

September 17, 2010

Office of Consumer Information and Insurance Oversight
Department of Health and Human Services
Attention: OCIIO-9992-IFC
PO Box 8016
Baltimore, MD 21244

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

Internal Revenue Service
CC: PA: LPD: PR, (REG-120391-10)
Room 5025
P.O. Box 7604 Ben Franklin Station
Washington, DC 20044
Attention: REG 120391-10

RE: File Code OCIIO-9992-IFC/RIN 1210-AB44/REG-120391-10, 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

Dear Secretary Sebelius, Deputy Commissioner Miller, Assistant Secretary Borzi, Assistant Secretary Mundaca and Director Angoff:

The National Women's Law Center appreciates the opportunity to provide comments to the Department of Health and Human Services 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 (hereinafter the Affordable Care Act).

Since 1972, the National Women's Law Center has worked to protect and advance the progress of women and their families in core aspects of their lives, with an emphasis on the needs of low-income women. With a staff of over sixty, supplemented by legal fellows, interns, and *pro bono* assistance throughout the year, the Center utilizes a wide range of tools—including public policy research, monitoring, and analysis; litigation, advocacy, and coalition-building; and public education—to achieve gains for women and their families in education, employment, family economic security, health, and other critical areas. The National Women's Law Center has long advocated for health care reform that provides access to comprehensive, affordable health care for all women and their families. The Center's efforts reflect extensive research regarding the many challenges women face in securing affordable, comprehensive health coverage.

The National Women’s Law Center strongly supports Section 2713 of the Public Health Service Act, as added by the Affordable Care Act, which requires new health insurance plans to provide benefits for and prohibit the imposition of cost-sharing requirements for certain preventive health services. Making preventive care more affordable is critical for women. On average, women use more preventive care than men,ⁱ and are more likely than men to forgo key preventive services, such as a cancer screening or dental exam, due to cost.ⁱⁱ Studies have shown that even moderate co-payments for preventive services such as mammograms or pap smears deter patients from receiving the service.ⁱⁱⁱ We are pleased that the Affordable Care Act, through Section 2713 of the Public Health Service Act, will address these critical needs by making a number of recommended preventive health benefits more affordable and accessible to women. The Center has joined other comments on this Interim Final Rule that recommend ways to strengthen the broad protections provided under Section 2713.

The purpose of this comment is to provide additional recommendations specifically on Section 2713(a)(4), known as the Women’s Health Amendment. The Women’s Health Amendment requires the Health Resources and Services Administration (HRSA) to identify preventive health services for women, in addition to those recommended by the United States Preventive Health Services Task Force (USPSTF), that should be covered and protected from cost-sharing in all new health insurance plans. This important amendment—the first offered during Senate debate—was intended to supplement other key provisions in the bill and ensure coverage of annual well-woman visits,^{iv} screening for intimate partner and family violence,^v and preconception care visits.^{vi}

The Women’s Health Amendment was also intended to provide coverage of and cost-sharing protections for family planning services,^{vii} including the full range of FDA-approved prescription contraceptives. Contraception—nearly universal among women in the United States of reproductive age—is a key component of preventive health care for women and critical to helping women achieve healthy pregnancies. A woman whose pregnancy is unplanned is less likely to seek prenatal care in the first trimester and more likely not to obtain prenatal care at all;^{viii} less likely to breastfeed,^{ix} and more likely to expose the fetus to harmful substances, such as tobacco or alcohol.^x Women who wait for some time after delivery before conceiving their next child—which typically requires contraception—lower their risk of adverse perinatal outcomes, including low birth weight, preterm birth, and small-for-size gestational age.^{xi} In addition, there are a number of noncontraceptive preventive benefits of oral contraceptives, the most commonly used form of contraception in the United States, including lower rates of pelvic inflammatory disease, cancers of the ovary and endometrium, recurrent ovarian cysts, benign breast cysts and fibroadenomas, and discomfort from menstrual cramps.^{xii}

We offer the following recommendations to strengthen and improve the Interim Final Rule and to ensure that Section 2713(a)(4), when fully implemented, meets the full range of women’s preventive health needs.

The Department Should Develop A More Timely Process for Identifying Additional Women's Health Services to Be Covered and for Requiring Plan Compliance

We appreciate that the Interim Final Rule establishes a timeline for the development of guidelines, supported by the Health Resources and Services Administration (HRSA), for the additional preventive care and screenings for women that must be covered and protected from cost-sharing. We are concerned, however, that absent some change in the Interim Final Rule, women will not see the benefit of these protections until January 2013, two years after the rest of the Sec. 2713 requirements will have been implemented.

There are a number of ways the Department could address this concern. The Department could create a shorter, more intensive process for identifying some or all of the services to be covered under the Women's Health Amendment. If, for example, the guidelines were required to be completed by January 1, 2011, rather than August 1, 2011, women will see the benefit of these protections for new plans a full year earlier. Alternatively, the Department could eliminate or shorten the one-year interval between the completion of women's health guidelines and the date they become effective for new plans. The statute applies the minimum one-year interval only to preventive services rated A or B by the USPSTF, immunizations recommended by the Advisory Committee on Immunization Practices, and services provided for in comprehensive guidelines supported by HRSA for infants, children, and adolescents; it does not require this minimum interval for services required under the Women's Health Amendment. The statute's silence provides flexibility to create a process that results in more timely coverage requirements for women. Finally, the Department could, as it has in other areas, make clear its intention with respect to this provision and urge insurance plans to comply voluntarily in advance of the formal guideline development. In sum, we urge the Department to amend the Interim Final Rule and provide a more timely process for developing and implementing preventive health guidelines for women.

The Process for Developing the Recommended Women's Preventive Services Should Take Into Account a Range of Relevant Factors and Result in Coverage of Key Preventive Services Not Contemplated or Recommended by USPSTF

We understand that the Department intends to contract with the Institute of Medicine (IOM) to recommend the preventive services that will be covered and exempted from cost-sharing under the Women's Health Amendment. We urge the Department to work with IOM to ensure that any panel convened for this purpose is guided by current clinical guidelines for women; standards and opinions of federal agencies and national medical societies with women's health expertise; Congressional intent with respect to the specific services intended to be included; and by federal public health goals, including *Healthy People 2010*. The panel itself should have appropriate representation from women's health experts, including those with expertise in clinical standards and practice, expertise in insurance industry practices, and consumer representatives with expertise in the barriers women face in obtaining quality, affordable preventive health care.

If these principles and processes are followed, the Center is confident that the panel will recommend coverage of an appropriate range of preventive services for women, including an

annual well-woman visit; family planning, including the full-range of FDA-approved contraceptive drugs and devices; screening and counseling for intimate partner and family violence; and a preconception care visit. We urge any final regulations to describe this process in detail in order to ensure that it results in timely and complete recommendations for women.

Implementation of the Women’s Health Amendment Must Include a Mechanism for Regular Updates to Reflect New Technologies and New Evidence

The final rule should establish a process that ensures that the list of covered services is periodically updated to reflect the most up-to-date evidence available, as well as advances in technology and changing clinical practices.

Thank you again for the opportunity to comment on these important regulations. We look forward to working with you in the future as you continue to implement the Affordable Care Act.

ⁱ U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Health Statistics, “Utilization of Ambulatory Medical Care by Women: United States, 1997-98,” *Vital and Health Statistics*, Series 13, Number 149 (Hyattsville, Maryland: U.S. Department of Health and Human Services, July 2001); Asch et al., Who is At Greatest Risk for Receiving Poor-Quality Health Care?, *The New England Journal of Medicine* 354, no.11 (March 16, 2006) 1147-56.

ⁱⁱ Sheila D. Rustgi, Michelle M. Doty, and Sara R. Collins, The Commonwealth Fund, *Women at Risk: Why Many Women are Forgoing Needed Health Care* (2009). Available at <http://www.commonwealthfund.org/Content/Publications/Issue-Briefs/2009/May/Women-at-Risk.aspx>.

ⁱⁱⁱ Solanki G and Schauffler HH, *Cost-sharing and the utilization of clinical preventive services*, Am J Prev Med 17, no.2 (Aug 1999) 127-133; Trivedi et al., *Effect of Cost Sharing on Screening Mammography in Medicare Health Plans*, New England Journal of Medicine 358, no.4, 375-383 (January 2008).

^{iv} S12027 CONG. REC. H.R. 3590 (daily ed. Dec. 1, 2009) (statement Sen. Shaheen); S12059 CONG. REC. H.R. 3590 (daily ed. Dec. 1, 2009) (statement Sen. Cardin).

^v S12025 CONG. REC. H.R. 3590 (daily ed. Dec. 1, 2009) (statement Sen. Boxer),); S12027 CONG. REC. H.R. 3590 (daily ed. Dec. 1, 2009) (statement Sen. Gillibrand); S12059 CONG. REC. H.R. 3590 (daily ed. Dec. 1, 2009) (statement Sen. Cardin).

^{vi} S12027 CONG. REC. H.R. 3590 (daily ed. Dec. 1, 2009) (statement Sen. Shaheen).

^{vii} S12025 CONG. REC. H.R. 3590 (daily ed. Dec. 1, 2009) (statement Sen. Boxer); S12027 CONG. REC. H.R. 3590 (daily ed. Dec. 1, 2009) (statement Sen. Gillibrand); S12028 CONG. REC. H.R. 3590 (daily ed. Dec. 1, 2009) (statement Sen. Mikulski); H.R. 3590 (daily ed. Dec. 1, 2009) (statement Sen. Cardin); S12059 CONG. REC. H.R. 3590 (daily ed. Dec. 1, 2009) (statement Sen. Feinstein).

^{viii} U.S. Department of Health and Human Services, *Healthy People 2010: Understanding and Improving Health*, 9-32 (November 2000). Available at <http://www.healthypeople.gov/Document/pdf/Volume1/09Family.pdf>.

^{ix} *Id.*

^x *Id.*

^{xi} *Id.*

^{xii} Centers for Disease Control and Prevention, *Achievements in Public Health, 1900-1999: Family Planning*, Morbidity and Mortality weekly Report 48(47), 1073-1080 (December 3, 1999). Available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm4847a1.htm>.