



FAQ: Alternatives to PAIN

How would the bill help Seniors?

This legislation would ensure that Medicare beneficiaries can easily access non-opioid pain management approaches under Medicare Part D. In doing so, the legislation ensures that seniors have choices in managing their acute pain and avoid unnecessary exposure to prescription opioids, which can have significant long-term consequences.

Research shows that exposure to opioids carry long-term risks. Rates of opioid use disorder (OUD) among seniors have been steadily increasing in recent years. In fact, a recent report from the Office of the Inspector General (OIG) shows 1.1 million Medicare beneficiaries with an OUD diagnosis in 2022. Fortunately, these diagnoses are preventable; by increasing access to non-opioids, and reducing unnecessary exposure to opioids, we can prevent opioid misuse, abuse, and overdose.

Over 60 million seniors across the country are enrolled in Medicare, and over 50 million Medicare beneficiaries are enrolled in Part D plans. In 2021, 23% of Medicare beneficiaries – or nearly 15 million Americans - received opioids through Part D. Voices believes that seniors deserve choices when managing their pain or recovering from surgery.

Would this bill increase Medicare spending?

This legislation has yet to be scored by the Congressional Budget Office (CBO), but we expect that this legislation may have a cost attached to it. However, costs associated with reducing patient cost sharing for non-opioids would be more than made up for by minimizing unnecessary exposure to prescription opioids among Medicare beneficiaries and avoiding the associated Medicare spending on opioid use disorder (OUD). The Moran Company reported that Medicare spent \$4.3 billion on newly diagnosed OUD patients in 2022 alone. If this figure applies to all 1.1 million Medicare beneficiaries with OUD, as identified by the HHS Office of Inspector General, the total economic impact on Medicare could be estimated at \$33 billion in 2022. Moreover, the Joint Economic Committee has estimated that the total cost of the opioid addiction crisis was \$1.5 trillion in 2020. Addressing the root causes of the opioid epidemic and focusing on prevention rather than merely treating its aftermath is the most cost-effective and economically efficient approach.

Would Part D plan design requirements specifically for non-opioids create a precedent for other drugs?

The unprecedented nature of the opioid epidemic, which is a public health emergency and claims tens of thousands of lives each year and is estimated to cost U.S. taxpayers \$1.5 trillion annually, has created the need for legislative action in this space. While the bill would set modest guardrails on Part D plan design requirements for non-opioids, it is not without precedent. Congress has previously enacted changes to safeguard vulnerable communities' access to essential

medications, such as banning utilization management (UM) for HIV medication and requiring mandatory coverage of drugs in Medicare's six protected classes. Considering the magnitude and consequences of OUD, adjustments to plan requirements are justified.

Would plans be required to put these non-opioid treatments on their formularies? Doesn't that remove incentives for rebates or competition for placement?

No, the bill does not force health plans to cover these products – there is no mandatory coverage requirement. Rather, the legislation attempts to correct for a market that inappropriately incentivizes cheap, generic prescription opioids by requiring plans to ensure appropriate access to these products if they do choose to cover them.

Plan sponsors retain the ability to negotiate with manufacturers and collect rebates. A recent GAO report found that rebates are often used to secure superior placement to competitor drugs, which would still be relevant. The bill strikes an important balance – it doesn't entirely remove market incentives, but it does ensure increased patient access for this narrow set of drugs.

What non-opioid products would the bill apply to?

The legislation applies to medicines approved by the Food and Drug Administration (FDA) to treat acute pain that do not act upon the body's opioid receptors. If there is a generic equivalent available, the brand medicine does not qualify. Lastly, medicines must be priced below the Medicare Part D specialty tier threshold.

There are several non-opioid medications on the market including nerve blocking pain medications, certain sedatives commonly used to treat pain, and several others. In addition to those already on the market, there is also a robust pipeline of non-opioid therapies that are scheduled to come to market in the coming years and would fall under Part D. Novel therapies are in development that are alternatives to the existing class of opioid medications, but Congress will need to act to ensure patients and providers have access to these new, non-opioid options. These are the same novel therapies that lawmakers hope to incent through past legislative initiatives including CARA and the SUPPORT Act that provided resources to the National Institutes of Health (NIH) and Food and Drug Administration (FDA) to spur innovation in this market; those investments are beginning to bear fruit and therefore lawmakers have a particular interest in ensuring Americans have access to these products.