



September 16, 2010

Office of Consumer Information and Insurance Oversight
Department of Health and Human Services
Attention: OCIIO-9992-IFC,
P.O. Box 8016
Baltimore, MD 21244-1850

In a notice published in the *Federal Register* on July 19, 2010 (Vol. 75, No. 137, pp. 41726–41760), the Departments of Health and Human Services (DHHS), Labor, and the Treasury issued an interim final rule (IFR) to implement a section of the Patient Protection and Affordable Care Act (PPACA) that requires group health plans and health insurance issuers in the group and individual markets to provide benefits, without cost-sharing, for a series of preventive services. On behalf of the Guttmacher Institute, a nonprofit organization dedicated to advancing sexual and reproductive health worldwide through research, policy analysis and public education, I am pleased to submit the following comments on this IFR. We believe that this provision, codified as Sec. 2713 of the Public Health Services Act and entitled Coverage of Preventive Health Services, and particularly Sec. 2713(a)(4), known as the Women’s Health Amendment (WHA) and sponsored by Sen. Barbara Mikulski of Maryland, has the potential, if implemented as intended, to remove significant financial disincentives to women’s access to and use of a wide array of reproductive health services.

Under Sec. 2713, beginning on September 23, 2010, all new health plans must cover, without cost-sharing, preventive services described in several sets of federally supported recommendations and guidelines, including recommendations from the U.S. Preventive Services Task Force (USPSTF) and the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention and guidelines on pediatric preventive care supported by the Health Resources and Services Administration (HRSA). These recommendations include some related to sexual and reproductive health, including Pap smears to head off cervical cancer, screening for chlamydia, gonorrhea, syphilis and HIV, immunization against human papillomavirus, and several components of prenatal care.

The fourth category, added by the WHA, are additional preventive care and screenings for women beyond those recommended by the USPSTF, as delineated by guidelines supported by HRSA. The guidelines needed to implement the WHA will be written by a panel of the Institute of Medicine (IOM) under a contract with DHHS.

We have several areas of concern regarding this IFR, relating to interpretation and implementation of both Sec. 2713 as a whole and the WHA specifically. These concerns are detailed below.

Identifying Women's Preventive Services

The central question for implementing the WHA is the identification of the specific women's preventive services to be included. In that regard, we urge that several important principles be kept in mind:

The final list of protected services should be based on and informed by current, reputable scientific evidence of the benefits and drawbacks of specific services for women's health; by the legislative history of the amendment; and by precedents in federal law and policy. To that end, the panel should consult with and be guided by the current clinical guidelines, standards and opinions of federal agencies and mainstream national medical societies with an expertise in women's health, such as the Centers for Disease Control and Prevention and the American College of Obstetricians and Gynecologists. It should pay heed to statements from supporters of the amendment during the Senate floor debate. It should look to the preventive care required by law under federal and state programs funding health care access and coverage. Similarly, it should take into consideration the official preventive and public health goals for the nation set by *Healthy People 2010*, and the services that DHHS has highlighted to help meet those goals.

For example, inclusion of contraceptive services and supplies in the panel's recommendations is supported by all of these measures. A wide range of public and private expert bodies—including the IOM itself—have repeatedly endorsed contraception for its preventive health benefits for women and their children, as well as its broader social and economic benefits. The *Healthy People* series has since its inception always included family planning as a priority area, with the most recent version calling specifically for increased insurance coverage of contraceptive supplies and services. Medicaid and the Sec. 330 Health Center program both require family planning and label it preventive care (Medicaid exempts it from cost-sharing), and states have long used funding from the Maternal and Child Health Block Grant for these services as well. In the private sector, the National Business Group on Health has recommended that its membership of large employers include the full range of contraceptive methods and services as a covered health benefit without cost-sharing, as a means of enhancing maternal and child health. Indeed, during the floor debate over this amendment, Senator Mikulski and many of her colleagues specifically mentioned family planning as among the services they expected to be included.

The panel should be clearly tasked with identifying the list of specific items and services for which coverage without cost-sharing is mandated by the law, and not be tasked more broadly with creating a new set of clinical guidelines for women's preventive health.

The panel should also be clearly informed that it is not authorized to take the cost-effectiveness of specific services into account in its recommendations. The other recommendations referred to in Sec. 2713, such as those from the USPSTF, do not take cost-effectiveness into consideration, and there is nothing in the statutory language nor the legislative history implying that cost-effectiveness should or may be considered.

On a related note, part of the IOM panel's task is to evaluate models for DHHS to use in regularly updating the WHA guidelines. Taking into account the panel's findings, *the final rule should establish a science-based, politically insulated 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.*

If these principles are followed, we are confident that the panel will include an appropriate range of vital preventive services for women, including an annual well-woman visit; family planning, including contraceptive drugs and devices and related medical services; assessment and counseling for lifetime and current exposure to intimate partner violence; and a preconception care visit.

Timely Implementation of the Women’s Health Amendment

Under the timeline for action indicated by the IFR, the services included in the guidelines to be created under the WHA will not be required in most new plans until January 2013, two years after the rest of the Sec. 2713 requirements will affect plans. That is the result of three factors:

- the timeline for issuing the WHA guidelines (given a tentative due date of August 1, 2011, according to the IFR);
- a one-year interval between when the guidelines are issued and when they become effective for new plan years (therefore, August 1, 2012); and
- the fact that for a typical group plan, the plan year starts January 1 (therefore, January 1, 2013).

We urge the Departments to exercise their authority to accelerate this timetable and eliminate this unnecessary delay, with a goal ensuring that services required under the WHA guidelines would affect plans starting in January 2012—one year earlier than the current schedule.

The simplest way for the Departments to expedite this process would be to set a shorter interval between when the initial women’s preventive health guidelines are issued and when they become effective for new plan years. Under Sec. 2713(b), the Secretary shall establish a minimum interval, to be at least one year, before new recommendations or guidelines take effect as required services under the provision. In a footnote in the IFR, the Departments acknowledge that the law, as written, does not specifically apply to the WHA requirements under Sec. 2713(a)(4), but asserts that “there is no plausible policy rationale for treating them differently.” We disagree with this interpretation. Because the provision does not specifically apply to (a)(4), the Secretary can, in our view, establish a shorter interval for the initial guidelines under the WHA, and the unnecessary delay—which will amount to an extra year for most women in group plans—is a sufficient rationale for treating the initial WHA guidelines differently. Moreover, a shorter interval could be established without imposing a significant burden on insurers: They will already have developed procedures for exempting preventive health services from cost-sharing, and the open and lengthy process of establishing the initial WHA guidelines will allow insurers to anticipate much or all of the coverage that will be required. (We agree that it would not make sense to treat any future changes to the WHA guidelines differently from future changes to the other three sets of required services.)

Individual Services in the Context of Office Visits

As currently written, the IFR applies the cost-sharing protections to a recommended service when it is billed or tracked separately from the office visit. When it is not billed or tracked

separately, the visit itself is free of cost-sharing only if delivery of the protected services is “the primary purpose of the office visit.”

However, the term “primary purpose” is not defined in the IFR, and the examples provided present obvious, extreme cases. There is no guidance for how to address middle-ground cases, in which both protected and unprotected services are major reasons behind the visit. For example, a prenatal care office visit typically includes a large number of recommended screening, counseling and vaccination services, including screening for anemia, urinary tract infections, Rh incompatibility and various STIs, and counseling about tobacco and alcohol use and to support breast feeding. It also typically includes a variety of services not subject to the Sec. 2713 protections. It is not clear from the IFR whether the recommended services amount to “the primary purpose” of the prenatal care visit and that the entire visit should receive cost-sharing protections. (We believe it was the intent of Congress that such visits should, indeed, receive cost-sharing protections.)

Therefore, we ask that the Departments modify the regulatory language and examples included in the IFR to provide more adequate guidance to insurers, providers and patients about how the cost-sharing protections apply for office visits that include a mix of services covered and not covered by the Sec. 2713 protections.

In addition, we are concerned that insurers may attempt to undermine the intent of the provision by inappropriately bundling newly mandated preventive services into billing and payments for office visits or other, unprotected services. This could have the effect of negating the cost-sharing protections for patients. It could also be used to shift costs to providers, if services were bundled without increasing the overall payment to providers. Such actions by insurers could have a significant effect on patients’ ability to access these important preventive services. The Departments can take two steps to head off these potential problems:

- *Establish reasonable standards to prohibit inappropriate bundling of services that have the clear result of undermining Sec. 2713 protections.*
- *Clarify that the HRSA-supported guidelines for children and for women by definition include office visits for the purpose of providing preventive services delineated in those guidelines, including pediatric, well-woman, family planning and prenatal visits.*

Respecting Patients’ and Providers’ Judgment

The IFR’s preamble and regulatory language include several statements and provisions that appear to defer to insurers’ judgment, rather than to that of patients and their health care providers, about appropriate preventive care.

For example, the IFR states that “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, the plan or issuer can use reasonable medical management techniques to determine any coverage limitations.” Although the preamble states that insurers “may rely on established techniques and the relevant evidence base” in making these decisions, there is no definition of “reasonable medical management techniques” to guide even that voluntary

standard. In effect, this endorses a standard by which insurers are making decisions about whether and when a service is medically or even financially appropriate, rather than leaving those decisions to the judgment of health care providers with the informed consent of their patients. *The final rule should include a definition of “reasonable medical management techniques” and should require, rather than permit, insurers to rely on medical evidence and allow providers to deviate from standards when needed to meet the needs of individual patients.*

Similarly, the IFR does not state it clearly, but it appears to assume 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. It is true that recommendations from groups like the USPSTF and clinical guidelines from medical professional groups are sometimes tied to specific patient characteristics (e.g., for women up to a specified age), timetables (e.g., every two years) or other specific techniques, technologies or settings. Nevertheless, these recommendations and guidelines are based on the needs of typical patients, and they recognize that some patients’ risks and needs vary and may necessitate services that deviate from the standards. *The final rule should make clear that such specifications do not apply when a patient’s health care provider deems the preventive service medically appropriate for that particular patient.*

In addition, the preamble to the IFR states that the Departments are developing guidelines about the “utilization of value-based insurance designs” by insurers. It specifically asks for public comments for designs that “promote consumer choice of providers or services that offer the best value and quality, while ensuring access to critical, evidence-based preventive services.” However, the one example included in the IFR—the ability to restrict coverage and require cost-sharing for preventive services provided out-of-network—does not clearly promote that end; rather, some insurers may instead develop their provider networks with an eye toward their own profitability, rather than patient health or value. *The final rule should not allow value-based insurance designs that undermine the provision’s goal of maximizing the use of recommended preventive health services.*

Finally, the IFR includes no measures to help ensure that the provision is implemented in the best interests of patients. *The final rule should include processes to monitor, enforce and encourage compliance with the Sec. 2713 requirements.* Those processes should allow consumers to issue complains and make appeals when insurers, providers or pharmacies do not adhere to the law and consumers are inappropriately denied access to or required to absorb some of the cost of protected services and supplies. To encourage compliance, HHS should provide technical assistance and education to health plans, health care providers, pharmacies and the general public.

On a related note, the goals of the Sec. 2713 provision could also be undermined by insurance industry procedures that unintentionally abrogate confidentiality for dependents, such as by sending an explanation-of-benefits form to the policyholder when a dependent receives care or services under the policy. The Guttmacher Institute submitted comments related to this concern in August, and we are attaching that letter again, for your convenience.

We hope you find these comments useful as you move to finalize the IFR. If you need additional information about the issues raised in this letter, please feel free to contact Adam Sonfield in the Institute's Washington office. He may be reached either by phone at 202-296-4012 or by email at asonfield@gutmacher.org.

Thank you for your consideration.

Sincerely yours,

A handwritten signature in cursive script that reads "Cory L. Richards". The signature is written in black ink and is positioned above the printed name and title.

Cory L. Richards
Executive Vice President
Vice President for Public Policy



August 11, 2010

Office of Consumer Information and Insurance Oversight
Department of Health and Human Services
Attention: OCIO-4150-IFC
P.O. Box 8016
Baltimore, Maryland 21244-1850

In a notice published in the *Federal Register* on May 13, 2010, the Department published an interim final rule for group health plans and health insurance issuers relating to dependent coverage of children to age 26 and solicited public comment on those rules. On behalf of the Guttmacher Institute, I am pleased to submit the following comments on the implications of these important rules for individuals seeking reproductive health services.

The extension of dependent coverage to young adults is a critical component of the health care reform legislation. Historically, young adults have been the age-group most likely to lack health insurance coverage.¹ When it comes to reproductive health, individuals aged 18–24 have the highest rate of unintended pregnancy; in this age-group, more than one unintended pregnancy occurs for every 10 women, a rate twice that for women overall.²

Allowing young adults to obtain coverage as dependents on their parents' policies will provide a critical pathway to insurance for many. However, in order for this coverage to be usable for the care individuals in this age-group need—including the reproductive health services that are among the services accessed most frequently by individuals in this age-group—additional steps must be taken to ensure that they are able to obtain care on a confidential basis. To do so, it is of the utmost importance that attention be paid to widely used claims-processing procedures that unintentionally abrogate confidentiality, such as by sending an explanation-of-benefits form to the policyholder when a dependent receives care or services under the policy. Although this practice was established for the laudable goal of protecting policyholders and insurers from fraud and abuse, it often precludes the receipt of confidential care.

The inability to access confidential services may have serious consequences. For example, someone who foregoes or even delays testing and treatment for STIs puts not only himself or herself at risk, but his or her partners as well. Similarly, the specter of parental notification has distressing implications for teens and young adults seeking contraceptive services. A nationwide study of adolescents attending family planning clinics found that 60% younger than 18 said their parents knew they used a clinic for sexual health services—typically because they had told parents themselves or their parents had suggested it. But among teens who said they had not already

¹ Cohen RA, Martinez ME and Free HL, *Health Insurance Coverage: Early Release of Estimates from the National Health Interview Survey, 2007*, National Center for Health Statistics, 2008, <<http://www.cdc.gov/nchs/data/nhis/earlyrelease/insur200806.pdf>>, accessed Aug. 9, 2010.

² Finer LB et al., Disparities in unintended pregnancy in the United States, 1994 and 2001, *Perspectives on Sexual and Reproductive Health*, 2006, 38(2):90–96.

discussed their clinic visit with a parent, 70% said they would not seek family planning services and one-quarter said they would have unsafe sex if they were unable to obtain confidential care.³

National data show that many insured teens and young adults already appear unwilling to use insurance coverage to pay for their contraceptive care. According to an analysis by the Guttmacher Institute of data from the National Survey of Family Growth, only 68% of privately insured teens and 76% of privately insured young adults aged 20–24 who obtained contraceptive services used their coverage to pay for their care, compared with 90% of insured women older than 30.⁴

Feeling that they are unable to use their insurance coverage, teens and other dependents often turn to publicly funded services to obtain confidential care. This puts a severe strain on scarce public resources, such as those available for the federal Title X family planning program, to provide care that is already being paid for as part of a family's insurance coverage. In short, failure to provide confidential access under health insurance drains public programs while leaving private insurers to reap a windfall from having factored the cost of care into the premiums they charge without actually being asked to pay for the services delivered.

We therefore urge the Department to move quickly to address this critical issue. As a first step, we urge the Department to examine the authority available under the Health Insurance Portability and Accountability Act, as well as any avenues possible through state law and policy, to afford protection to dependents needing confidential access to care. To do so, it will be critical that the Department work in concert with insurers, state departments of insurance and health care provider groups—such as the American Academy of Pediatrics, the Society for Adolescent Health and Medicine, the American Congress of Obstetricians and Gynecologists and the American Medical Association—to develop methodologies that ensure access to confidential care for those who need it.

We hope you find these comments useful as you move to ensure that young adults have insurance coverage they are able to use to access the health care services, including reproductive health care services, they need. If you require additional information about the issues raised in this letter, please feel free to contact Rachel Benson Gold in the Institute's Washington office. She may be reached either by phone at (202) 296-4012 or by email at rgold@guttmacher.org.

Thank you for your consideration.

Sincerely yours,



Cory L. Richards
Executive Vice President
Vice President for Public Policy

³ Jones RK et al., Adolescents' reports of parental knowledge of adolescents' use of sexual health services and their reactions to mandated parental notification for prescription contraception, *Journal of the American Medical Association*, 2005, 293:340–348.

⁴ Gold RB, Unintended consequences: how insurance processes inadvertently abrogate patient confidentiality, *Guttmacher Policy Review*, 2009, 12(4):12–16.