

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

THE AMERICAN HOSPITAL
ASSOCIATION,
et al.,

Plaintiffs,

–v–

XAVIER BECERRA, in his official capacity as
the Secretary of Health and Human Services, *et*
al.,

Defendants.

Civil Action No. 18-2084 (RC)

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

Plaintiffs respectfully submit this Supplemental Notice to advise the Court that Defendants have now issued the 2023 Hospital Outpatient Prospective Payment System (OPPS) Final Rule, which has implications for Plaintiffs’ Motion, ECF 69.

1. Following the Supreme Court’s unanimous decision in this case, Defendants solicited “public comments on the best way to craft any proposed, potential remedies affecting calendar years 2018–2022.” 2023 OPPS Proposed Rule, 87 Fed. Reg. 44,505, 44,649 (July 26, 2022).

2. In briefing before this Court, Defendants have repeatedly emphasized this pending rulemaking, arguing that “the Court should remand to allow the agency to take appropriate remedial action following receipt of public comment that will inform the agency’s decision-making on these complex issues.” HHS Opp’n, ECF 76 at 19. “Indeed,” Defendants underscored, “that process is already underway.” *Id.* Defendants further stated that “[t]he public comment period

ended on September 13,” and so the “Court should remand and allow the agency to complete that administrative process, instead of cutting that process short and imposing Plaintiffs’ preferred remedy.” HHS Opp’n, ECF 76 at 19; *see id.* at 2 (“the Court should allow the agency to complete th[e] administrative process and devise an appropriate solution.”); HHS Opp’n ECF 71 at 2 (same).

3. On November 2, 2022, Defendants issued the 2023 OPPS Final Rule.¹ The Department of Health and Human Services (HHS) began by noting that the “majority” of public comments urged it to (A) “promptly pay hospitals the additional amounts owed for 340B drug payments from 2018 to 2022”; and (B) “not seek recoupment of funds received ... for the increased rates for non-drug services from 2018 through 2022, arguing that budget neutrality can be applied only prospectively and that there is no precedent for a retrospective budget neutrality adjustment.” *Id.* at 649.

Defendants chose to do nothing. Instead of announcing a remedial plan, Defendants again adopted an approach that will indefinitely delay any remedy, stating that they “plan to issue a separate proposed rule detailing our proposed remedy for CYs 2018 to CY 2022 in advance of the CY 2024 OPPS/ASC proposed rule.” *Id.* at 652. Importantly, the Final Rule only states that Defendants will issue a *proposed* rule sometime before the release of the CY 2024 OPPS Proposed Rule next summer; the agency makes no commitments whatsoever about when a *final* remedial proposal will be released. The government’s attempt at continued delay is unacceptable.

¹ Although not yet published in the Federal Register, the Final Rule is available on HHS’s website. HHS, *Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, Final Rule* (Nov. 1, 2022) (“2023 OPPS Final Rule”), https://www.cms.gov/files/document/cy_2023-hospital-outpatient-prospective-payment-system-and-ambulatory-surgical-center-final-rule.pdf.

HHS has had more than enough time to decide how to implement a remedy in this case. As this Court is well-aware, this was already the *second* comment period in which HHS asked for input regarding how to implement a remedy. After this Court held the 2018 and 2019 OPSS Rules unlawful, HHS solicited comments in the 2020 OPSS Proposed Rule on “approaches to the CY 2018 and 2019 remedy . . . so we are poised to propose those policies in the CY 2021 rule if necessary.” 2020 OPSS Proposed Rule, 84 Fed. Reg. 39,504 (Aug. 9, 2019); *see also* 2020 OPSS Final Rule, 84 Fed. Reg. 61,142, 61,325–27 (Nov. 12, 2019). Despite having already sought comment twice, HHS has again deferred announcing any specific remedy proposal and indicated that it will solicit a *third* round of comments. But no further public comments are needed for the agency to remediate years of illegal underpayments and for Defendants to promptly pay 340B hospitals the difference between ASP plus 6% and what they were previously paid, without seeking retroactive claw backs in the name of budget neutrality. In fact, following this Court’s September 28 Order with respect to the remainder of 2022, Defendants quickly announced that they would cease their illegal conduct and be able to “reprocess claims our contractors paid on or after September 28, 2022.”² By swiftly acceding to the Court’s order, HHS fatally undermined its arguments that such an order would be administratively difficult or unconstitutional. *See* HHS Opp’n, ECF 71 at 10.

Given HHS’s continued delay in implementing or even proposing a remedy on its own, Plaintiffs respectfully submit that the Court should order HHS to promptly repay 340B hospitals.³

² CMS, *Hospital Outpatient PPS* at <https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps>.

³ The 2023 OPSS Final Rule issued this week also discredited HHS’s argument that another remedial option would involve conducting a new cost survey. HHS Opp’n at 12. In the 2023 OPSS

For the reasons Plaintiffs have explained in prior briefing, ordering Defendants to do so is no longer a “close question” (Mem. Op. ECF No. 50 at 16), and Defendants’ continued delay only cinches that conclusion. “At this point, it seems that only an order from this Court can provide a fair remedy for the Defendants’ illegal conduct.” Pls.’ Reply at 5.

Dated: November 4, 2022

Respectfully submitted,

/s/ William B. Schultz

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Final Rule, HHS pushed back against a commenter who asked that it conduct a cost survey to inform drug payment rates for 2024, noting that “we are under no statutory obligation to necessarily conduct a drug cost survey to inform the payment rate for any given year.” 2023 OPFS Final Rule at 656. HHS added that GAO has recommended that HHS conduct cost surveys “only occasionally” because they “create a burden for hospitals and the data collector.” *Id.* This response from HHS further demonstrates that it “is impossible to take HHS’s suggestion of a new acquisition cost survey seriously as a practical matter,” Pls.’ Reply at 8, and HHS should not be allowed to invoke the possibility of a survey to avoid being ordered to repay 340B hospitals the difference between what they were previously paid and ASP plus 6%.

CERTIFICATE OF SERVICE

I hereby certify that, on November 4, 2022, I caused the foregoing to be electronically served on counsel of record via the Court's CM/ECF system.

/s/ Ezra B. Marcus _____

Ezra B. Marcus