



SUBMITTED VIA EMAIL

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Office of Consumer Information and Insurance Oversight
Department of Health and Human Services
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Re: File Code OCIO-9992-IFC

To whom it may concern:

On July 19, 2010, the Department of Health and Human Services issued an interim final rule for group health plans and health insurance issuers relating to coverage of preventive services under the Patient Protection and Affordable Care Act of 2010 (Affordable Care Act). HHS invited comments on the regulation to be submitted on or before September 17, 2010.

The regulation specifies that the Department of HHS is developing guidelines on “evidence-informed preventive care and screening” for women which must be covered by group health plans and health insurance issuers under the Affordable Care Act.¹ These guidelines will be issued no later than August 1,

¹ Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 131, (Mar. 23, 2010), available at http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=111_cong_public_laws&docid=f:publ148.111.pdf; Interim Final Rules for Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive

2011, and will include coverage requirements for medical care not already required by the Affordable Care Act.²

In response, Americans United for Life (AUL), a public-interest law and policy organization, submits the following comments:

1. Section 2713(a)(4) of the Affordable Care Act does not explicitly include elective abortions or abortifacients in “preventive care and screenings” for women, and the Senate floor debate over the addition of Section 2713(a)(4) to the Act demonstrates that they are not included, and;
2. It would be inappropriate to require group health plans and health insurance issuers to cover elective abortions or abortifacients, including the recently-approved drug *ella*.

1. Section 2713(a)(4) of the Affordable Care Act does not explicitly include elective abortions or abortifacients in “preventive care and screenings” for women, and the Senate Floor debate over the addition of Section 2713(a)(4) to the Act demonstrates that they are not included.

The Affordable Care Act does not explicitly require private group health plans and health insurance issuers to cover elective abortions or abortifacients as part of “evidence-informed preventive care and screening.”³

Services Under the Patient Protection and Affordable Care Act, 75 Fed. Reg. 41726, 41731 (July 19, 2010) (to be codified at 45 C.F.R. pt.147).

² *Id.*

³ “**SEC. 2713. COVERAGE OF PREVENTIVE HEALTH SERVICES.** (a) IN GENERAL.—A group health plan and a health insurance issuer offering group or individual health insurance coverage shall, at a minimum provide coverage for and shall not impose any cost sharing requirements for— . . . (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 for purposes of this paragraph.” Paragraph (1) as referenced above includes “evidence-based items or services that have in effect a rating of ‘A’ or ‘B’ in the current recommendations of the United States Preventive Services Task Force.” This list **does not** include abortion or abortifacients.

Section 2713(a)(4), which requires private insurance plans to cover certain preventive services for women, was added to the Affordable Care Act by amendment on December 3, 2009. Senator Barbara Mikulski (D-MD), who offered the amendment, issued a press release providing the following description of her amendment:

Services that would be covered under the Mikulski Amendment are likely to include cervical cancer screenings for a broad group of women; annual mammograms for women under 50; pregnancy and postpartum depression screenings; screenings for domestic violence; and annual women's health screenings, which would include testing for diseases that are leading causes of death for women such as heart disease and diabetes.⁴

In her prepared floor statement, Senator Mikulski concluded:

Often health care doesn't cover basic women's health care like mammograms and cervical cancer screenings. My amendment is about saving lives and saving money to give women access to comprehensive preventive services that are affordable and life saving.⁵

The press release and floor statement do not mention elective abortions or abortifacients. Further, during debate over the amendment on the Senate Floor on December 3, 2009, Senator Mikulski had the following exchange with Senator Robert Casey (D-PA):

Mr. CASEY. There is one clarification I would like to ask the Senator. I know we discussed it during the HELP markup and it was not clarified at that time and thus I chose to vote against the amendment because of the possibility that it might be construed so broadly as to cover abortion. But I understand that the Senator has now clarified specifically that this amendment will not cover abortion in any way. Specifically, abortion has never been defined as a preventive service and there is neither the legislative intent nor the language in this

⁴ Press Release, Senator Barbara Mikulski, Mikulski Puts Women First in Health Care Debate (November 30, 2009), *available at* <http://mikulski.senate.gov/Newsroom/PressReleases/record.cfm?id=320304>.

⁵ *Id.*

amendment to cover abortion as a preventive service or to mandate abortion coverage in any way. I ask the Senator is that correct?

Ms. MIKULSKI. Yes, that is correct. This amendment does not cover abortion. Abortion has never been defined as a preventive service. This amendment is strictly concerned with ensuring that women get the kind of preventive screenings and treatments they may need to prevent diseases particular to women such as breast cancer and cervical cancer. There is neither legislative intent nor legislative language that would cover abortion under this amendment, nor would abortion coverage be mandated in any way by the Secretary of Health and Human Services.⁶

This exchange buttresses the plain language and clear purpose of Section 2713 in the Affordable Care Act – to provide screenings and care for Americans to prevent disease, not to end pregnancies.

2. It would be inappropriate to require group health plans and health insurance issuers to cover elective abortions or abortifacients, including the recently-approved drug *ella*.

a. Abortion is not preventive care.

Pregnancy is not a disease. Therefore, it is illogical to include elective abortions and abortifacients in preventive care and screenings.

Plan B, a so-called “emergency contraceptive,” should not be included in preventive care. When the FDA approved Plan B, it acknowledged that the drug not only prevented fertilization but “may also work by...preventing attachment (implantation) to the uterus. . . .”⁷

⁶Cong. Rec. S12274 (daily ed. Dec. 3, 2009) (colloquy between Sen. Mikulski and Sen. Casey), available at <http://thomas.loc.gov>. On December 1, 2009, Senator Mikulski stated: “There are no abortion services included in the Mikulski amendment. It is screening for diseases that are the biggest killers for women--the silent killers of women. It also provides family planning--but family planning as recognized by other acts.” Cong. Rec. S12028 (daily ed. Dec. 1, 2009) (statement of Senator Mikulski), available at <http://thomas.loc.gov>.

⁷ Labeling - Plan B (0.75mg levonorgestrel) Tablets, (8/24/2006), available at http://www.accessdata.fda.gov/drugsatfda_docs/label/2006/021045s011lbl.pdf.

Likewise, because of its abortifacient potential, the newly-approved drug “*ella*” should not be included in the definition of preventive care. While the FDA is allowing the drug to be deceptively marketed as an “emergency contraceptive,” the agency’s prescribing instructions for the drug admit that *ella* may cause abortions.⁸

That *ella* may kill an embryo is unsurprising, as it has a similar chemical make-up to the abortion drug RU-486. Both are selective progesterone receptor modulators (SPRMs). By blocking progesterone, an SPRM can “affect” an embryo in two ways. It can either prevent a developing human embryo from implanting in the uterus, or it can kill an implanted embryo by starving it to death.⁹

The FDA contraindicates *ella* for “known or suspected” pregnancy. The FDA admits, “There are no adequate and well controlled studies in pregnant women.” It cites studies in animals with high rates of pregnancy loss, and it acknowledges that the effects on a fetus that survives *ella* are unknown.¹⁰

Clearly, *ella* and any other form of “emergency contraception” that may cause abortions should not, like surgical and other chemical abortions, be included in preventive care under Section 2713(a)(4).

- b. Requiring insurance companies to cover abortions would violate the consciences of many Americans, and would contradict promises by President Obama that the Affordable Care Act does not undermine existing conscience protections in law.

In a speech on health care before Congress, President Obama stated that under health care reform “federal conscience laws will remain in place.”¹¹ He repeated his promise to defend conscience rights in his executive order: “Under the Act, longstanding Federal laws to protect conscience (such as the Church Amendment, 42 U.S.C. §300a-7, and the Weldon Amendment, Pub. L. No. 111-8, §508(d)(1) (2009)) remain intact and new protections prohibit discrimination

⁸ *ella* Labeling Information, (8/13/2010), available at

http://www.accessdata.fda.gov/drugsatfda_docs/label/2010/022474s0001bl.pdf.

⁹ See, e.g., I.M. Spitz et al., *Early Pregnancy Termination with Mifepristone and Misoprostol in the United States*, N.E. J. MED. 338:1241-47 (1998).

¹⁰ *Supra* note 8.

¹¹ Press Release, The White House, Remarks by the President to a Joint Session of Congress on Health Care (Sept. 9, 2009), available at www.whitehouse.gov/the_press_office/Remarks-by-the-President-to-a-Joint-Session-of-Congress-on-Health-Care/.

against health care facilities and health care providers because of an unwillingness to provide, pay for, provide coverage of, or refer for abortions.”¹²

The Affordable Care Act also explicitly prohibits Title I or amendments thereto from requiring qualified health plans that participate in the new Exchanges to provide elective abortion coverage as part of their “essential health benefits.”¹³ This prohibition, in effect, extends conscience protections to health insurers.

Therefore, it is nonsensical that HHS would issue regulations defining “preventive care,” a group of services that must be covered by all group health plans and health insurance issuers, to include elective abortions and abortifacients. Such an inclusion would clearly violate the conscience rights of insurance providers, betray President Obama’s promise, and in the case of those health plans participating in the Exchanges, violate the Affordable Care Act.

Conclusion

It would be inappropriate for HHS to require group health plans and health insurance issuers to cover elective abortions and abortifacients, including *ella*, under the pretext of “preventive care and screenings.” Section 2713(a)(4) of the Affordable Care Act does not require it, and the Senate floor debate over the addition of Section 2713(a)(4) demonstrates that they were not intended to be included. Further, it is clearly inappropriate for HHS to require such coverage given President Obama’s promise to maintain conscience protections.

Sincerely,

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Senior Vice President of Legal Affairs

¹² Posting of Dan Pfeiffer to The White House Blog, <http://www.whitehouse.gov/blog/2010/03/21/one-more-step-towards-health-insurance-reform> (March 21, 2010, 16:16 EST). President Obama was referring to Section 1303(b)(4), which provides: “NO DISCRIMINATION ON BASIS OF PROVISION OF ABORTION.—No qualified health plan offered through an Exchange may discriminate against any individual health care provider or health care facility because of its unwillingness to provide, pay for, provide coverage of, or refer for abortions.”

¹³ *Supra* note 1, at 897.