

September 11, 2023

Chiquita Brooks-LaSure
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-0057-P
P.O. Box 8016,
Baltimore, MD 21244-8016

Submitted electronically via <http://www.regulations.gov>

Re: CY 2024 Medicare Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System Proposed Rule (CMS 1786-P)

Dear Administrator Brooks-LaSure:

On behalf of the Society of Gynecologic Oncology (SGO), thank you for the opportunity to provide these comments on the CY 2024 Medicare Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System proposed rule. Specifically, we wish to comment on the proposal to establish and maintain a buffer stock of essential medicines. While we understand that CMS' proposal would apply to the Inpatient Prospective Payment System (IPPS), it is critical that the agency develop policies to support patient access to essential medicines in the outpatient and physician office settings as well.

SGO is the premier medical specialty society for healthcare professionals trained in the comprehensive management of gynecologic cancers. Our more than 2,800 members include physicians, advanced practice providers, nurses, and patient advocates who collaborate with 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.

The ongoing chemotherapy shortages have significantly affected our members and their patients. Undoubtedly, we are amid the worst chemotherapy drug shortage in the country's history, with fifteen indispensable chemotherapy drugs in short supply simultaneously. Carboplatin and cisplatin, which 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; however, similar shortage episodes over the past two decades have resulted in sub-standard cancer care. A recent survey indicated that 45% of gynecologic cancer providers are still experiencing drug shortages, which include methotrexate, fluorouracil, paclitaxel docetaxel, leucovorin, vinblastine, and liposomal doxorubicin. Liposomal doxorubicin is a preferred first-line standard-of-care treatment for patients with platinum-sensitive ovarian cancer and a preferred second-line standard-of-care treatment for patients with platinum-resistant ovarian cancer. Before the pegylated liposomal doxorubicin shortage onset, the SGO estimated that over 500,000 patients were affected by chemotherapy drug shortages.

The American Society of Health-System Pharmacists (ASHP) recently surveyed that 99% of hospital pharmacists reported shortages, causing 85% to ration treatments and 84% to rely on different dosages.¹

Since the causes of these chemotherapies are multiple and complex, we believe that a comprehensive approach is required to prevent future shortages. Therefore, SGO is pleased that the Centers for Medicare & Medicaid Services (CMS) included a proposal to create separate payment under the IPPS to support the establishment and maintenance of buffer stock of essential medicines. The agency's proposals are designed to mitigate and prevent future drug shortages. However, we have concerns about the proposed policy and recommend refinements before this and other policies are implemented in the inpatient, outpatient, and physician office settings.

Definition of Essential Medicines

To determine which medicines would qualify under this proposal, CMS refers to the *Essential Medicines Supply Chain and Manufacturing Resilience Assessment* report developed by the Office of the Assistant Secretary for Preparedness and Responses (ASPR). This report prioritized eighty-six essential medicines as critical for minimum patient care in acute settings, or important for acute care of respiratory illnesses and conditions with no comparable alternative available. The only chemotherapeutic drug on this list is cyclophosphamide.

While SGO understands that this proposal for application in the inpatient settings, and potentially expanded to the hospital outpatient and physician office setting, we urge CMS to develop a broader definition of essential medicines to include the chemotherapies currently in shortage, not just drugs used in acute care. The report referenced in the proposed rule, which lists the eighty-six essential medicines, was developed in response to a White House Executive Order² on supply chain resilience to ensure better preparedness for future pandemics and a more resilient and stable U.S. manufacturing environment. Carboplatin, cisplatin, and the sterile injectable chemotherapies currently in shortage may not be key to improving the country's pandemic preparedness; however, these are key examples of drugs produced in circumstances where supply chain resiliency must be improved. Half of the cisplatin used in the United States was sourced from the Intas plant in India, which the Food and Drug Administration (FDA) found to have significant quality control problems, and these problems were a primary driver of the current shortage. A disruption at this single plant led to this current cisplatin shortage when other manufacturers were unable to increase production to meet demand and helped precipitate the carboplatin shortage by increasing demand for this alternate therapy. Some SGO members have reported that their institutions are not anticipating having a regular supply of these drugs until 2024. Patients should not be forced to navigate chemotherapy supply disruptions of this magnitude, which create unnecessary stress and uncertainty as they are already navigating a cancer diagnosis and subsequent care plan.

Buffer Stock Supply

Specifically, CMS requests comment on whether a three-month supply is appropriate for an essential medicine's buffer stock or if an alternative duration should be considered. As SGO and its members have

¹ <https://www.ashp.org/-/media/assets/drug-shortages/docs/ASHP-2023-Drug-Shortages-Survey-Report.pdf>

² <https://www.whitehouse.gov/briefing-room/presidential-actions/2021/02/24/executive-order-on-americas-supply-chains/>

navigated the current chemotherapy shortages, the institutions where our members practice have exhausted their supplies for three-months and longer. It is likely that there is no ideal amount of drug to keep in reserve; and therefore, we recommend that CMS implement this program using a three-month supply for buffer stocks and that this policy be reevaluated annually until enough data is available to see if this supply influences drug shortages.

Establishing and Maintaining a Buffer Stock of Essential Medicines

SGO shares CMS' goal of ensuring patients have access to commonly prescribed therapies when they need them. Maintaining a buffer stock of essential medicines is a good practice. However, we have concerns about how this provision would be implemented should it be finalized.

CMS should delay the implementation of this program for any essential medicines in shortage until the shortages are resolved. Otherwise, providing incentives to hospitals to establish and maintain buffer stocks could encourage drug hoarding and exacerbate existing shortages, particularly for those institutions that serve underserved populations that may not be as well-resourced. SGO's primary interest is our members' patients, and we must ensure that they have opportunities to access standard-of-care therapies without unnecessary delay or burden.

Furthermore, we encourage CMS to ensure that implementing a policy of this nature does not limit access to essential medicines in community health settings and safety net institutions that may not have the resources of large academic medical centers when it is implemented for drugs not in shortage. During the current chemotherapy shortages, access to these drugs has not been universal across institutions as some have been better able to maintain supply than other institutions. Patients with cancer and other serious or chronic conditions should not be burdened with searching for institutions with adequate supply or be forced to travel great distances for care.

Other Recommendations

SGO has actively advocated for Congress to prevent future chemotherapy shortages and ensure that cancer patients do not have to endure the uncertainty that surrounds their treatment when standard-of-care chemotherapies have limited or no availability. To prevent future shortages, hospitals should be incentivized to purchase essential medicines, including chemotherapies, which meet high-quality standards and are produced by resilient supply chains.

We also recommend that CMS provide incentives to realign hospital purchasing practices to promote the purchase of high-quality generic drugs. Currently, hospitals purchase drugs from group purchasing organizations (GPOs), pharmacy benefit managers (PBMs), and entities that provide the lowest prices because there are no incentives for purchasing drugs from more reliable manufacturers at higher prices. Information on drug quality and manufacturing practices, which the FDA should be empowered to collect, could be used to inform standards and best practices for contracts with GPOs and PBMs and allow the agency to establish a voluntary reporting system that would include financial rewards for purchasing drugs from manufacturers with more resilient supply chains. A recent article from the Brookings Institution titled "*Federal Policies to Address Drug Shortages*" addresses this concept in detail.³ We believe this policy would empower hospitals to be informed consumers of essential medicines, providing a concrete benefit to the patients they treat.

³ <https://www.brookings.edu/articles/federal-policies-to-address-persistent-generic-drug-shortages/>

Thank you for the opportunity to submit these comments. SGO welcomes the opportunity to work with CMS to ensure that patients have access to chemotherapies and other essential medicines. Should you require further information, please contact Erika Miller, Partner, CRD Associates, emiller@dc-crdc.com.

Sincerely,



Angeles Alvarez Secord, MD, MHSc
President, 2023-2024