

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)

**MOTION TO VACATE THE UNLAWFUL PORTION OF THE 2022 OPPTS RULE**

The Supreme Court has now unanimously held that, unless Defendants rely on the survey data required by the statute, they cannot reimburse drugs acquired under the 340B Program at a lower rate than other drugs under the Medicare Outpatient Prospective Payment System (“OPPS”). *American Hospital Association v. Becerra*, 142 S. Ct. 1896 (2022). Yet every day, under the 2022 OPPTS Rule that is now in effect, Defendants continue to do exactly that, in violation of their legal obligations as announced by the unanimous Supreme Court. Under the 2022 OPPTS Rule, Defendants have “continue[d] [their] payment policy . . . to pay for separately payable drugs and biologicals, ***with the exception of 340B-acquired drugs***, at ASP+6%,” while paying for 340B drugs “at a rate of ASP minus 22.5%.” 2022 OPPTS Rule, 86 Fed. Reg. 63,458, 63,640 (Nov. 16, 2021) (emphasis added). With every passing day, Defendants continue to underpay for 340B drugs pursuant to this unlawful “exception.”

Plaintiffs ask the Court expeditiously to hold the “exception” contained in the 2022 OPPS Rule unlawful, as the Supreme Court did for the identical 2018 and 2019 rules, and to forbid Defendants from underpaying 340B claims for the remainder of 2022. Specifically, Plaintiffs ask the Court to: (1) vacate the portion of the 2022 OPPS rule that carves out 340B drugs from the general payment rate for separately payable drugs and (2) order Defendants to immediately begin reimbursing 340B drugs at ASP plus 6% for the remainder of 2022—the same rate that would apply if they had not been acquired under the 340B Program and the same rate that Defendants recently conceded was appropriate for 2023. *See* CMS, 2023 OPPS Proposed Rule. 87 Fed. Reg. 44,502, 44,647 (July 26, 2022) (“We fully anticipate applying a rate of ASP+6 percent to [340B drugs] in the final rule for CY 2023, in light of the Supreme Court’s recent decision.”).

Plaintiffs are concurrently filing a separate motion addressing relief for Defendants’ unlawful action from 2018 through the first portion of 2022. But because time is particularly of the essence with respect to the remainder of 2022, Plaintiffs seek a standalone ruling on the 2022 OPPS Rule so that Defendants immediately comply with their statutory obligations for the remainder of the year. Plaintiffs are contemporaneously moving for the instant Motion to be considered on an expedited basis.<sup>1</sup>

## **BACKGROUND**

As the Court is aware, Plaintiffs have challenged Defendants’ policy, beginning with the 2018 OPPS Rule, of cutting Medicare reimbursements for drugs acquired under the 340B Program from ASP plus 6% to ASP minus 22.5%. The Supreme Court has now held that, “absent a survey of hospitals’ acquisition costs, HHS may not vary the reimbursement rates for 340B hospitals”

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<sup>1</sup> Concurrently with filing this Motion, Plaintiffs are submitting an unopposed motion to file a Second Supplemental Complaint that would add a challenge to the 2022 OPPS Rule (as well as the 2020 and 2021 OPPS Rules) to this case.

relative to other hospitals, and “HHS’s 2018 and 2019 reimbursement rates for 340B hospitals were therefore contrary to the statute and unlawful.” *Am. Hosp. Ass’n v. Becerra*, 142 S. Ct. 1896, at \*8 (2022).

While this litigation has been pending, Defendants have issued OPPS Rules each year, through and including the 2022 OPPS Rule that is now in effect, in which they continued their policy of reimbursing 340B-acquired drugs at a rate of ASP minus 22.5%. *See* 2022 OPPS Rule, 86 Fed. Reg. 63,458, 63,648 (Nov. 16, 2021). For each year from 2018 through 2022, Defendants have continued to reimburse drugs that are *not* acquired under the 340B Program at a rate of ASP plus 6%. *See, e.g., id.* at 63,640–41. And for each year from 2018 through 2022, Defendants have paid these differential rates to 340B and non-340B hospitals without relying on the requisite survey data.

Defendants continued their policy of underpaying claims for 340B-acquired drugs despite being aware of the possibility that the rate cut would ultimately be held unlawful. In particular, when Defendants issued the 2022 OPPS Rule, they knew that the Supreme Court had granted certiorari in this case and would issue a decision in 2022 that could invalidate the reimbursement cut for 340B drugs. *See id.* at 63,644 (referencing grant of certiorari). Nevertheless, Defendants carried forward their policy of reimbursing 340B drugs at the reduced rate of ASP minus 22.5% for 2022, without issuing any express contingency plan in the 2022 OPPS Rule that would go into effect in the event that the reimbursement cut were to be held unlawful. Notwithstanding the Supreme Court’s ruling, Defendants are continuing to reimburse 340B drugs at a lower rate than drugs not acquired under the 340B Program pursuant to the exception contained in the 2022 OPPS Rule that is still in effect.

Moreover, in the proposed 2023 OPSS Rule that was recently published on July 15, 2022, Defendants effectively acknowledged that they have no intention of stopping their unlawful underpayments of 340B drugs for the duration of 2022. To the contrary, Defendants solicited comments on “how to apply the Supreme Court’s recent decision” to 2022. 2023 OPSS Proposed Rule, 87 Fed. Reg. at 44,649. Given Defendants’ stated timeline for accepting and considering public comments, the fact that they have solicited comments on “how to apply the Supreme Court’s decision” to 2022 means that, unless this Court directs them to stop, they plan to indefinitely continue violating their statutory obligations as announced by the unanimous Supreme Court.

### **ARGUMENT**

The Court should expeditiously hold the 2022 OPSS Rule unlawful because it provides for paying drugs acquired under the 340B Program at a lower rate than drugs not acquired under the 340B Program and enjoin Defendants from underpaying 340B claims for the remainder of 2022.

Under the circumstances here, the law amply supports vacating the relevant provisions of the 2022 OPSS Rule, which carve out 340B drugs from the general reimbursement rate for separately payable drugs of ASP plus 6% and provide for them to be paid at a reduced rate of ASP minus 22.5%. Vacating the carve-out for 340B drugs would mean that Defendants would immediately be required to pay for those drugs at the *general* rate for separately payable drugs: ASP plus 6%. At minimum, the Court should order Defendants within 30 days to take action, through an interim final rule or otherwise, providing that 340B drugs will be reimbursed at a rate of ASP plus 6% for the remainder of 2022.

**I. The Court Should Hold Unlawful Defendants’ Policy of Underpaying for 340B Drugs Pursuant to the 2022 OPPS Rule.**

The Supreme Court has held that HHS has no authority to reduce reimbursement rates for a single class of hospitals, such as 340B hospitals, absent the statutorily required cost survey data. As the Court explained, “absent a survey of hospitals’ acquisition costs, HHS may not vary the reimbursement rates for 340B hospitals.” *Am. Hosp. Ass’n v. Becerra*, 142 S. Ct. 1896, at \*8. Because in 2022—just as in 2018 and 2019—Defendants are continuing to pay 340B Hospitals at a lower rate than non-340B hospitals without relying on the required survey data, the “reimbursement rates for 340B hospitals [are] contrary to the statute and unlawful.” *Id.*

The Supreme Court’s recent ruling definitively establishes that Defendants’ policy of underpaying 340B drugs without relying on the required survey data is unlawful. Defendants recognize this, but have thus far refused to halt their unlawful 2022 policy on their own. *See* 2023 OPPS Proposed Rule, 87 Fed. Reg. at 44,648–49 (“[I]n light of the Supreme Court’s recent decision in *American Hospital Association*, we fully anticipate reverting to our prior policy of paying for drugs at ASP+6 percent, regardless of whether they were acquired through the 340B program for CY 2023. . . . We are still evaluating how to apply the Supreme Court’s recent decision to cost years 2018-2022.”). Accordingly, the Court should hold unlawful Defendants’ adherence to that policy in the 2022 OPPS Rule.

**II. The Court Should Vacate the Unlawful Portions of the Rule So that Defendants Will Cease Underpaying for 340B Drugs for the Remainder of 2022.**

The law amply supports immediately vacating the unlawful payment reduction for 340B drugs. Vacating the exception for 340B drugs would result in those drugs being paid at the general rate for separately payable drugs for 2022 of ASP plus 6%. *See* 2022 OPPS Rule, 86 Fed. Reg. at

63,640–41 (finalizing 2022 policy of “pay[ing] for separately payable drugs and biologicals, *with the exception of 340B-acquired drugs*, at ASP+6 percent” (emphasis added)).

Applying the factors set forth in *Allied Signal, Inc. v. U.S. Nuclear Regulatory Comm’n*, 988 F.2d 146 (D.C. Cir. 1993), there could hardly be a stronger case for vacatur. Now that the Supreme Court has resolved the merits of the parties’ dispute, “the extent of doubt whether the agency chose correctly” is zero, *Allied Signal, Inc.*, 988 F.2d at 150; there is *no* chance of the same rule being adopted on remand; and there is little chance of disruption via “an interim change that may itself be changed,” *id.* at 150–51, since the law gives CMS no leeway for the remainder of 2022. Furthermore, Defendants are on weak ground to complain of any disruption that might be caused by a mid-year injunction, having failed on their own either to take reasonable steps to prepare for the possibility that their policy would be held unlawful mid-year, or to act promptly in the wake of the Supreme Court’s ruling.

If the Court vacates CMS’ unlawful policy of carving out 340B drugs as an “exception” from the generally applicable payment rate for separately payable drugs under the OPPS Rule, then 340B drugs would immediately become subject to the generally applicable payment rate of ASP plus 6% for the remainder of the year. CMS described the reduced payment rate for 340B drugs as an *exception* to the general payment rate for separately payable drugs:

For 2022, we proposed to continue our payment policy that has been in effect since CY 2013 to pay for separately payable drugs and biologicals, *with the exception of 340B-acquired drugs*, at ASP+6 percent in accordance with section 1833(t)(14)(A)(iii)(II) of the Act (the statutory default). We proposed to pay for separately payable nonpass-through drugs acquired with a 340B discount at a rate of ASP minus 22.5 percent (as described in section V.B.6). . . .

2022 OPPS Rule, 86 Fed. Reg. at 63,640–41 (emphasis added); *see also id.* at 63,660 (“Separately payable drugs are paid at a rate of ASP+6 percent *with the exception of 340B-acquired drugs*, for

which we proposed to pay ASP minus 22.5 percent.”) (emphasis added). If the Court vacates the 340B-specific exception to the general payment rate, then Defendants will immediately be required to pay for 340B drugs at the general rate that would otherwise apply absent the exception. *See Am. Hosp. Ass’n v. Azar*, 2019 WL 5328814, at \*2 (D.D.C. Oct. 21, 2019) (“CMS created an exception to OPPS reimbursement rates for only E&M services and only at applicable off-campus provider-based departments; vacating the rate reduction for [those services] merely reverted such off-campus provider-based departments to the general rule.”), *rev’d on other grounds*, 964 F.3d 1230 (D.C. Cir. 2020).

If the Court decides against vacating the unlawful rate reduction, then the Court should order Defendants to take action, such as through an interim final rule, providing that within 30 days of the Court’s Order, and for the remainder of 2022, 340B drugs will be reimbursed at a rate of ASP plus 6%—the same rate that would apply if they had not been acquired under the 340B Program. *See* 2022 OPPS Rule, 86 Fed. Reg. at 63,640–41.

### **CONCLUSION**

It is in the interest of all parties that Defendants correct the unlawful aspects of the 2022 OPPS Rule as quickly as possible. Plaintiffs respectfully request that the Court hold unlawful and vacate Defendants’ policy of underpaying for 340B drugs in the 2022 OPPS Rule so that, for the remainder of 2022, Defendants pay for 340B drugs at a rate of ASP plus 6%. Now that the unanimous Supreme Court has invalidated Defendants’ policy of underpaying 340B hospitals, Defendants should be ordered to immediately cease that policy for the remainder of 2022.

Dated: August 3, 2022

Respectfully submitted,

/s/ William B. Schultz

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## **CERTIFICATE OF SERVICE**

I hereby certify that, on August 3, 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