

June 10, 2008

Honorable Max Baucus  
Chairman, Committee on Finance  
U.S. Senate  
Room 219  
Dirksen Senate Office Building  
Washington, DC 20510

Dear Senator Baucus:

The Academy of Managed Care Pharmacy (AMCP) strongly objects to Section 176 of S. 3101, the "Medicare Improvements for Patients and Providers Act of 2008" you introduced on June 6. The provision, "Formulary Requirements with Respect to Certain Categories or Classes of Drugs," would require the Department of Health and Human Services:

- to identify classes of drugs used to treat major or life threatening conditions where access to multiple drugs in that class due to unique chemical actions and pharmacological effects is required
- to require formularies of Medicare Part D drug plan sponsors to include "all or substantially all" drugs in the classes that are identified

AMCP believes this provision would undermine the current process mandated by the Medicare Modernization Act by which drugs are evaluated for clinical effectiveness and safety. We also believe this provision is unnecessary and inconsistent with the competitive structure that forms the foundation of the Part D benefit.

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 improve health care for all. The Academy's 5,700 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 a managed care pharmacy benefit.

AMCP has been a strong advocate of the Medicare Part D prescription drug program and its reliance on private sector plan sponsors to deliver safe and effective medications to beneficiaries. Most of the entities that qualified as Part D plan sponsors had many years of experience in the delivery of commercial drug benefits using managed care tools and principles.

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As a result, the competitive model that is the foundation for the Medicare drug benefit has proven successful in providing improved access to medications and affordable premiums for beneficiaries. This approach has led to a high degree of beneficiary satisfaction and lower-than-projected program costs for the federal government.

Drug formularies are one of the principal tools used when organizations design a drug benefit. A formulary is a continually updated list of medications which represent the clinical judgments made by experts in the diagnosis and treatment of disease. Decisions as to which drugs are included on a formulary are made by a Pharmacy and Therapeutics (P&T) Committee, comprised of physicians, pharmacists and other health care professionals. The committee uses scientific evidence to evaluate overall clinical effectiveness and safety in order to determine which drugs meet the needs of the patient population being served by the plan. Due to the vast array of drugs on the market, the continuous introduction of new drugs, and the information learned about drugs after they are broadly available to the general population, a drug formulary is a dynamic and continually changing document.

### **Congressional action would undermine and politicize what is currently an evidence-based drug evaluation process under Part D**

The current statutory and regulatory framework for the Part D formulary decision-making process undertaken by Part D prescription drug plan sponsors is responsive to both changing individual beneficiary needs and evolving medication therapy. It requires that decisions be based on the strength of scientific evidence and standards of practice, including assessing peer-reviewed medical literature. Congressional action that requires that a regulatory process be established that would lead to specific drugs being included on Part D formularies undermines the ability of Part D plans to evaluate the clinical effectiveness and safety of covered drugs through their formulary P&T committee process. It would substitute an approach that arbitrarily includes all drugs in a class notwithstanding a determination as to the effectiveness or safety of individual drugs within a class which could place beneficiaries at risk and would therefore be a serious mistake.

Congressional action to establish such a process will almost certainly result in organizations and interest groups lobbying as to why drugs in therapeutic or disease state categories are deserving of mandatory inclusion in Part D formularies. We believe the result will be advocacy that is more likely to be based on political and grassroots initiatives than on clinical, evidence-based considerations despite the criteria stated in Section 176.

### **Congressional action is not necessary**

CMS has determined that it has the same or similar authority for formulary inclusion under existing law that the provision would provide. One of the regulatory guidances issued by the Centers for Medicare and Medicaid Services (CMS) when the Part D benefit was initially implemented in January 2006 required all Part D plan formularies to include “all or substantially all” drugs in six specified therapeutic classes (anticonvulsants, antineoplastics, antiretrovirals, antidepressants, antipsychotics and immunosuppressants). The requirement established by this guidance has been retained and could be expanded or restricted according to CMS thus, Congressional action would appear to provide no additional protection to beneficiaries.

Current law gives Part D plans flexibility to develop and manage drug formularies for their enrollees subject to the statute and regulatory guidelines issued by CMS, such as the guidance referenced above. In-depth reviews of each drug plan’s formulary are conducted annually by CMS to assure statutory and regulatory compliance.

Another reason as to why Congressional action is not necessary is that there are procedures (the “coverage determination” process) in place under current law designed to ensure that beneficiaries have access to non-formulary medications if it can be demonstrated that a formulary medication is not appropriate or effective for the beneficiary. The law provides specific requirements for this formulary exceptions process in order to ensure that non-formulary medications are made available to the beneficiary in a timely manner.

## **Congressional action would be inconsistent with the competitive structure of the Part D program**

Establishment of a regulatory process to identify drug classes where all or substantially all drugs within a therapeutic category would have to be included on Part D formularies would impose mandatory national uniformity on a program built on the premise of encouraging competition.

Given the importance of the formulary decision making process as a component of a Part D plan's benefit design, we believe action by Congress mandating that a regulatory process be established that would require that specific drugs be included on a Part D formulary would limit the competitive foundation of the Part D benefit and has the potential to undermine its long term financial sustainability.

The ability of Part D plans to negotiate favorable pricing would be compromised with respect to those classes or categories that would be identified under such a regulatory process. A manufacturer that has a drug in a class that must include all or substantially all drugs is essentially guaranteed formulary placement and therefore has little incentive to negotiate price.

We urge the Members of the Senate to reject the establishment of a requirement that CMS establish a regulatory process for the purpose of identifying therapeutic classes of drugs for which Part D formularies would have to include "all or substantially all" drugs.

Should you have any questions regarding our views or wish additional information, please contact me at (703) 683-8416 [or jcahill@amcp.org](mailto:jcahill@amcp.org).

Sincerely,

Judith A. Cahill  
Executive Director