



H.R. 987, STRENGTHENING HEALTH CARE AND LOWERING PRESCRIPTION DRUG COSTS ACT

This Omnibus Bill Reduces Drug Costs by Promoting Generic Competition, Strengthens Health Care, Reverses GOP Sabotage, and Rescinds Junk Plan Rule

Key Points:

- This omnibus bill combines three key bills to lower drug costs by promoting generic competition and four key bills to strengthen health care, reverse GOP sabotage, and rescind the Trump Administration's devastating junk plan rule. All seven of these bills were reported by the Energy and Commerce Committee on April 3, 2019.
- This omnibus bill invests most of the savings of \$13.8 billion created by its three bills promoting generic competition and its bill cracking down on junk plans into strengthening health care – funding about 500,000 additional enrollees in nongroup coverage and Medicaid (the result of restoring funding for consumer outreach and enrollment education activities) and helping interested states set up their own state-based marketplaces, which outperform the Federal marketplace.

LOWERING PRESCRIPTION DRUGS COSTS BY PROMOTING GENERIC COMPETITION

Background:

- The Prices of Rx Drugs Continue to Grow Rapidly: The American people are justifiably demanding action by Congress to make prescription drugs more affordable. Prices are so high that recent data show that 24 percent of Americans didn't fill a prescription in the past year due to the high costs. In addition, 19 percent of Americans said they skipped a dose or cut pills in half in the previous year because of the high costs.
- Certain Brand-Name Manufacturers Are Gaming the System to Reap Profits at Consumers' Expense: Brand-name drug manufacturers reap high profits from patent-protected products, which give an incentive to devise methods to delay generic competitors from coming to market. According to a 2016 JAMA article, consumers and payers lose out on at least \$5.4 billion in savings a year due to delay tactics used by brand-name drug companies.
- Bringing Generics to Market Faster Will Lower Costs for Consumers: One key way to reduce drug prices is to ensure generics can come to market as soon as patent and exclusivity periods end. Generic market entry saved \$265 billion in 2017, including \$82.7 billion for Medicare alone, or \$1,952 per enrollee. According to one estimate, the average drug price decreases by 50 percent in the first year of generic entry, with an 80 percent reduction in five years. Ensuring generic products can come to market faster leads to substantial cost savings for consumers.

H.R. 938, The BLOCKING Act

- H.R. 938, The BLOCKING (Bringing Low-Cost Options and Competition While Keeping Incentives for New Generics) Act was introduced by Rep. Kurt Schrader (D-OR) and Buddy Carter (R-GA) on January 31 and was reported by the Energy and Commerce Committee by voice vote on April 3.
- Under current law, the first generic applicant to FDA is granted 180 days of market exclusivity, which begins to run when the generic drug is first marketed. The purpose of this exclusivity is

to provide an incentive for generic products to enter the market to compete with brand-name drugs. However, some first applicants delay seeking final approval after beginning the application process – also known as parking. This stops the exclusivity from beginning to run while simultaneously blocking any subsequent generic competition from coming to market – hurting consumers. According to FDA, this occurs an average of five times a year, and each time delays competition an average of 12 months.

- This bill contains provisions that would discourage the parking of 180-day exclusivity by a first generic applicant that is blocking the approval of other generics. Specifically, the bill allows the FDA to approve a subsequent generic drug application that is ready for full approval if no first applicant has received final approval and other conditions are satisfied. In such cases, the exclusivity period would be triggered and would run for 180 days after which time the subsequent generic applicant could enter the market.
- CBO estimates that the bill’s provisions would allow generic drugs to enter the market earlier, on average, than they would under current law. Because of the earlier entry of lower-priced generic drugs, CBO estimates that enacting the bill would reduce federal spending on prescription drugs, reducing the deficit by \$442 million over ten years.

H.R. 1499, Protecting Consumer Access to Generic Drugs of 2019

- H.R. 1499, Protecting Consumer Access to Generic Drugs of 2019, was introduced by Rep. Bobby Rush on March 5 and was reported by the Energy and Commerce Committee by voice vote on April 3.
- Currently, brand-name drug manufacturers can enter into a “pay-for-delay” agreement in which the brand-name drug manufacturer provides the generic manufacturer with a form of compensation to delay bringing a generic equivalent to market – significantly hurting consumers. Similarly, manufacturers of biologics can enter into a “pay-for-delay” agreement with biosimilar and interchangeable product manufacturers to delay entry of biosimilar and interchangeable products. In 2010, the Federal Trade Commission estimated that these “pay-for-delay” agreements cost consumers and taxpayers \$3.5 billion annually.
- This bill makes these “pay for delay” agreements illegal.

- CBO estimates that the bill's provisions would accelerate the availability of lower-priced generic or biosimilar drugs that would have been affected by the agreements prohibited by the bill and reduce the average price of drugs paid by federal health programs that purchase drugs or provide health insurance that covers drugs. As a result, CBO estimates that enacting the bill would reduce the deficit by \$613 million over ten years.

H.R. 965, The CREATES Act

- H.R. 965, The CREATES (Creating and Restoring Equal Access to Equivalent Samples) Act, was introduced by Reps. David Cicilline (D-RI), James Sensenbrenner (D-WI), Jerrod Nadler (D-NY), Doug Collins (R-GA), Peter Welch (D-VT), and David McKinley (R-WV) on February 5 and was reported by the Energy and Commerce Committee by a vote of 50 to 0 on April 3.
- Currently, certain brand-name drug manufacturers game regulatory requirements to delay competition, such as using safety protocols as an excuse to withhold or delay access to generic manufacturers to the brand drug samples that the generic manufacturer needs to develop their products.
- This bill would establish a process by which generic manufacturers could obtain sufficient quantities of brand drug samples for testing, thereby deterring the gaming of safety protocols that brand name drug companies use to delay or impede generic entry.
- Currently, brand-name drug companies also delay negotiations with generic companies on developing single, shared protocols, and the bill also deters this behavior by enabling FDA to allow for comparable protocols.
- CBO estimates that the bill's provisions would allow generic drugs (including biosimilar versions of biologics) to enter the market earlier, on average, than they would under current law. Because of the earlier entry of lower-priced generic drugs, CBO estimates that enacting the bill would reduce the deficit by \$3.9 billion over ten years.

STRENGTHENING HEALTH CARE, REVERSING GOP SABOTAGE, & CRACKING DOWN ON JUNK PLANS

Background:

- **From Day One, the Trump Administration Has Been Sabotaging Americans' Health Care:** Since the day he took office, President Trump has been sabotaging health care – from empowering agencies to take steps to undermine the ACA, to slashing the open enrollment period in half, to stopping federal cost-sharing payments that help lower-income consumers with their deductibles and co-pays. The one step of stopping federal cost-sharing payments increased premiums by 20 percent.
- **The Trump Administration Has Made It Harder for American Families to Access and Sign Up for Affordable Coverage:** The Trump Administration has slashed the open enrollment period in half, slashed funding for consumer outreach and enrollment education activities by 90 percent, and slashed funding for Navigators by 84 percent. As a result of this sabotage, enrollment in the Federal marketplace has dropped each year under President Trump.
- **The Trump Administration's Sabotage Has Increased Premiums and the Number of Uninsured:** The Trump Administration's sabotage has been raising premiums. Premiums increased by 17 percent in 2018 compared to 2017. The GOP sabotage is also reversing some of the coverage gains under the ACA. Having fallen from 18 percent in 2013 to 10.9 percent at the end of 2016, the uninsured rate of U.S. adults has now climbed from 10.9 percent to 13.7 percent under President Trump, the highest uninsured rate in four years.
- **The Trump Administration's Devastating Junk Plan Rule Has Expanded Junk Plans From The Previous Three-Month Limit and Made Them Available for Up to Three Years:** These junk plans discriminate against people based on pre-existing conditions, set higher premiums based on age, gender, and health status and can deny or rescind coverage altogether for pre-existing conditions. These junk plans also deny access to basic benefits such as prescription drugs and mental health and substance abuse treatment.

H.R. 1385, The SAVE Act

- H.R. 1385, The SAVE (State Allowance for A Variety of Exchanges) Act was introduced by Reps. Andy Kim (D-NJ) and Brian Fitzpatrick (R-PA) on February 27 and was reported by the Energy and Commerce Committee by a vote of 29 to 22 on April 3.
- The Affordable Care Act provided states the option to establish their own marketplaces or rely on the federal marketplace. The law also provided grants to states to support the planning and establishment of state-based marketplaces. However, these grants could be awarded only up until January 1, 2015. Accordingly, states no longer have access to this funding to establish a state-based marketplace.
- This bill provides \$200 million to HHS to provide grants to interested states to be used to create their own state-based marketplace. This will empower states to implement new approaches to expand coverage, lower costs, and combat the Trump Administration's sabotage.
- Currently, only 11 states and the District of Columbia have state-based marketplaces and their own website. States that operate their own marketplaces have greater flexibility and control over their insurance markets. [Studies](#) show that state-based marketplaces have higher enrollment and lower premiums, overall, compared to the Federal marketplace.
- For example, [a recent report](#) by three state-based marketplaces (California, Washington, and Massachusetts) finds that they have successfully used the tools of the ACA to achieve lower premiums and higher new enrollment than states in the Federal marketplace, finding specifically:
 - The cumulative premium increases from 2014 to 2019 in these three state-based marketplaces was less than half the increases in the states using the federal marketplace.
 - These three state-based marketplaces are also doing better on attracting new enrollees to the marketplace than the performance of the Federal marketplace.

H.R. 1386, The ENROLL Act

- H.R. 1386, The ENROLL (Expand Navigators' Resources for Outreach, Learning, and Longevity) Act was introduced by Reps. Kathy Castor (D-FL), Lisa Blunt Rochester (D-DE), Frederica Wilson (D-FL) and Charlie Crist (D-FL) on February 27 and was reported by the Energy and Commerce Committee by a vote of 30 to 22 on April 3.
- This bill reverses a key act of the Trump Administration's health care sabotage – which was slashing funding for the Navigator program by 84 percent over two years – down to \$10 million a year. The Navigator program provides grants to independent outside groups to help Americans enroll in marketplace plans.
- Unfortunately, the GOP sabotage has been successful in reducing enrollment numbers. Indeed, about 8.4 million people enrolled in the Federal marketplace during 2019 Open Enrollment, down from 9.2 million during 2017 Open Enrollment.
- The bill restores the funding for Navigators, bringing it up to \$100 million a year. Specifically, the bill requires CMS to annually obligate to the Navigator Program \$100 million of the user fees collected from insurers participating in the Federal marketplace.
- On top of slashing Navigators' funding, the Trump Administration has taken several other actions to undermine the Navigator program. For example, it has reduced the duties the ACA had given Navigators to the one narrow duty of enrollment. Also, it has stipulated that entities applying for Navigator funding must demonstrate their ability to make individuals aware of inadequate junk plans, like so-called "short-term, limited duration" plans and association health plans, in addition to ACA-compliant plans.
- In addition to restoring funding, the bill also includes provisions to reverse the Trump Administration's various actions to weaken the Navigator program. For example, the bill:
 - Requires HHS to ensure that Navigator grants are awarded to organizations that have a demonstrated capacity to carry out all of the duties specified in the ACA.
 - Requires there be at least two Navigator entities in each state.
 - Prohibits HHS from taking into account an entity's capacity to provide information relating to association health plans or so-called "short-term, limited duration" plans in awarding Navigator grants.

- Finally, the bill further strengthens the Navigator program by giving Navigators new duties of enrolling individuals in Medicaid and the Children’s Health Insurance Program. It also clarifies that Navigators can provide year-round assistance.

H.R. 987, MORE Health Education Act

- H.R. 987, MORE (Marketing and Outreach Restoration to Empower) Health Education Act, was introduced by Reps. Lisa Blunt Rochester (D-DE), Kathy Castor (D-FL), Lucy McBath (D-GA), and Dan Kildee (D-MI) on February 6 and was reported by the Energy and Commerce Committee by 30 to 22 on April 3.
- This bill reverses a key act of the Trump Administration’s health care sabotage – which was slashing the funding for consumer outreach and enrollment education activities by 90 percent – to \$10 million.
- Unfortunately, the GOP sabotage has been successful in reducing enrollment numbers. Indeed, about 8.4 million people enrolled in the Federal marketplace during 2019 Open Enrollment, down from 9.2 million during 2017 Open Enrollment. In particular, there has been a significant decline in new enrollment in the Federal marketplace since 2017. Approximately 1 million fewer new consumers enrolled during 2019 Open Enrollment than during 2017 Open Enrollment.
- This bill restores this funding. Specifically, the bill appropriates \$100 million each year beginning in 2020 for CMS to expand consumer outreach and enrollment education activities.
- CBO estimates that the bill’s spending \$100 million a year over 10 years for these purposes would increase enrollment in nongroup insurance coverage and Medicaid by about 500,000 each year over the 2020-2029 period.
- Also, having strong consumer outreach and enrollment activities can lower premiums. For example, Covered California estimates that its strong outreach and enrollment education activities have lowered premiums by up to 8 percent from what they would be without those activities.

H.R. 1010, Rescinding Trump Administration's Final Rule Promoting Junk Insurance Plans

- H.R. 1010, Rescinding Trump Administration's Final Rule Promoting Junk Insurance Plans, was introduced by Reps. Kathy Castor (D-FL), Nanette Barragan (D-CA), Stephen Horsford (D-NV), Gwen Moore (D-Wi), Lauren Underwood (D-IL), and Mark DeSaulnier (D-CA) on February 27 and was reported by the Energy and Commerce Committee by a vote of 30 to 22 on April 3.
- One of the most damaging acts of sabotage by the Trump Administration has been, on August 3, 2018, issuing a final rule promoting junk insurance plans (so-called 'Short-Term, Limited Duration' plans). This critically vital bill would rescind this damaging rule, ensuring that the strong pre-existing condition protections in the ACA will not be undermined.
- Under President Obama, "Short-Term, Limited Duration" Insurance (STLDI) plans could only last three months – they were designed, for example, to help people bridge a gap in health coverage, as when between jobs. By contrast, the Trump Administration's rule extends the maximum duration of STLDI plans from three months to 12 months and also allows insurers to renew STLDI plans for up to 3 years.
- These STLDI plans are truly junk insurance plans. They discriminate against people with pre-existing conditions, set higher premiums based on age, gender, and health status, and can deny or rescind coverage altogether for pre-existing conditions.
- These junk plans also deny access to basic benefits such as prescription drugs and mental health and substance abuse treatment, and set dollars limits for health care services, leading to huge surprise bills for consumers.
- Expanding junk plans also makes health insurance less affordable for consumers with pre-existing conditions, by undermining the market for comprehensive coverage. Indeed, the CBO estimates that this bill, by rescinding the junk plan rule, will lower premiums in the nongroup market.
- A coalition of groups representing millions of Americans with pre-existing conditions, including the American Cancer Society Cancer Action Network, American Heart Association, and American Diabetes Association, issued [a statement strongly opposing the final junk plan rule](#) in August, when it came out, stating, "The Administration has finalized a rule that will reintroduce health insurance discrimination based on gender, health status, age, and pre-existing conditions."