PCMA

October 13, 2015

Submitted electronically to www.regulations.gov

Centers for Medicare and Medicaid Services (CMS)
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development
Attention: Document Identifier/OMB Control Number: 10572
Room C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear CMS:

RE: Transparency in Coverage Reporting by Qualified Health Plan Issuers – CMS 10572

The Pharmaceutical Care Management Association (PCMA) appreciates the opportunity to submit comments on the proposed PRA on transparency in coverage reporting by QHP issuers. PCMA is the national association representing America's pharmacy benefit managers (PBMs), which administer prescription drug plans for more than 246 million Americans with health coverage through Fortune 500 companies, health insurers, labor unions, Medicare and Medicaid. PCMA members are committed to providing low-cost, quality, safe and effective pharmacy benefit programs to our clients and their employees and policyholders.

Initially, we note that PCMA commends CMS for beginning the implementation of the transparency requirements under Section 1311 of ACA to help achieve its goal to "aid consumers in efficiently selecting a health plan and using their benefits." CMS further notes that "these new standards will lead to greater transparency for consumers and assist in the decision-making process."

Towards that end, there is one aspect of the proposed information collection which we believe will be contrary to CMS's stated goals of helping consumers make fully informed QHP decisions. Specifically, under the section on "Other information as determined appropriate by the Secretary," there is a bullet addressing the following: "Drug exceptions timeframes and enrollee responsibilities (The issuer would provide an explanation of the internal and external exceptions process for people to obtain drugs pursuant to 45 CFR 156.122(c). The explanation should explain the time frame for a decision, how to complete the application, and the review process.)" (page 5).

We believe this information will not assist consumers in understanding their coverage and should not be displayed for the following reasons:

1. It is clear that the otherwise applicable enrollee appeal rights (e.g., appeals of denials of a formulary drug under prior authorization protocols) are included in the list of data elements for display. However, consumers may not understand the difference between the "exceptions timeframes and enrollee responsibilities" that apply to formulary drugs that are denied as compared to non-formulary

Pharmaceutical Care Management Association
325 7th Street, NW, 9th Floor
Washington, DC 20004
www.pcmanet.org

drugs for which an exception is requested. We have repeatedly – and so far unsuccessfully – tried to explain to CCIIO regulators that federal regulations already require an internal appeal and external review process for denied exception requests for non-formulary drugs.

2. There continues to be substantial uncertainty about the provisions in 45 CFR 156.122(c) and how those timeframes and processes may interact with already established state protocols, which, in many instances, may conflict with or duplicate the specifics of this rule when it takes effect in 2016. As we have advised CCIIO repeatedly, we continue to believe that provisions in that section are at variance with state insurance regulations and existing ACA external review and appeal processes. Thus, we remain very concerned that the conflicts and uncertainties on how these duplicative and additional burdensome requirements will only serve to confuse consumers or, even worse, provide them misleading information.

3. Finally, consumers should be encouraged to select plans that best meet their needs including ones that provide coverage of their drugs on formulary. CCIIO's current initiative on machine-readable formularies is intended to achieve that goal. To the extent this proposed standard would draw attention to a process for consumers to obtain coverage for non-formulary drugs, it would appear to be at cross-purposes with the effort to encourage the public to select plans that cover their needed drugs—as well as undermining the important role formularies play in maintaining affordable prescription drug coverage.

At a minimum, we urge CMS not to include this information until there has been time to see how state insurance regulators decide to proceed with the regulatory conundrum created by 45 CFR 156.122(c) and how these provisions are actually implemented. CCIIO has stated to us that they are going to wait and see what happens with this issue in the marketplace. We think it is only prudent that this aspect of the information collection be deferred as well.

We appreciate the opportunity to comment and we urge CMS to consider PCMA's recommendations as set forth above.

Sincerely,

Wendy Krasner

Wendy Krasner
Vice President – Regulatory Affairs