How the IRA's Drug Price-Setting Program Threatens Seniors' Access to Medicines

When the government steps in between patients and their doctor to decide the value or price of a treatment, patient access suffers. That's exactly what is predicted to happen to Part D medicines affected by the Inflation Reduction Act's (IRA's) flawed new price-setting program – both those directly price-set and also other therapeutic competitors within the same class.

For some medicines, Part D plans may change their formulary and coverage rules to disadvantage the medicine selected for price setting, making it harder for patients to get access through more utilization management or higher cost-sharing. In other instances, plans may change their formulary and coverage rules to disadvantage a medicine not selected for price setting, subjecting a government price-set medicine to increased utilization management or higher patient cost-sharing because it is financially advantageous for them to do so.

How Seniors Could Face Access Barriers to Medicines Selected for Price Setting

Example Patient: Lisa, 72, Maryland

Non-Insulin Oral Diabetes Medicine: Greater restrictions on a medicine subject to government price-setting leads to access delay

Lisa has diabetes and chronic kidney disease. Based on her medical needs and current clinical guidelines, Lisa's doctor prescribed a specific diabetes medicine to help control her blood sugar and slow the progression of her kidney disease. Other diabetes medicines could put her kidneys at risk.

As a result of the IRA, the medicine Lisa's doctor prescribed will now have a government-set price. Consequently, her health plan switched the formulary status of Lisa's medicine to require prior authorization. By forcing patients like Lisa onto a competing product with a higher list price and rebate, health plans may make more money. However, Lisa cannot switch to a different medicine because the other options are not recommended for her level of kidney function.

Lisa's doctor worked with her Part D plan to go through the prior authorization process for 4 months before the medicine Lisa had been stable on was covered under the changed formulary. Lisa rationed her medicine (without telling her doctor) in fear that she would run out before the appeal was complete.

The bottom line: Lisa faced a 4-month access delay to the clinically necessary diabetes treatment she needed and skipped several doses of her medication because of flawed government price-setting under the IRA.

Example Patient: Jeff, 81, Oregon

Anticoagulant Therapy: Forced switching creates patient stress and burden of additional monitoring

Recently, Jeff was prescribed a direct oral anticoagulant to reduce the risk of stroke. Jeff has been stable on an antidepressant medicine for years, so his doctor took that into account. Jeff and his doctor chose a particular anticoagulant because some antidepressants, when combined with anticoagulants, can lead to increased risk of excessive bleeding or decreased efficacy of the anticoagulant medicine.

However, the oral anticoagulant that Jeff's doctor prescribed will now have a government-set price because of the IRA. As a result, Jeff's Part D plan now prefers competing medicines with higher list prices and bigger rebates. Jeff was told he must either switch to a different oral anticoagulant or pay more out of pocket to stay on his existing medicine, which his plan moved to a higher formulary tier.

To keep his treatment affordable, Jeff switched medicines, but his doctor raised concerns that he may face greater risks of side effects and required additional treatment monitoring for several months.

The bottom line: The IRA government price-setting disrupted Jeff's treatment regimen, putting him at risk of additional health issues and increasing his spending for additional blood test monitoring.

How Seniors Could Face Access Barriers to Medicines *Not* Selected for Price Setting

Example Patient: Carl, 84, Wisconsin

Cancer Medicine: Greater utilization management means access delays or lack of coverage all together

Carl is newly diagnosed with a form of chronic leukemia. Carl's doctor prescribed a specific medicine that will give Carl the best odds of survival while mitigating against certain cardiovascular risks, which may prove problematic given his medical history and other health conditions.

The medicine that Carl's doctor prescribed was not selected for a government-set price under the IRA, but another medicine in the same therapeutic class was selected. As a result, Carl's Part D plan imposed step therapy on his prescribed medicine, requiring him to try (and fail) on a medicine that will have a government-set price before covering the medicine he was prescribed.

Carl tried the medicine his Part D plan prefers for 3 months and unfortunately his cancer progressed. He and his doctor then had to work with his Part D plan to get approval for his originally prescribed medicine.

The bottom line: Forcing Carl to take the price-set medicine may have saved the government money, but Carl's health was put at risk.

Example Patient: Stephanie, 67, Georgia

Autoimmune treatment: Excluding medicines from formularies limits treatment options for patients

Stephanie has been on an effective medicine to manage her psoriasis and psoriatic arthritis for years. She and her doctor carefully worked to find the right treatment, allowing her to successfully achieve disease remission.

The medicine that Stephanie's doctor prescribed was not selected for a government-set price under the IRA, but another medicine in the same therapeutic class was selected. Because the IRA requires Part D plans to provide formulary access for the selected medicines, her plan decides to make formulary changes and no longer covers the medicine she was prescribed.

Stephanie was left worrying that her condition would flare up and she would not be able to maintain disease remission because she was forced to switch to another medicine in the class.

The bottom line: IRA is interfering in plan formulary decisions. Denying Stephanie access to the medicine she has been stable on because it isn't selected for price setting may have saved her Part D plan money, but Stephanie's health was put at risk.

These are just some of the many potential ways seniors and people with disabilities in Medicare Part D could be negatively impacted by the IRA. Policymakers should make it a priority to protect access to needed medicines, not make it harder for Part D patients to access the medicines they have been stable on and know work for them.