CATHOLIC MEDICAL ASSOCIATION
Upholding the Principles of the Catholic Faith in the Science and Practice of Medicine

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-9968-P

Dear Sir or Madam:

On behalf of the board and members of the Catholic Medical Association, we respectfully submit the following comments on the Notice of Proposed Rulemaking ("NPRM") on preventive services. 78 Fed. Reg. 8456 (Feb. 6, 2013).

With almost 2,000 national members representing over 75 specialties in medicine, and many hundreds of local members across the country, the Catholic Medical Association (CMA) is the largest membership association of Catholic physicians and healthcare professionals in the United States. CMA members are inspired and guided by their faith to care for thousands of patients and to provide important service to their communities and to the Catholic Church.

This is the third time that the Catholic Medical Association has provided comment on Rule on Preventive Services[1] (the Rule or Mandate) at the request of the Department of Health and Human Services.[2] The CMA finds that several of the same substantive flaws criticized in earlier

[1] The Rule on Preventive Services has been created by an interpretation of the Patient Protection and Affordable Care Act, Public Law 111–148 and the Health Care and Education Reconciliation Act of 2010, Public Law 111–152 (collectively, the Affordable Care Act), which modified provisions of part A of title XXVII of the Public Health Service Act (PHS Act) relating to group health plans and health insurance issuers in the group and individual markets and adds section 715(a)(1) to the Employee Retirement Income Security Act (ERISA) and section 9815(a)(1) to the Internal Revenue Code (Code) to incorporate the provisions of part A of title XXVII of the PHS Act into ERISA and the Code, and make them applicable to group health plans. Section 2713 of the PHS Act, combined with guidelines supported by the Health Resources and Services Administration (HRSA) issued on August 1, 2011 (HRSA Guidelines) force non-grandfathered group health plans and health insurance issuers offering group or individual health insurance coverage to provide benefits for certain preventive health services without the imposition of cost sharing, including "[a]ll Food and Drug Administration [(FDA)] approved contraceptive methods, sterilization procedures, and patient education and counseling for all women with reproductive capacity," as prescribed by a provider. See HHS, *Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services Under the Patient Protection and Affordable Care Act*, 77 Fed. Reg. 8725 (Feb. 15, 2012).

[2] For copies of prior CMA statements, see http://www.cathmed.org/issues_resources/publications/press_releases/cma_provides_comment_on_hhs_definiti

comments are still present in the latest NPRM and that the modifications proposed in the most recent NPRM from HHS do not remedy key aspects of the rule which, as they stand, violate the religious freedom and conscience rights not only of churches and people of religious faith, but of American citizens and corporations. For these reasons, the CMA again calls upon HHS to rescind the Rule on Preventive Services in its entirety.

Unresolved Substantive Flaws in the Rule on Preventive Services

The Rule on Preventive Services requires all non-grandfathered group health plans and health insurance issuers offering group or individual health insurance coverage to provide benefits for certain "preventive health services" without the imposition of cost sharing, including ''[a]ll Food and Drug Administration [(FDA)] approved contraceptive methods, sterilization procedures, and patient education and counseling for all women with reproductive capacity," as prescribed by a provider.[3] There are several fundamental flaws in logic, health and medicine, and law with the Rule as written and enforced:

- Designating contraceptives as "preventive services" fails the tests of logic and sound science. Real "preventive services" prevent serious disease, dysfunction, and/or injury which would require treatment to restore health or function. The rule effectively classifies pregnancy as a disease and seeks to enact, as public policy, the prevention of childbirth as a cost-savings measure.
- Designating and distributing 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, liver cancer, and breast cancer—in particular, there is a disturbing connection between OC use and triple-negative breast cancer (for which OCs raise the risk by 2.5 to 4.2 times). Moreover, 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. Finally, because "all FDA-approved [4]contraceptive methods" include so-called emergency contraceptives such as ulipristal acetate ("ella") which function as abortifacients, the Mandate conflates abortifacients with contraceptives and violates the religious beliefs of many Americans opposed to abortion on religious, ethical, and/or personal grounds.

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on_of_religious_employer/ (CMA comment on HHS definition of "religious employer") andhttp://www.cathmed.org/issues_resources/publications/press_releases/cma_provides_comments_on_hhs_proposed_accommodation/ (CMA comments on HHS "proposed accommodation").

[3] HHS, *Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services Under the Patient Protection and Affordable Care Act*, 77 Fed. Reg. at 8725 (Feb. 15, 2012).

[4] See, e.g., Consolidated Appropriations Act, 2012, Pub. L. No. 112-74, Div. F, § 507(d) (2012).

- Because the Rule on Preventive Services fails to demonstrate a compelling governmental interest in achieving increased access to contraception, sterilization, and abortion services in this manner—i.e., in compelling institutions and individuals with religious beliefs to finance such services for themselves and others— the Rule violates the Religious Freedom Restoration Act (RFRA) in addition to violating the Free Exercise Clause of the First Amendment. Moreover, because of the inclusion of abortifacient drugs under the rubric of "emergency contraception," the Rule violates the Weldon Amendment, those provisions of the Affordable Care Act dealing with abortion,[5] and President's Obama's own assurances in Executive Order 13535.[6]

Flaws in Proposed Compromise in 2013 Notice of Proposed Rulemaking

HHS has announced two proposed changes to deal with past objections to the Mandate: to "amend the criteria for the religious employer exemption"; and (2) "establish accommodations for health coverage established or maintained by eligible organizations, or arranged by eligible organizations that are religious institutions of higher education, with religious objections to contraceptive coverage."[7] Neither of these proposed solutions will suffice to protect the religious and civil rights that have been enjoyed by all Americans to date and that are being jeopardized by this Administration's overriding interest in forcing people of faith to subsidize a new entitlement which violates their religious faith and conscientious convictions.

New Definition of Religious Employer. HHS has proposed to amend the definition of what constitutes a "religious employer" ostensibly to expand it—i.e., "to ensure that an otherwise exempt employer plan is not disqualified because the employer's purposes extend beyond the inculcation of religious values or because the employer serves or hires people of different religious faiths."[8] It is true that the NPRM removes the first 3 prongs of the infamous 4-prong test put forward by the ACLU and provides employers which qualify under this new definition with an exemption from the Mandate. However, there are two problems with this part of the NPRM. First, because of the reliance on IRS Code section 6033(a)(1) and 6033(a)(3)(A) (i) or (iii), the definition of religious employer has not been expanded in any meaningful way. The Administration admits as much in the NPRM, stating that "The Departments believe that this proposal would not expand the universe of employer plans that would qualify for the exemption beyond that which was intended in the 2012 final rules"[9] Thus the new definition fails recognize most of the ministries of service—including Catholic hospitals, schools, and social service agencies—traditionally recognized as "religious employers" under the law. The fact that the Administration continues to treat "houses of worship" as distinct from the rich tapestry of ministries that have been inspired and guided by the faith of American citizens to serve the

[5] See, e.g., the Patient Protection and Affordable Care Act, Public Law 111–148 , Section 1303(b)(1)(A) ("nothing in this title shall be construed to require a qualified health plan to provide coverage of [abortion] services … as part of its essential health benefits for any plan year").
[6] *Ensuring Enforcement and Implementation of Abortion Restrictions in the Patient Protection and Affordable Care Act*, 75 Fed. Reg. 15599 (Mar. 24, 2010).
[7] HHS, *Coverage of Certain Preventive Services Under the Affordable Care Act,* 78 Fed. Reg. 8458-59 (Feb. 6, 2013).
[8] Id.
[9] Id. At 8461.

public over so many years is unprecedented in American tradition and law. Moreover, it appears that the NPRM actually narrows the scope of respect for religious freedom held out in the prior NPRM. That is, as the comment filed by the United States Conference of Catholic Bishops (USCCB) points out, in March 2012, the Administration opined that if employees of a non-exempt religious organization enrolled in the health plan of an affiliated, exempt religious employer, that exempt religious employer's plan would not be required to include contraceptive coverage.[10] Now, however, the latest NPRM states that such opportunities will not be available.[11]

"Accommodation" for "Eligible Organizations." The NPRM contains an approach to deal with the many other ministries of service that do not meet the narrow definition of religious employer. Some elements of the proposed definition of "eligible organization" proposed are constructive and flexible. The Administration claims it will recognize as eligible organizations those that are organized and operated as a nonprofit and hold themselves out as religious organizations, that object to "some or all of the contraceptive services" and self-certify that they meet the three preceding criteria. Such organizations, according to the NPRM, will not have to contract, arrange, pay, or refer for contraceptive coverage to which they object on religious grounds; however, the Administration is determined to ensure that women employees and female dependents will still be provided with abortifacient, contraceptive, and sterilization benefits at no cost. Despite the constructive elements and flexibility noted above, there are two key problems with this approach to "eligible organizations":

1. The accommodation granted is clearly a different and lesser level of respect for rights of religious freedom of these organizations that have long enjoyed full protection under the law. As noted above, the Administration's creation of a two-tiered approach to religious freedom—treating "houses of worship" differently from charitable, educational, and social ministries that have been inspired and guided by the faith of American citizens to serve the public over so many years—is unprecedented in American tradition and law. An "accommodation" under the law is not the same as an exemption based on an explicit recognition of religious freedom. Eligible organizations cannot be sure that this "accommodation" will be maintained by the current Administration, or changed by a future administration.
2. The content of the "accommodation,"—separating the eligible organization from contracting, arranging, paying, or referring for the services in question—is insufficient in principle. The content of the accommodation is unacceptable in principle because the employer is still a necessary link in the provision of unethical services. Whether or not the employer purchases group health insurance or self-insures, it is still necessary for the employer to provide employee information to some third party which will ensure the provision of the unethical services. In addition, it is precisely the status of employees of a specific "eligible organization" that triggers the provision of pre-paid benefits to which the organization objects. Apart from problems

[10] HHS, *Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services Under the Patient Protection and Affordable Care Act*, 77 Fed. Reg. 16501, 16502 (Mar. 21, 2012).
[11] HHS, *Coverage of Certain Preventive Services Under the Affordable Care Act,* 78 Fed. Reg. at 8467 (Feb. 6, 2013).
[11] Id.

in principle, this "accommodation" is either unjust, illegal, and/or unworkable in practice:

- The "accommodation" will be unjust if the cost of the new contraceptive benefits are simply passed along, sooner or later, in increased premiums paid in whole or in part by the eligible organization;
- The "accommodation" will be both unjust and illegal if the costs of benefits for employees of eligible organizations are passed along to companies and employees of other organizations; or
- The "accommodation" will be unworkable, particularly for organizations which self-insure. The NPRM proposes a complex set of proposals regarding the role and reimbursement of outside insurance companies and third-party administrators that have never been tested, much less found consistent with the law, policies, and contracts under which these companies and administrators function.[12]

Other Flaws in the NPRM. To the extent that the two modifying proposals above focus (inadequately) only on certain religious groups or institutions, HHS makes no provision to respect the religious and civil rights of individuals and for-profit organizations (whether religiously affiliated or not) who have religious and ethical objections to some or all of the Rule on Preventive Services. Individuals, whether they receive health insurance through an employer or purchase qualifying health insurance on the exchanges, will be forced to pay for abortifacient, contraceptive, and sterilization services for themselves and for their dependents, whether or not they have religious and ethical objections to such services. There is no mechanism for them to object and to be exempted from the Rule. Many for-profit organizations have objections to some of all of the Rule on Preventive Services. Currently, 25 for-profit organizations have filed lawsuits articulating such objections and 17 have received injunctive relief from the courts.[13] This latest proposal by HHS make absolutely no provision for such organizations.

Conclusion

For the reasons stated above, the CMA calls upon HHS to rescind the Rule on Preventive Services in its entirety. Until HHS so acts, the CMA will continue to seek redress in Congress and the courts of law.

Sincerely,

John I. Lane, M.D.
President

John F. Brehany, Ph.D., S.T.L.
Executive Director

[12] See, e.g., Self-Insurance Institute of America, Inc., Comments on the NPRM (Feb. 25, 2013).
[13] See hhsinformationcentral/.