American College of Physicians
Leading Internal Medicine, Improving Lives

January 25, 2021

Liz Richter
Acting Administrator for the Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Re: Most Favored Nation (MFN) Model [CMS-5528-IFC]

Dear Acting Administrator Richter,

On behalf of the American College of Physicians, I am pleased to share our comments on the Centers for Medicare and Medicaid Services' (CMS) interim final rule (IFR) on the Most Favored Nation (MFN) Model for Medicare Part B drug payment. The College is the largest medical specialty organization and the second-largest physician group in the United States. ACP members include 163,000 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.

The College appreciates the Administration's interest in considering a variety of approaches to address the issue of surging prescription drug costs. Rapidly rising drug prices are increasingly creating financial barriers that threaten access to many of the therapies that improve the health and lives of millions of patients. High prices have been found to be associated with decreased utilization for some prescription drugs.[1] **ACP is deeply concerned that the high cost of prescriptions drugs in the U.S. has a major impact on patients' ability to adhere to their medication treatment plans and control their chronic medical diseases and acute illnesses. As a consequence, those medical problems deteriorate causing worse outcomes for patients and much greater financial strain to the nation's health care system.** One study found that medication non-adherence contributes to roughly 125,000 deaths, 10 percent of hospitalizations, increased morbidity and mortality rates, and costs the health care system anywhere from $100-$300 billion a year in the United States.[2]

[1] 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.
[2] Viswanathan, Meera, Carol E. Golin, Christine D. Jones, Mahima Ashok, Susan J. Blalock, Roberta CM Wines, Emmanuel JL Coker-Schwimmer, David L. Rosen, Priyanka Sista, and Kathleen N. Lohr. "Interventions to improve

Physicians have a particular interest in ensuring a sustainable marketplace and lower costs for our patients as prescription drugs comprise a crucial part of a physician's comprehensive toolkit in managing the health of the public. ACP has long advocated for solutions to reign in prescription drug prices and has published a series policy papers that offer recommendations to improve transparency, value, and competition for prescription drugs, with the goal of creating a sustainable and affordable prescription drug marketplace.[3,4,5,6] While innovative approaches and studying evidence-based best practices from peer nations are necessary as part of an approach to meaningfully control drug prices, the College urges CMS not to overlook the many opportunities to make policy changes in the domestic market to lower prices.

Most Favored Nation Model

ACP agrees with the Administration that the rising costs incurred by Medicare for drugs and biologics covered under Part B is unsustainable. Under the current Medicare Part B "buy-and-bill" system, physicians purchase and administer the drugs and biologics and are reimbursed by the Medicare program for the average sales price (ASP) + 6%. As reimbursement is tied to drug price, this creates the potential financial incentive for the use of more expensive drugs and may contribute to rising drug spending.

To address this, the College supports the further study of payment models in federal health care programs, including methods to align payment for prescription drugs administered in-office in a way that would reduce incentives to prescribe higher-priced drugs when lower-cost and similarly effective drugs are available, as outlined in the 2019 position paper *Policy Recommendations for Public Health Plans to Stem the Escalating Costs of Prescription Drugs*. ACP believes that prior to implementing any such payment model, further study is needed to establish whether they truly would result in cost savings, their potential effect on physician practices of varying size, whether they would affect patient access, and potential unintended consequences. It is crucial that any demonstration projects or pilots be developed with robust stakeholder input—including from physicians, should be appropriately scaled, and should have safe guards in place to ensure patient access to medications.

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adherence to selfadministered medications for chronic diseases in the United States: a systematic review." Annals of internal medicine 157, no. 11 (2012): 785-795.

[3] Daniel, Hilary. "Stemming the escalating cost of prescription drugs: a position paper of the American College of Physicians." *Annals of internal medicine* 165, no. 1 (2016): 50-52. https://www.acpjournals.org/doi/abs/10.7326/M15-2768

[4] Daniel, Hilary, and Sue S. Bornstein. "Policy Recommendations for Public Health Plans to Stem the Escalating Costs of Prescription Drugs: A Position Paper From the American College of Physicians." *Annals of Internal Medicine* 171, no. 11 (2019): 825-827. https://www.acpjournals.org/doi/full/10.7326/M19-0013

[5] Daniel, Hilary, and Sue S. Bornstein. "Policy Recommendations for Pharmacy Benefit Managers to Stem the Escalating Costs of Prescription Drugs: A Position Paper From the American College of Physicians." *Annals of Internal Medicine* 171, no. 11 (2019): 823-824. https://www.acpjournals.org/doi/full/10.7326/M19-0035

[6] Daniel, Hilary, Josh Serchen, and Thomas G. Cooney. "Policy Recommendations to Promote Prescription Drug Competition: A Position Paper From the American College of Physicians." *Annals of Internal Medicine* 173, no. 12 (2020): 1002-1003. https://www.acpjournals.org/doi/full/10.7326/M19-3773

Under the IFR, CMS proposes transitioning away from the current Medicare Part B reimbursement methodology for physician-administered drugs and biologics towards an MFN approach, which sets the reimbursement rate at the lowest price (adjusted for per-capita GDP) paid by Organisation for Economic Co-operation and Development (OECD) countries with a per capita GDP of at least 60% that of the United States for 50 drugs responsible for the highest spending under Part B. Calculating appropriate drug prices under such a model is a function of the quality of the input data. ACP remains uncertain about the Agency's ability to access and obtain high-quality international pricing information that is necessary to accurately calculate prescription drug prices under the proposed model.

While we do not have comment on the specific methodology and approach of determining prices, ACP has reservations about the impact this IFR would have on patient access to necessary drugs and on physician practices. **Reducing reimbursement rates for Medicare Part B physician-administered drugs and biologics without imposing any sort of mechanism to ensure drug suppliers and manufacturers adjust their pricing to approximate MFN prices could create financial challenges for physician practices, particularly small and rural practices, and create access issues for patients.** One independent analysis of international 2019 pricing data for drugs impacted by the IFR found that on average, the MFN price is 33% of the ASP.[7] If suppliers and manufacturers do not lower their prices to align with the Medicare Part B MFN reimbursement rates as proposed in this IFR, ACP is concerned about the impact this would have on the financial feasibility for physicians to provide this service and the impact that would have on patient access to these crucial drugs. The CMS Office of the Actuary estimates the IFR would result in an elimination of 19% of Part B drug utilization as certain drugs may not be provided at all if physicians are unable to negotiate favorable prices from manufacturers that are more aligned with the new Medicare reimbursement rate.[8] While the high cost of prescription drugs is a significant issue facing the American public, ACP contends that price should not be the sole determining factor in making drugs available to patients. CMS must ensure any Medicare reimbursement changes maintain appropriate reimbursement levels reimbursement to account for the administration of drugs and investments in care delivery infrastructure in order to prevent the degradation of patient access and undue financial burden on physician practices.

Administrative Burden

In comments provided on the advanced notice of proposed rulemaking (ANPRM) for the prior iteration of this rule, ACP shared the need to center evaluating and minimizing administrative burden in any sort of new payment model and expressed concern about the additional administrative complexity that would be added by introducing third-party vendors to procure drugs. While this IFR does not include the third-party vendor arrangement for procuring drugs as proposed in the ANPRM, CMS should continue to evaluate the proposed model for sources of administrative burden and make efforts to eliminate them. As outlined in the position paper

[7] https://d1198w4twoqz7i.cloudfront.net/wp-content/uploads/2020/12/08190732/Most-Favored-Nation-Model-Strategy-Insight_Final.pdf
[8] https://www.healthaffairs.org/do/10.1377/hblog20201122.298613/full/

Putting Patients First by Reducing Administrative Tasks in Health Care,[9] 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. 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.

Rulemaking Process

Finally, ACP is deeply concerned about the unconventional rulemaking process surrounding this IFR. In 2018, CMS released the prior iteration of this rule, an ANPRM that aimed to lower spending on drugs administered in an outpatient setting by instituting an international price index approach. While federal law typically requires the publication of a notice of proposed rulemaking (NPRM) as part of the rulemaking process, the MFN Model was issued directly as an IFR from an ANPRM, without taking the steps of issuing an NPRM. The College believes that by not going through the usual rulemaking procedures, CMS did not allow for the appropriate and necessary input by stakeholders on a rule of significant impact prior to it taking effect.

Conclusion

We appreciate the opportunity to provide comments on this rule and welcome further chances to work together to address the urgent issue of high prescription drug prices. Although manufacturers are solely responsible for setting their price, it is important to keep in mind that other factors (i.e. PBMs, payers, physicians, regulations, patents, etc.) play a role in how manufacturers set them, regardless of other motivations. Any solution addressing the many issues surrounding prescription drug pricing cannot be as straightforward as unilateral action by a single actor—it will require commitment by all stakeholders. In addition to innovative models, we urge the federal government to consider other avenues such as improving price and cost transparency for health plans, pharmaceutical benefit managers, and manufacturers; allowing Medicare and other federal programs to directly negotiate drug prices; and measures to increase competition. Please contact Josh Serchen, Associate, Health Policy at jserchen@acponline.org if you have any questions or need any additional information.

Sincerely,

Jacqueline W. Fincher, MD, MACP
President

[9] Erickson, Shari M., Brooke Rockwern, Michelle Koltov, and Robert M. McLean. "Putting patients first by reducing administrative tasks in health care: a position paper of the American College of Physicians." *Annals of Internal Medicine* 166, no. 9 (2017): 659-661. https://www.acpjournals.org/doi/10.7326/M16-2697