



PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION

September 17, 2010

Jay Angoff  
Director  
Office of Consumer Information and Insurance Oversight  
U.S. Department of Health and Human Services  
Hubert H. Humphrey Building  
Room 445-G  
200 Independence Avenue, S.W.  
Washington, DC 20201

Attention: OCIO-9992-IFC

Dear Mr. Angoff:

The Pharmaceutical Care Management Association (PCMA) appreciates the opportunity to submit 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),” published in the Federal Register on July 19, 2010. PCMA is the national association representing America’s pharmacy benefit managers (PBMs), which administer prescription drug plans for more than 210 million Americans with health coverage through Fortune 500 companies, health insurers, labor unions, and Medicare.

PCMA appreciates all the tasks that the Departments of Treasury, Labor, and Health and Human Services must complete to implement PPACA and we value opportunities to comment on the many aspects of regulations to implement the law. PCMA is generally supportive of the Preventive Services IFR, but we do have concerns with certain provisions that we address in our detailed comments below.

**Coverage of Preventive Health Services (26 CFR 54.9815-2713T, 29 CFR 2590.715-2713, and 45 CFR 147.130)**

Section 2713 of the PHS Act, as amended by PPACA, requires group health plans and health insurance issuers to provide benefits and prohibits the imposition of cost-sharing for items or services rated A or B in the current recommendations of the U.S. Preventive Services Task Force (USPSTF). These recommendations are for a variety of screening and counseling measures for primary care clinicians and health systems to encourage patients to engage in behaviors to promote disease prevention (for example, to participate in tobacco cessation interventions, take over-the-counter medications (such as aspirin), apply topical fluoride, or take dietary supplements (such as iron supplementation)).

It is important to note that the mission of the U.S Preventive Services Task Force is “to evaluate the benefits of individual services based on age, gender, and risk factors for

disease; make recommendations about which preventive services should be incorporated routinely into primary medical care and for which populations; and identify a research agenda for clinical preventive care.” When developed, the recommendations were not intended to apply to insurance coverage decisions, which may explain the discrepancies between the language of the recommendations and standard coverage policies. PCMA does not believe the USPSTF recommendations require insurers to provide coverage for products that may be recommended by the consulting physician during a consultation or screening. PCMA notes that the infrastructure to match individual pharmacy claims to an individual’s diagnosis currently does not exist and it would be impossible for a health plan or PBM to know whether a product is recommended by a physician for the condition specified by the USPSTF.

***PCMA Recommendation:** PCMA recommends that the Departments clarify that the required coverage for preventive services is for consultation and screenings provided by physicians and other qualified health care providers, as recommended by the U.S. Preventive Services Task Force, and not for any products that may be discussed or recommended during such consultations or after such screening tests are performed. This is consistent with the language in the preamble that describes the “aspirin to prevent CVD” recommendation as “discussing aspirin use with high-risk adults” and the “tobacco cessation interventions” recommendation as “counseling related to tobacco cessation.”*

### **Guidelines to Utilize Value-based Insurance Designs**

PPACA gives the Departments the authority to develop guidelines for group health plans and health insurance issuers to utilize value-based insurance designs as part of their preventive services. The IFR preamble describes such designs as the provision of information and incentives that promote access to and use of higher value services. The preamble also solicits comments on value-based designs that promote consumer choice of providers or services while ensuring access to evidenced-based preventive services. PCMA members have been leading the way on value-based design beginning with the implementation of the tiered drug formulary, through which PBMs have been very successful in increasing access to proven therapies while also controlling drug cost inflation. More recently, PBMs have begun to implement more sophisticated value-based designs that, for example, use incentives like reduced or waived cost-sharing to encourage subscribers to use low-cost, high-value generic drugs. PBMs also encourage, through plan design, coverage of preventive uses of medications, thereby reducing or avoiding higher costs later.

PCMA members applaud HHS for recognizing in the IFR that, in addition to encouraging high-value drug therapies, value-based design also includes incentivizing subscribers to use the most efficient, cost-effective care delivery channel (co-pay differentials for in network and out of network was cited as an example). For drug benefits, this includes plan designs that selectively steer patients to retail pharmacies, mail order pharmacies, or specialty pharmacies depending on the specific needs of the subscriber. PCMA members

have long recognized the potential of preventive care to control costs and improve outcomes.

***PCMA Recommendation:** PCMA urges HHS to clarify that health plans and their PBMs have the flexibility, under existing value-based design models, to incorporate USPSTF recommendations and other preventive drug therapies through the most efficient, effective channel possible.*

### **Reasonable Medical Management**

Paragraph (a) (4) of the IFR states that nothing prevents a plan or issuers from using “reasonable medical management techniques” to determine the frequency, method, treatment, or setting for an item or service described in paragraph (a)(1) to the extent such services are not specified in the referenced recommendations or guidelines. PCMA supports this aspect of the IFR because it recognizes the need for discretion and flexibility in managing preventive services benefits.

***PCMA Recommendation:** PCMA supports this provision.*

### **Services Not Described**

Paragraph (a)(5) of the IFR states that nothing in the rule prohibits a plan or issuer from providing coverage for items or services in addition to those recommended by the named organizations, such as the U.S. Preventive Services Task Force or CDC’s Advisory Committee on Immunization Practices. PCMA supports this aspect of the IFR because it allows plans and issuers the discretion and flexibility to expand the range of covered preventive services beyond those recommended by the named groups. This encourages innovation and competition among plans and issuers, which will benefit subscribers by allowing them more choices and greater access to new preventive services.

***PCMA Recommendation:** PCMA supports this provision.*

We appreciate your consideration of our comments and look forward to continuing to work with the Departments of Treasury, Labor, and Health and Human Services to ensure successful implementation of PPACA.

Sincerely,



Michelle Galvanek  
Vice President, Regulatory Affairs