340B UPDATE: D.C. COURT OF APPEALS UPHOLDS MEDICARE PART B REIMBURSEMENT CUT

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U.S. Health Care Alert

On July 17, 2018, the U.S. Court of Appeals for the District of Columbia rendered a decision upholding the reimbursement cut that took effect on January 1, 2018. The reimbursement cut applies to drugs purchased under the 340B Drug Discount Program ("340B Program" or "340B") that are reimbursed under the Medicare hospital Outpatient Prospective Payment System ("OPPS"). Accordingly, 340B covered entity hospitals will continue to absorb the financial impact of the 28.5% cut under the OPPS for the time being. However, as discussed below, the Court of Appeals left the door open to consider the merits of the case in the future, so many hospitals are assessing the financial impact of the cuts and taking steps to preserve potential remedies if the cuts are ultimately overturned or reversed.

BACKGROUND

As discussed in previous alerts (see here and here), the Centers for Medicare and Medicaid Services ("CMS") issued a final rule last year reducing reimbursement under the OPPS for 340B drugs from the drug's average sales price ("ASP") plus 6% to the current rate of ASP minus 22.5%. The American Hospital Association ("AHA") and other trade organizations, along with several lead plaintiff hospitals, challenged CMS's authority to implement the cut under the Social Security Act.

In December 2017, the U.S. District Court for the District of Columbia dismissed the lawsuit on the grounds that the plaintiffs had failed to satisfy the Social Security Act's requirements, which state that prior to challenging such a decision in federal court, a plaintiff must first: (1) present a valid claim to the Secretary of Health and Human Services ("HHS") (a requirement which is not waivable by the court); and (2) exhaust administrative remedies relating to the claim (which may be waived). [1] At the time the District Court issued its ruling, the OPPS cut had not yet taken effect.

CIRCUIT COURT OF APPEALS DECISION

In its opinion, the Court of Appeals noted that the key issue before the District Court was "not *whether* [plaintiffs] may obtain review of their challenges to the new OPPS reimbursement regulation, but when and *how* they may do so through the special-review scheme for Medicare claims." [2] In other words, must the plaintiffs first present a claim to the HHS Secretary prior to filing the suit, and could the plaintiffs satisfy this presentment requirement by filing comments in informal rulemaking and/or having begun filing OPPS claims for 340B drugs while the case was pending?

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The Court of Appeals affirmed the District Court's determination that it lacked subject matter jurisdiction due to the fact that the plaintiffs failed to satisfy this presentment requirement. Moreover, based on the rationale that a regulation cannot be equated to a "final decision" as defined in Section 405(g) of the Social Security Act, the Court concluded that the plaintiffs cannot satisfy the presentment requirement through comments submitted pursuant to an informal rulemaking process. The Court also held that the presentment requirement cannot be satisfied by "retroactive creation of district-court jurisdiction based on new facts that occurred only during an appeal." [3]

Notably, the Court of Appeals did not go any further to consider the exhaustion issue, nor did it consider the merits of the plaintiffs' case. As a result, the AHA has already indicated that it plans to refile the lawsuit now that hospitals have filed OPPS claims for reimbursement for 340B drugs, stating in a press release: "We will continue our fight to reverse these unwarranted cuts and protect access for patients, and we expect to refile promptly in district court." [4]

If the plaintiffs decide to refile, the District Court will once again be faced with the question of whether the plaintiffs are required to exhaust any administrative remedies and whether the decision by CMS to impose the reimbursement cut is even subject to appeal.

PROVIDER TAKE AWAYS

Given that a resolution on the merits will likely be delayed, many 340B covered entities are considering whether or not to file appeals on 340B drug claims that are reimbursed under the OPPS, which may be required if the courts hold in the next round that in addition to presentment, providers must have also exhausted their administrative remedies. With this said, CMS has suggested it will summarily deny any appeals on the basis of the lower rate because CMS reimbursement decisions are not reviewable under the Social Security Act. However, as noted above, the Court of Appeals did not provide any additional clarity on whether hospitals would be required to have filed and pursued such appeals in order to preserve the right to claim the higher reimbursement that would result if the courts ultimately reverse the OPPS cut on 340B drugs. Providers should analyze the administrative and financial cost of appealing 340B claims under the OPPS, and pursuing these appeals within CMS during the pendency of the litigation, against the benefit that could be attained if the courts rule in this manner.

K&L Gates' Health Care practice can assist 340B covered entities in conducting this analysis and will continue to closely monitor developments in the 340B Program OPPS litigation and an otherwise dynamic reimbursement landscape. Looking ahead, stakeholders should assess their compliance with existing 340B Program and related Medicare, Medicaid, and commercial 340B billing requirements and continue to plan for future changes to the 340B Program that could result from the OPPS litigation, additional regulatory action, or potential legislation from Congress.

Notes:
[1] *See* American Hospital Ass'n v. Hargan, No. 17-2447 (RC) (D.D.C. Dec. 29, 2017), ECF No. 24.
[2] American Hospital Ass'n v. Azar, No. 18-5004 (D.C. Cir., July 17, 2018) (emphasis in original).
[3] *Id*.

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[4] "Hospital Groups to Continue Fight to Reverse Cuts for 340B Hospitals," *American Hospital Association*, https://www.aha.org/press-releases/2018-07-17-hospital-groups-continue-fight-reverse-cuts-340b-hospitals (July 17, 2018).

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