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*The mission of the American College  
of Cardiology and the American  
College of Cardiology Foundation  
is to transform cardiovascular care  
and improve heart health.*

December 11, 2018

Seema Verma

Administrator - Centers for Medicare and Medicaid Services  
U.S. Department of Health and Human Services  
Hubert H. Humphrey Building, Room 445-G  
200 Independence Avenue, SW  
Washington, DC 20201

**Re: CMS Proposed Rule: Medicare and Medicaid Programs; Regulation To Require Drug Pricing Transparency (CMS-4187-P)**

Dear Administrator Verma,

The American College of Cardiology (ACC) appreciates the opportunity to provide input on the CMS Proposed Rule: Medicare and Medicaid Programs; Regulation To Require Drug Pricing Transparency (CMS-4187-P).

The ACC envisions a world where innovation and knowledge optimize cardiovascular care and outcomes. As the professional home for the entire cardiovascular care team, the mission of the College and its more than 52,000 members is to transform cardiovascular care and to improve heart health. The ACC bestows credentials upon cardiovascular professionals who meet stringent qualifications and leads in the formation of health policy, standards and guidelines. The College also provides professional medical education, disseminates cardiovascular research through its world-renowned JACC journals, operates national registries to measure and improve care, and offers cardiovascular accreditation to hospitals and institutions.

**General Comments:**

**In this letter ACC is offering comments on drug price transparency in direct to consumer advertising and payment codes for drug pricing counseling.**

The College supports CMS's efforts to reduce the costs of prescription drugs, including requiring that television advertisements for certain prescription drugs include their list price. ACC also requests that CMS remain cognizant of relevant administrative burdens in the conversation regarding drug pricing. Finally, the College is pleased to share with CMS its policy principles on patient access to

prescription drugs. These principles were approved by ACC's Board of Trustees during its October 2018 meeting.

### **Drug Price Transparency in Direct to Consumer Advertising:**

**ACC supports efforts to increase pricing transparency across the pharmaceutical distribution chain.** Accurate information on drug prices, plan benefits, formulary changes, and discounts must be readily available to enable clinicians and patients to be better informed about expected cost-sharing when discussing treatment plans. **The College also supports including drug price transparency requirements in advertisements in media beyond television.** This could include radio, magazines, newspapers, internet websites and other forms of social media. **CMS should emphasize price transparency efforts that are easily accessible to individuals with limited technology literacy, such as older adults, the medically frail, and the low-income.** These individuals may not have access or ability to utilize web-based tools, such as the Drug Spending Dashboards. While Drug Spending Dashboards are an important resource for researchers and technology literate individuals, CMS should ensure that price transparency information is accessible to all patients regardless of circumstance.

The College encourages CMS to emphasize transparency beyond only the list price of certain drugs. Drug transparency efforts should also place an emphasis on value, as assessed through scientific evidence and analysis of both comparative effectiveness and cost-effectiveness. Any movement toward transparency must also prioritize the impact on patient outcomes and not consider cost as the sole criterion.

### **Payment Code for Drug Pricing Counseling:**

The College appreciates CMS recognizing the importance of clinician engagement with patients on their prescription drug out-of-pocket costs. Clinicians already regularly counsel patients on their out-of-pocket costs and the importance of filling their prescriptions. Therefore, the creation of a new payment code for drug pricing counseling may not be necessary to incentivize this dialogue. **ACC is concerned that the creation of a new payment code may create an additional administrative burden and unintentionally reduce the incentive to engage in this necessary patient-clinician discussion.** Furthermore, the budget neutral nature of the approach CMS discusses may further reduce the incentive to utilize the code and engage in the conversations it seeks to incentivize.

### **ACC's Policy Principles on Patient Access to Prescription Drugs:**

The College has advocated that access to healthcare is not merely about availability of care. Cost plays a significant role in access and must be treated as such. To that end, the ACC supports affordable access for all patients, regardless of insurance coverage or lack thereof, to all approved prescription drugs with scientific evidence of net clinical benefit or as articulated in clinical practice guidelines.

Recognizing the increasing role that pharmaceuticals play in conversations on health care access and affordability, the College drafted policy principles on patient access to prescription drugs with its Health Affairs Committee during Summer 2018. ACC is pleased to share these principles with CMS as part of the larger nationwide discussions on drug pricing, access, and patient affordability. If CMS has any questions regarding these policy principles, ACC would appreciate the opportunity to discuss this work further with CMS.

*Policy Principles for Patient Access to Prescription Drugs*

Patient Access: The ACC advocates for affordable access for all patients, regardless of insurance coverage or lack thereof, to all approved prescription drugs with scientific evidence of net clinical benefit or as articulated in clinical practice guidelines.

Barriers: Excessive out-of-pocket expense represents an insurmountable hurdle for many patients. It is essential to diminish any financial barriers including co-pays, co-insurance and deductibles. In addition, the ACC calls for the reduction of administratively burdensome processes that hamper patient access to evidence-based, approved therapies.

Transparency: The ACC urges transparency toward price determination throughout the distribution chain. Accurate information on drug prices, plan benefits, formulary changes, and discounts must be made readily available so clinicians and patients can be better informed about expected cost-sharing when discussing treatment plans.

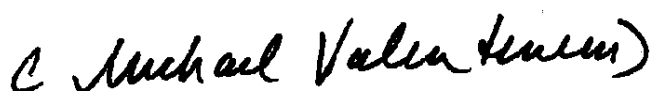
Value-Based Pricing: Pricing decisions should be made with an emphasis on value, as assessed through scientific evidence and analysis of both comparative effectiveness and cost-effectiveness. Any movement toward value-based pricing must prioritize the impact on patient outcomes and not consider cost as the sole criterion.

**Conclusion:**

ACC is committed to working with CMS and providers to ensure access to affordable drugs for all patients. The College looks forward to ongoing discussion and collaboration with CMS on drug pricing and transparency initiatives.

If you have any questions or would like additional information regarding any recommendations in this letter, please contact Bryant Conkling, Associate Director, Payment Reform, at (202) 375-6399 or [bconkling@acc.org](mailto:bconkling@acc.org).

Sincerely,



C. Michael Valentine, MD, FACC  
President