



May 9, 2016

The Honorable Andy Slavitt
Acting Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Re: CMS-1670-P

Dear Acting Administrator Slavitt:

On behalf of the American College of Physicians (ACP), I am writing to share our comments on the Centers for Medicare and Medicaid Services' proposed Medicare Part B Payment Model. ACP is the largest medical specialty organization and the second largest physician group in the United States. ACP members include 143,000 internal medicine physicians (internists), related subspecialists, and medical students. Internal medicine physicians are specialists who apply scientific knowledge and clinical expertise to the diagnosis, treatment, and compassionate care of adults across the spectrum from health to complex illness.

ACP appreciates that the Administration is considering efforts combat the high prices and costs of prescription drugs in the United States. The increase in the price of prescription drugs and the growth in spending associated with prescription drugs is an alarming trend that is projected to continue into the next several years, particularly with the introduction of more high-priced specialty drugs and fewer drugs going off patent. ACP recently published the position paper *Stemming the Escalating Cost of Prescription Drugs*¹ addressing the issue of rising prescription drug pricing. The paper details the current state of rising prescription drug prices and notes specifically that the United States lacks many of the regulations or price controls that keep the cost of many drugs lower in other countries. ACP believes that a truly competitive marketplace can help to control prescription drug costs from spiraling out of control; however, the current market is broken and in some cases even the introduction of competitor products may not achieve meaningful reductions in price or costs for patients. The College believes that action needs to be taken by all stakeholders to bring down the price of prescription drugs and reduce the costs to patients who need these critical medications.

¹ Daniel, H. *Stemming the Escalating Cost of Prescription Drugs: A Position Paper of the American College of Physicians*. *Ann Intern Med*. Published online 29 March 2016. doi: 10.7326/M15-2768

This demonstration project proposed by CMS focuses specifically on drugs paid for through Medicare Part B and may particularly affect internal medicine physicians who practice subspecialties in areas such as oncology, rheumatology, or hematology. These physicians are more likely to prescribe and dispense drugs paid for by Medicare Part B and therefore be impacted the most by the proposed changes.

General Comments Regarding the Proposed Model

The proposed rule suggests testing if two different payment structures for drugs paid for under the Medicare Part B program would result in a reduction in costs while maintaining or enhancing the quality of care. ACP believes that the sharp increase in the price of some prescription drugs and in turn, the cost to patients, is a serious issue that will take comprehensive efforts of all stakeholders including the pharmaceutical industry, public and private payers, and health professionals to curb.

Physicians have a responsibility to be stewards of health care resources while still acting in the best interest of their patients and their patients' health. The way the proposed demonstration project is structured primarily makes it the responsibility of the prescriber to bear the burden of keeping drug costs down and reallocates how funds are distributed between providers. The model may particularly provide challenges for small, independent practices and/or practices in rural or medically underserved communities. Individual practices negotiate the prices for the acquisition of certain drugs and small practices do not have the same leverage as larger practices or hospital settings in their negotiations. As a result, some practices may ultimately pay a higher price for obtaining a drug than the ASP and could lose money in this process.

The proposed model would also randomly assign practices one of four model arms and keep those practices in their assigned arm for the duration of the model with very few exceptions. Being able to assess this data is important in the evaluation of the model's effectiveness; however, CMS should consider if certain geographic or demographic criteria may increase the potential for economic hardship to those practices.

Phase 1

Phase 1 of the model would replace the current system of paying average sales price plus six percent (ASP+6%) with the average sales price plus 2.5 percent plus a flat fee of \$16.80 (ASP+2.5%+\$16.80). The current average sales price plus 6 percent (ASP+6) system was established in 2003 under the Medicare Modernization Act as a way to prevent excessive profits under the previous system in which drugs were reimbursed at 95% of the average wholesale price. Since the 2012 sequestration cuts, the add-on percentage has dropped from 6% to 4.3%. The same mandatory sequestration cuts would also apply to this model, effectively reducing the add-on percent to 0.8%.

While there are some exemptions for certain drugs and products in the rule, extremely inexpensive or very high-priced drugs would be paid the same way under the same new system.

In certain drug classes, there are very few options for treatment, or for which there is not sufficient price variation. In this situation, a physician would be limited in their prescribing ability. The reduction in reimbursement amount from ASP+6 to ASP+2.5%+\$16.80 may be of particular concern in the case of low-priced or generic drugs. The addition of a \$16.80 flat fee may not be enough to compensate for the reduction in percentage add-on for some drugs such as albuterol. Moreover, the low reimbursement rate for some generic oncology drugs has been reported as a contributing factor to recent shortages for these drugs².

ACP strongly urges CMS to reassess implementing the proposal to change the current ASP+6% payment structure to the proposed ASP+2.5%+\$16.80 rate because of the severe negative impact it may have on some physicians and their practices and appropriate patient access to needed medications. The adjustment may especially cause an adverse impact, especially on smaller subspecialty practices that treat patients who benefit from these drugs or who have few treatment options. Although this demonstration project seeks to test if adjusting Medicare Part B payments will result in a reduction of costs overall in the long-term, the potential for the new payment structure to negatively affect some practices may be felt immediately.

Additionally, other factors that are not included in the average sales price should be taken into account when considering adjustments to payments for prescription drugs that are administered by physicians, such as special handling or storage requirements commonly associated with some higher-priced specialty or biologic drugs. ACP believes physicians should be paid adequately for the services provided which includes the acquisition and administration of drugs in-office. When assessing a new payment system for prescription drugs, a reassessment of practice expenses must also be taken into consideration to ensure that the program is not creating additional financial burden on practices despite reducing expenditures in other areas.

Phase 2

Phase 2 of the demonstration project would introduce value-based payment models into care. ACP is supportive of research into value-based models and decision making. As part of the position paper on prescription drug pricing, ACP took the position:

ACP supports research into novel approaches to encourage value-based decision making, including consideration of the following options:

- a. Value frameworks;*
- b. Bundled payments;*
- c. Indication-specific pricing;*
- d. Evidence-based benefit designs that include explicit consideration of the pricing, cost, value, and comparative effectiveness of prescription medications included in a health plan's benefit package.*

² Kantarjian H. Chemotherapy Drug Shortages in the United States Revisited. *Journal of Oncology Practice*. September 2014; 10(5): 329-331. Doi: 10.1200/JOP.2014.001514.

The proposed rule did not provide a detailed overview of how these various value-based payment methods would specifically be applied, implemented, or how value would be determined or measured. However, ACP strongly encourages CMS to engage physician groups and physician subspecialists groups on how to assess and measure value. This is especially important in reference pricing and indication-specific pricing models. With regards to the reference pricing model, there is concern that paying the same for all drugs within a drug class may result in more uniform pricing in the class by pharmaceutical companies, causing an increase in price for drugs that would otherwise cost less. ACP believes it is important to engage those prescribing the drugs on how drugs within those classes differ.

Similarly, ACP feels that CMS should encourage physician engagement with regards to indications-based pricing in order to understand the ways effectiveness is determined for the same drug in different conditions or over different periods of time. For example, measuring effectiveness in chronic illness must be measured over a long period of time, perhaps longer than the duration of the proposed model. Engaging with physicians will help in determining the most efficient way to capture this information and the variation in the measure of effectiveness. Several value-based assessment tools have been developed by groups such as the American Society for Clinical Oncology and the American College of Cardiology/American Heart Association that are intended to help patients assess the value of certain drugs based on what the patient considers most important.

ACP believes that the discontinuing or eliminating patient coinsurance amount for Part B drugs deemed to be high in value is a beneficial proposal that should be included as part of Phase 2. A literature review of articles and studies looking at the relationship between patient cost sharing and medication adherence and outcomes showed that despite variations in interventions, measures, and populations, 85% of the articles showed increasing the patient share of medication costs was associated with a decrease in adherence³. A prescription drug is only as effective as a patient's ability to access that drug and complete the medication cycle as prescribed. Increasing adherence may help reduce costs overall by helping to prevent costlier medical interventions at a later date.

Thank you again for the opportunity to provide comments on the proposed project. Please contact Hilary Daniel at hdaniel@acponline.org or (202) 261-4546 if you have questions regarding these comments.

Sincerely,



Robert McLean, MD, FACP, FACR
Chair, Medical Practice and Quality Committee
American College of Physicians

³ Eaddy MT, Cook CL, O'Day K, Burch SP, Cantrell CR. How Patient Cost-Sharing Trends Affect Adherence and Outcomes: A Literature Review. *P.T.* 2012 Jan; 37(1): 45-55.