Arizona,<sup>33</sup> incorporate the restrictions of Section 6033. Arizona, however, does not require religious employers to claim that inculcation of religion is the purpose of their organization.<sup>34</sup> Thus, social services, for example, which churches or their auxiliaries directly provide primarily through and for members of the faith, arguably would come within Arizona's exemption.

Three other states define "religious employer" somewhat similarly to HHS' proposal.<sup>35</sup> Hawaii, however, expressly includes within its exemption "any educational, health care, or other nonprofit institution or organization owned or controlled by the religious employer [.]"<sup>36</sup> Further, in Arkansas<sup>37</sup> and North Carolina,<sup>38</sup> religious employers are only required to operate 501(c)(3) organizations, have the inculcation of religious values as only one of their primary purposes, and employ, but not serve, primarily members of the faith. Such qualifications would clearly include parochial schools within the exemption and possibly social service ministries.

In contrast, five states mandating contraceptive coverage -- Connecticut,<sup>39</sup> Maine,<sup>40</sup> Massachusetts,<sup>41</sup> New Jersey,<sup>42</sup> and Rhode Island<sup>43</sup> -- incorporate in whole or in part the provisions of Section 3121(w) of Title XXVI, which accommodates certain employers' right to religious freedom regarding payment of Social Security taxes. By including parochial schools within its exemption,<sup>44</sup> as well as qualified church-controlled organizations, not required to have the inculcation of religious values as their purpose or primarily to employ or serve members of the faith,<sup>45</sup> Section 3121(w) accommodates the beliefs of religious employers more

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<sup>33</sup> See ARIZ. REV. STAT. ANN. § 20-826(Z), (AA)(3); *id.* at, § 20-1057.08(B),(G); *id.* at § 20-1402(M), (N)(3); *id.* at § 20-1404(V)(W)(3); *id.* at § 20-2329 (B), (F).

<sup>34</sup> See *id.*

<sup>35</sup> Cf. Michigan Civil Rights Commission, Declaratory Ruling 7-26-06\_169371\_7 (Aug. 21, 2006), Available at [http://www.michigan.gov/documents/Declaratory\\_Ruling\\_7-26-06\\_169371\\_7.pdf](http://www.michigan.gov/documents/Declaratory_Ruling_7-26-06_169371_7.pdf) (accessed Sept. 4, 2011)(declaring employers' failure to include contraceptive coverage in comprehensive drug benefits pregnancy discrimination but recognizing a religious employer exemption, not incorporating § 6033, that would include, for example, certain private religious schools and colleges). Mandate's enforceability has been questioned.

<sup>36</sup> See HAW. REV. STAT. § 431:10A-116.7(a) (West 2011). Unlike the proposed exemption, Hawaii only requires the religious entity to constitute a 501(c)(3) nonprofit organization and may serve persons not primarily of the employer's faith. See *id.*

<sup>37</sup> See ARK. CODE ANN. § 23-79-1102(3) (West 2011); *id.* at § 23-79-1104(b)(3).

<sup>38</sup> See N.C. GEN. STAT. ANN. § 58-3-178(e) (West 2011). Though the entity must be "organized and operated for religious purposes" *id.* at § 58-3-178(e)(1), the inculcation of religious values need be only one among its primary purposes. See *id.* at § 58-3-178(e)(1)-(2).

<sup>39</sup> See CONN. GEN. STAT. ANN. § 38a-503e (b)(1),(f) (West 2011); *id.* at § 38a-530e (b)(1),(f) ("qualified church-controlled organization," as defined in 26 U.S.C. § 3121, or church-affiliated organization).

<sup>40</sup> See ME. REV. STAT. ANN. tit. 24, § 2332-J (2) (2011); *id.* at § 2756 (2) ; *id.* at § 2847-G (2) ; *id.* at § 4247(2) (Section 501(c) (3) "church," as defined in 26 U.S.C. § 3121(w)(3)(A)).

<sup>41</sup> See MASS. GEN. LAWS. ANN. ch. 175 § 47W(c) (West 2011); *id.* at 176A § 8W(c); *id.* at 176B § 4W(c); *id.* at 176G § 4O(c) ("church" or "qualified church-controlled organization," as defined in 26 U.S.C. § 3121(w)(3)(A) & (B)).

<sup>42</sup> See N.J. STAT. ANN. § 17:48-6ee(A) (West 2011); *id.* at § 17:48A-7bb(A); *id.* at § 17:48E-35.29(A); *id.* at § 17:48F-13.2(A); *id.* at § 17B:26-2.1y; *id.* at § 17B:27-46.1ee; *id.* at § 17B:27A-7.12; *id.* at § 17B:27A-19.15; *id.* at § 26:2J-4.30 (Section 501(c)(3) "church," as defined in 26 U.S.C. § 3121(w)(3)(A)).

<sup>43</sup> See R.I. GEN. LAWS § 27-18-57(b), (c) (West 2011); *id.* at § 27-19-48(b),(c); *id.* at § 27-20-43(b), (c); *id.* at § 27-41-59(b), (c) ("church" or "qualified church-controlled organization," as defined in 26 U.S.C. § 3121).

<sup>44</sup> See 26 U.S.C. § 3121(w)(3)(A) (2011). All but Connecticut incorporate this provision. See *supra* notes 20-23.

<sup>45</sup> See *id.* at § 3121(w)(3)(B)(Such organization must be tax-exempt under § 501(c)(3) and may not normally receive more than 25% of its revenue either from the government or from the sale of goods, services, or facilities to the general public at fair market value in the course of related business activities.). Connecticut, Massachusetts, and Rhode Island incorporate this provision. See *supra* notes 19, 21, and 23.



broadly than the exemption HHS proposes.<sup>46</sup> Similarly, another four states -- Maryland,<sup>47</sup> Missouri,<sup>48</sup> New Mexico,<sup>49</sup> and West Virginia<sup>50</sup> -- do provide exemptions broad enough to include a broad range of religious employers.<sup>51</sup> It is also worth noting that, like Missouri,<sup>52</sup> Nevada,<sup>53</sup> and Texas<sup>54</sup> exempt health benefit plans, issued by entities associated with religious organizations, from covering contraceptives services. Likewise, Illinois protects “health care payers,” without further restriction, that refuse to pay for services which violate their conscience.<sup>55</sup>

Lastly, despite claims to the contrary and unlike the mandates in the Rule, it is rare to find a state mandate providing surgical sterilization coverage. Plainly, states mandating contraceptive coverage pursue a patch-work of approaches to exemptions for religious employers. Nevertheless, to claim that HHS’ proposal is consistent with a majority of such states is simply wrong. Many states have robust conscience protections/religious exemptions, much broader than those in the Rule, which inaccurately uses examples from state law to justify its unjust mandates. Furthermore, when examining legislative intent, it is clear that the IOM’s recommendations, as promulgated in the Rule, have created new law. As indicated earlier, on December 1, 2009, Senator Mikulski clearly stated: “There are no abortion services included in the Mikulski amendment. It is screening for diseases that are the biggest killers for women—the silent killers of women. It also provides family planning--*but family planning as recognized by other acts.*”<sup>56</sup> [Emphasis added.] No other federal act mandates the provision of contraceptives, abortifacients, and surgical sterilizations, with no co-pay, with so limited a religious exemption, that it is virtually meaningless.

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<sup>46</sup> See instructions to Form 8274 for Electing the Exemption under § 3121, available at [http://www.irs.gov/pub/irs-access/f8274\\_accessible.pdf](http://www.irs.gov/pub/irs-access/f8274_accessible.pdf) (accessed Sept. 2, 2011). In contrast, “seminaries, religious retreat centers, or burial societies generally will be eligible[;]” “[a] church-run orphanage or home for the elderly that is open to the general public may qualify[;]” “[c]hurch pension boards, fund-raising organizations, and auxiliary organizations such as youth groups and ladies auxiliaries generally may make the election.” *Id.*

<sup>47</sup> See MD. CODE ANN., INS. § 15-826(c) (1) (West 2011) (religious organization (not otherwise restricted)).

<sup>48</sup> See MO. ANN. STAT. § 376.1199(4)(1) (West 2011) (entities whose “moral, ethical, or religious” tenets oppose the provision of contraceptive services).

<sup>49</sup> See N.M. STAT. ANN. § 59A-22-42(D) (West 2011); *id.* at § 59A-46-44(c) (religious entity (not otherwise restricted)).

<sup>50</sup> See W. VA. CODE ANN., § 33-16E-7(a) (West 2011); *id.* at § 33-16E-2(5) (an entity is a “religious employer” if its “sincerely held religious beliefs or sincerely held moral convictions are central to . . . [its] operating principles” and if it is listed either under § 501(c)(3), under § 3121, or in the Kennedy Directory).

<sup>51</sup> See also DEL. CODE ANN. tit. 18, § 3559(d) (West 2011) (exemption for religious employer (not otherwise restricted) from coverage for “insertion and removal and medically necessary examination associated with the use of . . . contraceptive drug[s] or device[s].”).

<sup>52</sup> See MO. ANN. STAT. § 376.1199(4)(3) (West 2011).

<sup>53</sup> See NEV. REV. STAT. ANN. § 689A.0415(5) (West 2011); *id.* at § 689A.0417(5); *id.* at § 689B.0376(5); *id.* at § 689B.0377(5); *id.* at § 695B.1916(5); *id.* at § 695B.1918(5); *id.* at § 695C.1694(5); *id.* at § 695C.1695(5) (insurer or health maintenance organization affiliated with a religious organization (not otherwise restricted)).

<sup>54</sup> See TEX. INS. CODE ANN. art. 8 § 1369.104(a) (West 2011); *id.* at § 1369.108(a) (entity issuing health benefit plan associated with a religious organization (not otherwise restricted) are to offer the option to employers).

<sup>55</sup> See 215 ILL. COMP. STAT. ANN. 5/356z.4 (a) (West 2011); *id.* at 745 ILCS § 70/11.2-4.

<sup>56</sup> <http://thomas.loc.gov/cgi-bin/query/F?r111:l:/temp/~r111ulsMjy:e58173:>

**4. The Catholic Church is the largest provider of non-governmental health care, social services, and education; thus the virtually meaningless “religious exemption” violates the religious freedom of thousands of faith-based entities.**

The Catholic Church is the largest provider of non-governmental health care, social services, and education in the United States. The Catholic Church has been engaging in its ministries for centuries, long before the government became involved in these endeavors. Based on the Free Exercise Clause of the United States *Constitution*<sup>57</sup> these ministries have every right to the religious freedom guaranteed by that *Constitution*, to continue to engage in these ministries without having to violate the very tenets that led to the creation of such ministries. The proposed Rule clearly threatens the continuation of such ministries. Catholic Charities of the United States serves over 9 million persons in need annually, who are of any or no faith, through 1,700 of its agencies. Furthermore it provides employment to 65,227 employees who would no longer be employed if the very existence of such ministries is compromised.<sup>58</sup> Similarly, each year one in six patients, regardless of religious affiliation, is cared for in a Catholic hospital. Catholic hospitals admit 5.6 million patients, and provide for 19 million emergency room visits, and 102 million outpatient visits annually. Furthermore, they employ over 750,000 employees, again, providing for the economic stability of communities.<sup>59</sup> Likewise, 400 years after the first Catholic School in the United States opened in Florida, there are 7,000 elementary and secondary schools in the United States, with 1.2 million students, a significant number of whom are not Catholic.<sup>60</sup> Also, there are over 221 Catholic colleges and universities, accounting for half of all institutions of higher education in the United States. These institutions enroll 720,000 students annually, with only 65% of them of the Catholic faith.<sup>61</sup> Thus, the very narrow exception contained in the Rule would violate the religious freedom of over 7200 Catholic education institutions, both at the basic and higher education levels, 1,700 Catholic Charities agencies, and hundreds of Catholic health care facilities/agencies in the United States.

While the aforementioned ministries are sponsored by the Catholic Church, there are many more non-Catholic faith-based ministries whose religious liberties will be violated by this mandate. Thus, if this unsound mandate is not rescinded, there is a need for a robust religious exemption, consistent with other constitutionally sound protections of religious freedom/conscience in existing state law, as indicated above. Furthermore, there are numerous and historical federal statutory provisions to respect religious freedom/conscience, most notably, the statutory prohibition in the PPACA against mandating that health care providers participate in assisted suicide<sup>62</sup> or abortion.<sup>63</sup> There is no reason why such rights of religious freedom/conscience, intended to be protected by our United States *Constitution*,

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<sup>57</sup> “The Constitution of the United States”, Amendment One.

<sup>58</sup> Catholic Charities USA, “At a Glance” (2009), and Annual Report (2010). Accessible at [www.CatholicCharitiesUSA.org](http://www.CatholicCharitiesUSA.org).

<sup>59</sup> Freedom2Care, “Impact of Faith-Based Health Care.” Accessible at [www.Freedom2Care.org](http://www.Freedom2Care.org).

<sup>60</sup> National Catholic Education Association, “A Brief Overview of Catholic Schools in America” (2010). Accessible at <http://www.ncea.org/about/historicaloverviewofcatholicschoolsinamerica.asp>.

<sup>61</sup> “Catholic Colleges and Universities in the United States,” *International Student Guide to the United States of America*. Accessible at [http://www.internationalstudentguidetotheusa.com/articles/catholic\\_colleges.php](http://www.internationalstudentguidetotheusa.com/articles/catholic_colleges.php).

<sup>62</sup> PPACA, §1553.

<sup>63</sup> PPACA, §1303.



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 faith-based provider in this country, which has clearly and consistently indicated that contraception and abortifacients are inconsistent with its tenets.

**5. Pregnancy is not a disease to be prevented, nor is the embryo an enemy who once conceived has no right of access to the nurturing womb of his or her mother.**

Pregnancy is a normal physiological process in human beings and animals, alike; and designating contraceptives as “preventive services” negates sound science since “preventive services” prevent serious disease, dysfunction and/or injury which would require treatment to restore health or function. Fertility is a natural quality of human nature, and pregnancy is a natural human condition. If they were not, the federal government would be mandating coverage to “cure” pregnancy. Pregnancy follows its own natural course which ends in the live birth of a baby, if not interrupted by medical intervention or miscarriage. The “cure” or “treatment” to eliminate this condition would have to be an abortion. But as a matter of clear statutory policy, PPACA prohibits any federal mandate to cover abortion as an essential health benefit in *all* circumstances. [PPACA, §1303(b)(1)(A)]. Indeed, the Act not only leaves health plans free to exclude abortion, but explicitly allows each state to forbid coverage of abortion throughout its exchange. [*Id.*, §1303(a)(1)]. Finally, with regard to the multi-state qualified health plans established under PPACA, at least one of these plans must exclude most abortions. [*Id.*, §1334(a)(6)]. In these provisions, the PPACA treats pregnancy as a healthy condition, and does not treat the existence of an unborn human life as an illness or condition requiring the “treatment” of abortion. It would be inconsistent to *require* all health plans to commit themselves to preventing this same condition.

Furthermore, 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,<sup>64</sup> as well as cervical cancer, and liver cancer.<sup>65</sup> 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.<sup>66</sup> Designating contraceptives as “preventive services” would give the false impression that these are safe and standard medications. This is particularly true when the Rule speaks of the urgency to assure their availability to college students, whose potential for long-term use and ignoring of risks, such as smoking, are heightened.

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<sup>64</sup> 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](http://www.rxlist.com/ortho_tri-cyclen-drug.htm).

<sup>65</sup> National Cancer Institute, “Oral Contraceptives and Cancer Risk: Questions and Answers,” *National Cancer Institute Fact Sheet*. Available at <http://www.cancer.gov/cancertopics/factsheet/Risk/oral-contraceptives>.

<sup>66</sup> 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.

**6. The Institute of Medicine (IOM) conducted a flawed process of engaging the health care community in determining the definition of “preventive services” within the *Patient Protection and Affordable Care Act*.**

As stated, the Catholic Church is the largest provider of non-governmental health care in the United States. Yet, not one representative of such health care was among the invited presenters or the IOM committee charged with studying this issue. Even if there had been an invitation extended and declined to a particular provider, there are thousands of other such providers who could have officially represented Catholic health care in the United States. The impact of the recommendations of the IOM which would violate the religious freedom of Catholics is significant, leaving one to ask, why was there such a glaring lack of balanced inclusion of presenters? At the same time there was an obvious effort to provide inclusion on parameters of ethnicity and gender identity. Yet, the glaring lack of inclusion of Catholic faith-based sponsorship was very disturbing,

The presenters overwhelmingly were representatives of agencies which will benefit financially, as contraceptives and abortifacients now are included as mandated preventative services. There were invited presenters associated with groups that have demonstrated negative attitudes toward Catholic health care, including Planned Parenthood and Merger Watch.

Presenters claimed that 50% of the United States pregnancies are unplanned and stated that this was a reason to require health plans to include contraceptives as preventive services. As demonstrated earlier, this conclusion is erroneous; contraception is universally available in the United States. Yet, as was stated during the IOM hearings, the United States has the highest unplanned pregnancy rate in the developed world. Contraceptive availability has not reduced unplanned pregnancies, and the facts support the more accurate conclusion that contraceptive availability has fostered an unhealthy sexual life-style for women.

One comment made by a presenter should be offensive to any woman, particularly those who have advanced a feminist program. The presenter opined that one reason for so many advanced degrees of women present in the room, was due to family planning. The assumption is that women who have chosen not to contracept are less educated than those who choose contraception. All women who purport to value freedom to choose their family size should be offended by such a bias. Furthermore, the comments made by presenters that contraception should be a mandated “preventive service” violate the consciences of all who hold a differing view.

The biased and incomplete data presented were a reflection of the mechanism used to recruit presenters. The United States Department of Health and Human Services knows the experts reflective of the true diversity of health care in this county. The Department interfaces with these Catholic agencies regularly, and should have made sure that there was diversity of representation in a forum which was in search of truth. We regret that such a diversity was not only not in evidence, but processes to attempt to achieve equal representation also were not in evidence. This is not the appropriate mechanism for achieving true inclusiveness of opinion so critical to the American democratic process.

In summary, treating pregnancy as a disease that should be prevented is medically, socially, and anthropologically inaccurate and sexually biased. By treating pregnancy as a disease to be prevented one can only conclude that the treatment for such a “disease” is an abortion. Thus, the Rule is acting against the very provision in the PPACA and its legislative history, that state that abortion is not one of the “preventive services” to be included in the “services” provided. Yet the Rule clearly mandates coverage at no cost for contraceptives and sterilizations to prevent the “disease” of pregnancy, genetic screening of existing pregnancies whose “treatment” will for some include abortion, and abortifacients which cause the termination of the newly conceived human being. These and other contraceptives are presented inaccurately as a deterrent to unplanned pregnancies, when the very data presented by the IOM to support such claims belie these claims. Empowering women to know and act with their bodies to manage their fertility in a responsible manner is the real answer to the physiological, social, and psychological problems created by a culture encouraging women to engage in unhealthy life styles. Then, forcing others to participate in and to pay for the life style choices of others, which clearly and demonstrably have been detrimental, is the utmost violation of the United States *Constitution*. The legislative intent never was to mandate that all insurance plans be required to provide, with no co-pay, contraceptives, abortifacients and sterilizations. This Rule not only is creating new law, but violating the *Constitutional* protections of religious freedom in the process. At a minimum, a robust protection of religious freedom is needed, to protect the very foundation upon which this country was based; and of great importance to the wellbeing of this county is the recognition that the existing Rule is merely going to replicate and maximize the failed initiatives to address the problem of unplanned pregnancies and sexual irresponsibility.

Sincerely yours,

A handwritten signature in cursive script that reads "Marie T. Hilliard". The signature is written in black ink and is positioned below the text "Sincerely yours,".

Marie T. Hilliard, MS (Maternal Child Health Nursing), PhD, RN  
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