Government to Drop Appeal of 340B Rebate Pilot Program Injunction

On January 12, the U.S. Department of Justice filed a short correspondence with the U.S. Court of Appeals for the First Circuit indicating that the government intends to return the approvals of manufacturer rebate pilot plans to the Health Resources and Services Administration (HRSA), for reconsideration and to dismiss its appeal of a preliminary injunction that paused the implementation of the controversial 340B Rebate Pilot Program that HRSA had attempted to implement on January 1, 2026.

This effectively means that 340B stakeholders can expect that the status quo will continue and the 340B Rebate Pilot Program will not be reinstated by the courts through this appeal process. Nonprofit, safety-net health care providers that are registered as 340B covered entities can continue to order pharmaceutical products at the discounted 340B price instead of having to outlay for product at manufacturer list prices (known as WAC), submit data, and wait for a rebate payment to get to the 340B price or invest in administrative overhead to monitor the new rebate process.

We think it is reasonable to expect that HRSA's reconsideration will take some time and that there will be an implementation period for any new attempts at a HRSA-required or HRSA-approved rebate program.

We also think it is reasonable to expect that many pharmaceutical manufacturers will continue to fight for more control and transparency in the 340B program and will continue attempts to reduce the scope of 340B discount availability through a variety of means at the state and federal levels. Any of these efforts should be expected to increase administrative burdens and decrease 340B margin for 340B covered entities.

We also have no reason to believe that that pharmaceutical manufacturers will cease funding (directly or indirectly) negative campaigning against the 340B program and particular 340B covered entities, including the potential for more misleading political ads suggesting the 340B program is rife with the misappropriation of taxpayer funds, is growing through widespread abuse, or is linked to abortion or health care for undocumented immigrants (notably, there has not been documentation supporting these allegations and 340B margin is not funded by taxes). In these efforts, the funding by manufacturers far exceeds the collective funding of all 340B covered entities to attempt correcting the record or counter-messaging.

Unfortunately, the burden of these efforts by manufacturers has a significant impact on the ability of 340B covered entities to realize the goals of the 340B program in offering margin from sales of discounted 340B products to help 340B covered entities stretch scarce resources to provide essential safety-net health care in their communities. Most 340B covered entities are small, local and rural clinics and hospitals that have a hard time automating or staffing new requirements. We hope that future changes to the 340B program at the state and federal level will prioritize ensuring those safety-net providers are receiving the funding they need to continue providing these essential services.

This blog post was drafted by Beth Siemer and Aurora Kammerer, attorneys in the St. Louis, Missouri, and Overland Park, Kansas, offices of Spencer Fane, respectively. For more information, visit spencerfane.com.

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