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ASSOCIATION FOR CLINICAL ONCOLOGY
KNOWLEDGE CONQUERS CANCER

May 7, 2025

Secretary Howard Lutnick
U.S. Department of Commerce
Bureau of Industry and Security
Office of Strategic Industries and Economic Security

RE: BIS-2025-0022; XRIN 0694-XC120; Docket No. 250414-0065; Notice of Request for Public Comments on Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients

Submitted electronically via www.regulations.gov

Dear Secretary Lutnick,

We appreciate the opportunity to respond to the Notice of Request for Public Comments issued by the Commerce Department and published in the Federal Register April 16, 2025. Since 2010, the Association for Clinical Oncology (ASCO) and its affiliate, the American Society of Clinical Oncology, has been raising profound concerns regarding chronic and episodic shortages of critical treatment and supportive care drugs. Herein, we address the pharmaceutical supply chain in the context of drug shortages, as we have long pointed out that an at-risk supply chain contributes significantly to shortages of critical and essential medications.

ASCO is a national organization representing more than 50,000 physicians and other health care professionals specializing in cancer treatment, diagnosis, and prevention. We are also dedicated to conducting research that leads to improved patient outcomes, and we are committed to ensuring that evidence-based practices for the prevention, diagnosis, and treatment of cancer are available to all Americans.

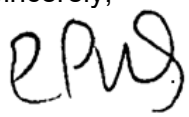
In addition to simply raising concerns, ASCO has, along with partner organizations, issued recommendations aimed at increasing the resilience of the supply chain and addressing the underlying economic factors that contribute to these shortages, especially in generic and sterile injectable drugs. Our leaders and physician volunteers have testified before multiple Congressional Committees investigating drug shortages. We have kept our membership informed and educated on this topic, in addition to hearing directly from them about the impact shortages have on their patients and practices. ASCO has highlighted drug shortages at our Annual Meeting and hosted or co-hosted numerous meetings (in-person and virtual) that bring together provider

and patient organizations to share information and help inform recommendations moving forward.

We offer for your review [Attachment A] a previous comment letter our organization submitted to the Centers for Medicare & Medicaid Services (CMS) in response to the agency's solicitation of comments related to the implementation of Medicare Part B and Part D inflation rebates paid by manufacturers. In our communication, we highlighted the intersection of financial penalties such as rebates and the ability of some manufacturers to maintain production, especially in the generic drug market.

We appreciate the opportunity to comment.

Sincerely,



Eric P. Winer, MD, FASCO
Chair of the Board
Association for Clinical Oncology

Attachment A

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March 11, 2023

Dr. Meena Seshamani, MD, PhD
CMS Deputy Administrator and Director of the Center for Medicare
Department of Health & Human Services
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

RE: 1) Medicare Part B Drug Inflation Rebates Paid by Manufacturers: Initial Memorandum, Implementation of Section 1847A(i) of the Social Security Act, and Solicitation of Comments, and
2) Medicare Part D Drug Inflation Rebates Paid by Manufacturers: Initial Memorandum, Implementation of Section 1860D-14B of Social Security Act, and Solicitation of Comments

Submitted electronically via IRARebateandNegotiation@cms.hhs.gov
(*"Medicare Part D Inflation Rebate Comments*" and *"Medicare Part B Inflation Rebate Comments"*)

Dear Dr. Seshamani,

The Association for Clinical Oncology (ASCO) is pleased to offer comments on the CMS guidance, *Medicare Part B Drug Inflation Rebates Paid by Manufacturers: Initial Memorandum, Implementation of Section 1847A(i) of the Social Security Act, and Solicitation of Comments* and *Medicare Part D Drug Inflation Rebates Paid by Manufacturers: Initial Memorandum, Implementation of Section 1860D-14B of Social Security Act, and Solicitation of Comments*.

Between them, the memoranda provide initial guidance to manufacturers, Medicare Part D Prescription Drug Plans, and Medicare Advantage-Prescription Drug Plans regarding the payment by manufacturers of inflation rebates for Part B and Part D rebatable drugs. CMS is voluntarily seeking comment on certain topics, including CMS' approach to waivers or reductions of rebates for drugs in shortage or, in some cases, at risk of being in shortage.

ASCO is a national organization representing nearly 45,000 physicians and other health care professionals specializing in cancer treatment, diagnosis, and prevention. We are also dedicated to conducting research that leads to improved patient outcomes, and we are committed to ensuring that evidence-based practices for the prevention, diagnosis, and treatment of cancer are available to all Americans.

Background

In calculating the estimated rebate amount for a Part B rebatable drug for a calendar quarter, the Secretary is required to reduce or waive the rebate amount for a Part B rebatable drug for a calendar quarter in two cases:

1. when a Part B rebatable drug is described as currently in shortage on the shortage lists established under section 506E of the Federal Food, Drug and Cosmetics Act (FD&C Act) at any point during the calendar quarter; or
2. for a biosimilar biological product when the Secretary determines there is a severe supply chain disruption during the calendar quarter, such as that caused by a natural disaster or other unique or unexpected event.

The statute provides that CMS reduce or waive the rebate amount with respect to a Part D rebatable drug for an applicable period in three cases:

1. for a Part D rebatable drug that is described as currently in shortage on the FDA drug shortage list in effect under section 506E of the FD&C Act at any point during the applicable period;
2. for a Part D rebatable drug that is a generic or biosimilar when CMS determines there is a severe supply chain disruption during an applicable period; and
3. for a generic Part D rebatable drug when CMS determines that without such a reduction or waiver in the rebate, the drug is likely to be described as in shortage on the FDA drug shortage list during a subsequent applicable period.

Applicability. The rebate provisions of the Inflation Reduction Act apply only to single source drugs. For Part B, single source drugs are defined as biologics and drugs marketed and distributed under new drug applications (NDAs). For Part D, single source drugs are defined as biologics, NDAs, and single source generics (with some exceptions). Inflation rebate requirements do not apply to single source drugs for which average Medicare annual charges are less than $100 per patient.

Current Shortage Landscape and CMS Considerations for Rebate Reductions and Waivers

According to the University of Utah Drug Information Service (UUDIS) and the American Society of Health-System Pharmacists (ASHP), in the fourth quarter of 2022 there were 295 active drug shortages, the highest in almost a decade.[1] In 2022, 48% of drugs newly in shortage were injectables.[2] (The Food and Drug Administration (FDA) lists approximately 125 drugs as currently in shortage; the FDA uses different criteria for its drug shortage list compared to ASHP. These differences have been well characterized previously.[3])

[1] University of Utah Drug Information Service. Available at https://www.ashp.org/drug-shortages/shortage-resources/drug-shortages-statistics
[2] University of Utah Drug Information Service. Available at https://www.ashp.org/drug-shortages/shortage-resources/drug-shortages-statistics
[3] FDA and ASHP Shortage Parameters. Contrasting the FDA (CDER) and ASHP Drug Shortage Websites: What Are the Differences? Available at https://www.ashp.org/drug-shortages/current-shortages/fda-and-ashp-shortage-parameters

For cancer therapies and supportive care drugs, it has been widely noted that for years, many of the most impactful drug shortages have been shortages of multi-source, generic, sterile injectables. These drugs are not subject to the inflationary rebate requirements, and thus are not impacted either by rebates or the reduction or waiver of such rebates. ASCO, in partnership with several stakeholder groups, has previously released recommendations for improvement in the resilience of drug and healthcare supply chains; we refer you to the most recent set of recommendations for further information.[4]

As CMS and others have noted, there is a balance to be achieved between providing flexibility to manufacturers in the form of reduced or waived rebates when a drug is in shortage or in danger of being in shortage, and not providing incentives for manufacturers to intentionally keep their drug or biological in shortage for the purpose of avoiding rebate payments. Many shortages occur due to "quality" issues and are under the control of the manufacturer: a UUDIS investigation found that in 2022, the reason for 56% of drug shortages as reported by manufacturers were characterized as "unknown/[manufacturer] would not provide."[5] Compared to circumstances outside of the manufacturer's control—natural disasters, other unexpected events—shortages due to quality issues at the level of the manufacturer will likely merit greater scrutiny of the rebate reduction level by CMS.

Currently, there appear to be a very small number of single source part D generic drugs that are in shortage. However, precisely because these drugs are single source, it will be important for CMS to assess the reason for these shortages as well as previous patterns of shortage. If, for example, a drug is extremely low margin and the cost of producing the drug is increasing, the manufacturer may realistically need to raise the price of the drug in order to just maintain these low margins and remain in the market. If the price increase is high enough, the manufacturer would then become subject to the inflationary rebate, and at that point may decide to withdraw from the market. These single source, low margin drugs likely merit more generous rebate reduction levels in order to keep them viable.

For Part B drugs and biologics subject to both inflationary rebates and the associated drug shortage provisions, CMS should consider the totality of the reason(s) for the shortage, the impact on patients, and efforts by the manufacturer to mitigate or resolve the shortage. In general, manufacturers of branded drugs have more of an incentive and ability to quickly resolve shortages of these drugs, due to higher margins and often more resilient supply chains. However, certain older branded drugs may lack generic competition for a variety of reasons. If these older single source branded drugs are low margin and facing increasing production costs, they may be risk of market exit as described above for single source generics and should be considered in a similar fashion.

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[4] Improving the Quality and Resilience of the United States Healthcare Supply Chain. Recommendations from the American Medical Association, American Society of Anesthesiologists, American Society of Health-System Pharmacists, Association for Clinical Oncology, and the United States Pharmacopeia. Available at https://www.ashp.org/-/media/assets/news-and-media/docs/Healthcare-Supply-Chain-Recommendations

[5] University of Utah Drug Information Service. Available at https://www.ashp.org/drug-shortages/shortage-resources/drug-shortages-statistics

We thank you for the opportunity to comment on these initial memoranda. Please contact Karen Hagerty (karen.hagerty@asco.org) with any questions.

Sincerely,

Lori Pierce, MD, FASTRO, FASCO
Chair of the Board
Association for Clinical Oncology