



55th Anniversary

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September 29, 2004

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Mark McClellan, MD, PhD  
Administrator  
Centers for Medicare and Medicaid Services  
Attention CMS-4068-P  
P.O. Box 8014  
Baltimore, MD 21244-8014

**RE: Medicare Prescription Drug Benefit: Proposed Rule**

Dear Dr. McClellan:

The American College of Cardiology (ACC) is a 31,000 member non-profit professional medical society and teaching institution whose purpose is to advocate for quality cardiovascular care-through education, research promotion, development and application of standards and guidelines-and to influence health care policy. The College represents more than 90 percent of the cardiologists practicing in the United States.

The ACC appreciates the opportunity to comment on CMS' Proposed Medicare Drug Benefit. We recently provided similar comments to the United States Pharmacopeia (USP) on their draft Model Guidelines.

The ACC suggests CMS should closely evaluate the current classification system proposed by USP due to the significant potential for omission of vital cardiovascular medications. The ACC believes that overly restricting the availability of drugs within a pharmaceutical class could potentially violate the standard of care and deny access to the most safe and effective therapeutic interventions. An example we provided to USP is that with the two drugs per class provision, it is feasible that statin drugs may become optional on drug formularies. Several randomized controlled studies show cholesterol lowering with HMG CoA Reductase inhibitors (statins) can decrease the risk of death and cardiovascular events in patients with and without heart disease.<sup>1,2,3</sup> Due to this evidence, statins of proven efficacy need to be included in all drug plans. A proposed solution is adding statins as a class.

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Congestive heart failure specific *B*-blockers, ace inhibitors, and angiotensin II receptor blockers (ARBs) are other examples of clinically efficacious drugs used by millions of patients which could be omitted using the current classification system in the Medicare USP model guidelines.

*B*-blockers are beneficial for many patients including patients post myocardial infarction, hypertensive patients, and patients with congestive heart failure. A few *B*-blockers have been shown to improve heart function, improve survival, and decrease hospitalizations in patients with congestive heart failure.<sup>4,5</sup> In contrast, some *B*-blockers have not shown improvement in survival when used in the treatment of severe heart failure.<sup>6</sup> This suggests all *B*-Blockers do not have similar effects and cannot be considered equivalent for the treatment of heart failure. In fact, only two *B*-blockers are FDA approved for the treatment of congestive heart failure. Heart failure specific *B*-blockers need to be included in drug plans. A proposed solution is adding a drug class “Heart Failure Specific *B*-blockers.”

Ace inhibitors and ARBs have been proven to be beneficial for multiple problems including heart failure and after myocardial infarction. The ACC/AHA Guidelines for Heart Failure recommend ace inhibitors as class I therapy for patients post myocardial infarction and in patients with decreased left ventricular function.<sup>7</sup> ARBs are the recommended alternative medication to ace inhibitors in patients intolerant to ace inhibitors and also have been shown to be efficacious in the treatment of hypertension. We encourage CMS not to allow drug plans the discretion of eliminating clearly proven drugs such as statins, heart failure specific *B*-blockers, ace inhibitors, and angiotensin receptor blockers from their formularies.

The ACC also requests CMS and USP evaluate the need for combination therapy in the Model Guidelines. Hypertension is an important example of where combination therapy is commonly used in current medical practice. Twenty-five percent of people in the United States have hypertension. Many of these patients require several medications for adequate blood pressure control. The use of combination agents can simplify a patient’s drug regimen by

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decreasing the number of medications needed and therefore may improve compliance. By improving compliance, the complications associated with hypertension including stroke, coronary artery disease and heart failure will potentially decrease.

Another important issue that CMS needs to address is the appeals rights provisions set forth in the proposed rule. Beneficiaries must have adequate appeals rights if a drug is not on a formulary because it is omitted from the USP Model Guidelines or if a prescription drug plan chooses not to cover a specific drug that is judged by a physician to be the most clinically appropriate for the patient.

The ACC is concerned about CMS' proposed appeals process and the aggregate amount of time that it might take an enrollee to resolve a coverage issue when the requested drug is not on the formulary. The overall timeframe between a beneficiary's initial request for a coverage determination, and moving to an external review process, could be three months or longer. In the meantime, the beneficiary must pay out of pocket for the drug. In situations where the patient is not financially capable of paying out-of-pocket, he/she could be left without potentially life-saving treatment. The burden is also on the beneficiary and his/her physician throughout the process to provide the evidence that the prescription drug should be covered as though it were a formulary drug. The ACC recommends that CMS consider shortening the timeframes for each of the steps of the coverage determination, re-determination and appeals process in order to maintain beneficiary access to appropriate drugs and not provide undue burden.

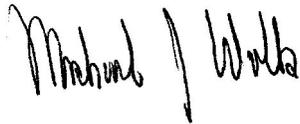
CMS also needs to address the issue of FDA approval of new drugs once the Model Guidelines are finalized. There needs to be a mechanism where health plans evaluate these new drugs for incorporation into their formularies. Again, there also needs to be an appropriate, time efficient appeals mechanism for a beneficiary to request a new drug if the physician determines it is the clinically preferred treatment for that patient.

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We appreciate CMS consideration of ACC's comments and those of many additional organizations. Since the implementation date of this new benefit is not until 2006, we urge CMS to fully evaluate all constructive recommendations in order to develop a comprehensive Medicare drug prescription drug benefit for beneficiaries.

Please contact Anne Marie Bicha, Associate Director, Regulatory Affairs, at 301-493-2384, or [abicha@acc.org](mailto:abicha@acc.org), if we may provide any additional information or assistance to CMS.

Sincerely,

A handwritten signature in black ink that reads "Michael J. Wolk". The signature is written in a cursive, slightly slanted style.

Michael J. Wolk, MD, FACC  
President

cc: Christine McEntee, ACC