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**As of August 2010*

Jodi Magee
President/CEO

September 30, 2011

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201
Attention: CMS-9992-IFC2

Office of Health Plan Standards and Compliance Assistance, Employee Benefits Security
Administration, Room N-5653
Department of Labor
200 Constitution Avenue, NW
Washington, DC 20210
Attention: RIN 1210-AB44

CC:PA:LPD:PR, Room 5205
Internal Revenue Service
P.O. Box 7604, Ben Franklin Station
Washington, DC 20044
Attention: REG-120391-10

RE: CMS-9992-IFC2 GROUP HEALTH PLANS AND HEALTH INSURANCE ISSUERS RELATING TO COVERAGE OF PREVENTIVE SERVICES UNDER THE PATIENT PROTECTION AND AFFORDABLE CARE ACT

Dear Madam or Sir:

Physicians for Reproductive Choice and Health (PRCH) is a doctor-led national advocacy organization that relies upon evidence-based medicine to promote sound reproductive health policies. PRCH supports the recent recommendation of the Institute of Medicine (IOM) to include contraception in the preventive health benefits[1] for women under the Patient Protection and Affordable Care Act (ACA)[2] and the decision of the Department of Health and Human Services (the Department) to adopt this recommendation in its draft regulations.[3] As physicians, we know that access to contraception is essential to the health and well-being of our patients.

[1] Institute of Medicine, Clinical Preventive Services for Women: Closing the Gaps (July 19, 2011).
[2] Patient Protection and Affordable Care Act, Pub. L. No. 111-148 (Mar. 23, 2010) and Health Care and Education Reconciliation Act, Pub. L. 111-152 (Mar. 30, 2011).
[3] 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 (proposed Aug. 3, 2011) (to be codified at 45 CFR Part 147).

Regular use of contraception prevents unintended pregnancy and reduces the need for abortion.[4] Contraception also allows women to determine the timing and spacing of pregnancies, protecting their health and improving the well-being of their children.[5] Contraceptive use saves money by avoiding the costs of unintended pregnancy and by making pregnancies healthier, saving millions in health care expenses.[6] Several contraceptives also have non-contraceptive health benefits, such as decreasing the risk of certain cancers and treating debilitating menstrual problems.[7] Making contraception more affordable is a significant step forward for the health of women and their families.

PRCH recognizes the importance of the Department's decision to include in the draft regulations the coverage of all forms of birth control,[8] allowing patients access to the method that best meets their needs. Contraceptive methods vary and women with their health care providers need to be free to select from the full range of FDA-approved contraceptives. Not all contraceptives are clinically appropriate for every woman.[9] We also know that women and couples are more likely to use contraception successfully when they are given their contraceptive method of choice, be it a birth control pill, a vaginal ring, or an intrauterine device (IUD).[10] The draft regulations hold the promise of making contraception more affordable and easier to access for millions of women.

While we strongly support the Department's action to include contraception as preventive care, we are deeply troubled by the provisions that exempt certain employers from compliance. These draft regulations threaten to compromise the very important protections they would put in place. As physicians who care for patients who may be deprived of the affordable contraceptive coverage that all women deserve, we outline our concerns in the comments below.

I. Women employed by religious employers should be ensured the same preventive reproductive health care coverage as all other women.

The draft regulations allow certain religious employers to refuse to provide access to essential reproductive health care coverage for contraception.[11] That means that some

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[4] Deschner, A., Cohen, S.A. (2003). "Contraceptive Use Is Key to Reducing Abortion Worldwide." The Guttmacher Report on Public Policy 6(4): 7-10.

[5] Testimony of the Guttmacher Institute, submitted to the Committee on Preventive Services for Women, Institute of Medicine, 2011, available for download at http://www.guttmacher.org/pubs/CPSW-testimony. pdf (accessed September 28, 2011).

[6] Gold, R.B. (2011). "Wise Investment: Reducing the Steep Cost to Medicaid of Unintended Pregnancy in the United States." Guttmacher Policy Review 14(3): 6-10.

[7] Burkman, R., Schlesselman, J.J., Zieman, M (2004). "Safety concerns and health benefits associated with oral contraception." American Journal of Obstetrics and Gynecology 190(4): S5-22.

[8] The draft regulations properly include forms of emergency contraception in the birth control coverage provisions. Some groups have claimed this is a violation of federal law, arguing that emergency contraception is an abortifacient. This is medically inaccurate. Emergency Contraception. Practice Bulletin No. 112. American College of Obstetricians and Gynecologists. Obstet Gynecol 2010;115:1100–9.

[9] Bonnema, R.A., McNamara, M.C., Spencer, A.L. (2010). "Contraception choices in women with underlying medical conditions." American Academy of Family Physicians 82(6): 612-8.

[10] Frost, J. J. and J. E. Darroch (2008). "Factors Associated with Contraceptive Choice and Inconsistent Method Use, United States, 2004." Perspectives on Sexual & Reproductive Health 40(2): 94-104.

[11] The Interim Final Rules define an employer that can invoke the exemption as one that:
(1) Has the inculcation of religious values as its purpose;
(2) primarily employs persons who share its religious tenets;

women, because they work for religious employers that fail to allow this benefit, will be denied access to affordable birth control coverage. That is grossly unfair to these women, and from a medical perspective would constitute indefensible health policy. All women deserve access to affordable birth control—an important component of preventive health care, as the Department and the IOM have recognized—no matter where they work.

Some of the most vocal opposition to the inclusion of birth control as a preventive service comes from the United States Conference of Catholic Bishops (USCCB).[12] It is worth noting that virtually all women, including 98 percent of Catholic women, use contraception at some point during their lifetimes.[13] Moreover, the decision to use birth control should be left to the *individual.* Employers should not have the power to interfere in private health care decisions by withholding coverage for care. A key promise of the ACA is that women will no longer be subjected to extra charges for necessary preventive prescriptions and treatments. Birth control should not be treated any differently. Employers should remain entirely free to express their opposition to birth control, but that opposition should never translate into substandard preventive medical care coverage.

One of our physicians had a patient we will call Susan.[14] Susan worked in administration at a Catholic Archdiocese and her employer provided health insurance that did not cover contraception because of the employer's belief that birth control is immoral. Susan was in a relationship and did not want to become pregnant. Her partner refused to use condoms and the burden to prevent pregnancy fell on her. Because of her high blood pressure, Susan could not take birth control pills, and she and her doctor decided that an IUD was her best preventive health care option. But Susan could not afford the hundreds of dollars for the device and insertion. She went without any birth control, became pregnant and then had an abortion that should have never become necessary.

Susan was a victim of second-class preventive medical care. Susan and women in similar employment situations deserve access to affordable contraception. In the preamble to the rule, the Department discusses the need to respect the relationship between a house of worship and its *ministerial* employees (emphasis added).[15] Yet the draft rule is not limited to ministerial employees. As physicians, we believe that medical evidence should govern healthcare and that every one of our patients should have access to high quality preventive reproductive health services. If the Department elects to offer an option to limit coverage for

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(3) primarily serves persons who share its religious tenets; and
(4) is a non-profit organization under section 6033(a)(1) and section 6033(a)(3)(A)(i) or (iii) of the Code. Section 6033(a)(3)(A)(i) and (iii) refer to churches, their
integrated auxiliaries, and conventions or associations of churches, as well as to the exclusively religious activities of any religious order.

[12] "HHS Mandate for Contraceptive and Abortifacient Drugs Violates Conscience Rights," USCCB press release, August 1, 2011. See also, comments from USCCB submitted to the Centers for Medicare & Medicaid Services, August 31, 2011.

[13] Jones. R.K. and Joerg Dreweke, "Countering Conventional Wisdom: New Evidence on Religion and Contraceptive Use," Guttmacher Institute, April 2011. Among all women who have had sex, 99% have used a contraceptive method other than natural family planning.

[14] Names of patients throughout these comments have been changed to protect privacy.

[15] "Specifically, the Departments seek to provide for a religious accommodation that respects the unique relationship between a house of worship and its employees in ministerial positions." Overview of the Amendment to the Interim Final Regulations, supra note 3 at 46623.

birth control at all, it should be limited to the far narrower set of women who are exclusively engaged in their religious employer's ministerial functions.

II. Women employed by organizations affiliated with religious institutions should be assured access to the same preventive reproductive health care coverage as all other women.

Opponents of contraceptive coverage without co-pays have argued for an expansion of employers who could refuse to provide coverage.[16] In their view, hospitals and social service agencies should have the ability to deny preventive reproductive health care coverage for their employees. These exclusions of care translate into significant hardships for our patients. Broadening the definition of a religious employer would make an already medically unsound policy even worse, depriving more women of essential preventive coverage.

One of our physicians has a patient we will call Melanie. Melanie has worked for many years as an emergency room nurse at a Catholic hospital. She wanted a long-acting, reversible contraceptive, specifically an IUD. But the hospital's health insurance did not cover birth control. Melanie paid for birth control pills out-of-pocket, but she had experienced an unintended pregnancy while on the pill and knew that an IUD would be more effective. However, Melanie could not afford the nearly one thousand dollars for the IUD and its insertion. Instead, Melanie obtained an IUD from a nearby study of a new, experimental type of IUD. Her need for an IUD plainly outweighed her worries about using a contraceptive without FDA approval.

Another of our physicians has a patient we will call Kristen. Kristen worked as a nursing assistant at a Catholic hospital. Like Melanie, her insurance did not cover contraception. Kristen, who is not Catholic, did not know about this policy until after she started working at the hospital. When Kristen first refilled her prescription for birth control pills, she discovered that she would need to pay fifty dollars per month, a new expense for which she had not budgeted as her last employer had covered contraceptives. Kristen was able to afford her prescription for a few months, but could not continue. She later had an unintended pregnancy and needed an abortion.

Yet another of our physicians takes care of many women who are employees and students at a large, well respected, Catholic college. These women have no objections to birth control—they are either not Catholic, or among the ninety-eight percent of Catholic women who have used birth control. Most have no idea their insurance does not cover birth control pills or any other contraceptive until they begin working or studying there. When they find out, some panic because they cannot afford the full cost.[17] These amounts can be prohibitive for a family on a budget. The college educates and employs thousands of women; they should not be denied affordable birth control as a condition of studying or working there.

As illustrated by our colleagues, it is important to the health of patients that affordable preventive reproductive health coverage be available to every woman in the American

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[16] In their August 1 press release, supra, note 12, USCCB noted their displeasure with the interim rules stating "Although this new rule gives the agency the discretion to authorize a 'religious' exemption, it is so narrow as to exclude most Catholic social service agencies and health care providers."

[17] For instance, per year, the pill ranges from $180 to $600 out of pocket, the vaginal ring from $180 to $840. An IUD, which lasts much longer and saves money over time, requires an initial investment of $500 to $1,000.

workforce without regard to the reproductive health position of their employers. In deciding the scope of contraceptive coverage, if the Department permits any exclusions, they should be as narrow and exclude as few of our patients as possible. Under no circumstances should the exclusion provisions in the draft regulations be broadened.

III. If the final regulations permit any religious employers to deny coverage for birth control, the regulations should also require employers to provide written notice of their policies to employees.

As an organization committed to comprehensive reproductive health care for all women, PRCH objects to the sanctioning of any denial of preventive contraceptive health care under the ACA. In the event that the Department decides to allow certain religious employers to deny this coverage to employees, we strongly urge the Department to require employers to provide notice of their decision to employees. Such a requirement should mandate:

1) Written notice to each employee, upon enrollment in the employer's health plan, listing the contraceptive health care services the employer refused to cover for religious reasons; and

2) Written information describing how an employee may directly purchase contraceptive coverage and the cost of the premium.[18]

These notice provisions are absent in the Department's draft regulations, but are included in many state laws requiring coverage of birth control to be equal to coverage of other prescription drugs. Several states require that employers give notice to employees when contraceptives are not covered**.** In Hawaii, employers must provide written notice to enrollees upon enrollment in the health plan, listing the contraceptive healthcare services the employer refuses to cover for religious reasons and provide prompt written information describing how to access contraception.[19] Missouri has a similar requirement, requiring employees to know whether the plan covers contraceptives and that an enrollee who is a member of a plan that does not cover contraceptives has the right to purchase such coverage.[20] Twelve other states including California, New York, Connecticut, and West Virginia require employees to be notified when their health plan does not cover contraceptives.[21] The Department references the exemptions of religious employers by many states in the preamble to the draft rule. We urge the Department to also consider the protections that states have put in place to ensure that employees are knowledgeable about

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[18] These recommendations mirror the law in New York, N.Y. Ins. Law §§ 3221, 4303, 4322 (Enacted 2002). A letter from the New York State Insurance Department states the requirements: "The religious employer opting not to include contraceptive coverage must provide written notice of its decision to prospective enrollees prior to enrollment with the plan, listing the contraceptive health care services the employer refuses to cover for religious reasons. Where such group contract holder makes an election not to purchase coverage for contraceptive drugs or devices, the Commercial Insurer, Article 43 Corporation, or HMO is to provide written notice to certificate holders upon enrollment of their right to directly purchase the coverage and of the premium cost therefor." Letter to Insurers, January 31, 2003 (available for download at http://www.ins.state.ny.us/circltr/2003/cl03_01.htm).

[19] Haw. Rev. Stat. Ann. §§ 431:10A-116.6 (Enacted 1993; Last Amended 2003), -116.7 (Enacted 1999, Last Amended 2003); 432:1-604.5 (Enacted 1999).

[20] Mo. Ann. Stat. § 376.1199 (Enacted 2001).

[21] Guttmacher Institute, State Policies in Brief: Insurance Coverage of Contraceptives, September 1, 2011 (available for download at http://www.guttmacher.org/statecenter/spibs/spib_ICC.pdf).

their rights. As demonstrated in the experiences relayed above, many employees do not realize the full extent of exclusions of coverage.

IV. If the final regulation permits religious employers to deny coverage for birth control, the regulation should include an obligation to cover FDA-approved contraceptives prescribed for purposes other than birth control.

Several states make clear that exclusions of contraceptive coverage do not apply to contraceptives that are prescribed for purposes other than birth control. For example, California mandates that employers, including religious employers, cover birth control when prescribed for the purposes of lowering the risk of ovarian cancer, eliminating symptoms of menopause, or for prescription contraception necessary to preserve the life or health[22] of an insured woman.[23] Hormonal birth control, in addition to preventing unintended pregnancies, helps address several menstrual disorders, helps prevent menstrual migraines, treats pelvic pain from endometriosis, and treats bleeding from uterine fibroids.[24] Oral contraceptives have been shown to have long-term benefits in reducing a woman's risk of developing endometrial and ovarian cancer, and short-term benefits in protecting against colorectal cancer.[25]All women, including women who have religious employers and women in ministerial roles, need insurance coverage that will cover effective treatments, including hormonal contraception, for these conditions. The acceptance of inadequate health care coverage should not be a condition of working for a religious employer or agency.

V. Conclusion

We request the Department to recognize the importance of these issues to women as the final regulations are written. The Centers for Disease Control and Prevention recognized family planning as one of the singular public health achievements of the twentieth century.[26] The ACA holds the promise of expanding health care coverage for millions of Americans and ensuring that all of our patients live healthier lives. Allowing religious employers, and possibly even organizations affiliated with them, to interfere with the personal reproductive health care decisions of their employees is poor public health policy that could harm too many American women and families.

Sincerely,

Douglas Laube, MD, MeD
Board Chair

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[22] An unintended pregnancy may have significant implications for a woman's health, sometimes worsening a preexisting health condition such as diabetes, hypertension, or coronary artery disease. Institute of Medicine, supra note 1.

[23] Cal. Health & Safety Code §1367.25(b)(2)(c) (enacted 1999): "Nothing in this section shall be construed to exclude coverage for prescription contraceptive supplies ordered by a health care provider with prescriptive authority for reasons other than contraceptive purposes, such as decreasing the risk of ovarian cancer or eliminating symptoms of menopause, or for prescription contraception that is necessary to preserve the life or health of an enrollee."

[24] Burkman, supra note 7.

[25] Id.

[26] Centers for Disease Control and Prevention, "Achievements in Public Health 1900-199: Family Planning," MMWR Weekly, December 03, 1999, 48(47);1073-1080.