July 22, 2022

The Honorable Charles Schumer
Majority Leader
United States Senate
Washington, DC 20510

The Honorable Mitch McConnell
Minority Leader
United States Senate
Washington, DC 20510

Dear Majority Leader Schumer and Minority Leader McConnell:

On behalf of the American College of Physicians (ACP), I would like to express our strong support for the ongoing discussions surrounding a reconciliation package that could include reforming prescription drug pricing, controlling out-of-pocket costs for insulin and extending premium subsidies afforded under the Patient Protection and Affordable Care Act (ACA) beyond the end of the current year. We believe these measures under consideration will improve access to care by helping Americans better afford their medications for illnesses and chronic conditions and help many retain and afford their health care coverage. ACP is disappointed, however, that current negotiations reportedly exclude measures to combat climate change and to reduce the emission of greenhouse gases (GHG) as they pose serious threats to the health of all Americans.

The American College of Physicians is the largest medical specialty organization and the second largest physician membership society in the United States. ACP members include 161,000 internal medicine physicians (internists), related subspecialists, and medical students. Internal medicine physicians are specialists who apply scientific knowledge, clinical expertise, and compassion to the preventive, diagnostic, and therapeutic care of adults across the spectrum from health to complex illness. Internal medicine specialists treat many of the patients at greatest risk from COVID-19, including the elderly and patients with pre-existing conditions like diabetes, heart disease and asthma.

In this letter, we will comment on policies under consideration that are consistent with ACP policy and reportedly being considered for a reconciliation package including prescription drug reforms and extending the ACA's premium tax credit and cost reduction subsidies. We also support efforts aimed at capping insulin-related costs and recommend that lawmakers consider such policies as part of any reconciliation package. ACP strongly believes that these are the types of measures that should engender bipartisan support.

Last year, ACP supported provisions in the House-passed H.R. 5376, the *Build Back Better Act* (BBBA). That bill, if passed by the Senate and signed into law, would have enacted policies ACP supports, including extending incentives and providing measures to combat climate change, providing PAID leave, increasing the health care workforce, improving prescription drug

pricing, addressing eldercare assistance, extending permanently the Children's Health Insurance Program (CHIP), expanding broadband coverage, and improving upon maternal and behavioral health services, while expanding coverage under the Patient Protection and Affordable Care Act (ACA).

I. Prescription Drug Reform

We are pleased that the Senate has released draft text aimed at lowering prescription drug costs. For many years, ACP has continued to express concern over the rising cost of prescription drugs, particularly for patients as they struggle to afford basic and life-saving medications prescribed by their physicians to treat diseases and chronic conditions. Now, with the ongoing effects of COVID-19, patients are even more concerned about whether they can afford their medications and whether they will have health coverage in general should they unexpectedly lose their job or incur other hardship as a result of COVID-19. In a May 2020 study by Gallup, "nearly nine in 10 U.S. adults were very (55 percent) or somewhat (33 percent) concerned that the pharmaceutical industry would leverage the COVID-19 pandemic to raise drug prices. Americans are also concerned -- to a somewhat lesser extent -- about rising health insurance premiums and the cost of care generally. Overall, 79 percent are very or somewhat concerned about their health insurance premiums rising and 84 percent are very or somewhat concerned about the cost of care generally rising, with 41 percent very concerned about each."

Reports show that although use of prescription drugs in the United States is high, it is not an outlier compared with nine other high-income nations. The primary differences between health care expenditures in the United States versus other high-income nations are pricing of medical goods and services and the lack of direct price controls or negotiating power by centralized government health care systems.

- **The legislative text allows for the Secretary of Health and Human Services (HHS) to negotiate a set number of drugs per year, rather than a range "up to" a certain amount starting with Medicare drug negotiations beginning in 2023. Starting in 2026, Medicare will choose 10 drugs eligible for negotiation. The next year, the number of eligible drugs will increase to 15, and in 2029 and every year after to 20.**

ACP has longstanding policy supporting the ability of Medicare to leverage its purchasing power and directly negotiate with manufacturers for drug prices. We supported a provision in H.R. 3, the *Elijah E. Cummings Lower Drug Costs Now Act*, that 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. In a 2019 estimate by the Congressional Budget Office, projections indicated that $456 billion in savings over 10 years would be realized by allowing Medicare to directly negotiate prescription drug prices with manufacturers.

The legislative text would require the Secretary of HHS to negotiate drug prices for the maximum number of prescriptions per year, precluding a future HHS Secretary from potentially

not negotiating lower prices. While ACP is supportive of efforts that the Secretary negotiate prices, we remain concerned that the language does not include the more robust provision of price negotiation in H.R. 3. We believe that giving HHS the authority to negotiate drug prices with manufacturers is one of the most effective ways to lower the cost of prescription drugs and we urge lawmakers to include that provision of H.R. 3 or similar legislation in the reconciliation package. While ACP reaffirms its support for a full repeal of the noninterference clause, ACP is also supportive of an interim approach, such as allowing the Secretary of HHS to negotiate for a limited set of high-cost or sole-source drugs, as outlined in the legislation**.**

According to a Kaiser Family Foundation tracking poll, granting Medicare Part D the authority to negotiate drug prices is favored by a bipartisan majority of the public, with more than 90 percent of Democrats, Republicans, and Independents agreeing with this approach. Negotiating authority was also endorsed in a report by the National Academies of Sciences, Engineering, and Medicine on improving the affordability of prescription drugs as part of a package of broader reforms for consolidating and leveraging purchasing power and strengthening formulary design.

While the legislation allows Medicare to negotiate some prescription drug prices, it does not preclude pharmaceutical manufacturers from setting higher prices at a product's launch. Pharmaceutical companies will retain the ability to make up lost revenues in pricing by increasing their launch prices to counteract lower returns in later years when a drug may become subject to Medicare negotiation, thus reducing the overall effectiveness of the legislation.

- **According to legislative text, sole-source drugs subject to negotiation will be chosen based in part on their total spending under Medicare Parts B and D. There is an exception for small biotech drugs from 2026 through 2028 such as vaccines and excludes certain orphan drugs as well.**

ACP has supported policies to promote competition and lower prescription drug prices, including increased competition for sole-sourced drugs. Increasingly, the pharmaceutical marketplace is narrowing its focus to highly innovative, biologic, or specialty drugs for which there are few, if any, competitors, creating monopolies and limiting the cost controlling power of competition. The focus on brand-name drugs and new biologics results in a greater desire for companies to protect the investments in these drugs and keeping them as profitable for as long as possible.

- **The text would impose a cap on Medicare Part B and D rebates by manufacturers for single-source drugs and biologics with prices increasing faster than inflation.**

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 also 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. 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."

We also support additional measures to improve transparency in the price of prescription drugs so that drug manufacturers disclose additional information concerning the reasons why drug prices may rise beyond the rate of inflation. ACP policy supports transparency in the pricing, cost, and comparative value of all pharmaceutical products. Pharmaceutical companies should disclose actual material and production costs to regulators, research and development costs contributing to a drug's pricing, including those drugs which were previously licensed by another company. Rigorous price transparency standards should be instituted for drugs developed from taxpayer-funded basic research.

- **The text would cap out-of-pocket costs at $2,000 a year for Plan D plan members and provide free vaccines to Medicare seniors and expand co-pay assistance for some low-income individuals beginning in January 2023. It provides monthly caps on cost-sharing payments under prescription drug plans in Medicare Advantage and Part D plans starting Jan. 1, 2025.**

ACP supports efforts to make prescription drugs more affordable in government and private health plans by reducing the out-of-pocket costs to consumers. We offered some proposals in our paper entitled "Policy Recommendations for Public Health Plans to Stem the Escalating Costs of Prescription Drugs." The paper examines the increasing price of prescription drugs in Medicare and Medicaid particularly for patients with chronic health conditions who are using multiple medications and patients in these programs taking high-priced brand-name specialty drugs. Shifts in benefit design, including higher deductibles and a movement away from copayments to coinsurance, have increased patient out-of-pocket costs and put pressure on program budgets.

In 2016, Medicare beneficiaries spent an average of $3,024 on out-of-pocket medical costs, including $756 (25 percent) on prescription drugs.[1] Medicare beneficiaries can face substantial out-of-pocket costs for prescription drugs if they take costly specialty drugs and reach the catastrophic coverage phase. Between 2007 and 2015, the number of seniors in Medicare Part D who reached the catastrophic limit of coverage doubled to more than one million. We support legislation that implements caps on out-of-pocket expenses for prescription drugs in the catastrophic phase of coverage to protect vulnerable seniors from being exposed to increased financial burden. ACP also supports modification to the Medicare Part D low-income subsidy program cost-sharing and copayment structures to encourage the use of lower cost generic or biosimilar drugs, such as eliminating cost sharing for generic drugs for such subsidy enrollees.

[1] **Schoen C**, **Davis K**, **Willink A**. Medicare beneficiaries' high out-of-pocket costs: cost burdens by income and health status. Issue Brief (Commonw Fund). 2017;11:1-14. [PMID: 28498650]

- **The legislative text includes a repeal of Part D rebate rule proposed during the Trump Administration which would have eliminated the safe harbor for Part D drug rebates and replaced it with a new one for point-of-sale discounts.**

Former President Trump advocated for lowering the prices of prescription drugs and issued a series of proposals designed to accomplish this goal. In May of 2018, the Trump Administration issued a blueprint to lower drug prices that identified four key strategies for reform including: improved competition, better negotiation, incentives for lower list prices and lower out-of-pocket costs. ACP issued a comment letter that shared our views concerning key elements of the blueprint, expressed our key recommendations to lower drug costs, and urged the HHS to use the rulemaking process to continue to seek input from stakeholders prior to the implementation of any policy.

The legislative text would repeal the creation of a new safe harbor protecting discounts offered to patients when they purchase their drugs at the pharmacy. It would also prevent the creation of a new safe harbor for fixed fee services arrangements between manufacturers and pharmacy benefit managers. While ACP does not have policy on the rebate rule, we note that the Biden Administration has delayed the rule from taking effect until January 2023.

The proposed rebate rule was released during the Trump Administration and sought to address Part D drug rebates that pharmaceutical manufacturers offer to pharmacy benefit managers (PBMs) in exchange for participation on their drug formularies. Rebates had a safe harbor that provides protection from federal anti-kickback laws. The rebate rule will replace the safe harbor for Part D rebates, meaning they could be targeted under the federal anti-kickback law, with a new safe harbor that applies only to discounts offered at the pharmacy counter at the point of sale.

During comments on the proposed rebate rule, insurers and PBMs complained the rule will raise premiums for Part D seniors, citing a report from the Centers for Medicare & Medicaid Services' actuaries that the rule would lead to a 19 percent hike in premiums. In addition, a Congressional Budget Office report projected that the rule would increase federal spending by $177 billion through 2029, coming from an increase in premiums and manufacturers implementing a chargeback system where they withhold some of the discounts they previously negotiated with payers. ACP also commented on the proposed rule and is very concerned about any rule that would increase premiums for healthcare, particularly for those who are now struggling to pay for their prescriptions and for the most vulnerable in our society.

II. ACA's Premium Tax Credit and Cost Reduction Subsidies

ACA supports legislation to permanently extend the premium tax subsidies created under the ACA through a reconciliation package. The recently-enacted American Rescue Plan Act (ARPA) provided premium tax credits to lower insurance premiums bought through the health insurance marketplace. That law contains provisions to fully subsidize the health coverage of certain individuals. According to the Urban Institute, over three million people may become uninsured if the enhanced premium tax credits are allowed to expire.

Last year, the Senate considered H.R. 5376 that would have provided temporary enhanced ACA Marketplace cost-sharing reduction assistance to individuals with household incomes below 138 percent of the federal poverty level (FPL) for calendar years (CY) 2022 through 2025. That bill would have expanded eligibility to taxpayers with household incomes below 100 percent of the FPL, specified that taxpayers with household incomes below 138 percent of the FPL with access to employer sponsored coverage or a qualified small employer health reimbursement arrangement could still receive credits. ACA cost-sharing reduction assistance is provided to individuals receiving unemployment compensation for CY 2022 through 2025.

H.R. 5376 also continued expanded eligibility created by ARPA through financial subsidies for health coverage purchased through the health insurance marketplace. Enrollees who make over 400 percent of the FPL would become eligible for subsidies and have their premium costs capped at 8.5 of income for three more years. ACP fully supports policies to eliminate the 400 percent FPL premium tax credit eligibility cap and to enhance the premium tax credit for all levels. The premium tax credit and cost-sharing subsidies have made nongroup coverage more affordable. While the ACA has extended comprehensive coverage to millions of people, many remain uninsured or underinsured. Extending these subsidies will help many of these uninsured and underinsured low- and middle- income Americans achieve health care coverage.

III. Insulin Costs

ACP applauds Sens. Collins and Shaheen for introducing the *Improving Needed Safeguards for users of Lifesaving Insulin Now (INSULIN) Act*. We encourage that this legislation be considered as a part of the ongoing discussions regarding prescription drug prices in a reconciliation package. This bipartisan legislation takes important steps to lower the price of insulin and reduce out-of-pocket costs for patients.

The legislation would ensure that patients have access to lower priced insulins, which would not be subject to the rebates normally collected by insurance plans and pharmacy benefit managers. For insulin products included in this new program, their list price will be reduced to the 2021 net price for Medicare Part D, or equivalent levels, which would be significantly lower costs as compared to the current insulin list price. These lower price insulins would be eligible for cost-sharing protections and would not be subject to formulary management requirements such as prior authorization or step therapy. This legislation would also limit out-of-pocket costs for patients with diabetes to no more than $35 per month for at least one dosage form in each insulin product category for people on Medicare and private insurance plans.

Insulin is a lifesaving drug for millions of people living with diabetes. For all people living with type 1 diabetes, insulin is the only option and must be taken for life. Over 7 million people in the United States use insulin to control their blood sugar and avoid lifechanging complications such as dialysis, heart disease and amputation. This life-saving medication remains unaffordable for many who rely on it. In the past 15 years, the price of insulin has nearly tripled making it difficult for people with diabetes to manage their care. In recent years, there has been widespread acknowledgement that access to affordable insulin is a serious problem. However, despite this acknowledgement the cost the insulin continues to be high and Americans living with diabetes continue to suffer. The House Energy & Commerce Committee recently

acknowledged that insulin prices continue to be unacceptably high despite their work to learn more about why prices have skyrocketed over the past 15 years.[2]

This legislation addresses the drivers of rising insulin prices and implements solutions that will lower the out-of-pocket costs for patients. ACP is supportive of legislation to reduce the cost of insulin and hopes that Congress will pass this important legislation this year, ideally as part of the reconciliation package.

IV. Conclusion

In conclusion, we are encouraged by the progress being made on a reconciliation package that could improve patient access to more affordable prescription drugs and expand vital health coverage through premium tax subsidies created by the ACA. We urge the Senate to finalize a package that includes the above-referenced policies and expedite its passage. If you have any questions, please contact George Lyons at glyons@acponline.org.

Sincerely,

Ryan D. Mire, MD, FACP
President

cc: Senate Budget Committee
Senate Finance Committee
Senate Health, Education, Labor and Pensions Committee

[2] E&C Leaders follow up with pharmaceutical manufacturers on the high cost of insulin. House Energy & Commerce Committee. August 19, 2021. Retrieved from: https://energycommerce.house.gov/newsroom/pressreleases/ec-leaders-follow-up-with-pharmaceutical-manufacturers-on-the-high-cost-of