

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

American Hospital Association, *et al.*,

Plaintiffs,

—v—

Xavier Becerra, Secretary of Health and Human
Services, *et al.*,

Defendants.

Case No. 1:18-cv-2084 (RC)

**RESPONSE TO PLAINTIFFS’ SUPPLEMENTAL NOTICE IN SUPPORT
OF PLAINTIFFS’ MOTION TO HOLD UNLAWFUL AND REMEDY
DEFENDANTS’ PAST UNDERPAYMENT OF 340B DRUGS**

Defendants respectfully submit this response to Plaintiffs’ Supplemental Notice, ECF No. 83.

HHS continues to work diligently to determine an appropriate remedy for claims implicated by the Supreme Court’s decision in the context of an Outpatient Prospective Payment System (“OPPS”) program that processes more than 100 million claims a year. Just weeks after the Supreme Court’s decision was issued, HHS invited public comment on a remedy. ECF No. 71, at 5, 11-12. It promptly implemented this Court’s September 28, 2022 order to change rates it would pay providers for the remainder of 2022 and developed and announced its remedial policy for 2023 claims in the recently issued calendar year 2023 OPPS final rule. HHS continues to work through the many complicated issues that must be resolved in order to unscramble the proverbial egg and determine an appropriate remedy for claims submitted from 2018 through September 27, 2022. It has committed to announcing that component of a remedy through special notice-and-comment rulemaking, which it intends to complete before the 2024 OPPS rulemaking cycle is

complete. Although in the typical case, an agency might reasonably wait for a remand before turning its attention to remedies, here HHS has taken these steps even though this case remains in active litigation and has not yet been remanded.

Despite the agency's proactive steps to facilitate a remedy, Plaintiffs insist that the agency already has had "enough time to decide how to implement a remedy in this case." Notice at 3. Respectfully, Plaintiffs fail to appreciate the complexities involved, the time necessary to determine an appropriate remedy, and the benefit of soliciting comments from all stakeholders on HHS's specific remedy proposal. In fact, HHS modified how it would incorporate the increased payments for 340B-acquired drugs into its 2023 budget neutrality factor in response to comments from stakeholders, including Plaintiffs here. *See HHS, Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, Final Rule* (Nov. 1, 2022), at 659–60 (reducing proposed budget neutrality factor from 4.04% to 3.09%).¹ Indeed, the Court has already observed that the need to resolve thorny issues of budget neutrality was "likely to cause disruption" on remand. ECF No. 50, at 20 n.19. And despite Plaintiffs' suggestion to the contrary, Notice at 1-2, Defendants never indicated that they would announce the remedy in the 2023 OPPS final rule.

In any event, the fact that Defendants have not yet determined the remedy is not relevant to Plaintiffs' pending motion. Plaintiffs believe that fact is grounds for the Court to "order HHS to promptly repay 340B hospitals," *id.* at 3, but they cite no decision of any court to support that proposition, and Defendants are aware of none. Injunctive relief is not appropriate simply because an agency has not determined a remedy for a claim that remains in active litigation.

¹ <https://www.cms.gov/files/document/cy2023-hospital-outpatient-prospective-payment-system-and-ambulatory-surgical-center-final-rule.pdf>

In closing, Plaintiffs are wrong to suggest that the government is deliberately delaying a decision on remedies. Notice at 2. Plaintiffs' supposed evidence for this weighty allegation is nothing more than their own subjective belief about the amount of time necessary for the agency process to unfold. It is not surprising that the parties have different perspectives on the appropriate timeline for the agency's decision, but that difference does not justify Plaintiffs' accusation of bad faith on the part of Defendants. As noted, Defendants promptly responded to the Supreme Court's decision in this case and have been working towards the different components of a remedy over the past months, even while the litigation of this case continues. Moreover, as Plaintiffs concede, Defendants acted swiftly in response to the Court's recent remedial order. Notice at 3.² Defendants are working diligently on the component of a remedy addressing 2018 through 2022, and there is simply no merit to Plaintiffs' unsupported speculation to the contrary.

Respectfully submitted,

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² Plaintiffs argue that "[b]y swiftly acceding to the Court's order, HHS fatally undermined its arguments that such an order would be administratively difficult or unconstitutional." Notice at 3 (citing ECF No. 71 at 10). But Defendants raised those administrative and constitutional arguments in response to Plaintiffs' request that the Court direct HHS to issue an interim final rule within 30 days. *See id.* The Court, however, ordered different relief. Thus, the fact that Defendants were able to quickly implement the Court's Order does not undermine Defendants' arguments, which, again, pertained to a different type of relief.

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