

Wyden Eyes Bipartisan Bill To Address GPOs' Role In Drug Shortages

By [Maaisha Osman](#) / December 6, 2023 at 9:00 AM

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Senate Finance Committee Chair Ron Wyden (D-OR) says he will work on bipartisan legislation to address the issue of three group purchasing organizations (GPOs) controlling 90% of the pharmaceutical market, saying the consolidation is contributing to the drug shortage crisis -- a [concern that aligns](#) with that of the generic drug lobby Association for Accessible Medicine (AAM).

Industry experts testifying at a Finance Committee hearing Tuesday (Dec. 5) pushed the idea of changing hospital buying patterns through long-term contracts that include a pay-for-performance mechanism.

A major problem of the current buying system for hospitals is that it frequently relies on GPOs to help buy generics at the lowest price, Wyden said, which ultimately creates a "race-to-the-bottom" situation and leads to generics exiting the market.

"The generic manufacturers that are awarded contracts by these middlemen do so by offering penny-on-the-dollar prices that mean they can't invest in the capacity or equipment needed to make reliable, high-quality medications," Wyden said in his [opening remarks](#) at the hearing. "This 'race to the bottom' price war for generics leads to quality control problems and factory shutdowns, which leads to shortages of generic drug products that are in high demand.

In recent remarks, AAM suggested a [separate payment system](#) for essential medicines would encourage more competition among generic drugs, ensuring their sustainability and preventing drug shortages.

Craig Burton, executive director at the Biosimilars Council and senior vice president of policy and strategic alliance at AAM, previously told *Inside Health Policy* that the current payment system forces suppliers to compete by further reducing the already low prices of generic drugs, leading some generic makers to exit the market eventually. Instead, Burton recommends a change in the [purchasing behavior of buyers](#). This can be achieved by requiring hospitals to purchase generic drugs under fixed-price and fixed-volume long-term contracts.

"Therefore, increasing the sustainability of generic competition requires examining changes in how and what CMS and other payers pay for generics," Burton said.

Experts at the Finance Committee hearing [touted the AAM endorsed](#) long-term purchasing contract model. The witnesses said long-term contract would create a reserve line space for generic manufacturers to continue their production.

"When the hospital or the purchaser enters a long-term agreement with a manufacturer, then that manufacturer is going to reserve line space [and] will know they have a market

for that product for a period of two years or five years or whatever it is, and they will continue to be there to meet the needs of their customer,” Allan Coukell, senior vice president of public policy in Civica Rx, said.

When Sen. Marsha Blackburn (R-TN) asked what would encourage hospitals to commit to long-term purchasing contracts, Marta Wosinska, senior fellow at the Brookings Institute’s Center on Health Policy, said the pay-for-performance mechanism would incentivize hospitals to take preventive measures against future drug shortages and encourages long-term contracts. These preventive measures would include maintaining surplus drug supplies and choosing manufacturers with a better track record of quality control.

Implementing this approach would require FDA to provide information about manufacturer quality and reliability. FDA’s Quality Management Maturity (QMM) pilot program for medical supply manufacturers mirrors recommendations AAM has made as the QMM metrics could play a pivotal role in the proposed pay-for-performance program.

But a recent Manhattan Institute report says Congress should monitor FDA’s efforts to identify and stem shortages as FDA [currently provides little data](#) on drug shortages. During Tuesday’s hearing, Sen. Elizabeth Warren (D-MA) applauded the Biden-Harris administration’s new plan to enhance HHS’ ability to use the Defense Production Act to bolster domestic manufacturing of key starting materials for essential medicines, but asked one of the experts whether this initiative alone is adequate in addressing drug shortages or whether the government should also consider manufacturing finished drugs.

In response, Coukell said that the majority of shortages are not occurring at the stage of key starting materials but rather in the manufacturing process of the finished dosage form.

“I agree that it’s a good thing to invest in key starting materials, but if we’re focused on shortages [being] the key starting materials, the precursors, even upstream of active pharmaceutical ingredient (API) are way upstream, and not usually the thing that’s causing the shortage,” said Coukell. “Most of the shortages are caused at the level of manufacturing the finished dosage form the vial or the syringe of drug.”

Warren also asked whether a nonprofit organization like Civica would be able to produce generic drugs that are completely unprofitable if the government steps in; Coukell said that would be an option.

“It is important to acknowledge that the market alone won’t fix the [drug shortage] problem,” Warren said.

The Massachusetts senator also announced that she will introduce legislation known as the Affordable Drug Manufacturing Act, which will direct HHS to sign contracts to manufacture generic drugs with non-profit organizations like Civica.

“Public manufacturing presents a powerful opportunity to resolve drug shortages, to secure the pharmaceutical supply chain and to ensure generic drugs are both accessible and affordable for patients,” Warren said. -- *Maaisha Osman*

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