

March 28, 2024

Ms. Polly Webster
Senior Counsel, Health
Majority Staff
U.S. Senate Committee on Finance
Washington, DC 20510

Mr. Conor Sheehey
Senior Advisor, Health
Minority Staff
U.S. Senate Committee on Finance
Washington, DC 20510

Dear Polly and Conor,

On behalf of the Society of Gynecologic Oncology (SGO), thank you for your work in developing a Medicare drug shortage prevention and mitigation program and the opportunity to submit these comments. Our members and their patients have been significantly affected by the chemotherapy shortages. We need a comprehensive solution to prevent future shortages and ensure that patients do not face the uncertainty and stress associated with a lack of access to drug therapies deemed standard of care. SGO welcomes the opportunity to work with you to explore Medicare policies to prevent future shortages.

The SGO is the premier medical specialty society for healthcare professionals trained in the comprehensive management of gynecologic cancers. Our 3,000 members include physicians, advanced practice providers, nurses, and patient advocates who collaborate with our foundation, the Foundation for Women's Cancer, to increase public awareness of gynecologic cancers and improve the care of those diagnosed with gynecologic cancers. Our primary mission focuses on supporting research, disseminating knowledge, raising the standards of practice in the prevention and treatment of gynecologic malignancies, and collaborating with other organizations dedicated to gynecologic cancers and related fields, all with the ultimate vision of eradicating gynecologic cancers.

Last year we faced one of the worst chemotherapy drug shortages in the country's history, with fifteen indispensable chemotherapy drugs in short supply simultaneously. Carboplatin and cisplatin, which are both generic, sterile injectable drugs and have been in shortage since mid-February 2023, are first-line therapies for ovarian, endometrial, and cervical cancers. Carboplatin serves as a backbone drug for most gynecologic cancer therapies. At the peak of the shortages, SGO estimated that over 500,000 patients were affected by chemotherapy drug shortages. Moreover, although the data is not yet available, we believe that individuals in marginalized communities and rural areas have felt the greatest negative impacts from drug shortages, and we are currently evaluating if the chemotherapy shortages have negatively affected survival outcomes for people with gynecologic cancers. Unfortunately, the shortages have continued into 2024, with many chemotherapy agents affected.

The draft program, as outlined by the Senate Finance Committee ("the Committee"), aims to incentivize hospitals, providers, and other key supply-chain participants to meet standards that are designed to support contracting prices that improve the reliability and sustainability of the supply chain for these sterile injectable drugs. SGO agrees that drug purchasers, including the providers and entities like group purchasing organizations (GPOs) have a role to play in preventing and mitigating shortages. We recognize that the Committee's jurisdiction does not include the Food and Drug Administration (FDA) but believe that addressing the root shortages of the ongoing drug shortage and future shortages will require Medicare and FDA policy changes.

Targeted Drugs

The SGO appreciates the Committee's focus on multiple-source injectable and infusible generic drugs, which are typically low-cost and vulnerable to manufacturing quality problems. A supply disruption drove the current shortage of generic chemotherapies and was the driver of the shortage just a decade ago. Preventing shortages in this category of drugs requires policy solutions that will be distinct from those applicable to more expensive drugs. Given the vulnerability to shortage of chemotherapies and other drugs in this class, we commend the Committee for focusing on them initially.

Financial Incentives

As envisioned by the Committee, payment-eligible providers would elect to participate in the program by entering into an agreement with program participants, including GPOs, wholesalers, nonprofits, and other similar entities. These agreements would specify which applicable generics would be included, and providers would purchase a percentage of their annual drug inventory under this agreement. Providers then would be eligible for incentive payments depending on whether the program's core standards are met.

Generally, the SGO is supportive of establishing financial incentives for provider organizations that purchase drugs that meet certain manufacturing standards and are produced by resilient supply chains. However, we urge the Committee to ensure that it makes these agreements and incentives accessible to, and attainable for the full range of providers. Small hospitals and practices, typically in rural and underserved areas with fewer resources, are the most vulnerable to supply chain disruptions, and in fact, they were the first to report shortages last year. Additionally, these providers tend to treat marginalized patient populations both geographically and in terms of health equity. Large academic medical centers and wealthier hospitals already have the means to deploy shortage-mitigation strategies through their contracts with GPOs and wholesalers and in acquiring buffer stocks. While there is room for improvement in these more resource-rich settings, SGO wants to ensure that this program does not perpetuate the existing inequities between large academic medical centers and small hospitals and practices. The Committee must structure the core standards or additional incentives to ensure the providers most vulnerable to supply disruptions will benefit.

Core and Advanced Standards

As outlined above, low-resource providers must be able to participate and benefit from the potential incentives. The core standards related to volume, contract length, limitations on off-contract purchasing, primary and redundant/contingent suppliers, and sustainable pricing which providers must meet to be eligible for the incentive appear reasonable. However, the Committee should consider tiering these requirements for providers depending on their patient volume and revenue to ensure that low resource institutions may succeed and benefit.

Additionally, the SGO supports the Committee's proposal for the use of advanced manufacturing technology in the production of generic drugs to be an advanced standard. For this metric to be meaningful and reduce drug shortages, there is a role for the FDA as recognized in the document. We recommend that the Committee work with the Health, Education, Labor, and Pensions Committee with jurisdiction over the FDA and the agency itself to ensure the Advancing Pharmaceutical Quality, Quality Management Maturity and Risk Management Programs are being used to support this measure. The expansion of these programs will play a key role in improving supply chain resiliency, which has a direct effect on the implementation of this shortage prevention and mitigation program.

Furthermore, the SGO encourages the Committee to consider ways to integrate increased transparency into this program. Providers will benefit from having more information on shortages related to individual manufacturers, FDA warnings and citations, inspection results, and greater price transparency, including the high and low-price benchmarks. This information will empower them as consumers to make better-informed purchasing decisions.

Thank you again for the opportunity to provide these comments on the initial framework for the Committee's drug shortage prevention and mitigation program. SGO welcomes the opportunity to collaborate with you as legislation is developed. Should you require further information or have questions, please contact Erika Miller at emiller@dc-crd.com.

Sincerely,

A handwritten signature in cursive script that reads "Amanda Nickles Fader".

Amanda Nickles Fader, MD
President