

Medicare Drug Negotiations: Insights from the Northern Virginia Health Policy Forum

On October 22, 2024, the Northern Virginia Health Policy Forum hosted a discussion on the price negotiations between the Centers for Medicare & Medicaid Services (CMS) and pharmaceutical companies. The conversation included two experts on CMS's drug price negotiation program and its potential impact on our healthcare system: John O'Brien, President of the National Pharmaceutical Council, and Jason Spangler, Chief Executive Officer of the Center for Innovation & Value Research. The panelists discussed, among other things, the status of the first round of negotiations, the need for transparency in the process, and the role of patients. Jim Scott, President and CEO of Applied Policy, led the wide-ranging conversation on the status of the ongoing Medicare drug price negotiations, and what may lie ahead for it.

LESSONS FROM THE FIRST ROUND

As part of their opening comments, O'Brien and Spangler cited the relatively short time frame that CMS had to implement the Inflation Reduction Act (IRA) statute governing the negotiations, and the resulting concerns raised by this compressed process. Spangler noted this first year of the negotiations has shown that this is "a very fluid process" as CMS and the manufacturers are still learning how to negotiate fair prices while keeping close to the statute. Spangler continued that CMS has "acknowledged that there's a lot of things that they might get wrong, and they want to get as much right as possible." Additionally, both panelists said that this initial highly politicized approach may not provide enough time and resources to create a process that will lessen the financial impact of high out-of-pocket costs for patients.

THE NEED FOR TRANSPARENCY

Both panelists criticized a lack of transparency in the price negotiation process, specifically related to how CMS arrived at the maximum fair prices (MFP) in the first round. They said that the emphasis on the "maximum fair price" raises questions about how CMS defines "fair" and whether it incorporates considerations of value and clinical benefit along with cost.



O'Brien discussed the uncertainty around what data and evidence CMS is using and that a clear understanding of the evidence that CMS has considered is important for stakeholders, so they are able to participate effectively in the policy process. Additionally, Spangler said that this lack of transparency could confuse the focus of any future research designed to align with CMS priorities.

UNINTENDED CONSEQUENCES

The panelists said that a range of unintended consequences of the negotiations needs to be mitigated before the program can be considered effective, and at this point any direct impact on patients' out-of-pocket expenses remains unclear. They cited other provisions in the IRA, such as the \$2,000 out-of-pocket cap on drugs, that are expected to have a more immediate positive impact on consumer spending. O'Brien and Spangler also expressed concern that the impacts on formularies and increases in the use of utilization management could negatively affect patient access to certain drugs. Additionally, O'Brien said that given the timeline for when drugs become eligible for negotiation, manufacturers may delay or abandon research developments for new uses of the medicine to avoid being included in price negotiations. The risk to drug development is especially acute in the oncology and rare disease community and O'Brien expressed the concern that "the message we're sending to manufacturers is either don't do this additional research to generate these new uses of medicines, or maybe do your research and wait until you have enough uses to then launch your drug, so you can slow the start of that IRA clock."

Spangler cited research showing that increasing drug spending, even within Medicare, decreases costs in other areas of Medicare. Spangler said this underscores the need to focus on overall value and not the specific cost of a drug, as "we'd rather have a patient take a drug and feel better than have to go into the hospital for some sort of procedure."

PATIENT INVOLVEMENT

Both panelists highlighted that it is extremely important that more patient input be incorporated into the process moving forward. Spangler expressed that "so far, CMS has only done patient listening sessions" in an effort to capture the "voices of diverse and Medicare specific patient populations." However, Spangler noted that some people who spoke during these sessions had no connection to the actual drug or disease condition being addressed. Likewise, both panelists expressed concern that underrepresented populations have not been involved in the process as much as needed. Given that health equity is one of the most important CMS strategic goals, the panelists explained that this should be addressed.

Spangler, in his concluding statement, emphasized the importance of focusing "on getting the patient more involved and the patient community engaged" so that the unintended

consequences of the programs can be mitigated, and the program can be focused on helping the patient and their families.

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The full Forum video as well as highlights can be found on both [Applied Policy's website](#) and the [Northern Virginia Health Policy Forum website](#).

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This extract was prepared by Applied Policy®.