March 29, 2024

Senate Finance Committee
219 Dirksen Senate Office Building
Washington, DC 20510

RE: Draft Medicare Drug Shortage Prevention and Mitigation Program

Oncology nurses are privileged to support people with cancer through the entire cancer experience, from diagnosis and treatment into survivorship or as they face their end-of-life journey. The mission of the Oncology Nursing Society is to lead the transformation of cancer care and promote excellence in oncology nursing and quality cancer care. Oncology nurses are the health professionals primarily responsible for the administration and monitoring of anti-cancer drugs and the associated side effects patients with cancer may experience. Every day, we see the pain and suffering caused by cancer and understand the physical, emotional, and financial challenges that people with cancer and their families face throughout their diagnosis and treatment.

As such, we write to thank you for your ongoing efforts to prevent and mitigate shortages of crucial generic sterile injectables. There is an urgent need to identify a long-term, nationally coordinated solution to overcome drug shortages that ensures access to safe, high-quality cancer care.

The draft proposal for the Medicare Drug Shortage Prevention and Mitigation Program would apply to “applicable generics, a category capturing multiple source injectable and infusible drugs (excluding vaccines).” There are several products frequently used in cancer care that are often subject to shortage, including carboplatin and cisplatin. These two drugs are used to treat multiple types of cancer, including lung, breast, prostate, and gynecologic cancers, as well as many leukemias and lymphomas. They are also essential in the pediatric oncology setting, where there are often limited or no alternative treatment options. A 2023 National Comprehensive Cancer Network survey found that 72% of cancer centers were experiencing a shortage of carboplatin and 59% were experiencing a shortage of cisplatin. We believe that these products are precisely the kind contemplated by this proposal and we urge you to provide sufficient specificity in legislative language to ensure that is indeed the case.

Ongoing generic drug shortages challenge health care professionals in every setting and directly affect patient care quality and outcomes. Oncology nurses, as frontline care providers, have a unique view of the direct impact of shortages on patients and their families which can result in treatment delays and necessitate the substitution of potentially less-effective medications.

A 2023 survey of health care professionals across a variety of disciplines from the Institute for Safe Medication Practices and ECRI found that shortages of necessary drugs, supplies, and equipment, including an increasing number of lifesaving drugs with no viable alternatives, are “making it nearly impossible to provide safe, high-quality patient care in a fiscally responsible manner.” Sixty percent of respondents reported that more than 20 drugs, single-use supplies, or durable medical equipment were involved in shortages during the six months prior to the survey and those shortages affected a wide range of specialties and subspecialties. Forty-four percent of respondents indicated that their ability to specifically provide safe, high-quality hematology/oncology care was...
affected. Examples of shortages compromising patient care include interrupted, modified, or delayed chemotherapy regimens, the use of more opioid analgesia because of lidocaine unavailability, and medication errors due to drug or vial size substitutions. The underlying approach of your proposed new program – to ensure purchasing commitments and pricing stability – will help right some of the unique issues with the generic injectables market that are contributing to shortages of those products.

Please know that ONS and its members very much appreciate your work to ensure patients have access to optimal cancer treatments. We would be happy to discuss ways in which ONS may be of assistance in this endeavor and would encourage you to contact Jaimie Vickery, ONS’ Director of Government Affairs and Advocacy, at healthpolicy@ons.org. We look forward to engaging in an ongoing dialogue to address issues of importance to our cancer patients and ways in which we can promote public health.

Sincerely,
The Oncology Nursing Society