



Office of the General Counsel

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By Hand

September 17, 2010

Office of Consumer Information and Insurance Oversight
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

**Re: Interim Final Rules Relating to Coverage of Preventive Services,
File Code OCIIO-9992-IFC**

Dear Sir or Madam:

On behalf of the United States Conference of Catholic Bishops (“the USCCB” or “Conference”), I offer the following comments on the Interim Final Rules for Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services Under the Patient Protection and Affordable Care Act, published at *75 Fed. Reg.* 41726 (July 19, 2010) (“Interim Final Rules”).

Interest of the United States Conference of Catholic Bishops

The Conference is a nonprofit corporation organized under the laws of the District of Columbia. All active Catholic bishops in the United States are members of the Conference. The Catholic Church, the largest religious denomination in the United States, has over 68 million adherents in over 18,000 parishes throughout the country. The Conference advocates and promotes the pastoral teaching of the bishops in such diverse areas as education, family life, health care, social welfare, immigration, civil rights, and the economy. The Conference participates in rulemaking proceedings of importance to the Catholic Church and its people in the United States.

The Conference has a particular concern that contraceptives and sterilization not be mandated as “preventive” services under the Patient Protection and Affordable Care Act (“PPACA”). To prevent pregnancy is not to prevent a disease -- indeed, contraception and sterilization pose their own unique and serious health risks to the patient. In addition, contraceptives and sterilization are morally problematic for many stakeholders, including religiously-affiliated health care providers and insurers. We believe that the Administration rightly does not include

contraceptives or sterilization as preventive services in the Interim Final Rules, and that future rulemaking or other guidance should also refrain from doing so.

Specifically, the Interim Final Rules defer a decision on “preventive care and screening” services specifically for women, stating that the Department of Health and Human Services expects to issue guidelines on these by August 1, 2011. *Id.* at 41728. Even this brief reference to preventive services for women, however, has prompted an announcement by Planned Parenthood that it will lobby public officials to insist on mandating “family planning” services under this rubric -- including mandatory coverage, without co-pays or out-of-pocket expenses, of “all forms of FDA-approved prescription contraception.”¹ These comments are prompted in part by that public announcement and campaign.

General Comments

In our view, prescription contraception as well as chemical and surgical sterilization are particularly inappropriate candidates for inclusion under mandated “preventive services” for all health plans. This is true for several reasons.

1. The meaning and purpose of “preventive services”

The justification for mandating coverage for preventive services, at no cost or low cost to enrollees, is obvious from the examples of recommended preventive services cited throughout the Interim Final Rules: blood pressure and cholesterol screening; diabetes screening for hypertensive patients; various cancer and sexually transmitted infection screenings; counseling related to aspirin use, tobacco cessation, and obesity; routine immunizations. *Id.* at 41731. These services are emphasized because they can prevent serious illnesses or life-threatening conditions that, once they do occur, will demand treatment to cure or reverse them – or at the very least, can provide an early warning so these conditions can be treated more quickly and with a greater likelihood of success.

This rationale simply does not apply to contraception and sterilization. Most drugs and devices in this area have a significant “failure” rate; but when they do succeed, what they most often “prevent” is a healthy pregnancy in a healthy woman of childbearing age. At various times women may have serious personal reasons for wanting to avoid or delay a pregnancy. However, these personal reasons do not transform a temporary or permanent condition of infertility into a prerequisite for health, or turn a healthy pregnancy into a disease condition.

Indeed, if contraception and sterilization were comparable to the preventive services recommended in the Interim Final Rules, the federal government would be mandating these services in order to obviate the need for providing the “cure” or treatment later (or to ensure that such cure or treatment is provided early, to enhance the likelihood of success). But the condition

¹ See “Planned Parenthood Supports Initial White House Regulations on Preventive Care: Highlights Need for New Guidelines on Women’s Preventive Health to Include Family Planning,” July 14, 2010, at www.plannedparenthood.org/about-us/newsroom/press-releases/planned-parenthood-supports-initial-white-house-regulations-preventive-care-highlights-need-new-33140.htm.

prevented by contraception and sterilization is pregnancy, which has its own natural course ending in live birth if not interrupted by medical intervention. 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). PPACA does not take this policy with regard to any other procedure.

In these provisions, the Act 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.

Some may claim that contraception and sterilization are “preventive services” in the sense that they “prevent” abortion. But this is implausible for several reasons. First, abortion is not itself a disease condition, but a separate procedure that is performed only by agreement between a woman and a health professional. Second, most pregnancies, including unintended pregnancies, end in live birth rather than abortion, so it would be arbitrary to claim that preventing such pregnancies primarily prevents abortion rather than live birth. Third, studies have shown that the percentage of unintended pregnancies that are ended by abortion is *higher* if the pregnancy occurred during use of a contraceptive.² Finally, numerous studies have shown that contraceptive programs do not reliably or consistently reduce abortion rates.³ For example, one review summarizing 23 separate studies found that not one of the studies could show a reduction in abortion rates from programs expanding access to so-called “emergency contraception.”⁴ An evidence-based approach to health care does not permit the claim that mandating contraceptive coverage will reduce abortions.

One particular drug recently approved by the Food and Drug Administration (“FDA”) for “emergency contraception” poses an especially obvious problem in this regard. Ulipristal (trade name “Ella”) is a close analogue to the abortion drug RU-486, with the same biological effect – that is, it can disrupt an established pregnancy weeks after conception has taken place.⁵ Therefore it is contraindicated for women who are or may be pregnant. Yet its proposed use is targeted precisely at women who may already have conceived, as it would be administered up to

² While 40% of unintended pregnancies end in abortion, this percentage rises to 54% for women who used a contraceptive during the month they became pregnant. Guttmacher Institute, “Facts on Induced Abortion in the United States,” May 2010, at www.guttmacher.org/pubs/fb_induced_abortion.html.

³ See fact sheets by the USCCB Secretariat of Pro-Life Activities, “Greater Access to Contraception Does Not Reduce Abortions,” July 17, 2009, at www.usccb.org/prolife/issues/contraception/contrafactsheet.pdf, and “Emergency Contraception Fails to Reduce Unintended Pregnancy and Abortion,” February 16, 2007, at www.usccb.org/prolife/issues/abortion/factsheetec21607.shtml.

⁴ E. Raymond et al., “Population Effect of Increased Access to Emergency Contraceptive Pills,” *Obstetrics & Gynecology* 109 (2007): 181-8.

⁵ Documentation on this and other medical aspects of the drug is cited in testimony submitted to the FDA by the American Association of Pro-Life Obstetricians and Gynecologists, available at www.aaplog.org/?page_id=808.

five days *after* “unprotected” sex or contraceptive failure. Plans to market this drug simply as a “contraceptive” are misleading at best, and deprive women of the opportunity for genuine informed consent.

The policy advanced by Planned Parenthood – mandating coverage for “all forms of FDA-approved prescription contraception” as a preventive service – would therefore be in direct tension with the statutory prohibition on mandating any abortion service, as at least one of the drugs covered by that policy is an abortifacient drug.

2. Medical realities of contraceptive drugs and devices

The preventive services recommended under the Interim Final Rules share a basic medical profile: they pose little or no medical risk themselves, and they help prevent or ameliorate identifiable conditions that would pose known risks to life and health in the future.

Contraception presents the opposite profile. It is almost always prescribed for personal or lifestyle reasons, not for any specific medical justification; and it poses its own serious risks and side-effects, some of which can be life-threatening. Use of prescription contraception actually *increases* a woman’s risk of developing some of the very conditions that the “preventive services” listed in the Interim Final Rules are designed to *prevent*. Therefore a policy mandating contraceptive services as “preventive services” would be in contradiction with itself.

Women who use oral contraceptives may have an increased risk of heart-related side effects such as stroke, heart attacks and blood clots, especially if they also smoke cigarettes. The publishers of the *Physicians’ Desk Reference* warn women of these “[s]erious, and possibly life-threatening, side effects,” and add: “Seek medical attention immediately if you have any of the following: chest pain, coughing up blood, or shortness of breath (indicating a possible blood clot in the lung); pain in the calf (indicating a possible blood clot in the leg); crushing chest pain or heaviness (indicating a possible heart attack); sudden, severe headache or vomiting, dizziness, fainting, vision or speech problems, weakness, or numbness in an arm or leg (indicating a possible stroke); sudden partial or complete loss of vision (indicating a possible blood clot in the eye); breast lumps (indicating possible breast cancer or fibrocystic breast disease); severe pain or tenderness in the stomach (indicating a possible liver tumor); difficulty sleeping, lack of energy, fatigue, change in mood (possibly indicating depression); yellowing of the skin or whites of the eyes (jaundice), sometimes accompanied by fever, fatigue, loss of appetite, dark-colored urine, or light-colored bowel movements (indicating possible liver problems).”⁶ According to other sources, various contraceptives have been associated with increased risk of myocardial infarction, stroke, venous thromboembolism, and hypertension, as well as sexually transmitted diseases such as Chlamydia and HIV.⁷

It needs to be recalled in this context that so many contraceptive drugs and devices are available only by prescription not primarily because they are medically indicated for any particular illness, but because they pose sufficient risks that it would be irresponsible to distribute them without medical supervision.

⁶ PDR Network, “Oral contraceptives,” at *PDRhealth* (2009), www.pdrhealth.com/drugs/rx/rx-mono.aspx?contentFileName=ora1310.html&contentName=Oral+contraceptives&contentId=554.

⁷ R.A. Hatcher et al., *Contraceptive Technology*, 18th rev. ed. (New York: Ardent Media, 2004), at 404-410, 445.

3. A threat to rights of conscience

Because any mandate for contraception and sterilization coverage under the rubric of “preventive services” would apply to a wide array of group health plans and health insurance issuers, it would pose an unprecedented threat to rights of conscience for religious employers and others who have moral or religious objections to these procedures. In this regard, the Administration’s promise that Americans who like their current coverage will be able to keep it under health care reform would be a hollow pledge. Currently, such employers, as well as insurance issuers with moral and religious convictions on these matters, are completely free under federal law to purchase and offer health coverage that excludes these procedures. They would lose this freedom of conscience under a mandate for all plans to offer contraception and sterilization coverage.

Such a mandate would also contradict longstanding federal precedents on respect for conscientious objection to such procedures and such coverage. For example:

- The Church amendment, a provision of federal law since 1973, protects conscientious objection to abortion *and sterilization* in various contests where federal funds are involved.⁸

- In foreign assistance programs for family planning, a statutory requirement renewed every year since 1986 has stated that “no applicant shall be discriminated against because of such applicant’s religious or conscientious commitment to offer only natural family planning” as opposed to contraceptive drugs or devices.⁹

- Every year since 2000, Congress has stipulated regarding any effort to mandate contraceptive coverage in the District of Columbia that “it is the intent of Congress that any legislation enacted on such issue should include a ‘conscience clause’ which provides exceptions for religious beliefs and moral convictions.”¹⁰

- In the United States’ international program for preventing and treating HIV/AIDS, organizations (specifically including faith-based organizations) are guaranteed the right to participate fully in the program without being required “to endorse, utilize, make a referral to, become integrated with, or otherwise participate in any program or activity to which the organization has a religious or moral objection.”¹¹

⁸ 42 U.S.C. §300a-7(b), (c)(1) and (e). The Church amendment also protects conscientious objection to any health service or research activity that is contrary to the religious beliefs or moral convictions of individuals participating in programs administered or funded by HHS. *Id.*, § 300a-7(c)(2) and (d).

⁹ Title III of Division F (Department of State, Foreign Operations, and Related Programs Appropriations Act) of the Consolidated Appropriations Act, 2010, Pub. L. No. 111-117.

¹⁰ Sec. 811 of Title VIII of Division C (Financial Services and General Government Appropriations Act) of the Consolidated Appropriations Act, 2010, Pub. L. No. 111-117.

¹¹ United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003, at 22 U.S.C. §7631 (d).

- Every year since 1999, in the only federal program to require health plans to cover contraception for a subset of the U.S. population, Congress has stated that this mandate in the Federal Employees Health Benefits Program will not apply to “any existing or future plan, if the carrier for the plan objects to such coverage on the basis of religious beliefs.” Moreover, any plan that enters into or renews a contract under this section may not subject any individual to discrimination on the basis that the individual refuses to prescribe or otherwise provide for contraceptives because such activities would be contrary to the individual’s religious beliefs or moral convictions.”¹²

These precedents reflect a longstanding commitment on the part of our federal government to respect the rights of conscience of all citizens, and to allow health care institutions and religious employers to participate fully in health programs (including programs for providing health coverage) without violating their moral or religious convictions. No federal law has yet been construed to require private health plans to provide coverage of contraception and sterilization. Instead, federal law has thus far left insurance issuers, employers and enrollees to negotiate such coverage in accord with their personal preferences and their moral and religious commitments. The federal government has no reason now to take away this freedom.

Conclusion

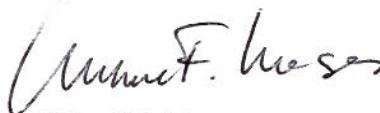
For the reasons stated above, the Department of Health and Human Services should not require coverage of contraception or sterilization in group or individual health plans as part of “preventive services.” These drugs, devices and procedures prevent not a disease condition, but the healthy condition known as fertility; they pose significant risks of their own to women’s life and health; and a federal program to mandate their inclusion would pose an unprecedented threat to rights of conscience. We hope these considerations will be taken into account as the Department continues deliberations on a final list of required preventive services for women.

Thank you for the opportunity to comment.

Sincerely,



Anthony R. Picarello, Jr.
General Counsel



Michael F. Moses
Associate General Counsel

¹² See Sec. 728 of Title VII of Division C (Financial Services and General Government Appropriations Act) of the Consolidated Appropriations Act, 2010, Pub. L. No. 111-117.