



September 25, 2019

The Honorable Nancy Pelosi
Speaker
U.S. House of Representatives
Washington, DC 20515

Dear Speaker Pelosi:

On behalf of the American College of Physicians (ACP), I am writing to express our appreciation for the recent release of the *Lower Drug Costs Now Act of 2019* (H.R. 3), legislation designed to address the rising cost of prescription drugs. As outlined in a recent ACP [statement](#) on the bill, we are encouraged by its provisions to empower the Secretary of Health and Human Services (HHS) to negotiate with drug companies for lower prices and to cap out-of-pocket costs for seniors enrolled in the Medicare Part D program. ACP appreciates this opportunity to provide feedback on specific aspects of the legislation where we have established policy and we look forward to working with you and the committees of jurisdiction to help advance these policies.

The American College of Physicians is the largest medical specialty organization and the second largest physician group in the United States. ACP members include 159,000 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.

For many years, ACP has continued to express concern over the rising cost of prescription drugs, particularly for our patients as they struggle to afford basic and life-saving medications prescribed by their physicians to treat diseases and chronic conditions. In 2016, ACP released a position paper entitled, [Stemming the Escalating Costs of Prescription Drugs](#), which provides an assessment of the causes of rising prescription drug prices and provides recommendations on policies that would lower prices. We remain concerned that since the release of this paper, drug prices have continued to rise, sometimes astronomically, and unless Congress takes action to address this issue, we fear for the health and financial future of our patients.

Title I – Lowering Prices through Fair Drug Price Negotiation

This title would mandate that the Secretary of HHS identify 250 brand name drugs that lack competition in the marketplace and that account for the greatest cost to Medicare and the U.S. health system and then negotiate directly with drug manufacturers to establish a maximum fair price for a bare minimum of 25 of those drugs. The legislation establishes an upper limit for the price reached in any negotiation to no more than 1.2 times the volume-weighted average of the price of six countries (Australia, Canada, France, Germany, Japan, and the United Kingdom), known as the Average International Market (AIM) price. An eligible drug that lacks price competition is defined as a brand-name drug that does not have a generic or biosimilar competitor on the market. Insulin would also be included on the list for negotiation with Medicare.

While negotiating price, the HHS Secretary would take the following factors into consideration: the research and development costs of the drug as well as the cost of production, information on alternative treatments and the value of the drug, and domestic and international sales information. If a manufacturer refuses to enter into negotiations after being selected by the Secretary or if the manufacturer leaves the negotiation before a maximum fair price is agreed to, then the manufacturer will be assessed an escalating excise tax levied on the manufacturer's annual gross sales—starting at 65 percent and increasing by 10 percent every quarter the manufacturer is out of compliance, to a maximum of 95 percent.

Once a price for a drug is negotiated through a voluntary bi-lateral negotiation process, the manufacturer may not increase the price faster than inflation in the subsequent years until sufficient price competition enters the market. A manufacturer would also be required to offer the negotiated price to the commercial market, to group and individual health insurance plans.

ACP has longstanding policy supporting the ability of Medicare to leverage its purchasing power and directly negotiate with manufacturers for drug prices, although we have no policy on applying that same negotiating power to the commercial market and group/individual health insurance plans. ACP also supports the repeal of the current law, known as the non-interference clause, which strictly prohibits HHS from interfering with negotiations between drug manufacturers and pharmacies and prescription drug plan sponsors. Absent repeal of the noninterference clause, we believe it should be modified to allow for this type of negotiation by the government for high-cost drugs in which Medicare has substantial financial interest as is included in Title I of this legislation.

A 2007 CBO assessment of repealing the non-interference clause asserted there would be modest cost savings if the government were able to negotiate prices, stating that the government would not be able to secure better prices than those already being negotiated without formulary restrictions similar to Veterans Administration (VA) or other specific circumstances, like for sole source drugs with no market competition. However, other estimates put potential savings much higher, up to \$16 billion per year, if the government is able to negotiate for Part D drugs and achieve the same prices as the VA or Medicaid. Granting Medicare Part D the authority to negotiate drug prices is favored by a bipartisan majority of the public with over 90 percent of Democrats, Republicans, and Independents favoring this approach.

Title II - Medicare Parts B and D Prescription Drug Inflation Rebates

Among other things, this title includes additional restrictions on the ability of drug manufacturers to raise Part B/D drug prices above the rate of inflation since 2016. Under H.R. 3, manufacturers would be permitted to either lower the price or be required to pay the entire price above inflation in a rebate back to the Treasury.

While ACP does not have specific policy regarding prescription drug inflation rebates, we remain alarmed by the egregious practices of some manufacturers that dramatically raise the price of their products, not only for new medications but for ones that have been in circulation for decades, to levels that are simply unaffordable to patients.

A report by the Senate's Homeland Security and Governmental Affairs Committee found that "the prices of many of the most popular brand-name drugs increased at nearly ten times the cost of inflation from 2012 to 2017. Prices increased for every brand-name drug of the top 20 most-prescribed brand-name drugs for seniors in the last five years. On average, prices for these drugs increased 12 percent every year for the last five years—approximately ten times higher than the average annual rate of inflation. Twelve out of the 20 most commonly prescribed brand-name drugs for seniors had their prices increased by over 50 percent in the five-

year period. Six of the 20 had price increases of over 100 percent. In one case, the weighted average wholesale acquisition cost for a single drug increased by 477 percent over a five-year period.”

Title III – Part D Improvement and Maximum Out-of-Pocket Cap for Medicare Beneficiaries

This title would establish an annual out-of-pocket limit of \$2,000 for Medicare beneficiaries enrolled in the Part D program. It would also realign incentives to require health plans to pay more of the costs when seniors reach the catastrophic phase of coverage and reduces government reinsurance subsidies.

ACP supports this policy as we believe that policymakers should implement caps on out-of-pocket expenses for prescription drugs in the catastrophic phase of coverage. Medicare beneficiaries can and do face substantial out-of-pocket costs for prescription drugs, especially when they take costly specialty medications and reach the catastrophic coverage phase. It is also important to note that caps have been proposed in other areas of Medicare; a 2016 House of Representatives Budget Committee budget resolution included a Medicare proposal with a catastrophic cap on annual out-of-pocket expenses which it called, “an important aspect of the private insurance market currently absent from Medicare that would safeguard the sickest and poorest beneficiaries.”

A significant number of seniors would benefit from an out-of-pocket cap in the Medicare Part D program. According to a study by the Kaiser Family Foundation, “between 2007 and 2015, the number of seniors in Medicare Part D who reached the catastrophic limit of coverage doubled to over one million. In 2015, those enrollees paid an average of over \$3,000 out-of-pocket with one in ten spending at least \$5,200, which was driven primarily by the cost of hepatitis C drugs. This group of beneficiaries is likely to be taking higher-priced specialty medications, defined by Medicare as drugs with a negotiated monthly price of more than \$670, for chronic conditions and may also be taking multiple drugs.”

Additional Policies to Lower Drug Costs

As the relevant committees of jurisdiction consider H.R. 3 and move it through the legislative process toward enactment, ACP urges lawmakers to consider and incorporate other policy reforms into this effort, including:

- **The Reforming Evergreening and Manipulation that Extends Drug Years (REMEDY) Act (S. 1209)**, which would amend the law to remove incentives for drug manufacturers to file excessive patents to keep generic drugs off the market, and would lift legal barriers that delay generic entry into the market.
- **The Prescription Drug STAR Act (H.R. 2113)**, which would require manufacturers to publicly justify large price increases for existing drugs and high launch prices for new drugs, and would require the Secretary of HHS to publicly disclose the aggregate rebates, discounts, and other price concessions achieved by pharmaceutical benefits managers (PBMs) on a public website, so consumers, employers, and other payers can understand and compare the discounts PBMs receive. It would also require all drug manufacturers to submit information to the Secretary on the average sales price (ASP) for physician-administered drugs covered under part B.
- **The Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act of 2019 (H.R. 965/S. 340)**, which would improve patient access to alternative low-cost prescription drugs and biological products by preventing prescription drug manufacturers from misusing the FDA’s Risk Evaluation and Mitigation Strategies (REMS) process to make it difficult for competing generics to be brought to the market.

Conclusion

ACP looks forward to working with you and the relevant committees of jurisdiction to further improve and advance this legislation, and other policies, in the coming months. We appreciate your continued effort to address the rising costs of prescription drugs and stand ready to serve as a resource if and when needed. If you have any questions, please do not hesitate to contact Brian Buckley at bbuckley@acponline.org.

Sincerely,

A handwritten signature in black ink, appearing to read "Robert M. McLean". The signature is fluid and cursive, with the first name being the most prominent.

Robert M. McLean, MD, FACP
President

cc: Chairmen and Ranking Members: House Committees on Energy and Commerce, Ways and Means, Education and Labor