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Upholding the Principles of the Catholic Faith in the Science and Practice of Medicine

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June 19, 2012

Submitted Electronically

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Ave., S.W.
Washington, D.C. 20201

Re: Advance Notice of Proposed Rulemaking on Preventive Services File Code No. CMS-9968 ANPRM

Dear Sir or Madam:

On behalf of the Catholic Medical Association (CMA), we are writing to provide comments on the Advance Notice of Proposed Rulemaking ("ANPRM") on preventive services, 77 Fed. Reg. 16,501 (March 21, 2012), which announces and explores the Obama administration's intent to issue additional regulations to implement the Final Rule issued on February 15, 2012, Group Health Plans and Health Insurance Issuers Relating to the Coverage of Preventive Services Under the Patient Protection and Affordable Care Act, 77 Fed. Reg. 8725 (Feb. 15, 2012) (the HHS Mandate or Mandate) while "accommodating" certain non-exempt religious institutions which otherwise would be fully subject to the terms of the Mandate.

The Catholic Medical Association is the largest association of Catholic physicians and health-care professionals in the United States, with over 1,800 members representing 75 medical specialties. The CMA is recognized as a national Catholic organization by the United States Conference of Catholic Bishops, and its members strive to uphold the principles of the Catholic faith in the science and practice of medicine. CMA members are greatly concerned by the HHS Mandate because of its impact on Catholic institutions, on the rights of American citizens, on the health of patients, and on the conscience rights of physicians and health-care professionals. We will outline our chief concerns with the HHS Mandate and the ostensible "accommodations" contained in the ANPRM, and will respond to specific HHS assertions and questions, as appropriate, below.

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1. The Original HHS Mandate Is Fatally Flawed

The CMA has pointed out on several occasions, but it bears repeating nevertheless, that the original decision of the Department of Health and Human Services (HHS) dictating that all health insurance plans must provide and fully subsidize all FDA-approved contraceptives (including abortifacients such as ulipristal ("ellaOne") described as contraceptives) and sterilization services is fatally flawed as a matter of logic, sound medical practice, and public policy—even apart from the issue of coercing religious institutions and employers to violate their beliefs.

- Designating contraceptives as "preventive services" fails the tests of logic and 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 feature of human nature, and pregnancy is a natural human condition, even if not always planned or desired.
- 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, depression, deep venous thrombosis, pulmonary emboli, cervical cancer, and liver cancer.[1] The relationship between OC use and breast cancer[2]—and in particular the disturbing connection between OC use and triple-negative breast cancer (for which OCs raise the risk by 2.5 to 4.2 times,)[3]—should cause caution and concern. Designating contraceptives as "preventive services" would give the false impression that these are safe and standard medications.
- Promoting contraceptives in order to reduce unplanned pregnancies has failed in the past and will fail in the future. Despite decades of such advocacy and millions, if not billions, of dollars spent in the effort, and despite the fact that 35 states mandate some level of contraceptive coverage as a part of prescription drug coverage, the Guttmacher Institute still reports that nearly half of all pregnancies among American women are unintended and that 54% of women who have abortions had used a contraceptive method during the month they became pregnant.

Moreover, it has become even clearer in retrospect that the process by which the Institute of Medicine arrived at a recommendation was significantly flawed. The IOM panel was stacked with representatives with records of being tied to or substantially supportive of Planned Parenthood and the National Abortion Rights Action League. Not one representative of a Catholic health-care institution was invited to make a formal presentation to the panel.[4]

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[1] See Rebecca Peck, M.D., C.C.D., Charles W. Norris, M.D., "Significant Risks of Oral Contraceptives (OCPs): Why This Drug Class Should *Not* Be Included in a Preventive Care Mandate," 79(1) *Linacre Quarterly* (Feb. 2012), 41-56.

[2] C. Kahlenborn, M.D., et al., "Oral Contraceptive Use as a Risk Factor for Premenopausal Breast Cancer: A Meta-analysis," *Mayo Clin Proc*. 2006;81(10):1290-1302

[3] 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

[4] See Arland K. Nichols, *Promised Objectivity, Americans Receive Planned Parenthood Ideology*, Feb. 1, 2012, available at http://www.hliamerica.org/truth-and-charity-forum/promised-objectivity-americans-receive-planned-parenthood-ideology/

2. The Final Rule Retains an Intolerable Violation of Religious Liberty

Apart from the significant flaws in substance and process, the HHS Mandate is also characterized by an unprecedented, illegal, and unjust attack on religious liberty. This attack has at its core a coercive demand that religious institutions and faithful American citizens directly pay for products and services which contradict their faith, and a 4-part, extraordinarily restrictive definition of what constitutes a religious institution. In this regard, it must be pointed out that:

The Final Rule attempts to establish a definition of religious institutions, and of religion itself, without statutory authority. According to the Final Rule, an organization can qualify as a "religious employer," only if it has: (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. 77 Fed. Reg. at 8726. Such a definition is not only without foundation in the law, it is incompatible with the beliefs of millions of Americans and, in particular, with millions of Catholics past and present, who do not restrict their religious identity or ministries to serving and/or employing only fellow Catholics and who do not proselytize as a condition of serving others.

Moreover, no federal law has ever required private health insurance plans to cover contraception or sterilizations. All attempts to enact such a requirement through legislation have failed. Therefore, the demand contained in the Mandate is utterly unprecedented in American history.

The HHS Mandate is illegal because it clearly violates the Religious Freedom Restoration Act (RFRA) on its face, and it is only a matter of time until such a finding is made by a federal court. Under RFRA, a federal law may substantially burden a person's exercise of religion only if it can be demonstrated that application of the burden to the person: (1) furthers a compelling governmental interest; and (2) is the least restrictive means of furthering that compelling governmental interest. Given the well-known universal availability of the very services the Administration seeks to mandate, the case cannot be made that there is a compelling governmental interest in forcing all private health insurance plans to subsidize them—including, in particular, the health plans offered by religious institutions. And, given the real conceptual and administrative challenges in reaching an accommodation, as outlined in the ANPRM, the case cannot be made that forcing religious institutions to participate in providing such services is the least restrictive means of furthering the interests of the Administration.

Ultimately, the Mandate is unjust, because it denies a fundamental human right, and the first among all rights contained in the Constitution (see below).

3. The ANPRM Fails to Propose Meaningful Relief for the Denial of Religious Freedom.

The ANPRM makes no change in the terms of the Mandate itself or in the unprecedented definition of religion. The proposals which the ANPRM makes for those religious institutions which HHS plans to offer an exemption are unsatisfactory because they still necessarily involve the religious institutions as participants in the scheme to provide the subsidized benefits, and because they are unduly burdensome.

One solution proposed in the ANPRM for those religious institutions which purchase group health insurance is to have the health insurance issuer provide and administer the desired subsidized benefits. However, the religious institution will still necessarily be involved in the transactions for two reasons: (1) because a condition of the subsidized benefits being offered in this manner is that the religious institution provide health insurance in the first place and (2) because it will be necessary for the religious institution to provide personnel information, including contact information, for its employees and their beneficiaries, to the issuer. Thus, the religious institution is still essentially involved in activities which violate its beliefs.

In the case of those (and, in fact, many) religious institutions which self-insure, the ANPRM proposes that a third-party administrator (TPA) both pay for and administer the subsidized benefits. Apart from the issue of unacceptable cooperation noted above, this scheme has the additional problem that TPAs do not have, and do not build into their services, the funding to provide such benefits and administrative services. All of the alternatives in this case are unacceptable; either the TPA will have to establish new charges for self-insured institutions which would provide it funding for services and administration; or the TPA would have to charge other customers extra to provide it with the funding; or the TPA will have to become uncompetitive in the marketplace and likely will go bankrupt. See the comments of Michael W. Ferguson, chief operating officer, Self-Insurance Institute of America, Inc., submitted May 7, 2012.

Finally, even if the problems above could be addressed, it remains the case that the ANPRM makes no provision for many other institutions and individuals, of many different faiths, which have ethical and religious objections to some or all of the HHS Mandate. A final rule which fails to protect the constitutional rights of all, as opposed to merely some religious institutions which can meet an arbitrary administrative test, is ultimately unsatisfactory.

4. The ANPRM Introduces New Problems and Provisions Impacting the Freedom and Well-Being of American Citizens

The ANPRM negatively impacts the freedom and well-being of millions of American citizens. First, the ANPRM claims in at least two places that the de novo, 4-part federal definition of religion "will not be applied with respect to any other provision of the PHS Act, ERISA, or the Code nor is it intended to set a precedent for any other purpose," 77 Fed. Reg. at 16,502, 16,504. However, there is no legal basis under which HHS could guarantee that this definition will be effectively quarantined. Moreover, the ANPRM then goes on to note that the scope of the religion- and conscience-based exemptions [to contraceptive mandates and to rights of religious freedom more generally] varies among the States. To deal with the potential discrepancy between federal and state law, the ANPRM invokes federal health insurance coverage regulation, which "creates a floor to which States may add consumer protections, but may not subtract. This means that, in states with broader religious exemptions than that in the final regulations, the exemptions will be narrowed to align with that in the final regulations because this will help more consumers," 77 Fed. Reg. at 16,502. In effect, the ANPRM erases state laws protecting conscience rights and religious freedom merely in the name of "helping consumers." This is a substantial loss of freedom for individuals and institutions, as well as a significant denial of the principle of federalism. If allowed to stand, this approach cannot help but to extend this policy and definition of "religious institution" as precedent.

Second, the ANPRM noticeably reduces the rights and freedoms of parents and patients. In the Final Rule issued February 15, the Administration indicated its plan to have insurers "offer contraceptive coverage directly to the employer's plan participants (and their beneficiaries) who desire it," 77 Fed. Reg. at 8725, 8728 (emphasis added). However, the ANPRM changes this language in a significant manner—now insurers and third-party administrators will be required by HHS to "provide this coverage automatically to participants and beneficiaries covered under the organization's plan" (for example, without an application or enrollment process), 77 Fed. Reg. at 16,505 (emphasis added). This undercuts the rights of parents, whose children will have access to these services whether they want it or not. More ominously, such a provision seems designed to facilitate the provision of such services to children without their parents knowledge, as recommended in a report from the Guttmacher Institute.[5] Apart from parents, individual women will lose their freedom to decline, and to decline to pay for, services which violate their religious beliefs and which they have no intention of utilizing. These are additional and significant problematic elements introduced by the ANPRM.

5. The Departments Should Adopt an Appropriate and Expansive Definition and Exemption for Religious Organizations

The ANPRM poses the question, "What entities should be eligible for the new accommodation (that is, what is a ''religious organization''? 77 Fed. Reg. at 16,504. The CMA holds that the Departments should adopt a definition that is based on sound statutory and historical precedent. As the National Catholic Bioethics Center has noted, there is already a legal source of identification for Catholic religious organizations, recognized by the United States federal government through its "Group Ruling." The United States Conference of Catholic Bishops' *The Official Catholic Directory* (the *Kenedy Directory*) is such a legal source. Those organizations listed in the *Kenedy Directory* have been determined by the Internal Revenue Service (IRS) to be exempt from federal income tax under section 501(c)(3) of the Internal Revenue Code since 1946. Each organization must meet three major criteria for inclusion in the Group Ruling: (A) it must be described in section 501(c)(3) of the Code; (B) it must be a public charity, rather than a private foundation, within the meaning of section 509(a) of the Code; and (C) it must be an agency, instrumentality, or an educational, charitable, or religious institution that is operated, supervised, or controlled by or in connection with the Roman Catholic Church in the United States. Criterion (C) provides a well-founded definition in federal law for what constitutes a Catholic religious organization. The CMA could accept such a definition of religious organizations, provided that the rights of other individuals and institutions were not prejudiced under the law.

The CMA specifically rejects, however, the application of Internal Revenue Code section 414(e) in this context to determine the definition of a "religious organization." The problem with this section is that, depending on how strictly courts interpret whether an organization shares "common religious bonds and convictions" with a church, many organizations, including nondenominational Christian schools, colleges, charities and other organizations that are not affiliated with a recognized "church," may be excluded from the definition of "religious organization" despite the fact that they were founded by and are operated in accordance with people of faith.

6. Conclusion: The ANPRM and Conscience Rights of Health-Care Professionals

[5] Guttmacher Institute, "Implications for Health Care Reform," in *Uneven & Unequal: Insurance Coverage and Reproductive Health Services* (Jan. 1995).

Apart from the many substantial flaws and inadequate solutions found in the HHS Mandate and the ANPRM, members of the Catholic Medical Association are gravely concerned at what this government policy presages for respect for rights of conscience in health care. In brief, members of the CMA are concerned that, if an Administration is willing and able to brazenly violate the most basic human and constitutional rights of American citizens in the name of advancing a flawed public policy, it can only be a matter of time before that Administration attacks the right of physicians and health-care professionals to exercise conscientious and professional judgment in medicine, for example, by declining to provide or participate in acts of abortion, contraception, and sterilization.

Members of the CMA watched with alarm the passage of the Patient Protection and Affordable Care Act, during which Senator Coburn's amendment (no. 828) protecting freedom of conscience for patients and health-care providers was defeated on a near party-line vote. While the final version of PPACA contained some protections for conscience rights within health-care exchanges and new protections against being forced to provide or participate in euthanasia or physician-assisted suicide, nevertheless it left many issues of conscience protection unresolved. Finally, CMA members were alarmed by the fact that the Department of Health and Human Services rescinded almost the entirety of the Final Rule Ensuring That Department of Health and Human Services Funds Do Not Support Coercive or Discriminatory Policies or Practices in Violation of Federal Law, 45 CFR Part 88, RIN 0991–AB48, issued December 19, 2008. Specifically, in February 2010, HHS removed all those sections which helped to effectively implement existing federal law, including definitions, statements of applicability, statements of requirements and prohibitions, and written certification of compliance.

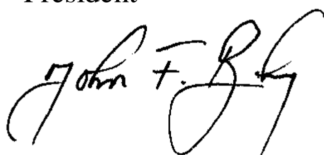
Attempted coercion of health-care providers will drive out of medical practice many physicians who take their ethical obligations and the Hippocratic Oath seriously. If this happens, millions of women will lose access to physicians who share their beliefs and to health care more generally.

In sum, then, given the substantial flaws present in the Mandate itself, its unprecedented definition of religion, and the ANPRM's inherently unsatisfactory attempts to "accommodate" religious liberty while privileging the mandatory subsidy of health insurance benefits for abortifacients, contraception, and sterilization, the Catholic Medical Association urges the responsible federal Departments to rescind the Mandate in its entirety.

Thank you.

Sincerely,

Maricela P. Moffitt, M.D., M.P.H.
President



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