Potential Unintended Consequences of the Inflation Reduction Act's Medicare Drug Price Negotiation Program for Patients

Provisions of the Inflation Reduction Act (IRA) could affect patients who rely on innovative treatments, cures, or new uses of existing medicines to get well or stay healthy. While some parts of the IRA will help patients — such as caps on out-of-pocket payments and the ability to predictably spread payments over the year — there are growing concerns about the potential unintended consequences of the IRA and the Medicare Drug Price Negotiation Program (DPNP). Recent research showed that:

The IRA may delay access to brand new medicines

Before a new drug is approved, research is done to determine whether a drug will be effective in treating more than one disease. Because the IRA starts a countdown clock toward price-setting based on when it is first approved by the FDA, the law creates an incentive to wait to launch a new drug until multiple indications are ready for approval at the same time. *Patients may have to wait longer to get access to new medicines.*

➡ Go Deeper: Read the peer-reviewed research in *The American Journal of Managed Care*.

The IRA may lead to fewer diseases getting additional approved treatment options

The timeline for the research and clinical trials required for the FDA to approve an existing medicine for another disease often goes beyond seven years. Now that the IRA allows the government to select some drugs for price-setting just seven years after launch, it reduces the incentive to conduct additional research and development. *Patients may see fewer diseases getting new treatment options approved.*

➡ Go Deeper: Read the peer-reviewed research in *The American Journal of Managed Care*.

The IRA may reduce the amount of available information used by providers to establish clinical guidelines

After a medicine is approved, it takes a long time to generate the evidence that clinicians and providers rely on to help establish guidelines and best practices to treat diseases. The IRA's short timeline to potential price-setting reduces the incentives to generate this evidence. *Providers may know less about the benefits of new medicines.*

➡ Go Deeper: Read the publication in *Health Affairs Forefront*.

The IRA may encourage insurers to restrict access for the selected drugs

What a patient pays for a medicine is a function of the insurance card in their pocket. Insurers also determine whether patients must navigate barriers such as prior authorization or step therapy. Right now, seniors have excellent access and experience few barriers to many of the first ten drugs selected — but that may change. *Increased utilization management requirements, which are likely in response to the IRA, could reduce patient access — exactly the opposite of what the program intends to do.*

➡ Go Deeper: Read the peer-reviewed research in *JAMA Health Forum*.

Additionally, the IRA may not incorporate or account for the patient perspective

People living with diseases ought to be a critical voice in a process that is supposed to help them. The final guidance from CMS was not clear on how patient preferences will be incorporated into their decisions. *Failing to incorporate the patient voice threatens access and continued innovation.*

➡ Go Deeper: Read the publication in *Value in Health*.

The National Pharmaceutical Council (NPC) is a health policy research organization focused on sharing data and potential policy impacts with patients and the groups who represent them. For more information on the potential consequences of the IRA and other policies impacting patients, visit www.NPCnow.org.