PCMA
PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION

July 25, 2011

Donald Berwick, MD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Attention: CMS-9993-IFC2

Dear Dr. Berwick:

The Pharmaceutical Care Management Association (PCMA) appreciates the opportunity to submit comments on the amendments to interim final rules for "Group Health Plans and Health Insurance Issuers: Rules Relating to Internal Claims and Appeals and External Review Processes," published in the Federal Register on June 24, 2011. 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 the Affordable Care Act and we value opportunities to comment on the many aspects of regulations to implement the law. PCMA commends the Departments for making many positive changes in response to comments received on the interim final rules published July 23, 2010. We believe these changes go a long way toward reducing the burdens on health plans without sacrificing protections for enrollees. We are pleased with the following modifications, among others:

- decision to follow the original DOL claims procedure regulation regarding notification of claimants of benefit determinations involving urgent care (allowing for a 72-hour outside limit instead of the 24-hour limit contained in the July 2010 interim final rule);
- elimination of the requirement to automatically provide diagnosis and treatment codes as part of a notice of adverse benefit determination and substitution of a requirement to notify of the opportunity to request diagnosis and treatment codes;
- modification of the deemed exhaustion of internal claims and appeals processes to allow for an exception to the strict compliance standard for errors that are minor and meet certain other specified conditions;
- removal of the "tagging and tracking" requirement regarding oral language services for non-English speaking individuals; and,

- suspension of the original rule in the July 2010 regulations regarding the scope of claims eligible for external review for plans using a Federal external review process, and narrowing the scope to claims that involve (1) medical judgment or (2) a rescission of coverage.

While PCMA is generally supportive of the amendments to the interim final rule, we do have concerns with specific provisions that we address in our detailed comments below.

Additional Notice Requirements for Internal Claims and Appeals

In PCMA's September 21, 2010 comments on the July 2010 Interim Final Rule, we noted that diagnosis and treatment codes currently are not provided on prescriptions and are not available for processing prescription drug claims in public and private health benefit plans. While the amended requirement to provide notice of the opportunity to request diagnosis and treatment codes and to provide them if requested is an improvement upon the previous requirement to provide diagnosis and treatment codes in every instance, the new requirement still is not practical, as PBMs do not receive or possess diagnosis and treatment code information. In order to provide diagnosis and treatment codes when requested, PBMs would have to call the prescriber or other providers (e.g., clinics, neighborhood health centers) and manually retrieve the codes on a per patient basis. If the volume of such requests is high, these calls would be highly disruptive to work flow in physicians' offices and clinics.

The information currently provided to subscribers regarding a determination of benefits involving a prescription drug provides them with more than adequate information with minimal risk of confusion. A typical drug benefit notice provides a subscriber with the prescriber's name, the name of the drug, the reason for denial, the standard applied to the decision, the date of the request and the date of the decision. The diagnosis and treatment codes are neither necessary for the subscriber to identify the claim nor relevant for a subscriber to understand an internal claims and appeal decision.

PCMA Recommendation: *PCMA recommends clarification that the amended notice requirement pertaining to diagnosis and treatment codes does not apply to prescriptions dispensed by retail and mail service pharmacies.*

Form and Manner of Notice

The Departments request comments on whether it would be appropriate to include a provision in the final rules requiring health insurance issuers providing group health insurance coverage to provide language services in languages that do not meet the requisite threshold for an applicable non-English language, if requested by the administrator or sponsor of the group health plan to which the coverage relates. PCMA believes strongly that plan sponsors should be able to request any language services they deem appropriate under the 10% threshold and that the terms and conditions of such requests are a matter of private contract between the plan and its insurers and other service providers. There is no need for the Departments to require, intervene in, or otherwise regulate the provision of language services that fall below the 10% threshold.

PCMA Recommendation: *PCMA recommends that the Departments should not extend the final rules to include a requirement for insurers to provide language-related services for populations that fall below the 10% threshold. Instead, the provision of such services should remain a matter of private contract between plan sponsors and insurers.*

Scope of Federal External Review Process

While PCMA supports the Departments' decision to narrow the scope of claims eligible for Federal external review, we have significant concerns with the requirement that medical judgment will be determined by external reviewers. We are not confident that most IROs are capable of making accurate and consistent decisions regarding medical judgment.

Further, PCMA is concerned about the balance between the costs and benefits of external reviews. We believe that the Departments should follow the lead of several states that have adopted a minimum threshold for the initiation of an external review. The states listed below are examples of states that have adopted a range of member cost thresholds for the initiation of an external appeal:

- Kentucky (member cost of at least $100)
- Ohio (member cost greater than $500)
- South Carolina (member cost of at least $500)
- Vermont (member cost of $100)
- West Virginia (member cost of at least $1,000; applies to HMOs only)

PCMA Recommendation: *PCMA urges the Departments to work more closely with the states and adopt thresholds for the initiation of an external appeal under the Federal external appeals process.*

PCMA very much appreciates your consideration of our comments and recommendations, and we look forward to continuing to work with the Departments of Treasury, Labor, and Health and Human Services to ensure successful implementation of the Affordable Care Act.

Sincerely,

Michelle Galvanek
Vice President, Regulatory Affairs