



August 2, 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 key provisions within the *Inflation Reduction Act of 2022* (“the IRA”), a proposed Senate amendment substitute to last year’s House-passed bill, H.R. 5376, the *Build Back Better Act* (BBBA). ACP [supported](#) a number of provisions in the BBBA consistent with our policy. The new \$739 billion Senate reconciliation measure includes provisions to lower prescription drug prices by allowing Medicare to negotiate the pricing of certain high-cost, sole source drugs, subsidize health care costs by extending the premium tax subsidies under the Patient Protection and Affordable Care Act (ACA) for three years, stimulate clean energy production through rebates, programs and tax credits and reduce greenhouse gas (GHG) emissions by 2030. 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. In addition, the IRA contains measures to combat climate change and to reduce the emission of 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 160,000 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 such as diabetes, heart disease and asthma.

In this letter, we will comment on proposals in the IRA that are consistent with ACP policy including prescription drug reforms, extending the ACA’s premium tax credit and cost reduction subsidies, promoting clean energy, reducing GHG emissions and promoting environmental justice. We continue to support efforts aimed at capping insulin-related costs and urge lawmakers to add such policies under consideration by the Senate as part of any reconciliation package. ACP strongly believes that these are the types of measures that should engender bipartisan support.

I. Prescription Drug Reform

We are pleased that the Senate has released bill [text](#) aimed at lowering prescription drug costs. For many years, ACP has expressed [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 should they unexpectedly lose their jobs 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 IRA allows for the Secretary of Health and Human Services (HHS) to negotiate a set number of [high cost](#) drugs per year, rather than a range “up to” a certain amount starting with Medicare drug negotiations beginning in 2023. “The number of [negotiated drugs](#) would be limited to 10 Part D drugs in 2026, 15 Part D drugs in 2027, 15 Part B and Part D drugs in 2028, and 20 Part B and Part D drugs in 2029 and later years.”**

ACP has longstanding [policy](#) supporting the ability of Medicare to leverage its purchasing power and directly negotiate with manufacturers for drug prices and further, the College has called for a full repeal of the noninterference clause. However, 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—and therefore express our support for this provision. We are also pleased to see that the IRA would require the Secretary of HHS to negotiate drug prices for the maximum number of prescriptions per year, provided such drugs are subject to negotiation, thus precluding a future HHS Secretary from potentially not negotiating lower prices.

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.

However, while the IRA 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.

Along these lines, 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. Therefore, we urge lawmakers to include that provision of H.R. 3 or similar legislation in the reconciliation package.

- **According to the IRA, certain sole-source, high-cost 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. Therefore, we are pleased to see that the IRA allows the federal government to negotiate certain sole-source, high-cost 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 IRA 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 starting in 2023.**

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 IRA 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. The IRA would cap annual out-of-pocket costs to \$2,000 per year, with the option to break that amount into affordable monthly payments. ACP's position [paper](#) entitled “Policy Recommendations for Public Health Plans to Stem the Escalating Costs of Prescription Drugs,” 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.ⁱ 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.

The IRA eliminates the partial subsidy status under Medicare Part D, giving those seniors the full low-income subsidy. Currently, the low-income subsidy program under Medicare Part D is fully available to all seniors earning less than 135 percent of the federal poverty level (FPL), and partially available to seniors earning less than 150 percent of the FPL. ACP supports modifications 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 as eliminating cost sharing for generic drugs for such subsidy enrollees.

Further, ACP is supportive of provisions to make all vaccines free in Medicare for seniors, the only population for which vaccines were not already free. ACP has [advocated](#) previously for funding for vaccination development and deployment to patients at no cost, particularly during the COVID-19 pandemic.

- **The IRA includes a repeal in 2027 of the 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.**

The proposed [rebate rule](#) was released during the Trump Administration and sought to address Part D drug rebates that pharmaceutical manufacturers offer to 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.

ACP [commented](#) on the proposed rule at the time it was released, noting our appreciation for taking some steps toward price transparency; however, we also expressed our concerns about any rule that would increase premiums for health care, particularly for those who are now struggling to pay for their prescriptions and for the most vulnerable in our society. Also, during the comment period, insurers and PBMs complained the rule would 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. Given our concerns, ACP is appreciative that the Biden Administration delayed the rule from taking effect until January 2023.

II. Insulin Costs

ACP applauds Sens. Collins and Shaheen for introducing the *Improving Needed Safeguards for users of Lifesaving Insulin Now (INSULIN) Act*. We are encouraged that the Senate is considering this legislation 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.ⁱⁱ

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.

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

ACP supports legislation to permanently extend the premium tax subsidies created under the ACA through a reconciliation package. The IRA would extend the premium subsidies for three years until the end of 2025 at a cost of \$64 billion. Last year's American Rescue Plan Act (ARPA), which was signed into law, provided premium tax credits to lower insurance premiums bought through the health insurance marketplace. That law also contains provisions to fully subsidize the health coverage of certain individuals. According to the [Urban Institute](#), over three million people may become uninsured in 2023 if the enhanced premium tax credits are allowed to expire. Therefore, we are pleased to see that under the IRA, 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. The extension does not impose additional restrictions on those who are eligible through a means test. Many middle-income families would qualify for financial help for the first time, while lower-income households would pay little or nothing for insurance.

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, even if not permanently, will help many of these uninsured and underinsured low- and middle- income Americans achieve health care coverage.

IV. Clean Energy and Climate Change

The IRA represents a major step in moving the nation forward in reaching the President's [goal](#) of cutting GHG emissions by 50 to 52 percent based on 2005 levels in economy wide net GHG pollution in 2030. This would be accomplished through \$370 billion of tax credits and rebates to help stimulate the adoption of clean energy technologies and spending for low-income and minority communities that suffer disproportionately from pollution.

ACP has extensive [policy on climate change](#) and the environment based on the following principles:

1. Mitigate and adapt to the effects of climate change, including by accelerating the rapid shift from use of fossil fuels to clean, renewable energy.
2. Support efforts to reduce waste and greenhouse gas emissions in the health care sector.
3. Ensure federal agencies communicate apolitical, science-based information regarding climate change and greenhouse gas emissions and eliminate any restrictions and agency guidance that interfere with the ability of career scientists to provide such information.
4. Protect career scientists and other federal employees engaged in this area.
5. Prevent contamination of the U.S. water supply and ensure everyone has access to clean, affordable drinking water.

- **Clean Energy and Climate Change**

The IRA provides tax credits, rebates and programs for investments to spur clean and renewable energy development and use and to reduce GHG emissions. The IRA also contains new incentives for renewable energy development and incentives for households to transform their energy use and consumption. It includes incentives for electric vehicle purchase and clean domestic manufacturing while providing support for green energy project financing and reducing emissions in the agricultural sector.

ACP [urges](#) Congress to pass strong, comprehensive climate change mitigation and adaptation policies, such as that contained in the IRA, including the transition from fossil fuels to clean energy and energy efficiency. ACP strongly supports the incentives for renewable energy and wind and solar production as that will help get the country to relying more on clean energy. The IRA's provision to create a green bank or Clean Energy and Sustainability Accelerator will leverage funds to invest in clean energy technologies. ACP believes the green bank will help the nation to become less dependent on fossil fuels and move towards clean energy. Finally, the IRA seeks to decarbonize the economy and reduce GHG emissions by 40 percent of 2005 levels by 2030. ACP fully supports efforts to reduce the harmful health effects to Americans caused by global warming and climate change as we have supported the goals of the Paris Climate Accord.

ACP's [policy](#) supports the investment in clean energy to mitigate the increased rate of disease, injuries and premature deaths associated with climate change. In 2016, ACP released a [policy paper](#) on climate change and human health calling for immediate action to mitigate and adapt to global climate change. The paper outlined the effect that climate change has on human

health, including increased risk of heat-related illness, respiratory diseases, and behavioral health issues. These health effects have a disproportionate effect on certain communities, including the elderly and outdoor workers. ACP recommended public health interventions, environmental sustainability in the health care sector, and aggressive mitigation and adaptation initiatives like promoting active transportation. Since then, ACP has signed the U.S. Call to Action on Climate, Health, and Equity: A Policy Action Agenda. This [framework](#) maintains “Climate change is one of the greatest threats to health America has ever faced—it is a true public health emergency” and recommends that policymakers transition from fossil fuels to clean, safe, renewable energy; encourage active transportation; promote healthy, sustainable agriculture; aid workers affected by climate change mitigation and adaptation policies; incorporate climate solutions into health care and public health systems; and build resilient communities. The call underscores that “equity must be central to climate action.”

- **Environmental Justice**

The IRA provides \$60 billion to address the disproportionate burden of pollution and climate change on low-income communities and communities of color. ACP signed a joint [letter](#) urging Congress to pass legislation making substantial investments that advance health equity and environmental justice. Environmental factors and other social drivers of health that disproportionately affect racial and ethnic minorities, including the effect on health of large-scale infectious disease outbreaks and climate change, must be addressed as recommended in “Envisioning a Better U.S. Health Care System for All: Reducing Barriers to Care and Addressing Social Determinants of Health,”ⁱⁱⁱ “Addressing Social Determinants to Improve Patient Care and Promote Health Equity,”^{iv} and “Climate Change and Health.”^{vi} These social drivers and environmental factors influence an individual’s health status even though they are sometimes not part of the health care system. ACP released the position [paper](#), “[Understanding and Addressing Disparities and Discrimination Affecting the Health and Health Care of Persons and Populations at Highest Risk](#),” which offered specific recommendations to address issues that disproportionately affect racial and ethnic minorities, including during the environment. ACP [supports](#) Congress and the Administration adopting policies that address the needs of communities disproportionately affected by climate change, including people with low-incomes, communities of color, outdoor workers, and the aged and disabled.

- **Methane Emission Reduction**

The IRA creates a Methane Emissions Reduction Program to reduce the leaks from the production and distribution of natural gas. Oil and gas companies that emit more than 25,000 metric tons of carbon dioxide equivalent annually will be fined beginning in 2025 if their methane leakage rate exceeds a certain threshold. In addition, the IRA gives the Environmental Protection Agency more than \$1.5 billion through Sept. 30, 2028, to help companies reduce methane emissions. ACP is supportive of these methane emission reduction policies.

V. 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 that insulin costs also be

addressed in the package. Provisions in the IRA to reduce GHG emissions and promote clean energy will help improve the health of all Americans. 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
Senate Judiciary Committee

ⁱ 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]

ⁱⁱ 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>

ⁱⁱⁱ Butkus R, Rapp K, Cooney TG, Engel LS et al. Envisioning a Better U.S. Health Care System for All: Reducing Barriers to Care and Addressing Social Determinants of Health. *Ann Intern Med*. 2020;172:S50-S59. doi:10.7326/M19-2410.

^{iv} Daniel H, Bornstein S, Kane GC et al. Addressing Social Determinants to Improve Patient Care and Promote Health Equity: An American College of Physicians Position Paper. *Ann Intern Med*. 2018;168:577-578. doi:10.7326/M17-2441.

^v Crowley R. Climate Change and Health: A Position Paper of the American College of Physicians. *Ann Intern Med*. 2016;164:608-610. [Epub ahead of print 19 April 2016]. doi:10.7326/M15-2766.

^{vi} Serchen J, Doherty R, Hewett-Abbott G, Atiq O, Hilden D; Health and Public Policy Committee of the American College of Physicians. Understanding and Addressing Disparities and Discrimination Affecting the Health and Health Care of Persons and Populations at Highest Risk: A Position Paper of the American College of Physicians. Philadelphia: American College of Physicians; 2021.