PUBLICATION

HHS Solicits Comments on Possible 340B Program Changes to Reduce Drug Prices

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The Department of Health and Human Services (HHS) is soliciting comments from the public on the Administration's proposals to reduce drug prices and is targeting the 340B drug pricing program as an area of focus. The 340B program requires drug manufacturers to sell outpatient drugs at discounted rates to certain public and non-profit hospitals that treat high volumes of low-income patients or are located in rural areas and other safety net providers that receive federal grant funding.

On May 14, 2018, HHS issued a request for information (RFI) to help the agency develop future policies to address high drug prices. HHS will formally publish the RFI in the Federal Register on May 16, 2018 and will allow 60 days for comments. The RFI largely mirrors the Administration's blueprint issued last week in conjunction with President Trump's speech on drug prices. See Baker Donelson's Summary of Trump Administration Drug Pricing Blueprint.

The blueprint questioned whether growth in the 340B program has contributed to higher drug prices, stating that the "additional billions of dollars in discounted sales and the cross-subsidization necessary may have created additional pressure on manufacturers to increase list price[s]." President Trump also alluded to the 340B program in his speech, mentioning that his administration "reformed the Drug Discount Program for safety net hospitals to save senior citizens hundreds of millions of dollars on drugs this year alone."

The RFI outlines actions the Administration may take to address high drug prices and poses questions related to other actions under consideration. HHS includes a discussion of the 340B program in the section listing other actions under review. Below is a summary of the questions raised related to 340B.

Program Growth

Noting that 340B drug spending totaled more than $16 billion in 2016, up by more than 30 percent over 2015 spending, HHS asks stakeholders a series of questions related to how 340B growth may affect drug prices, including:

- How has the growth of the 340B drug discount program affected list prices?
- Has it caused cross-subsidization by increasing list prices applicable in the commercial sector?
- What impact has this had on insurers and payers, including Part D plans?
- Does the Group Purchasing Organization (GPO) exclusion, the establishment of the Prime Vendor Program, and the current inventory models for tracking 340B drugs increase or decrease prices?
- What are the unintended consequences of this program?
- Would explicit general regulatory authority over all elements of the 340B Program materially affect the elements of the program affecting drug pricing?

Program Eligibility

HHS references program eligibility and asks the following question:

- Would changing the definition of "patient" or changing the requirements governing covered entities contracting with pharmacies or registering offsite outpatient facilities (i.e., child sites) help refocus the program towards its intended purpose?

Duplicate Discounts

The RFI also discusses the 340B statute's prohibition against duplicate discounts, which prevents drug manufacturers from paying both a 340B discount and a Medicaid rebate on the same drug and asks the following questions:

- Are the current mechanisms for identifying and preventing duplicate discounts effective?
- Are drug companies paying additional rebates over the statutory 340B discounts for drugs that have been dispensed to 340B patients covered by commercial insurance?
- What is the impact on drug pricing given that private insurers oftentimes pay commercial rates for drugs purchased at 340B discounts?
- Do insurers, pharmacy, PBM, or manufacturer contracts consider, address, or otherwise include language regarding drugs purchased at 340B discounts?
- What should be considered to improve the management and the integrity of claims for drugs provided to 340B patients in the overall insured market?
- What additional oversight or claims standards are necessary to prevent duplicate discounts in Medicaid and other programs?

Other 340B Questions

Other questions raised implicate the 340B program indirectly. For example, in discussing whether to allow drug manufacturers to exclude certain rebates or discounts provided in value-based arrangements from average manufacturer price (AMP) and best price calculations under the Medicaid drug rebate program, HHS questions what the impact would be on 340B ceiling prices.

HHS also queries how regulatory changes to help Medicaid managed care organizations (MCOs) negotiate value-based pricing agreements with manufacturers would affect the 340B program.

Implications for Stakeholders

The singling out of the 340B program in the Administration's recent proposals to address high drug prices highlights the Administration's concerns about 340B. A number of the questions raised by HHS suggest interest in making changes to 340B that could have a significant impact on hospital finances and operations. For example, changes to the definition of a 340B-eligible patient, contract pharmacy use, or child site eligibility have the potential to significantly restrict access to 340B savings. Moreover, references in the RFI to "unintended consequences" and "intended purpose" suggest a belief that providers are not using 340B appropriately and a desire to restrict the program.

Stakeholders will have 60 days to submit comments after HHS formally publishes the RFI in the Federal Register. Baker Donelson policy advisors and attorneys are available to assist clients with the drafting of comments to share with the agency.

If you have questions regarding the content of this alert, please contact Sheila Burke.