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American Retirees Education Foundation

NRLN

NATIONAL RETIREE LEGISLATIVE NETWORK

Congress Needs to Do More to Reduce Prescription Drug Prices

August 2022 Legislation Did Not Go Far Enough

1/10/202

The U.S. Senate and House cut short its usual month-long August 2022 recess to pass **H.R.5376, Inflation Reduction Act**, which included legislation intended to reduce the price of prescription The Senate passed the bill on August 7 by a vote of 51-50 with Vice President Kamala Harris providing the deciding vote to break the Senate's tied vote. The House passed the bill on August 12 by a vote of 220-207. President Biden signed the sweeping climate, health care and tax legislation bill into law at a ceremony at the White House on August 16.

While it is controversial whether the legislation will reduce inflation, there are some important elements in the bill beneficial to Medicare participants that the NRLN supported.

Now copays for a 30-day supply of any insulin that a Medicare drug plan covers will be capped at $35. Part D plans will be required to adhere to the $35 copay limit even if an enrollee has not met their annual deductible. Medicare enrollees do not have any out-of-pocket costs for vaccines that the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices recommends for adults.

Drug manufacturers are now required to pay rebates to Medicare if they increase prices faster than inflation for drugs used by Medicare beneficiaries**.** Pharmaceutical companies began January 2023 as they usually do raising the prices on hundreds of prescription medicines. On average, drugmakers hiked list prices by 5%, according to analysts who track the industry. That figure is in line with increases taken in the past four years, but below the national consumer inflation rate of 8.1% in December 2022. Companies typically make the bulk of their price adjustments at the beginning of each year, although some also bump up prices in July.

In 2024, Medicare beneficiaries will no longer have any out-of-pocket costs if they reach Medicare's catastrophic coverage. The way catastrophic coverage works in 2023 is that once an enrollee's out-of-pocket costs reach $7,050, they pay 5% of their prescription drug costs, with no limit. In 2024, the 5% coinsurance requirement will be gone, and enrollees won't have to pay anything for their prescription drugs for the rest of the year. Also beginning in 2024 and continuing through 2029, Part D premiums cannot increase by more than 6% a year.

Beginning in 2025, the amount of out-of-pocket money that Medicare Part D beneficiaries will have to pay each year for their prescriptions will be capped at $2,000. This out-of-pocket limit will apply to prescription drugs through a stand-alone original Medicare Part D plan or a Medicare Advantage plan for prescription drugs. If a Part D plan or MA plan has a prescription drug deductible, that will count toward the cap. Also beginning in 2025 is the requirement that Part D plan offer the option for "smoothed cost-sharing". This means Part D participants can opt to have their out-of-pocket costs spread out over the year. This is designed to protect from being hit with a big drug bill at one time that it may discourage filling prescriptions.

Medicare will begin negotiating drug prices in 2026 for 10 drugs and increase to 20 by 2028. Although it is historic that the new law will allow Medicare to eventually negotiate the price on some expensive prescription drugs it does not go far enough. The NRLN advocates Medicare should use the competitive bidding model

wherever two or more generic drugs, or two or more brand drugs, or a generic and brand drugs (upon patent expiration) that treat the same medical condition. Legislation is needed to end pay-for-delay and other brand name drugmakers' tactics that obstruct generic drugs from the market. Legislation is needed for importation of safe and less expensive drugs from Canada and other countries that meet Federal Drug Administration (FDA) quality standards.

Bill Doesn't Limit Price of New Drugs

H.R.5376 did not limit what drugmakers can charge for new drugs. Some industry experts say that could leave manufacturers even more reliant on higher launch prices.

"The industry will turn to new drugs to try to use the lever that remains uncontrolled," said Daniel Ollendorf, of the Center for the Evaluation of Value and Risk in Health at Tufts Medical Center.

The Journal of the American Medical Association (JAMA) published a study in June 2022 on prices for 400 new drug that showed that between 2008 and 2021, U.S. drug launch prices grew 20% annually.

NRLN Will Continue Lobbying to Reduce Drug Prices

Although legislation has passed to remove the prohibition on Medicare negotiating prescription drug prices the NRLN will lobby to:

1. Increase the number of drugs that Medicare will negotiate lower prices for seniors.
2. End pay-for-delay and other brand-name drugmakers' tactics that keep generic drugs off the market.
3. Allow individuals to import prescription drugs manufactured at FDA-inspected facilities from licensed Canadian sellers and import drugs from other countries that meet FDA safety standards.

The NRLN following bills were introduced in the 117th Congress to reduce the price of prescription drugs. The bills died on December 31, 2022. The NRLN will lobby for their reintroduction and passage in the 118th Congress that began on January 3, 2023.

Protecting Consumers Access to Generic Drugs Act, would prohibit the practice of "pay-for-delay," in which brand name drug companies compensate generic drug makers to delay the entry of generic drugs into the market. This practice leads to decreased competition and increased drug prices for Americans.

Safe and Affordable Drugs from Canada Act, would require the FDA to set regulations within 180 days of enactment permitting Americans to import prescription drugs from licensed Canadian pharmacies. The bill stipulates there must be a valid prescription issued by a U.S. physician for drugs for personal use and not greater than a 90-day supply. The drugs must have the same active ingredients, route administration, dosage form and strength as a prescription approved by the FDA.

Affordable and Safe Prescription Drug Importation Act, would instruct the Secretary of Health and Human Services, within 180 days after enactment of this Act, to issue regulations allowing wholesalers, licensed U.S. pharmacies, and individuals to import qualifying prescription drugs manufactured at FDA-inspected facilities from licensed Canadian sellers. After two years, the Secretary would have the authority to permit importation from countries in the Organization for Economic Co-operation and Development (OECD) that meet specified statutory or regulatory standards that are comparable to U.S. standards.

Stop Stalling Access to Affordable Medications, would reduce the incentives for branded pharmaceutical companies to file sham petitions with the Federal Drug Administration (FDA) to interfere with the regulatory approval of generics and biosimilars that would compete with their own products. This is a tactic that delays patient access to more affordable medications. The bill would give the Federal Trade Commission (FTC) enhanced authority to take action against those who file sham petitions.

Preserve Access to Affordable Generics and Biosimilars, would limit anticompetitive "pay-for-delay deals" that prevent or delay the introduction of affordable follow-on versions of branded pharmaceuticals. Pay-for-delay deals – the practice in which drug companies use pay-off agreements to delay the introduction of cheaper substitutes – increase the cost of prescriptions and impose significant costs on our health care system. The bill covers pay-for-delay deals affecting biosimilar and interchangeable biologics in addition to generic drugs.

Pharmacy DIR Reform to Reduce Senior Drug Cost Act, would ensure that all pharmacy price concessions are assessed at the point of sale and eliminate the retroactive nature of direct and indirect remuneration (DIR) claw back fees imposed by Pharmacy Benefit Managers (PBMs). The Centers for Medicare and Medicaid Services (CMS) estimates this change will save Medicare beneficiaries an estimated $7.1 to $9.2 billion in reduced cost sharing. PBMs have increasingly returned to pharmacies days or even weeks after the point-of-sale to demand more in DIR fees. Passage will increase transparency and hold PBMs accountable for retroactively assessing fees on pharmacies.

Prescription Pricing for the People Act, would require the FTC to study the role and recent merger activity of Pharmacy Benefit Managers (PBMs), including possible anticompetitive behavior. This includes having the FTC to examine the effects of consolidation on pricing and other potentially abusive behavior within the PBM industry and provide policy recommendations to Congress to improve competition and protect consumers. Recent consolidations between PBMs and insurance providers has resulted in vertical integration whereby a small number of companies now manage the vast majority of prescription drug benefits and often own other players in the healthcare industry.

Affordable Prescriptions for Patients Act, would curb drug companies' anti-competitive use of patents to prevent generic and biosimilar competition from coming to market. This bill specifically addresses an anti-competitive tactic known as "product hopping" and an abuse of the "patent dance" process for resolving patent infringement claims for biosimilars.

No Tax Breaks for Drug Ads Act, and **End Taxpayer Subsidies for Drug Ads Act**, would prohibit pharmaceutical manufacturers from claiming tax deductions for expenses on advertising directly to consumers. Under current law, drug Manufacturers are allowed to deduct the cost of advertising expenses from federal taxes. Advertising direct to consumers increases demand and motivates drug companies to increase prices.

American Made Pharmaceuticals Act, would reduce dependence on foreign pharmaceutical manufacturing and boost production in the U.S. The COVID pandemic exposed America's dependence on other countries for essential prescription drugs.

Pharma's Influence with Members of Congress

While passage of **H.R.5376** was a win for Medicare beneficiaries against the pharmaceutical industry's lobbying efforts, many members of Congress appear to be accountable to Pharma's huge sums of money for campaign contributions and lobbying.

Will Congress take action to further lower prescription drug costs? Many members of Congress have to prove they are not bound by obligations to pharmaceutical companies more than to their own constituents.

According to reports in OpenSecrets.Org, Center for Responsive Politics, the pharmaceuticals and health products industry contributed $13,000,487 in campaign and leadership PAC contributions to House and Senate incumbents and challengers in the 2021-2022 election cycle. In addition, the pharmaceutical and health products **industry spent $283.9 million lobbying in Washington, DC in 2022. The industry in 2022 had 1,726 lobbyists in Washington, DC. Fifty-nine percent of the lobbyists are former government employees.**

It's Time to Pass Additional Bills to Reduce Prescription Drug Prices

Too many Americans are having to choose between paying for medicines or food, housing and other necessities, or try to stretch out their drug supply by cutting the prescribed dose or worse, simply going without their medicines.

Retirees, prospective retirees, and most Americans are suffering with prescription drug price gouging. This is at the expense of deferring or passing up altogether the purchase of goods and services that prop up the U.S. economy and thus federal tax revenue that sustains our country. Pharma still has far too much influence over public policy on prescription drugs. It is time to change policy, to pass prescription drug importation and outlaw pay-for-delay and other obstructing tactics once and for all!

Retirees know that provisions in **H.R.5376** do not go anywhere near the realm of government price setting as some members of Congress believe. Retirees also know that the high prices they are paying for prescription drugs only serve to support market entry of those same drugs into countries around the world.