

September 17, 2010

Secretary Kathleen Sebelius
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

RE: Comments on **OCIIO-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:

The undersigned organizations, representing diverse women, families and communities throughout the United States, are submitting 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 (PPACA). We offer our strong support for the requirements that insurers cover preventive services without cost-sharing requirements. We also offer recommendations for strengthening the Rules, including a recommendation to eliminate unnecessary and unreasonable delays in the extension of these critical protections to women's preventive services, such as contraception, for which there is clear evidence, and a strong medical consensus in support, of their importance as a component of the standard of preventive care.

The importance of preventive services for women

Preventive health services are an essential component of health care at every stage of life, yet as you and co-author Assistant Secretary for Health Howard Koh noted in an article in the *New England Journal of Medicine* last month, in this country we receive only about half of the recommended preventive services.¹ One significant reason for this gap is that inadequate health insurance imposes burdensome cost-sharing requirements which research shows to be a barrier to receiving needed care. The Commonwealth Fund's 2007 Biennial Health Insurance Survey found that large numbers of respondents had delayed or avoided needed care because of cost; and this problem is even more pronounced for women. Even among women with insurance, a third reported that cost was a barrier to accessing needed care. Only 67 percent of women over the age of 50 with poor health insurance coverage received a mammogram in the past two years, compared with 85 percent of adequately insured women.² Cost-sharing may similarly serve as a barrier to women receiving other preventive health services such as cervical cancer screening, prenatal care, blood pressure screening and tests for diabetes.

¹ "Promoting Prevention through the Affordable Care Act," Howard K. Koh and Kathleen G. Sebelius, *NEJM*. August 25, 2010.

² "Women at Risk: Why Many Women Are Foregoing Needed Health Care," The Commonwealth Fund, pub. 1262 Vol. 52, May 2009.

Many of the health problems most prevalent in the United States are preventable, and reducing barriers to preventive care can improve health outcomes. In these challenging economic times, consumers will benefit greatly from the Section 2713 requirement that insurers offer coverage that provides benefits for evidence-based preventive health services and screening without imposing any cost-sharing charges. Particularly critical for ensuring that women will be able to get the preventive health care we need, is Section 2713(a)(4), the Women's Health Amendment, which was added to ensure that women's preventive health services would be covered and protected from cost-sharing. This will shrink the pool of women forced to choose between preventive care that may be critical for the long-term well-being of themselves and their families and the more immediately pressing economic needs of rent, food bills and other family expenses. This provision of the law may turn out to be among the most critical for the improving the health of women and our families.

Along with our strong support for the Rules you have proposed, we write to offer recommendations to strengthen the Rules. The most important strengthening recommendation relates to Section 2713(a)(4), the inclusion of women's preventive health services, and to the process for ensuring that women will not face unreasonable and unnecessary delays in gaining the protections mandated by the law.

Strong public health consensus supports treating contraception as preventive care

The PPACA uses two main sources to determine what qualifies as evidence-based preventive health care: the recommendations of the U.S. Preventive Health Services Task Force (USPSTF) and the immunization recommendations of the Centers for Disease Control and Prevention. But when Congress was writing the legislation, it recognized that reliance on those references left out some preventive health services that are critically important for the health of women and children so it added provisions to address that omission. Section 2713(a)(4) expands the prevention requirements to include preventive care and screenings for women as recommended by guidelines supported by the Health Resources and Services Administration (HRSA). The record of the legislative debate on PPACA shows clearly that Congress discussed and understood that this provision would include family planning. In addition to Congressional intent, there is a strong public health consensus that contraception is an essential tool in preventing bad health outcomes for women and children. It is, therefore, our expectation that comprehensive contraceptive care will be among the women's preventive health services detailed in the HRSA guidelines and consequently covered by insurance and protected from cost-sharing requirements.

Comprehensive contraceptive care is recognized throughout the mainstream medical community to be essential for reducing both unintended pregnancies and a host of preventable health problems affecting both women and children. According to the Association of Maternal and Child Health Programs, children born of unplanned pregnancies are more likely to be born prematurely, have lower birth weights and higher rates of infant illness and death. Additionally, women who experience unplanned pregnancies are less likely to seek prenatal care and more likely to suffer complications and morbidity during pregnancy and childbirth. Health care provider associations, such as the American Medical Association, the American Academy of Family Physicians, the American Academy of Pediatrics, the American College of Obstetricians and Gynecologists and the Society for Adolescent Medicine, discuss family planning as preventive care as do well-respected public health advocates like the American Public Health Association and the March of Dimes.

The federal policy record on contraception is equally clear. The legislative record shows that numerous Senators noted during the PPACA debate that Section 2713(a)(4) would ensure women's access to family planning. Moreover, there are strong precedents from other federal health programs:

- Family planning has been listed as a preventive health service in every edition of the federal Healthy People series from 1979-2010.
- The federal law authorizing community health centers lists family planning among the preventive health services that the centers are required to provide.
- Numerous federal block grants that focus on preventive care, including the Maternal and Child Health Block Grant and the Preventive Health and Health Services Block Grant, are used to fund family planning services in the states.

The clear scientific consensus and federal health policy history in support of providing contraception services as an essential component of standard preventive health care is matched by strong public support for ensuring coverage of contraception.³ Unfortunately, some on the margins of public opinion have at times succeeded in creating political controversy over the issue by intentionally confusing contraception with abortion. Although the facts show that contraception can reduce the need for abortion by preventing unintended pregnancy, people who are personally opposed to the use of contraception and who seek to impose their personal beliefs on others, have repeatedly put forward policy arguments that ignore or distort the science of reproductive health. Without this history of political controversy, there would be no question about whether comprehensive contraceptive care would be included in a list of evidence-informed women's preventive services. Any delay in extending the protections of Section 2713 to contraceptive services furthers the politicization of this medically straightforward issue. Given the high public health value of comprehensive contraceptive services for maternal and infant health, it is unconscionable to delay implementation of the provisions of the PPACA intended to reduce the barriers women face in getting such preventive health services.

Recommendation I: Eliminate unnecessary and unreasonable delays in extending these critical protections to women

The Rules state that the Department of Health and Human Services (HHS) is developing the HRSA guidelines for women's preventive health services to be covered and exempted from cost-sharing under this provision of the law. HHS has elaborated on this plan, explaining that HRSA is contracting the Institute of Medicine (IOM) to make recommendations about which women's preventive health services should be included in the HRSA guidelines. With respect to timing, the Rules state that HHS expects to issue the HRSA guidelines no later than August 1, 2011 and that when new guidelines are included in the recommended preventive services, insurers do not have to change coverage or cost-sharing requirements until the first plan year beginning on or after the date that is one year after the guideline went into effect. If the Department proceeds as outlined in the Rules, insurers will not be required to comply with the HRSA guidelines for women's preventive health services until January 2013, meaning that the protection from cost-sharing will not be extended to women's preventive health care until two years after the rest of the Sec. 2713 protections go into effect.

³ <http://www.nwlc.org/resource/opinion-survey-reproductive-health-coverage-health-reform>

This plan and timeline impose unnecessary and unreasonable delays on the extension of these critical protections to women, and we are urging HHS to revise the Rules to eliminate those delays. We recognize the importance of producing the HRSA guidelines for women's preventive health services according to an evidence-based process that has scientific integrity, however, the timeline that HHS has laid out in the Interim Final Rules for creating the HRSA guidelines and for bringing insurers into compliance with the requirement to extend the protections of the law to women's preventive health care is not acceptable. We propose the following revisions to the Rules to tighten the timeline of the process without undermining medical legitimacy of the HRSA guidelines.

- A. Establish a two-step process for the IOM.** We appreciate the selection of the IOM to evaluate the evidence and make recommendations to HHS. The IOM is a well-respected body whose members include top practitioners of all medical specialties, and it unquestionably has the expertise to evaluate research in this area. In light of the urgency of extending the Section 2713 protections to women, we recommend that HHS ask the IOM to establish a two-step process for making its recommendations. In the first step, IOM would review the evidence and convene a panel of experts. The experts would identify two categories of women's preventive health services: services for which the mainstream medical and public health communities recognize the service to be a part of the standard of care, with clear evidence supporting its inclusion in the list of services protected from cost-sharing; and services for which the evidence is less strong or services for which there is a difference of opinion within the public health and/or mainstream medical community regarding the strength of the evidence. The IOM would immediately forward a list to HRSA of services which fall into the first category, and HRSA would create an interim guideline mandating coverage of, and prohibiting cost-sharing for, those services. In the second step of the process, the IOM would complete its review and develop recommendations regarding the second category of services according to the timeline contemplated in the Interim Final Rules. This process would ensure that IOM is able to bring the full strength and integrity of its review to the recommendations without imposing an unnecessary and unreasonable delay in the timeline for implementing the women's preventive health provision of the law.
- B. Put insurers on a faster timeline for compliance.** The Rules unnecessarily apply a one-year interval between when the women's preventive health guidelines are completed and when they will become effective for new plans. Again in light of the compelling public health value of bringing the benefits of the provision to women, HHS should set a shorter interval of one month for compliance with the guidelines. Should the IOM process be amended as recommended above, the shorter interval would apply for both HRSA's interim and final guidelines. It is reasonable to establish a faster timeline for implementation of these protections because the broader requirements of Section 2713 will already be in effect, and insurers will already have a system in place for protecting preventive health services from cost-sharing. They will simply be adding a new bundle of services to the existing system to extend the protections to women's preventive health care. HHS should require insurers to act swiftly so that women will be relieved of the burden of cost-sharing as soon as practically feasible.

Recommendation II: Establish processes to monitor, enforce and encourage compliance

The Rules are silent as to enforcement and oversight of insurers' compliance with Section 2713 requirements. We recommend that regulations include processes to monitor, enforce and encourage

compliance with these important requirements. Those processes should allow consumers to issue complaints and make appeals when insurers, providers or pharmacies do not adhere to the law and consumers are inappropriately denied access to preventive health services 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 public.

Recommendation III: Define “not recommended” to clarify that it applies to services that receive a USPSTF grade of D

The law provides, and the Rules reflect, that insurers may deny coverage for preventive health services that are not recommended by the USPSTF. But neither the law nor the Rules provide more detail about the definition of “not recommended.” The Rules should clarify that this means insurers can deny coverage for preventive health services that receive a grade of D from the USPSTF, which the Task Force defines to mean that it has “found at least fair evidence that [the service] is ineffective or that harms outweigh benefits.” This additional fleshing out is necessary to make clear that insurers may not deny coverage altogether, let alone protections from cost-sharing, for recommended screenings that are simply not addressed by the USPSTF.

Recommendation IV: Establish a process for periodic updates to the HRSA guidelines based on science and evidence

The law and the Rules fail to articulate a process that HHS can use to update the women’s preventive health services guidelines. As research progresses, it will be important that the guidelines be updated to reflect advancing knowledge about the services that evidence supports for women’s preventive health care. The Rules should establish a process that ensures that the list of covered services is periodically updated to reflect the most current evidence available, as well as advances in technology and changes in clinical practices. This process must ensure that determinations and updates to the guidelines are based on science and evidence.



We look forward to working with you on the implementation of these provisions of PPACA to ensure that women and our families receive the full benefits of coverage for preventive health services with protection against cost-sharing burdens that serve as a barrier to care and to better health.

Sincerely,

Raising Women’s Voices for the Health Care We Need

National Organizations

- American Medical Women’s Association
- Black Women’s Health Imperative
- Childbirth Connection
- Community Catalyst
- EQUAL Health Network
- Ibis Reproductive Health
- National Council of Jewish Women

National Council of Women's Organizations
National Health Law Program
National Institute for Reproductive Health
National Latina Institute for Reproductive Health
National Network of Abortion Funds
National Organization for Women
National Women's Health Network
Our Bodies Ourselves
Reproductive Health Access Project
Reproductive Health Technologies Project
SisterSong: Women of Color Reproductive Justice Collective

Regional, State and Local Organizations

ACCESS Women's Health Justice (California)
ACT for Women and Girls (California)
Adagio Health (Pennsylvania)
Black Women for Wellness (California)
California Family Health Council
California Latinas for Reproductive Justice
California Pan-Ethnic Health Network
California Partnership
California Public Health Association-North
Cedar River Clinics—Feminist Women's Health Center (Washington)
Concord Feminist Health Center (New Hampshire)
Emergency Medical Assistance (Florida)
Family Planning Council, Philadelphia, Pennsylvania
Feminist Health Center of Portsmouth (New Hampshire)
Feminist Women's Health Centers of California
Having Our Say Coalition (California)
Healthy Monday Campaign (New York)
Legal Voice (Pacific Northwest)
Mabel Wadsworth Women's Health Center (Maine)
Maternal and Family Health Services (Pennsylvania)
Maternity Care Coalition (Pennsylvania)
Midwest Access Project
Montana Women Vote
Nevada County Citizens for Choice (California)
New Jersey Citizen Action
New Mexico Religious Coalition for Reproductive Choice
New York Alliance for Women's Health, a statewide coalition of 56 women's health organizations
NOW-NYC (New York)
Planned Parenthood of Arkansas and Eastern Oklahoma
Policy Connections West (New Mexico)
Public Health Association of New York City
Southwest Women's Law Center
WCLA – Choice Matters (New York)

West Virginia Free

West Virginia NOW

Wisconsin Alliance for Women's Health

Women's City Club of New York

Women's Health Center (Minnesota)

Women's Way (Pennsylvania)