

August 12, 2010

Office of Consumer Information and Insurance Oversight  
Department of Health and Human Services  
Attention: OCIIO-9991-IFC  
P.O. Box 8016  
Baltimore, MD 21244-1850

Re: Docket No. OCIIO-9991-IFC: Interim Final Rules for Group Health Plans and Health Insurance Coverage Relating to Status as a Grandfathered Health Plan Under PPACA

The Academy of Managed Care Pharmacy (AMCP) is pleased to provide comments in response to the Federal Register notice of June 17, 2010 on the Interim Final Rules for Group Health Plans and Health Insurance Coverage Relating to Status as a Grandfathered Health Plan Under the Patient Protection and Affordable Care Act (PPACA) – The Grandfathering Rule.

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 PPACA as modified by the Reconciliation Act provides that certain group health plans and health insurance coverage existing as of March 23, 2010 are subject to only certain provisions of the Act. The statute refers to those plans and health insurance coverage as "grandfathered" health plans. Grandfathered health plans are not required to comply with certain requirements. For example, a grandfathered health plan would not have to meet the requirement that preventive health services be covered without any cost sharing. Those plans that do not qualify for grandfathered status must meet this requirement for plan years beginning on or after September 23, 2010. The interim final regulations address the various changes that will lead to the cessation of grandfathered status.

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The Department of Health and Human Services (HHS) has determined that certain changes would cause a group health plan or health insurance coverage to cease to be a grandfathered health plan. However, HHS has invited comments on whether other changes should result in cessation of grandfathered health status for a plan or health insurance coverage. One of the changes in question includes “changes to a prescription drug formulary, and if so, what magnitude of changes would have to be made.”

AMCP strongly believes that the dynamic and constantly evolving nature of a drug formulary renders such a provision a non-compelling reason to discontinue grandfathered status.

The medications and related products listed on a formulary are determined by a pharmacy and therapeutics (P&T) committee or an equivalent entity. Due to the multiplicity of medications on the market, the continuous introduction of new medications, and the discovery of clinical misadventures once a product has been in use, a formulary must be a dynamic and continually revised listing. In order to keep a formulary current, the P&T committee meets regularly to review newly released drugs and to assess analyses of drugs already in the marketplace.

P&T committees are comprised of primary care and specialty physicians, pharmacists and other professionals in the health care field, and may also include legal experts and administrators. The P&T committee is responsible for developing, managing, updating and administering the formulary. The P&T committee also designs and implements formulary system policies on utilization and access to medications.<sup>1</sup>

The P&T committee reviews some or all of the following:

- Medical and clinical literature including clinical trials and treatment guidelines, comparative effectiveness reports, pharmacoeconomic studies and outcomes data;
- FDA-approved prescribing information and related FDA information including safety data;
- Relevant information on use of medications by patients and experience with specific medications;
- Current therapeutic use and access guidelines and the need for revised or new guidelines;
- Economic data, such as total health care costs, including drug costs;
- Drug and other health care cost data (not all P&T committees review drug specific economic data); and
- Health care provider recommendations.<sup>2</sup>

Formulary changes should not be considered to be benefit changes. Formulary changes must occur on a regular basis as the Food and Drug Administration approves new medications and new uses for existing medications. P&T committees must consider formulary changes as new evidence becomes available on medications which would change previous decisions on the effectiveness or safety of medications. Health plans and insurers must be able to make formulary changes to provide the most appropriate, cost-effective care to their members.

Medications may be added or deleted from a formulary as new medications or generic versions of existing medications become available. Examples of how new medications or generic versions of medications impact formularies include:

- If a medication loses patent exclusivity allowing generic versions of the medication to become available, adding the generic version of the medication to the lowest tier and transitioning the brand name version

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<sup>1</sup> Academy of Managed Care Pharmacy. *Concepts in Managed Care Pharmacy Series – Formulary Management*. 2009.

<http://www.amcp.org/amcp.ark?p=AAAC630C> (accessed July 23, 2010)

<sup>2</sup> Ibid.

to the highest tier on a formulary should not be cause for a plan to lose grandfathering status. This change by a health plan would allow members to have coverage for the generic version of the existing medication but at a lower cost.

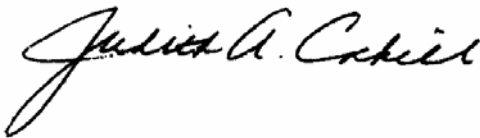
- If a manufacturer introduces a different formulation of an existing product (e.g. making a sustained release version of an already marketed product.), excluding the formulation should not be cause for a plan to lose grandfathering status. In this situation, health plan members would have coverage for one version of the medication.

The recognition that formulary changes are made on a regular basis is illustrated by the requirement instituted by the Centers for Medicare and Medicaid Services (CMS) for the Medicare Part D Prescription Drug Benefit. As directed in the *Medicare Prescription Drug Benefit Manual*, Chapter 6 – Part D Drugs and Formulary Requirements, section 30.1.4

The Part D sponsor's P&T committee should meet on a regular basis, but no less than quarterly. P&T committee decisions regarding formulary development or revision must be documented in writing.<sup>3</sup>

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

Sincerely,



Judith A. Cahill  
Executive Director

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<sup>3</sup> Centers for Medicare and Medicaid Services, Medicare Prescription Drug Benefit Manual, Chapter 6, section 30.1.4. <http://www.cms.gov/PrescriptionDrugCovContra/Downloads/Chapter6.pdf> (accessed August 1, 2010).