Medicare Part D is a vital source of prescription drug coverage for more than 44 million seniors and individuals with disabilities, providing access to a range of medications for patients. Unfortunately, the recent drive to address high prescription drug prices could lead to harmful legislative and regulatory changes that threaten to undermine the program’s structure and harm patients in the process.

**Current Threats**

**Repealing Non-Interference Clause and Replacing with Government Arbitration**

Included in the Medicare Part D program is a provision known as the non-interference (NI) clause, which prohibits the Secretary of Health and Human Services (HHS) from interfering in private negotiations between Part D plans, pharmacies and pharmaceutical manufacturers, requiring a particular formulary (i.e., list of covered drugs) or instituting a price structure for the Part D program.

Currently, insurers and manufacturers privately negotiate within the Part D marketplace to produce substantial discounts and rebates. This market-based structure fosters competition among plans and helps create savings for both seniors and the government. Still, policymakers believe the government can negotiate better prices than Part D sponsors and have introduced bills to repeal the NI provision.

Further concerning, some have suggested replacing the already successful market-based system with binding government arbitration, meaning the government would have the power to arbitrarily set prices for Part D drugs. However, this would put government officials without medical expertise in the position to make decisions on the price of treatments for patients. Arbitration is also likely to take aim at the newest, most innovative medicines, as they are often more expensive, likely leading to a reduction in incentives for the development of new drugs and breakthrough cures.

Ultimately, these proposed policies could threaten patient choice and restrict access to care, potentially increasing Medicare costs long term. The Congressional Budget Office (CBO) has repeatedly said allowing the government to negotiate drug prices would have a negligible impact on federal spending unless HHS were to also limit access to prescription medications. Restricted access to affordable prescriptions means patients may not receive the medicines they need in order to improve health outcomes and avoid costly emergency room visits and hospitalizations. This access restriction would not only impact health outcomes but could also lead to higher spending for other Medicare services.
Compulsory Licensing

Recently, legislation was introduced that would allow the government to grant compulsory licenses to generic drug and biologics manufacturers for Part D prescription drugs if a price is not determined during initial negotiations. Put simply, compulsory licenses negate any exclusivity protections and allow a company other than the patent holder to make, use, sell or import a drug without the permission of the patent holder.

This bill or any future proposal that permits compulsory licensing could significantly impact the wide-raging access to medications that Part D currently provides. Allowing the government to interfere with crucial patent protections undermines Part D’s competitive marketplace structure and could lead to a decrease in production of certain brand name drugs. In addition to reducing access to some drugs currently on the market, compulsory licensing could stifle investment in research and development efforts, limiting patient access to new and innovative medications in the future.