

Court of Appeals Weighs in on 340B

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Timing is everything. In yesterday's post on 340B, I stated in closing:

There is still one more shoe to drop. On May 4, 2018, the U.S. Court of Appeals heard oral arguments in the expedited appeal of American Hospital Association v. Azar, challenging the 30% CMS Medicare Part B OPPS reimbursement cut for many outpatient drugs purchased through 340B. We are all awaiting that decision.

Within hours the Court of Appeals issued a **ruling** in which it upheld the lower court's dismissal of the lawsuit on jurisdictional grounds. The Court found that because the original case was filed in advance of processing any actual claims under the new reimbursement formula, any challenge was theoretical in nature. The plaintiffs needed to have actual claims that were submitted and processed under the new reimbursement formula, and exhaust any administrative appellate rights on those claims, before a court challenge can be filed and heard.

The plaintiffs could apply for a rehearing of the case or even appeal to the Supreme Court, but the prospects are not good. It is likely the plaintiffs will file a new lawsuit based on claims submitted and processed after the changed formula went into effect, on which any administrative appeal rights have been exhausted.

It is important to note that both the lower court and the Appellate Court decisions were based on procedure, not on merit. No court has weighed in on the merits of plaintiffs' challenge that CMS exceeded its authority with the 340B Part B reimbursement cut, just that the challenge was filed prematurely.

Still, as far as CMS, I stand by my prediction from this morning. I will be watching and waiting for new administrative proposals by CMS to further change 340B reimbursement in Medicare and possibly Medicaid.

Authors