



September 8, 2010

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

Re: Comments on interim final regulations implementing the rules for group health plans and health insurance coverage in the group and individual markets under provisions of the Patient Protection and Affordable Care Act regarding preventive health services

To Whom It May Concern:

On behalf of The National Campaign to Prevent Teen and Unplanned Pregnancy, we appreciate the opportunity to comment on the Interim Final Regulations (IFR) relating to coverage of preventive services under the Patient Protection and Affordable Care Act (ACA), P.L. 111-148. The National Campaign is a research-based, nonpartisan, and non-profit organization whose mission is to improve the lives and future prospects of children and families by preventing teen and unplanned pregnancy. We are very supportive of this important step to eliminate barriers to preventive health services.

Recognizing the value of preventive services, Section 2713 of the Public Health Service Act in ACA requires that a group health plan and a health insurance issuer offering group or individual health insurance coverage provide benefits for and prohibit the imposition of cost-sharing requirements for: (1) preventive services designated with an “A” or “B” recommendation by the United States Preventive Services Task Force (USPSTF); (2) immunizations recommended by the Advisory Committee on Immunization Practices; (3) children’s preventive services based on evidence-based guidelines previously developed by the U.S. Department of Health and Human Services’ (HHS) Health Resources and Services Administration (HRSA); and (4) women’s preventive care and screening.

As discussed in the IFR, preventive services are currently underutilized, largely because many of the public health benefits of prevention are not immediately apparent. In addition, due to high turnover in the health insurance market, insurers have few market incentives to invest in long term health care strategies such as prevention.

Moreover, evidence suggests that primary care physicians often lack expertise—and therefore need training—in certain preventive counseling techniques. Many simply do not have adequate time

[Responsible behavior.](#) [Responsible policies.](#)

to devote to performing preventive services.¹ Clarifying the roles and responsibilities of primary care clinicians and providing them with state-of-the-art tools would help them better address preventive services. It would also be helpful to establish culturally appropriate evidence- and competency-based clinical guidelines for the prevention and management of unintended pregnancy that can be integrated into primary care and the broader health system and that are soundly based in comprehensive public health practices. All health professionals, and particularly primary care providers, have enormous potential for helping the nation reach a variety of established national health goals related to unintended pregnancy and reproductive health. Primary care clinicians, such as nurse practitioners, physicians and physician assistants, are uniquely trained in coordinated, family-centered patient care as well as the provision of culturally appropriate patient education. Primary prevention strategies should be integrated into all clinical settings in which primary care clinicians provide services.²

The US Preventive Services Task Force (USPSTF), first convened by the Public Health Service in 1985 rigorously evaluates clinical research in order to assess the merits of preventive measures, including screening tests, counseling, immunizations and preventive medications. The second edition of the USPSTF's *Guide to Clinical Preventive Services*, published in 1996, included a section on unintended pregnancy. The Guide established that periodic counseling on effective contraceptive methods for all women and men at risk for unintended pregnancy was an effective preventive measure and recommended a “B” rating, reflecting that “there is a high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial.” However, in spite of the continuing high rate of unintended pregnancy, especially among minority and low-income women, the USPSTF has yet to review the constellation of contraceptive services as *primary prevention* nor has it completed a focused review of FDA-approved contraceptive drugs and devices as *preventive medication* for women and men at risk for having or causing an unintended pregnancy.

While prevention is often narrowly framed in terms of preventing disease, it extends far more broadly, and can be linked to widespread health, social and economic gains for the nation as a whole. Like prenatal care, which is a core preventive health care service for women, family planning is an important preventive service that should be an integral and core component of preventive services provided with cost-sharing protections. The USPSTF currently recognizes the preventive value of prenatal counseling as well as important prenatal screening for sexually transmitted infections, nutritional deficiencies and other risks as well. The goal of comprehensive prenatal care is similar to that of family planning—to achieve healthy outcomes for the patient and her family. At present, fully one-half of all pregnancies in the United States are unintended, and those unintended pregnancies that result in a birth have significant health-related costs and consequences including late entry into prenatal care, absence of preconception health care, and an increased risk of both low infant birth weight and infant mortality.³ Unfortunately, more than ten percent of women at risk for unintended

¹ Yarnall KSH, Pollak KI, Ostbye T, Krause KM, Michener JL. Primary care: is there enough time for prevention? *American Journal of Public Health*. 2003;93(4):635.

² Diana Taylor, Amy Levi, and Katherine Simmonds. (2010). Reframing Unintended Pregnancy Prevention: A Public Health Model, *Contraception*, 81: 263-366.

³ Brown, S.S., and Eisenberg, L., ed. *The Best Intentions: Unintended Pregnancy and the Well-Being of Children and Families*. 1995, National Academy Press: Washington, DC.

pregnancy are not using any form of contraception and many more are using methods inconsistently or are relying on low-efficacy methods.

With the passage of ACA, there is a unique opportunity to ensure that family planning services—including contraceptive counseling and the full range of FDA-approved contraceptives and related outpatient services—are put on par with other preventive services and made available to consumers at limited or no-cost. We note that there is a parallel process specified by the Women’s Health Amendment to develop women’s health guidelines (the 4th category noted above); however, our comments below regarding the IFR reflect our hope and expectation that comprehensive family planning services will be designated as a preventive service through this process. Furthermore, we strongly recommend that the full range of family planning services, including contraceptive counseling, FDA-approved contraceptive prescriptions and devices, and related outpatient services be reviewed by the USPSTF.

Cost-Sharing Requirements and Definition of “Primary Purpose”

The IFR offers clarification regarding the cost-sharing requirements for patients when a recommended preventive service is provided during an office visit. The IFR presents several examples, illustrating various cost sharing scenarios. However, we remain concerned about the potential for unintended negative consequences which may come about as a result of some of the requirements and restrictions provided in the IFR.

Specifically, there is confusion regarding the definition of “primary purpose.” According to the IFR, “if a recommended preventive service is not billed separately from an office visit and the primary purpose of the office visit is the delivery of this service or item, then a plan or issuer may not impose cost-sharing requirements with respect to the office visit.” Preventive services are most often delivered during visits for which the primary purpose is *not* the preventive service itself. Typically, patients attend a “new office visit” which represents their initial point of contact with a new provider. Moreover, return visits are generally not scheduled for the sole purpose of providing preventive services; yet preventive services are often included in these subsequent visits. We are concerned that if preventive services are delivered during visits in which there is a different “primary purpose,” patients will be at risk for being exempt from the cost sharing protections conceived in the IFR.

In addition, the definition of “primary purpose” may encourage clinicians to schedule their patients for separate “preventive service” visits too frequently and unnecessarily. This could result in more, not fewer, patient visits, potentially increasing health care costs beyond recent estimates, and eliminating cost-sharing protections for those services. Furthermore, it is unclear if cost-sharing applies when a patient goes to the doctor for a visit where the primary purpose of the office visit is the delivery of a preventive service, and the patient ends up receiving services or consultations that do not fall under the scope of mandated preventive benefits.

Implications for Future Preventive Services

It is unclear how the IFR will affect the process of adding additional services to the list of covered preventive services and items. As provided in the IFR, “a plan or issuer may rely on established techniques and the relevant evidence base to determine the frequency, method, treatment or

setting for which a recommended preventive service will be available without cost sharing requirements.” This “reasonable medical management” requirement is vague and requires further clarification and specificity.

For example, if contraceptive counseling services were to be reviewed by the USPSTF and given a Grade A or B recommendation, it is unclear how insurance plans or issuers would incorporate these preventive services into reasonable medical management. Often, preventive services and tests will lead to treatment and follow-up care that does *not* fall under the umbrella of covered preventive services. A primary visit for contraceptive counseling, for instance, might result in return visits for insertion and removal of a long-acting reversible contraceptive. According to the interim final regulations it is unclear under what category follow-up visits would be classified, and therefore, whether cost-sharing protections would apply. When the patient is responsible for additional out-of-pocket costs for follow-up care, there is the risk that patients will be discouraged from having the screening or service in the first place or not receive appropriate follow-up care.

Given uncertainty about how and when preventive services are tied to primary visits, we recommend some additional consideration for how best to encourage primary visits for those services or, at the very least, information on how best to advise clinicians to incorporate these services into the potential newer models of payment such as value-based insurance design. Value-based insurance design promotes payment for quality, not quantity, in health care and can be an important mechanism to alter our current fee for service payment system that rewards quantity not quality.

Out-of-Network Providers

The IFR states that insurers are “not required to provide coverage for recommended preventive services delivered by an out-of-network provider.” This requirement will encourage consumers to use providers that are part of the insurer’s contractual agreement and provider network. However, in the context of the provision of preventive services, we suggest there is a competing consideration with respect to quality. Given HHS’ commitment to develop “additional guidelines regarding the utilization of value-based insurance designs by group health plans and health insurance issuers with respect to preventive benefits,” we believe that cost-sharing for out-of-network providers might need to be eliminated for recommended preventive services if the quality for the provision of the service is higher than that of an in-network provider in a plan.

Grandfathered Plans

We realize that there is still a great deal of confusion regarding the precise definition and implication of grandfathered plans that are not required to provide preventive services without cost-sharing; however, we are more concerned with the estimates provided by the Administration. The IFR notes that HHS expects roughly 18% of large employer plans and 30% of small employer plans to relinquish their grandfather status in 2011, increasing over time to 45% and 66% respectively by 2013. However, it is possible that this approximation overestimates the number of plans that will give up their grandfathered status, thereby decreasing first dollar coverage access to preventive services, especially in the individual and small group markets. We believe that the estimates might be high only because we are familiar with large plans, such as Anthem and others, which are not relinquishing grandfather status. We realize that plan turnover in the individual market is quite high, thus decreasing

the number of individual policies that will not be grandfathered, but we are still concerned about the validity of the estimates and encourage close monitoring of the grandfathered status plan estimates as various facets of implementation move forward.

In addition, it is unclear how plans that either lose or choose to relinquish their grandfathered status will fulfill any contractual obligations to providers. For example, most contracts include reimbursement rates that take into account deductibles and co-payments. Given the overlap with existing provider contracts and new changes to co-payments, this could result in confusion and unintended cost-shifting to providers, especially in the primary care setting. It is for these reasons that a concerted effort to closely watch the grandfathering process is critically important. If the grandfathering process is not closely monitored we are concerned about unintended consequences such as inconsistency among plan holders and only a partial realization of the benefits of preventive service coverage.

Distinction Between “Provider” and “Physician”

While it is not the intent of this IFR to address scope of practice issues, some of the language in the IFR is ambiguous. In some sections of the IFR there are references to “providers,” which one would assume is in keeping with previous definitions and can be broadly interpreted as medical doctors, doctors of osteopathic medicine, nurse practitioners, physician assistants and other medical practitioners. In other places, the IFR refers to “physicians,” which often has a more narrow interpretation. As an example, in the beginning of the document, the IFR reads, “These interim final regulations are expected to increase the take-up rate of preventive services and are likely, over time, to lead *physicians* to increase their use of these services knowing that they will be covered, and covered with zero copayment.” It is followed, not long after by, “A third issue involves health plans that have differential cost sharing for services provided by *providers* who are in and out of their networks.”

We recommend using the term “provider” throughout the regulation. This designation is particularly important given that a growing number of preventive services, including in the area of pregnancy planning and prevention, will be administered by a broad range of health professionals, leaving open the possibility of new delivery system designs.

Process of Women’s Preventive Service Determination

The IFR acknowledges that HHS is currently developing comprehensive guidelines for women’s evidence-informed preventive care and screening benefits, slated to be released by August 1, 2011. We understand that HRSA will contract with the Institute of Medicine (IOM) but are concerned that outside the IOM process, there will be no interim activities proposed at HRSA to explore this very important issue.

We would encourage the Administration, and more specifically HRSA, to convene an advisory body made up of experts in women’s health to work before and during the development of the guidelines, as well as after recommendations are made. The advisory board would ensure that IOM recommendations are comprehensive and reflect the health care needs of women as intended by the law; the group could also help to ensure that the IOM recommendations are carefully reviewed and incorporated where appropriate. We feel that this process is important and will help ensure that there

is a visible and transparent public component to the process given the high level of interest in this provision and the obvious limited opportunities that are part of the IOM process.

Uptake in Preventive Services

The IRF notes that uptake in certain preventive services that require time intensive visits and follow-up have generally been low, largely due to increased out-of-pocket and cost-sharing rules. The new law aims to address this problem by eliminating cost-sharing for recommended preventive services including, for example, dietary and weight-loss counseling. Historically, as the IRF notes, relatively few patients receive dietary counseling or weight-loss counseling recommendations from their physicians, and increased uptake (and subsequent economic and health gains) will depend largely on physicians changing their practice patterns.

The new rules will significantly increase patients' *potential* access to recommended preventive services, but we are concerned that certain preventive services will still not be performed with as much regularity as the law intends. Primary care physicians already experience significant time constraints, and we are concerned that there will be lower than expected uptake in the more time-intensive preventive services (despite the elimination of cost-sharing) and increased uptake in less time-intensive ones. For example, while cholesterol screening and vaccinations are more straightforward, alcohol counseling, STI counseling during pregnancy, depression screenings and nutrition counseling are all more time intensive.

We note in particular that provider misinformation and knowledge gaps (particularly among older providers and family physicians) about the full range of FDA-approved contraceptive methods often prevent patients from having a comprehensive understanding of all of their contraceptive options. In fact, some studies have suggested that unintended pregnancy may, in part, reflect a lack of satisfaction among women with the care offered by providers. Many women experiencing problems with their contraceptive methods believe that contraceptive service providers are not readily available to answer questions.⁴

Simply adding more preventive services to the USPSTF guidelines and eliminating the patient cost burden unfortunately won't remove other constraints experienced by primary care physicians, especially in light of a workforce shortage.⁵ We encourage HHS to consider the actual delivery of preventive services delivery options to ensure adequate time and educational resources are devoted to time-intensive and important health services.

Timing of Implementation of Women's Health Guidelines

Finally, we are concerned about the timeline in the IFR for developing the guidelines mandated by the Women's Health Amendment, which are currently scheduled to be completed by August 2011 and implemented by August 2012. The August 2012 start date would likely have the effect of delaying implementation until January 2013 when most insurance providers begin their new plan periods.

⁴ Frost, J.L., Singh, S., Finer, L.B. (2007). Factors associated with contraceptive use and nonuse, United States, 2004. *Perspectives on Sexual and Reproductive Health*, 39: 90-9.

⁵ Yarnall KSH et al.

Given the importance of this issue, we feel that completing the process sooner than the given deadlines should be an important priority for the Administration.

Thank you again for the opportunity to submit comments. If you have any questions or need additional information, please contact Lisa Shuger, Director of Public Policy at 202-478-8576 or lshuger@thenc.org.

Sincerely,

A handwritten signature in black ink that reads "Sarah Brown". The signature is written in a cursive, flowing style.

Sarah S. Brown
CEO