

To: E&C Health Subcommittee

From: Allan Coukell, Civica Inc.

RE: Response to QFR following hearing “Legislative Proposals to Prevent and Respond to Generic Drug Shortages.”

Date: 13 October 2023

The Honorable Earl L. “Buddy” Carter

- 1) Mr. Coukell - As you know, the Wall Street Journal recently reported that Civica is selling a drug for \$160 that usually costs about \$3000 in Medicare, but that PBM-owned specialty pharmacies have not been willing to dispense it. Mr. Coukell - Can you comment on how this affects our pharmaceutical supply chain and only further limits the availability of drugs? What do you believe Congress should do about this?

Thank you for this question, which relates to abiraterone, a drug that Civica launched with the goal of lowering costs for consumers at the pharmacy (as distinct from injectable drugs that Civica manufactures for hospitals in order to prevent drug shortages).

Civica is a non-profit generic drug company established to reduce drug shortages and ensure a reliable supply of essential medicines to hospitals at fair prices. CivicaScript is the operating unit of Civica that was established to lower costs for consumers at the pharmacy counter. CivicaScript was founded in partnership with 18 Blue Cross and Blue Shield plans, Federal Employee Program, and the BCBS Association. Additional members include health plans Elevance (formerly known as Anthem) and HCSC, additional Blue Cross Blue Shield plans, SelectHealth, the Boilermakers National Health and Welfare Fund, and two PBMs: Navitus and AffirmedRx.

In 2022, CivicaScript launched abiraterone 250mg. Abiraterone is a generic oral drug used in combination to treat prostate cancer. The average cost of a month’s supply of abiraterone 250mg to Medicare Part D in 2021 was over \$3000. However, CivicaScript’s selling price is \$160. Our recommended maximum price to the consumer, allowing for a fair pharmacy dispensing fee, is \$171.¹

While CivicaScript and its health plan partners have attempted to work with all the major PBMs, most have not been willing to deliver this drug at low cost, and average costs per claim remain high. The exception to this pattern is Navitus, which is making the drug available at the recommended price through its own specialty pharmacy, Lumicera.

¹ CivicaScript is the first company to introduce quality affordable generics with a transparent consumer price by making our maximum retail price (MaxRP™) of \$171 publicly available, including through a QR code on the packaging.

Based on publicly available pricing information,² it is likely that large vertical healthcare companies acquire competing products at lower cost than CivicaScript's \$160. But if so, the question remains: why are consumers, health plans and Medicare paying such high prices?

One possible reason is that, because of its cost, abiraterone is still classified as a "specialty drug," products that are normally dispensed through a "specialty pharmacy." Most specialty pharmacy dispensing in the United States occurs through PBM-owned specialty pharmacies.³ Therefore, the same entity that is theoretically working on behalf of health plans, consumers, and Medicare to reduce drug costs also has an incentive to maximize its revenues from dispensing.

CivicaScript's health plan partners have been creative in their attempts to get PBM-owned specialty pharmacies to dispense CivicaScript abiraterone, proposing a number of models, mechanisms and workarounds to get this drug to consumers at low cost. To date, with the exception of Navitus, a CivicaScript founding member, which is dispensing through its specialty pharmacy, Lumicera, none of the largest PBM-owned specialty pharmacies have dispensed CivicaScript abiraterone.

Specialty pharmacy dispensing accounts for an estimated 32 percent of total PBM gross profits.⁴ Due to the PBM and Generic Purchasing Organization (GPO) oligopolies that control the generic market and benefit from our complex and opaque system of generic drug purchasing and reimbursement, U.S. patients, health plans and the federal government are not realizing the tremendous potential savings that they should.

Several approaches that Congress may wish to consider are:

- 1) Ensuring transparency (to the health plan, the individual beneficiary, and the government) of the actual acquisition cost to the pharmacy (or a reasonable proxy, such as NADAC), so that this is clearly delineated from the total cost charged by the specialty pharmacy.
- 2) Alternatively, to support Medicare savings, Congress could require that specialty pharmacy reimbursement in Medicare be based on NADAC plus a defined dispensing fee, or specified percentage markup, similar to Medicaid reimbursement. In addition to abiraterone, numerous other specialty drugs have approved generic versions, and such a change may produce substantial savings to the program.

² On March 25, 2023, the publicly advertised cash prices for abiraterone 250mg ranged from \$186.90- \$8661.38 (GoodRx, accessed 27 March 2023). The National Average Drug Acquisition Cost (NADAC) published by Medicaid is \$229.10 for 2022

³ The top 3 SPs accounted for 65 percent specialty drug revenues in 2022. Drug Channels. <https://www.drugchannels.net/2023/04/dcis-top-15-specialty-pharmacies-of.html>

⁴ Estimated for 2019. Drug Channels. <https://www.drugchannels.net/2020/07/pbm-owned-specialty-pharmacies-expand.html>. Accessed 27 March 2023

- 3) In conjunction with any policy that relies on NADAC, Congress should ensure that it accurately represents current market prices by shortening the lag time and ensuring robust and representative pharmacy participation.

- 4) Currently in Medicare Part D, it is not possible for a plan to differentiate between different generic versions of a drug. That means that a plan does not have the option to, for example, remove a low-cost version of the drug from the specialty tier and make it available as a tier-one product. This is not due to a statutory or policy restriction, but is a technical artifact of how formularies are coded in Part D. Nevertheless, Congress could direct the Medicare program to address this technical limitation to enable savings to beneficiaries and the government.