



August 25, 2023

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The Honorable Cathy McMorris Rodgers  
Chair, House Energy & Commerce Committee  
1314 Longworth House Office Building  
Washington, DC 20515

Dear Chair McMorris Rodgers:

The Association for Clinical Oncology (ASCO) is pleased to provide feedback on the *Stop Drug Shortages Act* discussion draft. ASCO appreciates your efforts to protect patient access to lifesaving and life-prolonging treatments and your commitment to preventing future drug shortages.

ASCO is the world's leading professional organization representing more than 45,000 physicians and other health care professionals who care for people with cancer. ASCO works to ensure that all individuals with cancer have access to high quality, equitable care; that cancer care delivery systems support optimal cancer care; that our nation supports robust federal funding for research on the prevention, screening, diagnosis, and treatment of cancer.

Cancer drugs are a critical component of treatment for many cancer types and play an important role in controlling what can be debilitating symptoms. For well over a decade, the oncology community has experienced shortages of critical drugs that are used to treat a variety of conditions. Current shortages of anti-cancer drugs are the worst seen in over a decade. These shortages are caused by a multitude of factors, including quality issues, manufacturer business decisions, disruptions to raw ingredient and excipient supplies, natural disasters and other emergencies that take place in countries where many of these life-saving drugs are manufactured.

The *Stop Drug Shortages Act* would make meaningful progress toward addressing the root causes of serious and worsening disruptions in access to critical medicines. Please find specific feedback on the proposed provisions below. We look forward to working with you and your staff to make these and other meaningful drug shortage solutions a reality.

**Title II – 340B**

*SEC. 201. EXEMPTING CERTAIN GENERIC INJECTABLE DRUGS FROM THE 340B DRUG DISCOUNT PROGRAM.*

ASCO appreciates the drafter's efforts to exempt certain generic sterile injectable drugs from the 340B Drug Discount Program. We recommend the provision be amended to specifically target the suspension of 340B discounts for drugs currently on the Food and Drug Administration (FDA) drug shortage list or where there is an identified threat of potential shortage.

*SEC. 202. GAO REPORT.*

As noted in our [Statement for the Record](#) prepared for the Committee on Energy and Commerce Subcommittee on Oversight and Investigations, ASCO encourages Congress to require a Government Accountability Office (GAO) study that would examine all aspects of the drug supply chain to better understand the full range of issues exacerbating drug shortages. ASCO supports this provision, as a GAO report will better inform policymakers and stakeholders on the role of the 340B Drug Discount Program and other federal programs on access to generic drugs and drug shortages.

*SEC. 203. HRSA GUIDANCE.*

The proposed Health Resources and Services Administration (HRSA) guidance to allow transfer of 340B drugs in shortage from covered entities is a strong solution to addressing drug shortages. ASCO also appreciates the reporting language to ensure transparency and prevent possible fraudulent activity.

**Title III – Medicare**

*SEC. 301. REDUCING INFLATION REBATE AMOUNTS FOR CERTAIN SHORTAGE DRUGS SUBJECT TO REBATE WAIVERS UNDER THE MEDICARE PROGRAM.*

While ASCO appreciates the intent of this provision, we believe it is unlikely to help address cancer drug shortages based on the type of drugs typically on the shortages list. In Medicare Part B, the rebates only apply to single-source, brand name drugs, which are less likely to go into shortage. Part B generic sterile injectables, which are the drugs most frequently in shortage in oncology, are not included in the inflationary rebate policy. Additionally, shortages of oral anticancer drugs under Medicare Part D are not common.

As another approach, ASCO calls attention to the fact that multiple source drugs are likely to be impacted by artificially low reimbursement caused by delays in updating average sales prices (ASP). The Centers for Medicare and Medicaid Services (CMS) updates ASP using data from previous quarters. This creates a barrier to entry for new manufacturers of multiple source drugs, or for increasing production of multiple source drugs, as increased prices are not reflected in reimbursement for two quarters. Allowing the Secretary to determine an alternative basis for calculating allowed payment amounts for drugs in shortage, though no less than what would be calculated under ASP, would allow for immediate relief from artificially low rates.

*SEC. 302. STUDY ON MARKET-BASED PRICING FOR SHORTAGE DRUGS UNDER MEDICARE PART B.*

ASCO supports Section 302, to study Medicare reimbursement for drugs that are on, or at risk of being added to, the shortages list, including generic sterile injectable drugs. This will be valuable

information for more fully understanding the economic conditions leading to current drug shortages. To strengthen the study, drafters may consider specifying how they will determine which Medicare Part B drugs are at risk of going into shortage.

*SEC. 303. CMMI MODEL ON ALTERNATIVE PAYMENT FOR GENERIC STERILE INJECTABLE DRUGS.*

ASCO supports this provision to require the Center for Medicare and Medicaid Innovation (CMMI) to test reimbursement policy for generic sterile injectables. As noted in our response to your request for information, we believe an effective use of CMS's authority would be to investigate innovative reimbursement structures for sterile generic injectable drugs under CMMI's current authority. ASCO offers itself as a resource to the drafters and CMMI staff as it further explores market-based reimbursement policy.

*SEC. 304. STUDY ON MEDICARE CODING FOR DRUGS IN SHORTAGE OR IN DANGER OF SHORTAGE.*

Current Healthcare Common Procedure Coding System (HCPCS) codes for injectable drugs, whereby most multiple source drugs share a single HCPCS code, has resulted in reducing drug prices and protecting beneficiaries from different coinsurance amounts based on manufacturer prices. This contrasts with biologics, where biosimilars have different HCPCS codes, payment amounts, and beneficiary coinsurance amounts. While ASCO supports this provision to study Medicare coding policies for generic sterile injectables and other Part B drugs in shortage, we caution that allowing for separate billing codes may allow for some relief of artificially low prices for drugs in shortage, but it could also create disparities in profitability among manufacturers that would disincentivize increases in production. For example, if a new multiple source drug is paid a drastically higher rate than currently available alternatives, that may disincentivize current manufacturers from increasing production to address shortages.

*SEC. 306. STUDY ON FLAT FEE PAYMENT.*

Currently, Medicare reimburses Part B drugs at 106% of Average Sales Price (ASP). After the impact of sequestration, it is 104.3% of ASP. The 6% payment is used to cover the significant costs associated with chemotherapy treatments in physicians' offices, including the cost of procuring, storing, preparing, and handling the drugs.

Appropriate reimbursement for the costs associated with physician-administered drugs is a longstanding concern and is not limited to the issue of drug shortages. We have discussed payment reform with CMMI and the Medicare Payment Advisory Commission (MedPAC) and have explored alternative payment models. Previous analysis by ASCO on different Part B drug payment models showed drastic shifts in reimbursement unrelated to drug shortages, with some drugs and fluids increasing significantly and anticancer drugs decreasing.

This provision requires MedPAC to make recommendations for changing the add-on payment for Medicare Part B drugs to a flat fee-based payment. ASCO appreciates that it includes mitigation of the financial impact for small practices that may pay above ASP for the drug. Consideration must be given to differences in the cost of acquisition, storage, handling, and preparation of drugs of different classes.

We caution that shifting any component of drug reimbursement into the physician fee schedule could have devastating effects on the viability of office-based practices. Given how the physician

fee schedule insufficiently reimburses direct and indirect practice expenses, we believe this would result in oncology practices not being able to cover the cost of storage and handling of physician-administered drugs.

#### **Title IV – Transparency**

##### *SEC. 401. GROUP PURCHASING ORGANIZATION REPORTING REQUIREMENT.*

ASCO supports this provision as it would increase transparency into the market side of the supply chain allowing stakeholders to make more informed decisions when purchasing drugs or receiving care.

#### **Title V – Food and Drug Administration**

##### *SEC. 501. NONCOMPLIANCE LETTERS RELATING TO VOLUME REPORTING.*

ASCO appreciates the intent of this provision. To strengthen the impact of it, we recommend consideration of alternative penalties beyond posting a notification on the FDA's website of a manufacturer's noncompliance. FDASIA Title X required manufacturers to report anticipated shortages to the FDA, with the resulting penalty being the public posting of a notification letter on the FDA website—a similar approach to the current proposal. With no penalty for failure to comply, the shortage notification mandate is often disregarded.

##### *SEC. 502. INCENTIVE FOR SHELF-LIFE EXTENSION STUDIES.*

ASCO has supported manufacturers providing more data on shelf-life extension and supports the intent of this provision to incentivize shelf-life studies for drugs in shortage. We recommend consideration of whether the timelines outlined would be effective. Additionally, consideration should be given to how the Secretary would be able to determine if a new drug coming to market is at risk of going into shortage. As noted previously, single-source brand name drugs rarely go into shortage. For generic sponsors, this incentive may be challenging to take advantage of outside of the original generic maker still in exclusivity.

##### *SEC. 504. ADDITIONAL INFORMATION ON GENERIC DRUG ACTIVE PHARMACEUTICAL INGREDIENTS.*

ASCO appreciates the inclusion of this provision and believes it will increase visibility in the pharmaceutical supply chain. We recommend increasing the proposed supply threshold of 60% to full disclosure of all active pharmaceutical ingredient (API) suppliers and associated volumes. Full disclosure would allow the FDA to better understand and predict weak points in the supply chain and use its existing authority to prevent a supply chain breakdown leading to shortages.

##### *SEC. 505. REPORTING ON USE OF NEW AUTHORITIES AND REQUIREMENTS WITH RESPECT TO DRUG SHORTAGES.*

ASCO supports this provision to require the FDA to report on its available authorities to prevent drug shortages. This report would complement the annual report FDA provides to Congress and

FDA's recent guidance on volume reporting requirements. Additional reporting could be helpful in assessing areas of improvement in how U.S. federal agencies respond to shortages.

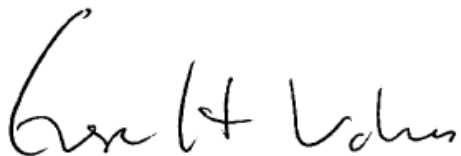
*SEC. 506. NEW DOMESTIC FACILITY INSPECTION PILOT PROGRAM.*

ASCO supports the proposed pilot program, which offers a sensible solution to expedite the licensure and distribution of domestically manufactured drugs. ASCO recommends extending the proposed sunseting of the program to allow more eligible entities to take advantage of it.

**Conclusion**

Thank you for the opportunity to provide ASCO's feedback as you continue the work to address drug shortages that are impacting patients with cancer across the country. We welcome opportunities to engage with Congress in a meaningful dialogue about these issues or expand on our previous recommendations to the Committee. Please contact Megan Tweed at [Megan.Tweed@asco.org](mailto:Megan.Tweed@asco.org) with any questions.

Sincerely,

A handwritten signature in blue ink, appearing to read "Everett E. Vokes". The signature is fluid and cursive, with a large initial "E" and "V".

Everett E. Vokes, MD, FASCO  
Chair of the Board