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Advancing Health in America

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March 11, 2023

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

Re: Medicare Part B Inflation Rebate Comments

Dear Administrator Brooks-LaSure:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our clinician partners — including more than 270,000 affiliated physicians, 2 million nurses and other caregivers — and the 43,000 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) initial guidance regarding certain Inflation Reduction Act (IRA) requirements. Specifically, CMS has issued guidance on establishing an inflation rebate for certain single source drugs and biosimilar biological products covered by Medicare Part B when drug companies raise the prices of these drugs faster than the rate of inflation.

The AHA supports the agency's guidance, which will help rein in the high and rising price of drugs through the implementation of inflationary rebates that apply to the Medicare Part B programs. Pharmacy-related expenses represent the fast-growing and, oftentimes, most unpredictable portion of a hospital's budget. High launch prices and continued price increases throughout the year for products already on the market make the current drug pricing environment unsustainable. Similarly, the high cost of drugs for Medicare beneficiaries can force individuals to make difficult decisions about their health care while also obligating the federal government with excessive cost. Inflationary rebates represent one mechanism that can help manage these challenges. Such policies have already demonstrated success through their use in the Medicaid program, which consistently achieves better pricing on drugs than Medicare. The implementation of a similar inflation cap on the price of drugs under the Medicare program should demonstrate similar success. Once established, this policy, in addition to generating savings, will protect the program and beneficiaries from dramatic price increases for drugs, such as the recent 533% for Miacalcin (used for treating bone

disease), 638% increase for Neostigmine (used in anesthesia) and staggering 1,261% increase for Vasopressin (used to treat diabetes and bleeding in critical care).

In order to make CMS's guidance on implementing the IRA Medicare Part B program inflationary rebates even more effective, we urge the agency to make two changes, discussed further below. Specifically, we urge the agency to:

- Mitigate the risk of incentivizing drug companies to artificially extend the duration of shortages of drugs to receive reductions in the IRA's inflation rebate.

- Not require the use of "JG" and "TB" modifiers for drugs purchased under the 340B program in implementing the IRA's inflation rebate.

MITIGATE THE RISK OF INCENTIVIZING DRUG COMPANIES TO ARTIFICIALLY EXTEND SHORTAGES IN ORDER TO RECEIVE REDUCTIONS IN THE INFLATION REBATE AMOUNT

Drug shortages have many causes, ranging from raw material sourcing, to manufacturing problems (quality control and compliance issues), to drug company consolidation and business decisions that result in drugs being discontinued. Hospitals and health systems have long been concerned about chronic and increasing drug shortages which have serious consequences for patient safety, quality of care and access to therapies. Addressing drug shortages is complex and costly to hospitals and health systems in terms of staff time and other resources required to manage the shortages, as well as the increased cost of buying alternative drugs "off contract."

The IRA includes provisions that require CMS to reduce or waive the rebate amount for a Part B rebatable drug when the drug is described as currently in shortage on the Food and Drug Administration's (FDA) drug shortage list. It also requires the same for a biosimilar biological product when the Secretary determines there is a severe supply chain disruption, such as that caused by a natural disaster or other unique or unexpected event.

In its initial guidance, CMS requests comments on how it can carry out this mandate in a way that does not create incentives for drug companies to misuse the drug shortage reporting process by intentionally maintaining their drug or biological is in shortage for the purpose of avoiding an obligation to pay a rebate. It notes that it is considering two options for implementing this policy. The first option is applying a variable reduction in the rebate amount that decreases with the length of time that a rebatable drug is on FDA's shortage list. The second option is applying a limited standard reduction in the rebate amount for a rebatable drug on the FDA's list with a reporting process under which drug companies may request a higher reduction or waiver for certain types of shortages.

The AHA recommends that CMS adopt the second option. This has the advantage of encouraging close coordination between CMS and FDA in order to validate drug company claims that increased relief from the rebate is needed. To obtain higher reductions, drug companies would have to participate in a reporting process under which they could request a higher reduction or waiver for certain types of shortages. In this process they would need to permit FDA to release relevant and likely proprietary data to CMS for the sole purpose of determining inflation rebate reductions. Such a process would provide guardrails against drug companies exaggerating or falsifying claims for extended or higher financial relief from paying the full rebate amount.

In assessing whether the drug company should have rebates significantly reduced or waived, the AHA recommends that CMS consider market size, spending per claim and manufacturing complexity. Specifically, according to a report from the Brookings Institution,[1] inflation rebates are less likely to adversely affect the ability of drug manufacturers producing high margin drugs to stay in the market because their prices are less tied to the marginal cost of production and more tied to the demand for the product. On the other hand, drug companies producing low margin drugs may be adversely affected by inflation rebates. A possible unintended consequence of inflation rebates for low margin drugs in shortage occurs when an input cost increases. According to the Brookings report, to maintain positive margins, the drug company would need to pass on those cost increases, but those cost increases would then have to be rebated back to Medicare. Depending on the level of needed pass through and share of the drug's sales in Medicare, the drug company may not find it feasible to continue marketing the product.

Finally, the AHA encourages CMS to work together with the FDA in determining whether to offer financial relief to drug companies with drugs on the FDA's drug shortage list and biosimilar biological products experiencing a severe supply chain disruption. The FDA drug shortage team has intimate knowledge of the drug markets, including assessing the medical necessity of drugs and therapeutic substitutes in the event of shortages. It determines whether a particular drug shortage is posted as active and when it has been resolved. FDA tracks industry data such as sales over time and can request drug company and wholesaler inventory data as well. All these data may be useful in determining when and how CMS should apply its authority.

DO NOT REQUIRE THE USE OF "JG" AND "TB" MODIFIERS FOR DRUGS PURCHASED UNDER THE 340B PROGRAM IN IMPLEMENTING THE REBATE

The IRA specifically excludes units of drugs that were purchased under the 340B program from being subject to the inflation rebate. In this initial guidance, CMS states that effective implementation of the Part B inflation rebate requires identifying units of

[1] "Drug shortages and IRA inflation rebates: Considerations for CMS", Brookings Institution, https://www.brookings.edu/essay/drug-shortages-and-rebates/ accessed on March 2, 2023.

drugs acquired through the 340B program for purposes of determining the Part B inflation rebate. Therefore, the guidance instructs all 340B covered entities to use the "JG" and "TB" modifiers (depending on the type of 340B hospital) for all Medicare Part B claims as soon as possible, but beginning no later than Jan. 1, 2024.

These claim modifiers were first introduced in the calendar year 2018 Outpatient Prospective Payment System (OPPS) rule as part of a policy to cut Part B reimbursement to certain hospitals participating in the 340B program. However, this policy was found to be unlawful by the U.S. Supreme Court in its unanimous ruling in *American Hospital Association v. Becerra* and is no longer in place. Despite this fact, CMS has chosen to continue to require certain 340B hospitals to use these claims modifiers to identify 340B drugs within the OPPS. CMS' IRA guidance would now require ***all*** 340B hospitals to use them going forward, even those that were previously not required to use these modifiers for 340B claims. In this case, CMS does have other viable alternatives that would be less burdensome on hospitals. For example, the agency could exclude all units of separately-payable outpatient drugs identified using the claim status indicator "K" that are billed by hospitals that participate in 340B. CMS also has the ability to identify which hospitals are currently participating in 340B, since that list is public and available through the Health Services and Resources Administration (HRSA) website. Under this alternative, the agency could use a far less burdensome approach, while still adhering to the IRA provision.

As many hospitals have reported, the use and implementation of modifiers adds significant administrative burden since it requires considerable investment in systems and staff time to ensure that the modifiers are appropriately appended to the claims. Forcing all 340B hospitals to undertake this cost and staff burden directly contravenes CMS' longstanding policy to reduce provider burden, especially when less burdensome alternatives exist. This is especially true at a time when many hospitals around the country are resource-strapped as they continue to deal with the aftereffects of the COVID-19 pandemic and the rapid growth in expenses and inflation.

The AHA urges the agency not to require the use of these modifiers for separately-payable drug claims purchased under the 340B program for implementation of the Medicare Part B inflation rebate. These modifiers are no longer used for Medicare Part B payment purposes, and while we recognize the value the inflation rebate offers in constraining the growth of high drug prices, its implementation should not come at the expense of 340B hospitals. Instead, AHA recommends that CMS consider alternatives that are less burdensome for 340B hospitals as we outline above.

We appreciate your consideration of these issues. Please contact me if you have questions or feel free to have a member of your team contact Roslyne Schulman, AHA's director for policy, at rschulman@aha.org.

Sincerely,

/s/

Ashley B. Thompson
Senior Vice President
Public Policy Analysis and Development