July 21, 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

Re: Docket No. OCIIO-9992-IFC

The Academy of Managed Care Pharmacy (AMCP) is requesting expedited clarification of certain requirements set forth by the Office of Consumer Information and Insurance Oversight (OCIIO) in 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 published in the Federal Register on July 19, 2010.

AMCP is a national professional association of pharmacists and other health care practitioners who serve society by the application of sound medication management principles and strategies to achieve positive patient outcomes. The Academy’s 6,000 members develop and provide a diversified range of clinical, educational and business management services and strategies on behalf of the more than 200 million Americans covered by managed care pharmacy benefits.

The interim final regulations require 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 with respect to evidence-based items or services that have in effect a rating of A or B in the current recommendations of the United States Preventive Services Task Force (USPSTF) with respect to the individual involved. The interim final regulations address the cost-sharing requirements when a recommended preventive service is offered during or separate from an office visit and include examples related to services.

Four of the recommendations made by USPSTF relate to medications. None of the four recommendations are addressed in the interim final regulations.

These recommendations are:
- Aspirin to prevent CVD: men – The USPSTF recommends the use of aspirin for men age 45 to 79 years when the benefit due to a reduction...
in myocardial infarctions outweighs the potential harm due to an increase in gastrointestinal hemorrhage.

- **Aspirin to prevent CVD: women** – The USPSTF recommends the use of aspirin for women age 55 to 79 years when the potential benefit of a reduction in ischemic strokes outweighs the potential harm of an increase in gastrointestinal hemorrhage.

- **Supplementation with folic acid** – The USPSTF recommends that all women planning or capable of pregnancy take a daily supplement containing 0.4 to 0.8 mg (400 to 800 µg) of folic acid.

- **Iron supplementation in children** – The USPSTF recommends routine iron supplementation for asymptomatic children aged 6 to 12 months who are at increased risk for iron deficiency anemia.

One of the above recommendations is indirectly referred to in the interim final regulations in a discussion of benefits that will result from the regulations:

> … these interim final regulations require a group health plan and a health insurance issuer offering group or individual health insurance coverage to provide benefits for and prohibit the cost-imposition of cost-sharing requirements with respect to the following preventive health services:
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> - Evidence-based items or services that have in effect a rating of A or B in the current recommendations of the USPSTF (Task Force). While these guidelines will change over time, for the purposes on this impact analysis, the Departments utilized currently available guidelines, which include blood pressure and cholesterol screening, diabetes screening for hypertensive patients, various cancer and sexually transmitted infection screenings, and counseling related to aspirin use [emphasis added], tobacco cessation and other topics.¹

Because the only reference to any of the four recommendations related to medications indicates that the service to be covered is “counseling related to” the medication, it appears that counseling related to aspirin use, folic acid use or iron supplementation is the intent of the regulations. It does not appear that the regulation requires coverage of the medication itself by a group health plan with no cost-sharing.

AMCP requests that OCIIO provide clarification of the requirements contained in 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 as those requirements relate to medications. In addition, the Academy requests the opportunity to meet with OCIIO staff to obtain clarification on the requirements of the regulation and asks that OCIIO issue a final rule with clarification of the above information before the implementation date. Pharmacy benefits are provided to group health plan members through an online claims payment process which requires significant lead time for adjudication system programming. A health plan would require clarification by September 1, 2010 to implement these changes for insured groups with a benefit year beginning on October 1, 2010.

AMCP appreciates the opportunity to comment on this important issue. If you have any questions, please contact me at (703) 683-8418 or at jcahill@amcp.org.

Sincerely,

Judith A. Cahill
Executive Director

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