



**COUNCIL for  
CITIZENS  
AGAINST  
GOVERNMENT  
WASTE**

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Dear House Budget Committee Health Care Task Force,

On behalf of the more than one million members and supporters of Citizens Against Government Waste (CAGW), I urge you to consider free market patient centered reforms to improve outcomes and reduce unnecessary federal healthcare spending.

**Eliminate Pharmaceutical Price Controls:**

Federal intervention in the healthcare marketplace, especially price controls in the name of reducing costs, has resulted in fewer choices and higher costs. On August 26, 2022, President Biden signed the [Inflation Reduction Act](#) (IRA) into law. This bill includes devastating price control provisions that will further distort the medical marketplace by allowing the federal government to set prices on drugs they deem too expensive.

On August 29, 2023, the Department of Health and Human Services (HHS) [announced](#) the first 10 drugs selected for Medicare drug price negotiations under the IRA: Eliquis, Jardiance, Xarelto, Januvia, Farxiga, Entresto, Enbrel, Imbruvica, Stelara, and Fiasp. Over the next four years, Medicare will begin negotiating prices for up to 60 drugs covered under Medicare Part D and Part B and up to an additional 20 drugs every year after that.

Before the passage of the IRA, investments in pharmaceutical research and development were already deemed high-risk. According to Deloitte's February 3, 2023, "13th Annual Pharmaceutical Innovation [Report](#): Pharma R&D Return on Investment Falls in Post-Pandemic Market," the return on investments in pharmaceutical research and development in 2022 fell to 1.2 percent, the lowest return in 13 years. Meanwhile, the average cost to develop a new drug from lab to market rose by \$298 million to \$2.3 billion in 2022.

An August 2022, University of Chicago [issue brief](#) by Tomas J. Philipson and Giuseppe Di Cera, "The Impact of Biopharmaceutical Innovation on Health Care Spending," found that price controls would increase healthcare spending by \$50.8 billion over the next 20 years and result in 135 fewer new drugs, negatively impacting the lives of 2.47 million patients. A November 29, 2021, University of Chicago [issue brief](#) by Philipson and Troy Durie phrased the impact of 135 fewer new drugs as "generating a loss of 331.5 million life years in the U.S., 31 times as large as the 10.7 million life years lost from COVID-19 in the U.S. to date. These estimated effects on the number of new drugs brought to market are 27 times larger than projected by the Congressional Budget Office which determined that only five drugs will be lost through 2039, equaling a 0.63 percent reduction."

The IRA's price control provisions quickly led to less drug research and innovation. In October 2022, Alnylam Pharmaceuticals [cancelled](#) its plan to expand and develop its RNA interference therapy to treat a rare eye disorder Stargardt disease, due to the Inflation Reduction Act provisions. Alnylam also did not [move](#) forward with a phase 3 study on Amvuttra, which was approved to treat a rare disease called transthyretin-mediated amyloidosis and was also being researched to treat Stargardt.

Eli Lilly confirmed in June 2023 it halted development of [three drugs](#) thus far due to the IRA price controls, including research into a Phase 1 drug undergoing studies for treating various blood cancers. Eli Lilly [stated](#), "The IRA changes many dynamics for small molecules in oncology and when we integrated those changes with this program and its competitive landscape, the program's future investment no longer met our threshold."

The IRA price controls have led to both fewer drugs and slower development of drugs. Genetech CEO Alexander Hardy [explained](#) in an August 10, 2023, STAT interview, "that in the world prior to the IRA drug makers were incentivized to get drugs on the market as fast as possible, regardless of which disease they would be approved to treat." He noted that the IRA price controls incentive structures have changed and encourage drug developers like Genetech to slow-walk research on certain drugs, including an ovarian cancer therapy, to ensure the company will sell more medicine in the window before Medicare is allowed to negotiate prices, because the clock for when discounts can kick in is based off of when the drug is first brought to market.

The adverse and deadly consequences of price controls should give members of Congress the incentive to not only repeal the relevant provisions of the IRA but also other price controls that have an adverse impact on the healthcare system.

### **Reform the 340B Program:**

Congress created the 340B program in 1992 to fix a problem it had created two years earlier when an overreaching government implemented [price controls](#) in the Medicaid drug benefit program. As a condition to participate in Medicaid, pharmaceutical companies are required to participate in the 340B program and give discounts of between 20-50 percent to certain federally funded healthcare facilities and disproportionate share hospitals (DSH) known as "covered entities" that serve large numbers of low-income, uninsured patients.

The savings are [intended](#) to give patients of these covered entities access to prescription drugs, and also allows, according to Congressional intent, the entities to "stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." But due to unclear legislation, legally questionable guidance by the Health Resources and Services Administration (HRSA), which [oversees](#) the program, and expansion under the Patient Protection and Affordable Care Act, the program has grown exponentially and is vulnerable to abuse.

CCAGW has long been concerned with the misuse of the 340B program. A May 14, 2014, blog [post](#) noted, "Because of a poorly written law and unclear regulations that allow a broad interpretation of the term 'patient,' permit too many organizations to qualify for the program, and provide little control over how the drug savings can be spent, consumers and

taxpayers ultimately end up paying for a program that has become nothing more than an ATM for nonprofit hospitals and pharmacies.”

A June 2015 Government Accountability Office (GAO) [report](#) on 340B, a September 2011 GAO [report](#) and a February 2014 HHS Office of the Inspector General (OIG) [report](#) that found “many troubling issues withing the program, such as 45 percent of covered entities had profited from the 340B program, that the savings from the discounted drugs were often not passed along to low-income patients, that drugs were being diverted to people that were not patients of the covered entities, and that drug manufacturers were providing duplicate rebates to covered entities and states via the 340B program and Medicaid respectively, both practices which are proscribed by law.”

An October 29, 2020, coalition [letter](#) led by CCAGW and signed by 18 organizations to then-Senate Health, Education, Labor, and Pensions Committee Chairman Lamar Alexander (R-Tenn.) and House Education and Labor Committee Ranking Member Greg Walden (R-Ore.) cited the June 2015 GAO report and findings from several other reports including the April 2016 Community Oncology Alliance [release](#) of, “Cost Drivers of Cancer Care: A Retrospective Analysis of Medicare and Commercially Insured Population Claim Data 2004-2014.” The report found that the movement of from lower-cost physician offices to higher-cost hospital outpatient settings led to increased costs in the 340B program. The coalition letter summarized the report’s findings by stating, “When a 340B hospital purchases a physician’s office, it can administer their heavily discounted drugs to its newly acquired patients that have insurance, charging the insurers the full reimbursable price and pocketing the difference.”

The coalition letter also cited a December 2017 Berkely Research Group (BRG) [report](#), “The Oncology Drug Marketplace: Trends in Discounting and Site of Care,” which echoed the Community Oncology Alliance’s findings. The BRG report noted that the “shift in site of oncology care from the physician office to the hospital outpatient setting has continued unabated since 2008, and almost 50 percent of 2016 Medicare Part B chemotherapy drug administration claims occurred in the hospital outpatient setting – up from just 23 percent in 2008” and “average profit margins on Part B-reimbursed physician-administered oncology drugs purchased at a 340B price increased from 40 percent in 2010 to 49 percent in 2015 and have created substantial financial incentives for 340B hospitals to expand oncology services, despite overall healthcare costs increasing as a result of this shift in site of care.”

The letter included a comment from the January 10, 2018, House Energy and Commerce Committee report, “Review of the 340B Drug Pricing Program,” that while HRSA prohibits diversion and resale of 340B drugs to ineligible patients, “a large percentage of HRSA’s audited entities diverted drugs to ineligible patients in FY 2012 through FY 2016.” Additional reporting on 340B cited in the letter included an October 2020 BRG report, “For-Profit Pharmacy Participation in the 340B Program” which found that, “more than 27,000 individual pharmacies (almost one out of every three pharmacies) participate in the 340B program as contract pharmacies” and that “hospitals now account for over 44 percent of all contract pharmacy arrangements, up from 2 percent in 2000,” a 4,228 percent increase, despite the lack of authorization for contract pharmacies in the 340B statute.

A November 2021 Xcenda [study](#), “340B and Health Equity: A Missed Opportunity in Medically Underserved Areas,” provided further evidence of how the program is not being used as intended to help low income and vulnerable individuals get access to low-cost prescription drugs. Instead, it is boosting hospitals’ coffers and their contract pharmacies’ profits that are largely located in areas that do not serve low-income people.

In 2014, 340B [discounted prices](#) were at \$9 billion, but by 2020, they reached \$38 billion, an increase of 27 percent from 2019 and a 322 percent increase from 2014. On April 14, 2023, the healthcare data analytics firm IQVIA released its [study](#), “The 340B Drug Discount Program Exceeds \$100B in 2022,” which showed a massive increase in spending and provided further evidence of the exploitation of the [program](#). The report found that the misuse of the funds by hospitals and contract pharmacies is ongoing, and patients are still not getting the benefits Congress intended them to receive.

A September 24, 2022, *New York Times* [article](#) analyzed how 340B was being abused at Richmond (Virginia) Community Hospital, owned by Bon Secours. Rather than reinvesting profits from 340B drug sales into its facilities and improving patient care, the money was being diverted to Bon Secours’ facilities in Richmond’s wealthier neighborhoods. Dr. Lucas English, who worked in the hospital’s emergency department until 2018, said, “Bon Secours was basically laundering money through this poor hospital to its wealthy outposts ... It was all about profits.” Dr. Peter B. Bach, who has written about the use of 340B profits to open more clinics in wealthier areas, said the hospitals are “nakedly capitalizing on programs that are intended to help poor people.”

Beyond the impact of the 340B program on pharmaceutical sales, biopharmaceutical drug companies are facing further market challenges due to government price controls. The IQVIA study noted that the Inflation Reduction Act’s (IRA) price controls will impose additional pressure on future research and development. CAGW submitted [comments](#) in response to the Center for Medicare and Medicaid Services (CMS), “initial guidance for implementation of the Negotiation Program for initial price applicability year 2026.” The price controls in the IRA will further distort the medical marketplace. Additionally, the [IRA expands](#) the 340B drug discount program despite its flaws.

Duplicate discounting for 340B is another going problem that could be addressed with more oversight from CMS. Improving and reporting requirements will help to ensure that the patients benefit from the program as intended.

Reforms Congress should consider also include a clear definition of a patient as an uninsured, low-income individual that does not qualify for Medicare or Medicaid. This could be easily fixed by tightening the current definition that has been loosely interpreted for far too long and go a long way to ensure that the program operates closer to the way it was originally intended.

There have been sufficient reports by Congress, the media, and outside organizations about the corruption, cost, failure, and abuse of the 340B program. All that remains is the will to get the job done, which will both save the taxpayers money and give low-income patients the discounts on drugs that they have long deserved.

## Protect PBM Benefits:

The substantial benefits provided by pharmacy benefit managers (PBMs) and the consequences of not using them have been demonstrated once again by a federal government agency. A March 31, 2023, Department of Labor (DOL) Office of Inspector General (OIG) Office of Audit [report](#) found that the DOL overspent \$321.3 million in a six-year span (fiscal years 2015-2020) on prescription drugs for the Federal Employees' Compensation Act (FECA) program because the Office of Workers' Compensation Programs (OWCP) did not use a PBM. There are approximately 2.6 million federal and postal workers in the FECA program. Prior OIG audits determined that OWCP did not have a PBM "to help contain costs."

The accounting firm conducting the audit for the OIG found that OWCP failed to manage pharmaceutical spending effectively, "did not pay the best available price for prescription drugs," and did not address "emerging issues" or "perform sufficient oversight of prescription drugs that are highly scrutinized and rarely covered in workers' compensation programs." These failures led to the purchase of "drugs that may not have been necessary or appropriate for FECA claimants," who received "thousands of inappropriate prescriptions and potentially lethal drugs, including 1,330 prescriptions for fast-acting fentanyl after issuing a policy that restricted its use." There were, therefore, not only adverse consequences for taxpayers, but also potentially deadly consequences for thousands of federal and postal workers in the FECA program.

PBMs administer drug plans for more than [275 million](#) Americans who obtain their health insurance from employers, unions, state governments, insurers, and other entities. The number of people PBMs serve year over year is consistently growing due to the popularity of PBMs and the lower priced drugs they provide. PBMs save an average of [\\$1,040](#) per payer and patient per year. They provide their customers with 40 to 50 percent savings on prescription drugs and related medical costs by negotiating on behalf of the large groups they serve; the savings are then passed onto health plan sponsors and patients. PBMs utilize a variety of tools to lower prices like rebates, pharmacy networks, drug utilization review, formularies, specialty pharmacies, mail-order, and audits to drive down drug costs, improve quality, increase patient medication adherence, and prevent fraud.

These capabilities help prevent the costly and potentially lethal consequences of what the OIG reported regarding the failure by the DOL to use a PBM.

The prior reports on PBMs came from the Federal Trade Commission (FTC) and the Government Accountability Office (GAO). As Citizens Against Government Waste President Tom Schatz noted in his May 25, 2022, [comments](#) to the FTC on its ongoing study of the impact of PBMs' business practices, "CAGW has for many years been involved in the debate over the regulation of pharmacy benefit managers (PBMs) as part of the effort to lower drug costs. The organization has consistently argued that government meddling in this area does the exact opposite and raises costs.

Since PBMs provide benefits for multitudes of employers and millions of patients, they are able to bring to bear increased negotiating power and get substantial price discounts from pharmaceutical companies based on volume. The savings are passed on to health plan sponsors, like employers, and consumers. Processing huge volumes of prescription drug programs is complicated and overwhelming, so in the 1960s, health insurers hired PBMs to fill that role. In

the 1980s, when insurance and pharmaceutical markets grew exponentially due to medical advances, PBMs expanded their roles to negotiating lower drug prices with pharmaceutical manufacturers and pharmacies. In 2005, before Medicare Part D was implemented, the Congressional Budget Office estimated it would cost taxpayers \$174 billion by 2015, but it cost only \$75 billion thanks to private-sector negotiations that included PBMs.”

An August 14, 2019, GAO [report](#), “Medicare Part D: Use of Pharmacy Benefit Managers and Efforts to Manage Drug Expenditures and Utilization,” examined how PBMs are used in voluntary Medicare Part D drug plans. In 2016, PBMs were used by drug plan sponsors, like insurers, to provide 74 percent of drug management services, while the sponsors provided the remaining 26 percent. In 2016, GAO found total gross expenditures in Part D were \$145 billion, with PBM-negotiated rebates and other price concessions offsetting that amount by 20 percent, or net Part D expenditures being \$116 billion.

While rebates and other price concessions grew faster than Part D net expenditures from 2014 to 2016, at 66 percent and 13 percent respectively, PBMs retained less than 1 percent of the rebates and passed the rest to their plan sponsors. The plans use these savings to help offset the growth in drug costs and keep drug benefit premiums low for Medicare beneficiaries. GAO also found PBMs are primarily compensated by fees obtained from plan sponsors, not the rebates.

Despite the growing evidence of the value provided by PBMs, some members of Congress are insisting on trying to impose pricing requirements or rate regulations, which will distort the medical marketplace and limit PBMs’ negotiating power, causing harm to the customers they serve and result in higher healthcare costs. Bills like S. 1339, Sen. Bernie Sanders’ (I-Vt.) PBM “reform” legislation, [would](#) take power away from patients and turn it over to government bureaucrats, opening the door to price controls and market manipulation, and move the country closer to government-run/socialized healthcare.

PBMs provide a valuable service by negotiating prices and delivering benefits that lower healthcare costs for patients. The serious financial and personal consequences of failing to choose to use a PBM were made clear in the DOL IG report. And the OWCP apparently got the message when it set up a competitive bid for a five-year contract with a PBM, which was awarded on February 5, 2021.

Instead of interfering in these private-sector negotiated healthcare plans, Congress should heed the reports from government agencies that show the use of PBMs should be expanded, not constricted. That would be the best way to create an environment that will spur competition and innovation and increase healthcare quality for all Americans.

### **Expand Health Saving Accounts:**

[Health savings accounts](#) (HSAs) in 2024 offer tax advantages for healthcare expenses by allowing pre-tax contributions up to [\\$4,150](#) for individuals and [\\$8,300](#) for families with high deductible health plans (HDHP). HSAs are a great savings tool, but must be coupled with a HDHP, meaning millions of Americans don’t have access to an HSA, including many Medicare patients. Even though Medicare patients have Medicare Advantage they still don’t have access to the additional benefits of an HSA. more than [63 million](#) of the patients with HDHPs and access to HSAs utilize the benefits of a health savings account.

Expanding HSAs to all Americans would improve their ability to save money and make more affordable healthcare choices. Eliminating the requirement that HSAs be coupled with HDHPs is a clear and simple fix. By casting a broader net to include all Americans, especially those who are younger, and allowing them to save and invest in an HSA, patients will be empowered to make their own medical decisions, while pursuing financial independence instead of relying on the government.

**Expand Telehealth:**

Unlike traditional healthcare, telehealth offers alternative means for underserved communities, particularly in rural or remote areas of the country, to access much-needed medical care primarily online using smartphones, computers, or tablets. Telehealth is not intended as a substitution for in-person care, but it provides an alternative pathway for patients to connect with their doctor and other providers. Telehealth expansion would increase options and lower costs for patients. [H.R. 1332](#), the Telehealth Modernization Act, introduced by Rep. Buddy Carter (R-Ga.), would expand telehealth services by making certain COVID-19-related telehealth services permanent for Medicare. Unleashing American innovation and permanently expanding telehealth will provide better options for far more patients. Telehealth offers accessible care for patients and should be prioritized as an approach to patient-centered care.

Congress should adopt policies that reduce government intervention into the marketplace and encourage innovation and competition to reduce unnecessary expenditures and lower healthcare costs. Policies should be adopted that would give patients more control of their own healthcare rather than allowing life-saving decisions to be made by the federal government.

Sincerely,

*Tom Schatz*