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Q & A
HHS Adopts IOM Report on Preventive Care Services for Women Contraceptive Mandate Will Violate Conscience Rights and Include Abortifacient Drugs

On August 2, 2011, the department of Health and Human Services (HHS) issued an amendment to the interim final rule adopting the recommendations of the Institute of Medicine (IOM) Report, "Clinical Preventive Services for Women: Closing the Gaps" to mandate coverage of contraceptives with no cost-share to patients obtaining these services. The new regulation provides very narrow conscience protections. All group and individual health plans will as of August 1, 2012 provide contraceptives approved by the Food and Drug Administration (FDA) with no copay.

Does the HHS Regulation Include Adequate Conscience Protections?

No. The new HHS regulation provides a conscience exemption only for a narrow category of "religious employers" which would essentially only include churches. The regulation limits "religious employers" to those who a) have the "inculcation of religious values as its purpose," b) primarily employs persons who share its religious tenets, c) primarily serves persons who share its religious tenets, and d) is a non-profit organization who under 26 USC 6003(a)(1) and 6033(a)(3)(A)(i) or (iii) is exempt from filing annual tax returns.

This narrow definition will not cover most religious non-profit organizations which employ people of different faiths, or which provide social services to people of *other* faiths. It does not protect religious entities providing health care services to the poor, or who perform missionary work to people in the United States or abroad. It does not include religious businesses, non-profit health care insurers, hospitals or even universities. Health care issuers in the individual market that are religiously affiliated are not covered at all.

Who is protected from the contraceptive mandate?

Only churches who hire people of the same faith, minister to people of the same faith, and have as their main purpose the inculcation of religious values. Under this narrow conscience exemption, some churches would not be required to provide health insurance with contraceptive coverage to their employees. Most religious organizations will be required to provide contraceptive coverage to their employees with no copay so that other employees will be forced to cover the additional costs.

Will the HHS Regulations be Amended?

No. HHS previously received public comment on the inclusion of contraceptives and other preventive services when they proposed a regulation implementing the laws requirement to cover general preventive care services in health plans as recommended by the U.S. Preventive Services Task Force (USPSTF). That proposed interim rule was finalized on July 19, 2010. This new regulation is an *amendment* to last year's interim rule and HHS claims to have already considered comments about additional preventive services for women (see below). While the new regulation is

now in effect, insurers have one year to comply. Therefore, health insurance issuers will be required to offer plans with contraceptive services, and other preventive services for women, starting August 1, 2012. HHS did not receive public comment to consider regulations on this matter, but did receive comments about the definition of "religious employer" through September 30, 2011. HHS stated that Health Resources and Services Administration (HRSA) has been delegated "flexibility" in accommodating conscience concerns. On February 10, 2012 the Administration finalized the regulation with no change to the contraception mandate or any expansion of "religious employer. It also left a one-year delay for those religious employers who object to covering contraception and abortifacients in their health plans. On March 21, HHS did issue an Advance Notice of Proposed Rulemaking (ANPRM) to ask public comment on a so-called "accommodation" by some accounting scheme in which the insurer would pay for the free contraceptives through the religious employer's health plans.

What Was the Report Released by the Institute of Medicine (IOM)?

Between November, 2010, and March, 2011, the Institutes of Medicine (IOM), contracted through the U.S. Department of Health and Human Services (HHS), hosted three expert committee meetings in Washington, D.C., to discuss and make decisions regarding the Mikulski Amendment in Obamacare that mandates all health care plans to cover specific women's preventive services with no cost-sharing to the patient. http://iom.edu/Activities/Women/PreventiveServicesWomen.aspx The report "Clinical Preventive Services for Women: Closing the Gaps" was released on July 19 and includes the formal list of recommendations for HHS.

What Legal Authority Provides for Women's Preventive Services at No Cost-sharing?

The "Patient Protection and Affordable Care Act" (PPACA, P.L. 111-148) as enacted contains a provision on preventive health services in Section 1001, which created a new section 2713 of the Public Health Service Act (PHSA) to mandate that all individual and group health plans provide coverage for preventive care in accordance with guidelines offered by the U.S. Preventive Services Task Force (USPSTF). Senator Barbara Mikulski (D-MD) offered an amendment (S.AMDT. #2791) that passed on December 3, 2009 to extend this mandate to include coverage of preventive services for women. Specifically, the Mikulski provision creates Section 2713(a)(4) of PHSA that would extend the coverage mandate to include, with no cost sharing requirements, the following: "(4) with respect to women, such additional preventive care and screenings not described in paragraph (1) as provided for in comprehensive guidelines supported by the Health Resources and Services Administration." Paragraph (1) would include all "items or services" that are currently recommended by the USPSTF. Paragraph (4) therefore would add to that mandate coverage of items and services not recommended by the USPSTF, but which would be provided for by the Health Resources and Services Administration (HRSA).

What Groups Were Involved in the IOM Recommendation Study Process?

Invited presenters included the following groups and/or representatives: the Guttmacher Institute; the American Congress of Obstetricians and Gynecologists (ACOG); John Santelli, the National Women's Law Center, National Women's Health Network, Planned Parenthood Federation of

America and Sara Rosenbaum, who recently testified on behalf of abortion rights advocates in the House committee hearings on the "No Taxpayer Funding for Abortion Act" (H.R. 3) and the "Protect Life Act" H.R. 358). No pro-life advocates were invited to present at the IOM meetings, despite asking for formal presentation time. By far the topic that received the greatest amount of attention was contraception coverage; inclusion of contraception for no co-pay was suggested by most invited speakers. Each meeting allowed opportunity for public comment. Family Research Council joined with other pro-life, pro-family groups during this period each session to request that embryocidal contraceptives, including Plan B which can cause an abortion prior to implantation, and the more recently approved drug, ella, which can cause an abortion after implantation, not be included in the recommended list for no co-pay. FRC argued that the conscience rights of insurance issuers, participants and providers be respected in matters related to life.

What Did the IOM Report Recommend and HHS Accept?

The IOM report recommends a broad number of preventive care services for women. These include, among other things, cancer screenings, counseling and screening for HIV, counseling for sexually transmitted diseases, counseling and screening for domestic violence, breastfeeding counseling, as well as the controversial recommendation to include all FDA approved contraceptives and sterilization methods.

What Are the Concerns with the IOM Recommendations and the HHS Regulation?

Family Research Council has serious concerns regarding the inclusion of certain contraceptives as a preventive service, in part because several drugs that have been approved by the FDA as "emergency contraceptives" (EC) work post-fertilization as well as post-implantation.

1. PLAN B. Levonorgestral, Plan B, is included in this category. The FDA approved Plan B as an "emergency contraceptive" despite the fact that it can work to prevent a newly formed embryo from implanting in the woman's uterus. It is a medical fact that Plan B can stop the implantation process, thereby causing the embryo's demise. The FDA approved label for Plan B suggests it can prevent "implantation" of a "fertilized egg" which is an embryo. This mode of action kills the embryo.

2. ELLA. FRC also objects to the inclusion of the recently approved drug, Ulipristal acetate, marketed as Ella by Watson Pharmaceuticals, as a preventive care item or service. While the FDA approved the drug application of Ella as an "emergency contraceptive," this drug is known to be chemically and functionally similar to the abortifacient drug, RU-486. In a study published in February, 2011 in the Annals of Pharmacotherapy, "the mechanism of action of ulipristal in human ovarian and endometrial tissue is identical to that of its parent compound, mifepristone."[1] In one study of ulipristal on monkeys, 4 out of 5 fetuses were aborted.[2] On one with rats, all were aborted.[3] "[E]xisting studies in animals are instructive in terms of the potential abortive effects of the drug in

1 Harrison, D, Mitroka, J Defining Reality: The Potential Role of Pharmacists in Assessing the Impact of Progesterone Receptor Modulators and Misoprostol in Reproductive Health. Annals of Pharmacotherapy January 2011, Volume 45.

2 Tarantal, A, et al, "Effects of Two Antiprogestins on Early Pregnancy in the Long-Tailed Macaque", Contraception. August 1996, 54(2):107-15.

3 Food and Drug Administration. Mifeprex label. www.accessdata.fda.gov/drugsatfda_docs/label/2000/20687lbl.htm (accessed 2010 Sept 26).

humans."[4] A recent study concluded that "it can be reasonably expected that the prescribed dose of 30 mg of ulipristal will have an abortive effect on early pregnancy in humans."[5] This is the dose of ulipristal now available as an EC in the United States.

Is Pregnancy a Disease to be Included as a Mandatory Prevention Category?

No. Including contraceptives such as levonorgestrel (Plan B) and ulipristal (ella) in the list of drugs covered as a preventive service would be based on the incorrect view that pregnancy is a disease. In fact, fertility and pregnancy are not diseases or illnesses; fertility occurs in healthy women. By their very nature, contraceptive services are elective, not medically necessary.

Will a Contraceptive Mandate Violate Conscience Rights?

Yes. The HHS decision to include contraceptives as preventive care under Section 2713 of the Public Health Service Act guarantees that the conscience rights of many people will be violated by a federal mandate for such coverage.

The effect is to guarantee that all participants in plans with contraceptive coverage will pay for the coverage of those services through higher premiums, since the individual patients are not required to make a copay and the insurer will not bear the cost. Moreover, issuers of health plans, and providers who contract with them, may object to inclusion of contraceptives as "preventive care" services because of ethical or religious concerns. Legally mandating these groups and individuals to participate in the coverage of contraceptives places the federal government not only at odds with the right of conscience of thousands of people, it also violates the principles of current conscience laws, specifically the Church Amendment 42 U.S.C. 300a-7(d). While the PPACA contains no direct conscience protection related to services other than abortion (Section 1303(b)(4)), the Church Amendments still exist to protect the conscience rights of individuals (Church (d)) in programs administered by the Health and Human Services Department. Clearly, mandating that all health care plans cover contraceptives, and that participants in such plans share the cost burden of such services, violates the principles of these conscience laws.

Does the Advance Notice of Proposed Rulemaking Provide an "Accomodation"?

No. The ANPRM simply requests public comment on how to force religious employers to provide contraceptives and abortifacients in their health plans while requiring the insurer to pay the direct cost of these free benefits. Under any accounting scheme proposed in the ANPRM, religious employers will still be forced to pay and contract for health plans for their employee, so that the

4 Harrison, D and Mitroka, J Defining Reality: The Potential Role of Pharmacists in Assessing the Impact of Progesterone Receptor Modulators and Misoprostol in Reproductive Health. Annal of Pharmacotherapy January 2011, Volume 45801 G Street, NW • Washington, D.C. 20001

5 Ibid

insurer will turn around and provide objectionable benefits to the employees. The religious organization is still the legal conduit of such benefits even if any of the services violate their beliefs.

Can Religious Employers Challenge the Contraception Mandate?

Yes. 43 Catholic organizations have brought 12 lawsuits challenging the contraception mandate, and other evangelical religious organizations have also brought several lawsuits. Several businesses have also challenged the mandate. Each have argued that the mandate violates the Religious Freedom Restoration Act by infringing on their religious liberties without a compelling governmental interest, and in such a way as that this burden is not the least restrictive means of achieving that purported goal of free contraceptives and abortifacients. These suits are still pending.

What Can be Done to Protect Conscience Rights?

The narrow religious employer definition is entirely insufficient for millions of Americans. Because the contraceptive mandate is not funded by the Federal government (it is mandated for insurance providers), the Church Amendment (d) may not offer the protections necessary for those who object.

While the lawsuits challenging the mandate are ongoing, Congress should pass the bi-partisan "Respect for Rights of Conscience Act of 2011" (H.R. 1179) sponsored by Rep. Jeff Fortenberry (R-NE) and Rep. Dan Boren (D-OK) and the Senate pass the companion bill (S. 1467) sponsored by Senator Roy Blunt (R-MO), Senator Marco Rubio (R-FL) and Senator Kelly Ayotte (R-NH). This bill would amend the PPACA to protect entities from being mandated to provide or participate in any item or service that they have religious or moral objections to. Passage of H.R. 1179 and S. 1467 would be consistent with the Church Amendments that protect against government discrimination in federally funded health programs because of moral or religious objections to abortion, sterilization or any health service that is funded or administered by the government.