ACOG
THE AMERICAN CONGRESS OF OBSTETRICIANS AND GYNECOLOGISTS

Office of the President
Richard N. Waldman, MD, FACOG
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September 17, 2010

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

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

CC:PA:LPD:PR, Room 5205
Internal Revenue Service
P.O. Box 7604, Ben Franklin Station
Washington, DC 20044
Attention: REG–120391–10

RE: 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 Sirs and Madams,

On behalf of the American Congress of Obstetricians and Gynecologists (ACOG), representing over 54,000 physicians and partners in women's health, I am pleased to offer comments on the Interim Final Rules (IFR) for Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services Under the Patient Protection and Affordable Care Act (ACA).

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

Additionally, the Senate adopted the Women's Health Amendment (WHA) which requires HRSA to support comprehensive guidelines that identify preventive health services for women. This important amendment—the first offered during Senate debate—was intended to supplement

other key provisions in the bill and ensure coverage of and cost-sharing protections for contraceptive services and supplies, annual well-woman visits, preconception care counseling visits and other preventive health services that are currently not among those addressed by the USPSTF.

To ensure meaningful implementation of these important provisions we request that you address the following issues:

Transparent Process for Identifying Covered Services, Ensuring Appropriate Representation of Women's Health Experts and Reference to Medical Societies' Existing Guidelines:
HHS has contracted with the Institute of Medicine (IOM) to help identify the list of services that will be covered and exempted from cost-sharing under the Women's Health Amendment. We have great esteem for the IOM, whose members include top practitioners of all medical specialties.

Requested Action:

- To ensure that the IOM panel addresses the full range of women's unique preventive health needs, we request that you ensure the panel includes physicians specializing in women's sexual and reproductive health, including ob-gyns.

- Require IOM to hold a dedicated session, inviting women's health specialists, to learn about existing guidelines.

- After HRSA receives the IOM panel's recommendations we request that HRSA consult during its final decision-making with relevant national medical specialty societies, including ACOG that have authored the most current evidence-based and evidence-informed clinical guidelines, practice standards and expert opinions, which are the basis for the standards of care for all medical practitioners in the United States.

Mechanism for Timely Updating of List of Services to Reflect Availability of New Evidence:
Part of the IOM panel's task is to evaluate models for HHS to use in regularly updating the WHA guidelines. The IFR outlines a timeline for insurance companies to update their coverage policies based on changes to USPSTF, ACIP and Bright Futures Guidelines; however the IFR does not lay out a process for updating and adoption of women's preventive health guidelines.

Requested Action:

- In addition to defining which women's preventive health care services health insurers must cover with no cost-sharing, it is essential that the Secretary outline a process through regulation that ensures that the list of covered services is periodically updated to reflect the most up-to-date evidence available. This process must ensure that determinations and updates are based on science and not political interests.

Barring Cost-Shifting to Physicians:
We are concerned that health insurers may attempt to pass on the cost of the elimination of cost-sharing to health care providers—which will have a significant effect on patients' access to these

important preventive services. Congress intended that plans cover and bear the cost of this – not pass it on to providers or make a profit on this. Requiring coverage is meaningless if access is compromised.

Requested Action:

- The IFR does not address the concern about insurer's responsibility to cover the full of the preventive services and visits. In order to ensure beneficiary access to providers, we request that, in implementing the preventive provisions of Section 2713, you bar insurers from passing on to providers the cost of eliminating cost-sharing. In cases where for example a provider is already in a multi-year contract with an insurance company at the time that changes to covered preventive services with beneficiary cost-sharing protections take place, the regulations must address how insurance companies will honor the total reimbursement rate stipulated in the contract to be coming from both patient co-pays and deductibles and insurance payments, now that providers will no longer be collecting any reimbursement from the patient.

Clarifying the Definition of "Primary Purpose" of a Visit When Determining Cost-Sharing Protections for the Visit:

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

Requested Action:

- The term "primary purpose" is not defined in the IFR, and the examples provided present obvious, extreme cases. There is no guidance however 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, and not be left up to the insurer's discretion. A similar situation may occur in the context of well-woman visits. HHS must 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, ensuring that insurers do not use this provision as an opportunity to deny cost-sharing protections of a visit.

Ensuring Medical Management Protocols Are Based on Physician Judgment, Medical Necessity and National Medical Society Guidelines:

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. 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. 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.

Requested Action:

- The final rule must include a definition of "reasonable medical management techniques" and require insurers to rely on medical evidence and allow providers to deviate from standards when needed to meet the needs of individual patients. In making decisions about the clinically appropriate frequency, method, treatment or setting of a service, insurers must be required defer to evidence-based and evidence-informed guidelines of national medical specialty societies, such ACOG.

Barring Use of Suggested Frequency of Services/Recommendations to Inappropriately Limit Coverage:

Similarly, the IFR does not state clearly, but 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. Some women may have unique preventive healthcare needs that require additional services not fully addressed by the USPSTF, HRSA and IOM, which generally will have assessed the needs of women with a low-risk health profile. Some women such as those with a prior history of gynecologic cancers, will require preventive services with greater frequency than suggested by USPSTF.

Insurers should not be allowed to use USPSTF or IOM recommendations to limit care to patients. While the USPSTF and IOM recommendations should serve as the baseline for covered preventive services, the current clinical practice guidelines of relevant, national medical specialty societies address the possible need for additional provision of preventive care for women with more complicated health needs, such as women with genetic risk for breast, cervical, and ovarian cancers and for women who have pre-existing conditions or illnesses, and should thus be followed in those cases.

Requested Action:

- 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.

Establishing a Process for Enforcement of the Preventive Provisions:

The IFR does not outline a process for compliance and enforcement of this provision.

Requested Action:

- The final rule should include processes to monitor, enforce and encourage compliance with the Sec. 2713 requirements. Those processes should allow consumers and providers to issue complaints and make appeals when insurers do not adhere to the law and are inappropriately denied access to or required to absorb some of the cost of protected services and supplies.

Ensure Confidential Adolescent Access to Preventive Services

Requested Action:

- The goals of Sec. 2713 may be undermined by insurance industry procedures that 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. ACOG, along with the Partnership for Prevention, American Academy of Pediatrics, and the Society for Adolescent Health and Medicine submitted comments related to this concern in August, and we are attaching that letter again.

As you continue to implement the Patient Protection and Affordable Care Act, we urge you to address the above issues. We look forward to working with you to improve the health and lives of women and their families and thank you for your consideration. If you have any questions or to let us know how we can be of assistance, please contact Nevena Minor, Manager, Government Relations at 202-314-2322 or nminor@acog.org.

Sincerely,

Richard N. Waldman, MD, FACOG
President
American Congress of Obstetricians and Gynecologists