



December 31, 2018

The Honorable Alexander M. Azar III
Secretary of Health and Human Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue SW
Washington, DC 20201

Re: Medicare Program; International Pricing Index Model for Medicare Part B Drugs [CMS-5528-ANPRM]

Dear Secretary Azar,

On behalf of the American College of Physicians (ACP), I am pleased to share our comments on the Centers for Medicare and Medicaid Services' (CMS) advanced notice of proposed rulemaking on payment for prescription drugs covered by Medicare Part B through the International Pricing Index (IPI). The College is the largest medical specialty organization and the second-largest physician group in the United States. ACP members include 154,000 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 the Administration's ongoing commitment to lowering the cost of drugs for American patients. The rising costs of prescription drugs is a significant issue for our members who relay the struggles of their patients in accessing or affording needed medications. High prescription drug costs have been associated with decreased utilization of some drugsⁱ and can affect medication adherence. If patients are unable to afford medications they run the risk of developing more serious health conditions adding costs to the health care system and significantly impacting a patient's quality of life. The very benefits of these therapies are lost when patients are simply not able to access or afford their cost.

The College strongly advocates for policies that would begin mending the broken prescription drug marketplace and improve transparency in prescription drug pricing, lower the price of medications, and lower out of pocket costs for patients. In 2016, ACP published the position

paper *Stemming the Escalating Cost of Prescription Drugs* which details the issues surrounding prescription drug pricing and offers a number of recommendations to improve competition, address gamesmanship by bad actors in the industry, and begin to repair the broken market for prescription drugs. ACP agrees that the rising costs incurred by Medicare for Part B drugs is unsustainable and actions should be taken to address potential incentives to keep prices high and for physicians to prescribe higher cost drugs. **ACP also believes that while the high cost of prescription drugs is a significant issue facing the American public, price should not be used as the sole criterion for choosing health care goods or services, including prescription drugs.**

Administrative Burden

ACP is concerned about the potential for added administrative burden on physicians by introducing additional intermediaries into the procurement, billing, and payment policies for Part B drugs. While the IPI model claims that the proposed improvements to the Competitive Acquisition Program (CAP) will reduce burden on physicians by putting the responsibility and financial risk of obtaining Part B drugs in the hands of third parties, the ANPRM does not describe how they intend to operationalize the program in a way that will not add unnecessary burden for physicians. In an analysis of the first CAP program, CMS found that providers that selected CAP did so because they believed it would reduce administrative burden and lower costs. However, they also found that these were two of the reasons providers did not participate in the CAPⁱⁱ. The report also showed that the program did not find large increases or decreases in administrative burdens on physicians.

ACP is concerned about the number of administrative tasks required by physicians and is committed to reducing administrative burden. ACP has extensive policy centered on a framework for assessing administrative tasks that would eliminate unnecessary or excessive tasks that may take away from more clinically important activities and may prevent patients from receiving timely or appropriate care or treatment. In this policy, **ACP calls on stakeholders external to the physician practice or health care clinician environment who develop or implement administrative tasks (such as payers, governmental and other oversight organizations, vendors and suppliers, and others) to provide financial, time, and quality-of-care impact statements for public review and comment. This activity should occur for existing and new administrative tasks. Tasks that are determined to have a negative effect on quality and patient care, unnecessarily question physician and other clinician judgment, or increase costs should be challenged, revised, or removed entirely.** ACP strongly advises CMS to consider how to reduce any potential administrative burden as part of a proposed rule and clearly communicate those program elements to participating providers.

Additionally, ACP urges CMS to engage stakeholders to collaborate on ways to leverage existing health information technology in accordance with ACP policy. **To facilitate the elimination, reduction, alignment, and streamlining of administrative tasks, all key stakeholders should collaborate in making better use of existing health information technologies, as well as developing more innovative approaches.** Further recommendations on how to assess and

reduce administrative burden on physicians can be found in the ACP position paper [Putting Patients First by Reducing Administrative Tasks in Health Care](#).

Ensuring Appropriate Payments to Physicians Administering Drugs

CMS has proposed it will consider a number of ways to pay physicians for administering Part B drugs that would not be tied to the list price of the drug. Although ACP has no comment on the suggested options, the College stresses that there should be **appropriate levels of reimbursement to account for administration of drugs and investments in care delivery infrastructure**. CMS should consider and make efforts to mitigate any potential negative impacts changes in payments for Part B drugs may have for a number of different practice types, including small independent practices or rural practices.

Comparing U.S. Pricing to that of Peer Nations

In 2015, the Government Accountability Office (GAO) issued a report analyzing the 84 most expensive drugs in Medicare Part B and found that 22 Part B drugs accounted for 30% of all Medicare spending on Part B drugs in 2015. Additionally, the report found and that Medicare represented over 50% of the market for those 22 drugsⁱⁱⁱ. Not only is the government paying more for drugs, patients are also experiencing higher costs than counterparts in peer nations. A recent study found that the cost of first-line chemotherapy treatments for metastatic colorectal cancer are twice the cost in the U.S. compared to Canada (\$12,345 v. \$6,195)^{iv}.

The U.S. relies on a competitive marketplace to keep prices down while other peer nations utilize strategies such as reference pricing, consideration of quality adjusted life years, or centralized government negotiation of drug prices to manage costs to their health systems. In those systems, prescription drugs are evaluated based on their efficacy, potential value, and economic impact, among other factors and prices are determined with consideration of this data. The proposed attempt to bring U.S. prices for Part B drugs in line with peer nations by establishing a methodology accounting for the various drug pricing policies among peer nations for prescription drugs and biologics overlooks the opportunity for changes rooted in domestic pricing policies. ACP urges the Administration to consider additional policy options as part of broader drug pricing reform efforts that would boost competition in the marketplace and address issues that are preventing competitor products, including biologics, from coming to market and driving the cost of medications down for patients.

Safety and Access of Part B Drugs

Many prescription drugs covered under the Medicare Part B benefit require special handling and storage to ensure the safety and integrity of the drugs or biologics. ACP believes CMS should have some involvement in assessing whether vendor agreements meet minimum requirements for ensuring the safety of covered drugs as well as confidentiality requirements and non-discrimination criteria. ACP believes that CMS should strongly consider access to medications when weighing the contractual responsibilities of model vendors. Allowing vendors to exclude some health care providers included in the ANPRM may result in negative unintended consequences by putting physicians in a situation in which they do not benefit from

competition among vendors, resulting in increased costs, or having difficulties obtaining needed drugs for their patients.

Conclusion

We appreciate the opportunity to comment and your consideration of our comments. We welcome the chance to further work with the Department to address the critical issue of high prescription drug prices. Please contact Hilary Daniel, Associate, Health Policy and Regulatory Affairs, by phone at (202) 261-4546 or via email at hdaniel@acponline.org with any further questions or if you need additional information.

Sincerely,



Ana María López, MD, MPH, MACP
President
American College of Physicians

ⁱ Khot UN, Vogan ED, Militello MA. Nitroprusside and Isoproterenol Use after Major Price Increases. *N Engl J Med*. 2017 Aug 10;377(6):594-595. doi: 10.1056/NEJMc1700244.

ⁱⁱ *Evaluation of the Competitive Acquisition Program for Part B Drug: Final Report*. RTI International CMS Contract No. 500-00-0024, T.O. 24. December 2009. Accessed at https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/downloads/CAPPartB_Final_2010.pdf

ⁱⁱⁱ United States Government Accountability Office. Medicare Part B: Medicare Represented at Least Half of the Market for 22 of the 84 Most Expensive Drugs in 2015. December 2017. Accessed at <https://www.gao.gov/assets/690/689082.pdf>

^{iv} Yezefski T, Le D, Chen L, et al: Comparison of chemotherapy use, cost, and survival in patients with metastatic colorectal cancer in Western Washington and British Columbia. 2018 ASCO Annual Meeting. [Abstract LBA3579](#). Presented June 3, 2018.