

340B UPDATE: D.C. DISTRICT COURT OVERTURNS OPPTS 340B REIMBURSEMENT CUT FOR CY 2018

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Health Care Alert

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On December 27, 2018, the U.S. District Court for the District of Columbia sided with the plaintiffs by granting a permanent injunction striking down the reimbursement cut for drugs purchased under the 340B Drug Discount Program ("340B" or "340B Program") finalized in the Centers for Medicare & Medicaid Services ("CMS") Calendar Year ("CY") 2018 Outpatient Prospective Payment System ("OPPS") final rule ("Final Rule"). However, in the opinion, the district court ordered supplemental briefing to determine an appropriate remedy, potentially including payment adjustments for all CY 2018, and declined to apply the ruling to application of the cut in the CY 2019 OPPS final rule. [1]

BACKGROUND

The Final Rule established a reduction in OPPS reimbursement for certain 340B drugs provided by a hospital paid under the OPPS that is not excepted from this payment adjustment. Effective January 1, 2018, these 340B drugs have been paid at the drug's average sales price ("ASP") minus 22.5 percent — a 28.5 percent cut from the previous rate of ASP plus 6 percent. The American Hospital Association, the Association of American Medical Colleges, and America's Essential Hospitals, along with several lead plaintiff hospitals (collectively, the "Plaintiffs") filed suit challenging the authority of the Department of Health and Human Services ("HHS") under the Social Security Act to implement the cut. For additional background on the Plaintiffs' complaint and other procedural history, please see our prior alerts here and here.

SUMMARY OF OPINION

As a threshold matter, the district court waived the requirement that the Plaintiffs exhaust all administrative remedies prior to judicial review on the grounds that requiring additional efforts in this regard would be futile. [2] Judge Rudolph Contreras also found that the Social Security Act did not preclude the court from reviewing the Plaintiffs' argument that the HHS Secretary's actions were *ultra vires*, i.e., outside the Secretary's legal authority. Applying this doctrine, Judge Contreras then concluded that the Secretary's decision to cut OPPS reimbursement for drugs acquired under the 340B Program was, in fact, *ultra vires*. In particular, although the Secretary argued that HHS has broad authority to make "adjustments" to OPPS reimbursement rates under the Social Security Act, Judge Contreras concluded that the term "adjustments" as used under the statute does not include the power to make "basic and fundamental changes" to the statutory scheme. [3] Given that the CY 2018 OPPS rate adjustment makes significant changes (i.e., a reduction of nearly 30 percentage points) to payments for thousands of pharmaceutical products, Judge Contreras wrote that the Secretary "fundamentally altered the statutory scheme" established by Congress and therefore exceeded his authority. [4] In reaching its decision, the

court went beyond denying HHS' Motion to Dismiss; rather, Judge Contreras took the extra step of indicating the case could be decided on the merits and granted the Plaintiffs' Motion for a Permanent Injunction.

UNCERTAIN EFFECTS

While the legal outcome is favorable for 340B covered entities, the remedies at this point are unclear. The Plaintiffs had asked the court to apply the OPPS CY 2017 reimbursement methodology of ASP plus 6 percent to OPPS payments for 340B drugs made in 2018. The Plaintiffs also requested that the Secretary pay the named hospitals and "all 340B Program participants who are members of the Association Plaintiffs" [5] the difference between the payments received in 2018 and the higher rate that applied in 2017. [6] However, the court found that the Plaintiffs' requested relief would be "highly disruptive" due to the OPPS budget neutrality requirement under the Social Security Act, which required that CMS increase non-drug payments under the OPPS (including payments to non-340B hospitals) to make up for the 340B reimbursement cut under the Final Rule. [7] The result would be a "quagmire that may be impossible to navigate considering the volume of Medicare Part B payments made in 2018." [8] Accordingly, Judge Contreras requested supplemental briefing on the appropriate remedy to apply. The parties have 30 days from the order to respond with supplemental briefing, and responses are due within 14 days after the supplemental briefs are filed.

Of particular note, Judge Contreras further indicated that the order is not applicable to the CY 2019 OPPS rule, which took effect on January 1, 2019. In this regard, Judge Contreras noted that the Plaintiffs have not presented any claims to challenge the CY 2019 rule, as required under the Social Security Act. [9] Therefore, the opinion as drafted has no immediate impact on CY 2019 rates.

NEXT STEPS

Ultimately, it is not clear how HHS intends to respond to the opinion in terms of 2018 claims or Medicare reimbursement for drugs and biologicals purchased under the 340B Program more broadly moving forward. In short, many of these issues are pending further guidance from HHS and substantive briefing by the parties to the litigation. K&L Gates will be closely following the supplemental briefs, motions, and appeals in this litigation, as well as any HHS announcements regarding the impact of the litigation on claims filing and processing. Stakeholders should do likewise and be prepared to adjust claims filings as directed.

Further litigation is also likely as a result of this decision. As noted above, the court's ruling does not extend to reimbursement under the CY 2019 OPPS rule, as claims for 2019 had not been filed at the time of the ruling. Additionally, the ruling does not extend to similar reimbursement cuts for non-expected provider-based departments finalized in the CY 2019 Medicare Physician Fee Schedule ("PFS") rule, discussed in our prior alert. Given the favorable precedent set by the court's decision, we anticipate that additional litigation may follow for the reimbursement changes in the CY 2019 OPPS and PFS rules as providers begin to file impacted claims.

As we begin 2019, 340B Program reimbursement and regulation remain at the forefront of issues affecting 340B Program stakeholders. K&L Gates' health care practice regularly assists clients in planning, assessing, and responding to commercial, state, and federal reimbursement program changes impacting 340B covered entities. We will continue to closely monitor developments in the 340B Program and ongoing litigation related to the same.

NOTES:

[1] Memorandum Opinion Denying Defendants' Motion to Dismiss; Granting Plaintiffs' Motion for a Permanent Injunction; Denying as Moor Plaintiffs' Motion for a Preliminary Injunction, *Am. Hosp. Ass'n v. Azar*, No. 18-2084 (Dist. D.C. Dec. 27, 2018), https://ecf.dcd.uscourts.gov/cgi-bin/show_public_doc?2018cv2084-25 (hereinafter cited as "Opinion").

[2] Opinion at 17.

[3] *Id.* at 25.

[4] *Id.* at 28.

[5] *Id.* at 33–34.

[6] In this regard, Judge Contreras' decision indicates it is only for the benefit of hospitals that are a member of at least one of these three associations named as plaintiffs.

[7] Opinion at 34.

[8] *Id.* at 35.

[9] *Id.* at 34. Notably, in December 2017, the U.S. District Court for the District of Columbia dismissed the Plaintiffs' initial lawsuit on similar grounds, holding 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 HHS (a requirement which is not waivable by the court), and (2) exhaust administrative remedies relating to the claim (which may be waived). See *Am. Hosp. Ass'n v. Hargan*, No. 17-2447 (RC) (D.D.C. Dec. 29, 2017), ECF No. 24. At the time of its prior ruling, the OPPS cut had not yet taken effect.

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