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HHS and HRSA Defend 340B Discount Model Against Pharma Rebate Plan

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Summary of Changes

In the fall of 2024, several pharmaceutical companies – specifically, Eli Lilly and Company, Sanofi-Aventis U.S. LLC, Bristol Myers Squibb Company, and Novartis Pharmaceuticals Corporation – reacted to HRSA's decision to prevent them from implementing a rebate model for their respective 340B Programs by filing lawsuits against HHS and HRSA claiming that the Department and its subagency violated their rights under the Administrative Procedure Act and took actions that conflicted with the language of the 340B statutory section, 42 U.S.C. § 256b(a)(1).

In its Cross Motion for Summary Judgment and Opposition to Plaintiffs' Motions for Summary Judgment, HHS and HRSA set forth several arguments undermining the Plaintiffs' argument that 42 U.S.C. § 256b(a)(1) necessarily permits and that the Pharmaceutical Pricing Agreements between HHS and pharmaceutical manufacturers should allow use of a rebate model to structure the 340B program. Specifically, HHS and HRSA asserted the following:

1. Under 42 U.S.C. § 256b(a)(1), pharmaceutical companies participating in the 340B Program must take "into account any rebate or discount, as provided by the Secretary," which permits HHS to establish whether the 340B ceiling price is set via an upfront discount or a subsequent rebate. HHS did not violate the Plaintiffs' rights by requiring HHS approval of any rebate program prior to its implementation.

2. HHS did not make a decision that ran counter to the evidence when it decided to block the Plaintiffs' use of a rebate program because the rebate program: (1) did not align with the requirements of the established Pharmaceutical Pricing Agreements which require that the manufacturers offer each covered entity covered drugs, at or below the applicable ceiling price if such drug is made available to any other purchaser at any other price; (2) did not align with the historic mechanisms by which 340B price reductions have been effectuated; and (3) was not necessary for Plaintiffs to ensure that discount duplication was not occurring.

3. HHS did not violate the Plaintiffs' substantive due process rights because: (1) the Plaintiffs' were not required to participate in the 340B Program; and (2) the Plaintiffs' were afforded mechanisms to have their request to utilize a rebate program heard by HHS and HHS responded to this request.

Although the PHSA contains no specific language as to whether the required reduction in price should be obtained by an initial reduction, i.e., discount, in the purchase price or a rebate after purchase, HHS and HRSA argued that historically, price reductions have been effectuated through discounts on the purchase price. The agencies further asserted that the manufacturers cannot unilaterally change the purchase structure without first obtaining approval from HRSA. HHS and HRSA maintained that Congress did not "contemplate a regime where a manufacturer could choose whether to offer discounts or rebates without approval of the Secretary." HHS and HRSA relied on the *status quo,* which has remained in place for over 30 years and has established how the 340B Program benefits are administered. Still, HHS and HRSA note in the motion that they are declining "to disturb the *status quo* for now."[1]

340B Program health care providers cannot walk away with full confidence that the *status quo* will never change, but for now, HHS does not intend to make a significant change in the mechanism by which 340B Program savings are administered.

Next Up for 340B Providers

1. Monitoring progress of cases

While the cross motion for summary judgment filed by HHS and HRSA demonstrates their continued adherence to the up-front payment model, it is important for 340B covered entities and impacted pharmacies to be mindful of the potential implications of a rebate model rather than up-front discounts on covered drugs. If the payment mechanism were to change to a rebate model, 340B health care providers could face significant financial increases in costs associated with purchasing drugs at WAC and waiting for manufacturers to determine whether they are eligible for rebates to offset or reduce costs. In addition, a rebate model would potentially result in operational costs for 340B covered entities and pharmacies because they would be required to designate resources to gather and submit information to the drug manufacturers post-purchase to obtain the rebates. It is unclear whether such a model would affect other billing and reimbursement mechanisms under Medicare and Medicaid. Further, a rebate model could result in reduced 340B savings because the manufacturers would have the power to determine eligibility for 340B discounts using their own interpretations of the PHSA.

2. Identify appropriate advocacy mechanisms

Several interested provider organizations have already collectively filed or submitted motions requesting to file amicus briefs in support of HHS and HRSA's cross motion for summary judgment. Pursuing advocacy mechanisms is one way to try to prevent the specific impacts that altering the administration of the 340B Program would have on your organization and similarly situated organizations, but other avenues exist and will arise as this contentious topic continues to be actively debated between 340B covered entities, pharmacies, 340B pharmaceutical manufacturers, and HHS.

For additional guidance on the best ways to react to the analysis provided in this HHS and HRSA filing and to stay informed about potential changes to the payment mechanism for the 340B Program, please contact Alissa D. Fleming, Gregory M. Fliszar, Katherine Denney, or any member of the Baker Donelson Health Law Team.

[1] *Eli Lilly and Company v. Robert F. Kennedy, Jr., et al.*, Case No. 1:24-cv-03220-DLF (2024), Doc. 35-1, pg. 13.