

September 17, 2010

VIA ELECTRONIC TRANSMISSION

Office of Consumer Information and Insurance Oversight
Department of Health and Human Services
Attention: OCIO-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

Re: OCIO-9992-IFC; 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:

Planned Parenthood Federation of America (“PPFA”) and Planned Parenthood Action Fund (the “Action Fund”) are pleased to submit these 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 (the “Affordable Care Act” or “ACA”), published on July 19, 2010 at 75 Fed. Reg. 41726 *et seq.* (herein, referred to as the “Interim Final Rule”). For over 90 years, Planned Parenthood health centers have been on the front lines providing basic preventive care to millions of individuals. We commend the efforts made by Congress and the Administration to provide Americans with much needed preventive health care without cost-sharing through Section 2713 of the Affordable Care Act. If implemented properly, this provision has the potential to improve the health of all Americans, as well as profoundly reform our health care delivery system for the better.

Ninety-seven percent of Planned Parenthood’s services are focused on preventive care to keep women, men and teens healthy, and to help women and couples plan their families. At our 840 health centers

located nationwide, Planned Parenthood provides essential health care including routine gynecological exams, breast and cervical cancer screenings, contraceptive services, abortion care, sexually transmitted infection (STI) testing and treatment, and HIV testing and education to more than three million patients, the vast majority of whom have incomes at or below 150 percent of the Federal Poverty Level. Because of the role we play in communities across the country, Planned Parenthood is all too aware of the critical need to expand health insurance coverage for basic preventive services, and in particular for women, the need to expand coverage for the full range of FDA-approved contraceptives and the annual well-woman visit.

At the same time, policies must be put in place to ensure that these coverage expansions will result in health care *access*. The availability of insurance coverage can quickly become meaningless without an adequate network of providers. As such, it's critical that the final rule on Section 2713 include provisions to ensure that health care providers are protected from inadequate reimbursement as a result of health plan implementation of the new coverage requirements.

We respectfully request that the Secretary address the following as a part of the Section 2713 rulemaking process:

- Include all Federal Food and Drug Administration (FDA)-approved prescription contraceptive drugs and devices and the annual well-woman visit in the list of recommended preventive services exempt from cost-sharing.
- Bar insurers from passing on the cost of the elimination of cost-sharing to health care providers.
- Institute mechanisms to monitor and enforce health plan compliance with Section 2713 and its implementing regulation.
- Establish a process to ensure that recommended preventive services for women are updated to reflect advances in science and public health.
- Address privacy concerns for the provision of sensitive preventive services.

I. The Secretary must ensure that the full-range of contraceptive options and the annual well-woman visit—key components of preventive care for women—are included in the list of recommended preventive services that are covered without cost-sharing.

Section 2713 of the Affordable Care Act requires that a group health plan and a health insurer offering group or individual health insurance cover certain recommended preventive health care services without cost-sharing: (1) items or services with a United States Preventive Services Task Force (USPSTF) rating of A or B; (2) immunizations recommended by the Centers for Disease Control and Prevention (CDC); (3) preventive care and screenings for infants, children and adolescents provided for in comprehensive guidelines supported by the Health Resources and Services Administration (HRSA); and, (4) preventive care and screenings for women provided for in comprehensive guidelines supported by HRSA that are not already recommended by USPSTF.

This last category of preventive services for women was added as an amendment by Senator Barbara Mikulski (the “Women’s Health Amendment”) to the original Section 2713 to address gaps in the current USPSTF recommendations. The USPSTF recommendations include some important women’s health services (such as pap smears), but due to a limitation in its methodology, they fail to address other essential preventive care for women, including the yearly well-woman visit and family planning care. Congress intended that the Women’s Health Amendment address this limitation and calls on HRSA to identify the “additional preventive care and screenings” that should be covered at no cost for women.

We support HRSA’s utilization of an Institute of Medicine (IOM) committee to make recommendations with respect to which women’s preventive services should be covered without cost-sharing, but encourage HHS to advise the Committee to consider—and ultimately have its recommendations reflect—Congressional intent, scientific evidence, medical standards adopted by professional medical societies, and precedents established in federal law and in federal programs. If these principles are followed, we believe there is no question that among other vital preventive services for women, family planning services and supplies as well as the annual well-woman visit would be among the list of recommended women’s preventive health care services.

Congress intended the Women’s Health Amendment to include coverage of family planning services and the well-woman visit, among other preventive services, at no cost-sharing.

Congress recognized the need for improved access to affordable family planning care under health care reform by passing the Women’s Health Amendment and made its intent clear (as reflected throughout the Congressional Record) that family planning services, in addition to other important preventive health care services and screenings (such as the well-woman visit) should be covered at no cost-sharing. In fact, Senator Mikulski, when introducing her amendment, clearly stated for the record: “[M]y amendment would cover family planning services.”¹ In addition, at least six other senators affirmatively reference family planning care as services that would be covered and exempt from cost-sharing under the Women’s Health Amendment.² Congress’ intent is clear and the reasons warranted: family planning improves health care outcomes and wellness for women and their families.

¹ Press release, Mikulski Puts Women First in Health care Reform Debate, Nov. 30, 2009, *available at* <http://mikulski.senate.gov/Newsroom/PressReleases/record.cfm?id=320304> (includes text from Senator Mikulski’s prepared remarks on the introduction of her amendment).

² Sen. P. Murray, Cong. 1 Rec. S12274, Dec. 3, 2009 (“Senator Mikulski’s amendment will make sure this bill provides coverage for important preventive services for women at no cost. Women will have improved access to well-women visits, important for all women; family planning services”). Sen. B. Nelson, Cong. Rec. S12277, Dec. 3, 2009 (“[I] strongly support the underlying goal [of Senator Mikulski’s amendment] of furthering preventive care for women, including mammograms, screenings and family planning.”). Sen. A. Franken, Cong. Rec. S12271, Dec. 3, 2009 (“Senator Mikulski’s amendment closes this gap [in USPSTF recommendations for women’s health by including other key services] such as the well-woman visit, prenatal care, and family planning.”). Sen. B. Boxer, Cong. Rec. S12025, Dec. 1, 2009 (“these health care services include ... annual women’s health screenings, and family planning services”). Sen. D. Feinstein, Cong. Rec. S12059, Dec. 1, 2009 (included family planning in describing the scope of the amendment). Sen. K. Gillibrand, Cong. Rec. SS12027, Dec. 1, 2009 (describing family planning as a covered service under Senator Mikulski’s amendment).

Contraception enables women to plan their pregnancies, improving health outcomes for women and children.

Contraception is considered basic preventive care for millions of American women, and improved use has had an enormous impact on not only improving women's and children's health, but on improving educational, social, and economic opportunities for women in the United States. More than 60 percent of women aged 15-44 are currently using a contraceptive method.³ Ninety-eight percent of sexually experienced women have used contraception at some point in their lives.⁴

Contraception enables women to better prevent unintended pregnancy and plan for pregnancy when they do want to have a child. When women plan their pregnancies, they are more likely to seek prenatal care, improving their own health and the health of their children. In fact, access to family planning is directly linked to declines in maternal and infant mortality rates.⁵ In addition to the primary purpose of allowing women to plan and prepare for pregnancy, other health benefits of contraception include reduced risk of endometrial and ovarian cancers, ectopic pregnancy, iron deficiency anemia related to heavy menstruation, osteoporosis, ovarian cysts, and pelvic inflammatory disease.

Given the many health benefits associated with contraception, our nation's premiere health care provider and public health associations have long considered it basic preventive health care for women and have argued that it should be made readily available and accessible. Premier health care provider and medical associations that support improved access to contraception include: the American Medical Association, the American College of Obstetricians and Gynecologists, the American Academy of Family Physicians, the Society for Adolescent Medicine, the American Public Health Association, and the March of Dimes. In addition, the federal government has embraced this notion in every version of its Healthy People initiative (e.g., setting multiple national goals to prevent unintended pregnancy and eliminate barriers to contraceptive access), and in many of the health care programs that it supports, including Medicaid (where coverage of family planning without cost-sharing is mandated), the Federally Qualified Health Center program, and the Maternal and Child Health and Preventive Health and Health Services Block Grants. Indeed, public policies and public health programs have long emphasized the importance of expanding access to family planning services as a way of improving the health of women, children, and communities.

Cost-sharing, even if minimal, prevents many women from being able to afford contraception.

Many insured women simply cannot afford the out-of-pocket costs associated with health care. In fact, a May 2007 report by the Commonwealth Fund found that more than half of women delayed or avoided preventive care because of cost.⁶ The impact of copayments and other cost-sharing as a barrier to

³ The Guttmacher Institute, "Facts on Contraceptives Use," *Facts in Brief*, January 2008.

⁴ Chandra A *et al.* Fertility, family planning and reproductive health of U.S. women: data from the 2002 National Survey of Family Growth. *Vital Health Statistics*, 2005, Series 23, No. 25.

⁵ Gold R., "Family Planning and Health Care Reform: The Benefits and Challenges of Prioritizing Prevention," *Guttmacher Policy Review*, Winter 2009, Volume 12, Number 1.

⁶ S. D. Rustgi, M. M. Doty, and S. R. Collins, *Women at Risk: Why Many Women Are Forgoing Needed Health Care*, The Commonwealth Fund, May 2009.

accessing affordable contraception is reflected in these sobering statistics: half of all pregnancies in the U.S. each year are unintended,⁷ and connected to this, the U.S. consistently lags behind other developed nations in maternal and infant mortality rankings (in recent rankings, the U.S. ranked 42nd in the world for maternal mortality and 30th in the world for infant mortality rates).⁸

There is no doubt that cost sharing is a barrier to accessing affordable birth control. This is particularly true for young women. A recent Ibis Reproductive Health report showed that even after gaining under Massachusetts' health care reform law, many young women still struggled with co-pays for contraception.⁹ Ensuring access to the full-range of contraceptive options without cost-sharing is especially critical for these young women, as many of them may opt for the catastrophic coverage option (available to individuals under age 30) under the health care reform law. The Affordable Care Act requires that these limited benefit plans cover at a minimum the recommended preventive services and three primary care visits. Given that fifty-two percent of young women (ages 20-29) who utilize contraceptives depend on prescription contraceptive methods¹⁰ (and this percentage would be expected to rise if it were available at no cost), including contraception in the Women's Health Amendment would meet a significant health care need for young women. And it would go a long way towards preventing unintended pregnancies and improving overall health for this group of women. Currently, fifty-one percent of pregnancies for young women (ages 20-29) are unintended.¹¹

The Secretary acknowledges in the Interim Final Rule that individuals are sensitive to prices for health services and as copayments (or other cost-sharing) declines, more services are demanded and utilized. Data from the public and private sector indicate that increased utilization of family planning not only improves health outcomes for women and families, but that it is extremely cost-effective and adds very little to overall insurance-related expenses for employers.

Publicly funded contraceptive services and supplies prevent nearly two million unintended pregnancies each year.¹² For every dollar invested in contraception, \$3.74 is saved in Medicaid expenditures for pregnancy-related care.¹³ The data in the private sector is equally compelling. Several studies conducted by employee benefit and actuarial consulting firms found that the inclusion of comprehensive coverage of contraception in private employee benefit plans had very little impact on overall employer costs and

⁷ Finer LB and Henshaw SK. Disparities in rates of unintended pregnancy in the United States, 1994 and 2001, *Perspectives on Sexual and Reproductive Health*, 2006, 38(2):90-96.

⁸ Maternal Mortality in 2005: estimates developed by WHO, UNICEF, UNFPA, and The World Bank, available at http://www.who.int/whosis/mme_2005.pdf. Centers for Disease Control and Prevention, NCHS Data Brief, No. 23 (Nov. 2009), available at <http://www.cdc.gov/nchs/data/databriefs/db23.htm#ref5>.

⁹ Ibis Reproductive Health, "Young adults, health insurance & access to contraception in the wake of health care reform," April 2010. <http://www.ibisreproductivehealth.org/work/contraception/documents/IbisRH-FGDRReport-FINAL.pdf>.

¹⁰ Mosher, Jones J. "Use of Contraception in the United States: 1982-2008." *National Center for Health Statistics* 23.29 (2010).

¹¹ Filmer L. and Henshaw S. "Disparities in Rates of Unintended Pregnancy in the United States, 1994 and 2001." *Perspectives on Sexual and Reproductive Health* (2006): 90-96.

¹² Gold R., "Family Planning and Health Care Reform: The Benefits and Challenges of Prioritizing Prevention," *Guttmacher Policy Review*, Winter 2009, Volume 12, Number 1.

¹³ Sonfield A., Contraception: An Integral Component of Preventive Care for Women. *Guttmacher Policy Review* 13(2)(Spring 2010).

insurance premiums.¹⁴ This is also true for the federal government, the nation's largest employer, which saw no increase in costs after a 1998 law required coverage of contraceptives for federal employees.

HHS must ensure that health plans cover all FDA-approved prescription contraceptives without cost-sharing.

The Interim Final Rule allows a plan or health insurance issuer to use reasonable medical management techniques to limit coverage if a recommendation or guideline for a recommended preventive service does not specify “the frequency, method, treatment, or setting for the provision of that service.”¹⁵ Although not explicitly stated, it also suggests that when a recommendation or guideline does specify frequency, method, treatment, or setting, then such specifications apply as a ceiling on the requirement for coverage without cost-sharing. While we understand the Secretary's effort to strike the right balance between coverage requirements and giving health plans and issuers some flexibility in the design of their benefit plans, we are concerned about how health plans may use this flexibility to limit coverage. Moreover, in the case of contraceptive care in particular, this policy presents some important considerations that must be addressed.

Women need access to a broad range of contraceptive options, including the option of brand-name versus generic formulation of contraceptive drugs.¹⁶ In fact, on average, a woman uses four different contraceptive methods over the course of her reproductive life.¹⁷ HHS recognizes the importance of broad contraceptive options for women in its Healthy People 2010 report where it states, “in the absence of comprehensive coverage, many women may opt for whatever method may be covered by their health plan rather than the method most appropriate for their individual needs and circumstances. Other women may opt to not use contraception if it is not covered under their insurance plan.”¹⁸

Assuming that contraception will be a recommended preventive service exempt from cost-sharing, it is critical that the Secretary describe this recommendation with specificity – namely, that all FDA-approved prescription contraceptive drugs and devices be covered. Without specificity, under the flexibility provided in the Interim Final Rule, health plans may very well limit the contraceptive options that many women have today – certainly, a scenario that Congress did not intend when it included Section 2713 in the Affordable Care Act. For example, copayments (and coinsurance) for brand name drugs have drastically increased over the last decade so much so that, in many cases, the beneficiary is paying for the majority of the cost of the drug or product and receiving only a marginal discount from what she would

¹⁴*Id.* (In describing the findings of studies conducted by: Buck Consultants – “The addition of coverage for the full range of reversible prescription contraceptive methods to a plan that included no contraception coverage at all would increase costs by about \$21 per employee per year.”); Washington Business Group on Health and William M. Mercer consulting firm – it costs employers 15-17% more to not provide contraceptive coverage; and the National Business Group on Health 2008 Guide for employers “recommended that all employer-sponsored health plans include comprehensive coverage of unintended pregnancy prevention services, free of any cost-sharing, as a part of a recommended minimum set of benefits for preventive care,” also noting that savings were expected to exceed costs of the benefit.)

¹⁵ 75 Fed. Reg. 41726, 41729.

¹⁶ Gold, RB., Sonfield A., Richards, C., Frost J. The Guttmacher Institute, Next Steps for America's Family Planning Program, Leveraging the Potential of Medicaid and Title X in an Evolving Health Care System.

¹⁷ *Id.*, citing Special tabulations of data on contraceptive method use from the 2002 National Survey of Family Growth.

¹⁸ Healthy People 2010, Volume I (second edition) (Nov. 2000), *available at* <http://www.healthypeople.gov/Document/HTML/Volume1/09Family.htm>.

have paid without insurance.¹⁹ In addition, coinsurance for long-acting methods, such as the intrauterine device (IUD) or implant, is notoriously high – making these long-lasting and cost-effective options out of reach for many women. It is not a stretch to assume that if a health plan is required to absorb this cost-sharing where it did not have to before, it may exclude brand name and long-acting reversible contraceptive methods, preferred methods for many women, from their formularies and benefit plans.

The Secretary also notes that health plans or issuers may impose limitations on the setting for the provision of recommended preventive services, if not otherwise specified in the recommendation or guideline. This kind of limitation could severely undermine women’s access to the providers they trust—requiring them to split health care where it would otherwise be offered in a singular setting. Millions of women look to Planned Parenthood health centers and other women’s health centers for low-cost, high-quality, and confidential health care, including contraception. It is essential that these women can continue to receive their health care, including their birth control pills and other contraceptive supplies, at Planned Parenthood and other women’s health centers. Health plans should not be allowed to unnecessarily erect barriers to access by restricting the settings or methods by which beneficiaries can obtain their health care, especially contraceptive care (e.g., by only allowing prescriptions to be filled through mail order). Beneficiaries must be given an array of options for filling or otherwise receiving prescription drugs and devices, including on-site dispensation at women’s health centers.

In sum, as the Obama Administration works to implement the Affordable Care Act, producing implementing guidance for the Women’s Health Amendment that includes comprehensive coverage of contraception and the well-woman visit should be a priority. To truly fulfill the promise of the Women’s Health Amendment, however, the Secretary must institute policies that guarantee access to these critical preventive services, including an adequate network of providers to supply them.

II. To ensure patient access to the recommended preventive services and the health care providers who offer them, the Secretary must bar health insurers from passing on the cost of the elimination of cost-sharing to health care providers.

In passing Section 2713, Congress clearly intended that the onus to pay for the recommended preventive services that are exempt from cost-sharing should fall on health plans and health insurance issuers. The Congressional history is replete with references to the health plans’ obligation to “fully cover”, “provide”, and “guarantee” recommended prevention and wellness benefits as set forth ACA and its implementing rule.²⁰ If health plans attempt to shift the cost of the elimination of cost-sharing to health care providers,

¹⁹ Average copayments for many brand name drugs in employer sponsored insurance have dramatically increased over the last decade, in many cases up to \$46. Sonfield A. Contraception: An Integral Component of Preventive Care for Women. *Guttmacher Policy Review* 13(2)(Spring 2010)(source: Kaiser Family Foundation and Health Research and Educational Trust, 2009).

²⁰ Sen. Feinstein, Cong. Rec. S12114, Dec. 2, 2009 (“[Section 2713] will require insurance plans to cover at no cost basic preventive services and screenings for women.”); Sen. Baucus, Cong. Rec. S13745, Dec. 22, 2009 (“Insurance companies will be required to cover – free of charge – preventive care for new policyholders.”); Sen. Baucus, Cong. Rec. S13231, Dec. 15, 2009 (“[T]his legislation requires that health insurers must provide prevention and wellness benefits but no deductibles and no cost-sharing requirements.”). Sen. Klobuchar, Cong. Rec. S13864, Dec. 23, 2009 (“With this bill insurance companies must immediately fully cover regular checkups that help prevent illness....”); Sen. Franken, Cong. Rec. S13817, Dec. 23, 2009 (“We will also guarantee routine checkups and recommended preventive care, ... are covered by all insurance plans at no cost”).

either directly under their provider agreements or indirectly by bundling newly mandated preventive services into payments for other services or visits without increasing the overall payment to providers, they are not “covering” the preventive benefits as required under the Affordable Care Act, and they may very well be compromising their beneficiaries’ access to these critical preventive services.

The Secretary also acknowledges in the Interim Final Rule that health plans, not health care providers, are responsible for absorbing the cost involved in the elimination of patient cost-sharing for recommended preventive services. The Rule explains that, “[c]ost-sharing, including co-insurance, deductibles, and copayments divides the costs of health services between the insurer and the beneficiaries.”²¹ The removal of cost-sharing results in a transfer in who pays for the services. “For example, costs that were previously paid out-of-pocket for certain preventive services ***will now be covered by plans and issuers under these interim final regulations.***”²² (emphasis added) We appreciate the Rule clarifying this important point, but believe that it can be strengthened by the Secretary affirmatively barring insurers from transferring this cost to health care providers.

Barring insurers from shifting the cost of the elimination of cost-sharing to health care providers is especially critical for essential community providers, such as Planned Parenthood health centers and other women’s health centers, who are struggling under the current economic recession to provide low-cost, quality health care to millions of economically disadvantaged women. Increases in unemployment and cuts in benefits are leaving many women and families without health insurance and dependent on providers like us for their reproductive health care. Demand for contraception and other preventive reproductive health care services is rising, while public funding and Medicaid reimbursement rates are falling. Health centers are having to do more with less and many have had to make difficult cutbacks – in hours, services, and staff – in order to keep their doors open. Losing the revenue stream from copayments and other cost-sharing could be devastating to women’s health centers like Planned Parenthood. Too many are already in precarious financial circumstances due to low payments provided by public payors such as Medicaid and private insurers. Having to absorb the loss of cost-sharing for recommended preventive services could make the difference in their viability. Allowing health plans to shift this cost to health care providers compromises patient access to their trusted community providers and to the preventive services to which they are entitled to under the law.

To ensure consumer access to providers and the recommended preventive health care services, Planned Parenthood respectfully requests that in the final rule the Secretary bar insurers from passing on to providers the cost of eliminating cost-sharing, as well as the cost of providing newly mandated preventive health care services. We also ask that the Secretary address how insurers will honor the total reimbursement rate in existing (or multi-year) provider contracts once the provisions in Section 2713 take effect and health plans are no longer requiring of enrollees copayments, coinsurance, or deductibles for services rendered.

²¹ 75 Fed. Reg. 41737.

III. The Secretary must institute mechanisms to monitor and enforce health plan compliance with Section 2713 and its implementing rule.

The Interim Final Rule is silent with respect to the enforcement and oversight of health insurance companies' compliance with Section 2713 requirements. To ensure that the Women's Health Amendment and the other preventive provisions are implemented as Congress intended, the Secretary must have mechanisms in place to monitor and enforce health plan compliance with these provisions. The Secretary should also employ processes that allow consumers and health care providers to file complaints or seek assistance regarding their rights under the law and violations by insurers.

IV. Establish a process to ensure that recommended preventive services for women are updated to reflect advances in science and public health.

The Interim Final Rule does not address how women's recommended preventive services under the Women's Health Amendment will be updated to reflect advances in science and technology, and changes in standard medical practice. The Secretary should establish a process with stakeholder input that ensures that the list of recommended preventive services for women is updated as needed to ensure that women are receiving appropriate preventive care at no cost-sharing.

V. The Secretary must address privacy concerns for the provision of sensitive preventive services.

In the context of a reformed, pro-insurance health care system, we strongly encourage HHS to pursue policies that better protect patient confidentiality, including policies that protect patient privacy with respect to explanation of benefits (EOBs). This is especially critical for many of the preventive services outlined by USPSTF and those potentially recommended under the Women's Health Amendment, including STI testing and treatment and contraceptive care.

VI. HHS should ensure that forthcoming guidance on value based insurance designs addresses access to women's preventive services and women's health providers.

The Interim Final Rule solicits comments regarding the development of guidelines for value-based insurance designs, including the provision of information and incentives for consumers that promote access to and use of higher value providers, treatments, and services. For the many reasons outlined above, contraception (or a package of reproductive health care services that includes contraception, cancer screenings, and STI screening and treatment) should be considered a high value preventive service and be included as such in any policies around value-based insurance design. In addition, essential community providers are high value providers that serve a wide variety of patients in communities across the country in a cost-effective and high-quality manner, and they should also be included and incentivized in any value-based insurance design. We look forward to working with the Department as these guidelines are developed.

Thank you for the opportunity to comment on the Interim Final Rule. If you have any questions, please do not hesitate to contact me at 202-973-4800.

Respectfully submitted,

A handwritten signature in cursive script that reads "Laurie Rubiner".

Laurie Rubiner
Vice President of Public Policy and Advocacy
Planned Parenthood Federation of America
1110 Vermont Ave., NW., Suite 300
Washington, D.C. 20005