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)**

REPLY IN SUPPORT OF PLAINTIFFS' MOTION TO VACATE
THE UNLAWFUL PORTION OF THE 2022 OPPS RULE

The Department of Health and Human Services (HHS) is asking the Court for permission to continue violating the law, each and every day, for the remainder of 2022. HHS agrees that "the 2022 OPPS Rule *is unlawful*," which is an unavoidable concession in light of the Supreme Court's decision in this case. Opp'n to Pls.' Mot. to Vacate the Unlawful Portion of the 2022 OPPS Rule ("HHS Opp'n"), ECF 71 at 5 (emphasis added). Yet in the same breath, HHS asks to be allowed to apply its unlawful policy to future reimbursement decisions for a period of time which *it alone* would determine. HHS's position should not be countenanced, especially given how much time HHS has had to prepare for the possibility of its policy being held unlawful (at least since the Supreme Court granted certiorari on July 2, 2021) and how long it has known to an absolute certainty that its policy violates the law (since the Supreme Court's decision on June 15, 2022).

HHS's central error is that it confuses fixing *past* violations with avoiding *future* ones. This basic distinction disposes of most of HHS's arguments. HHS asks the Court to decline to vacate the 2022 OPPS Rule so that it can have "an opportunity to fashion a remedy to *reimburse Plaintiffs' economic losses*." HHS Opp'n at 7 (emphasis added). But HHS never explains what it plans to do to stop violating the law going forward, so that it does not compound its past mistakes with months and months of more unlawful reimbursements. HHS's efforts to complicate this simple issue contravene blackletter administrative law: "When a rule is contrary to law, the ordinary practice is to vacate it." *Am. Bankers Ass'n v. Nat'l Credit Union Admin.*, 934 F.3d 649, 673 (D.C. Cir. 2019) (citation omitted).

None of HHS's arguments related to administrative disruption or budget neutrality, and none of the cases it cites, comes close to supporting the proposition that it should be allowed to continue applying a concededly unlawful policy to future payment determinations for the remainder of 2022. The Court should vacate the unlawful payment rate reduction for 340B drugs in the 2022 OPPS Rule.

ARGUMENT

Vacating the unlawful payment rate exception for 340B drugs is warranted under a straightforward application of the factors set forth by the D.C. Circuit in *Allied Signal, Inc. v. U.S. Nuclear Regulatory Commission*, 988 F.2d 146 (1993). Under *Allied Signal*, "[t]he decision whether to vacate depends on 'the seriousness of the order's deficiencies (and thus the extent of doubt whether the agency chose correctly) and the disruptive consequences of an interim change that may itself be changed.'" 988 F.2d at 150–51 (citation omitted). Here, there is no doubt that HHS chose incorrectly. After all, HHS concedes that "the 2022 OPPS Rule is unlawful." HHS Opp'n at 5. Nor is there any risk that vacatur would cause disruption by resulting in "an interim

change that may itself be changed," *Allied Signal*, 988 F.2d at 150–51, because there is only one way for HHS to comply with its statutory obligations for the remainder of the year: apply the same payment rate to 340B hospitals that currently applies to all other hospitals. As HHS acknowledges, "the 2022 OPPS Rule is unlawful *insofar as it varies the reimbursement rate for 340B hospitals from ASP plus six percent* absent a survey of hospitals' acquisition costs." HHS Opp'n at 5 (emphasis added). Since HHS has no cost survey data to support a different payment rate for 2022, the *only* way it can cease violating the law is to stop "var[ying] the reimbursement rate for 340B hospitals from ASP plus six percent." *Id.* The Court should therefore vacate HHS's policy of paying for 340B drugs at a rate less than ASP plus 6%.

I. There is only one way for HHS to stop violating the law for the remainder of 2022.

As this Court previously noted, courts typically do not afford an agency an opportunity to craft a remedy on its own "when there is only one rational course for the agency to follow upon remand." Order, ECF 50 at 15 (quoting *Berge v. United States*, 949 F. Supp. 2d 36, 43 (D.D.C. 2012)). Here, there is only one way for the government to stop violating the law going forward because the rationale of the Supreme Court's ruling dictates what HHS must do to fix its violation: reimburse 340B hospitals at the same rate as non-340B hospitals for the remainder of 2022. *See* Pls.' Mot. to Vacate, ECF 67 at 6; Pls.' Mot. to Hold Unlawful and Remedy Defendants' Past Underpayment of 340B Drugs, ECF 69 at 4–6.

HHS's misguided effort to identify multiple remedial "option[s]," HHS Opp'n at 8, only highlights that it is wrongly focused on *retrospective* relief and has no intention of trying not to commit further statutory violations during 2022. Notably, HHS is not arguing, as it did when the parties briefed remedies issues in 2019, *see, e.g.*, ECF 36 at 5–6, that it should be given another chance to try to "adjust" payment rates for 340B hospitals downward from ASP plus 6% (for

example, to ASP plus 3%). To the contrary, HHS has acknowledged (as it must) that "the 2022 OPPS Rule is unlawful insofar as it varies the reimbursement rate for 340B hospitals from ASP plus six percent." HHS Opp'n at 5. HHS is not suggesting that it has any "option" other than reimbursing 340B hospitals at a rate of ASP plus 6% for complying with the law for the remainder of 2022.

The principal "option" that HHS identifies is "adjusting reimbursement rates in future years" to make up for underpayments in the past. HHS Opp'n at 10; *see also id.* at 7–8. Citing *Shands Jacksonville Medical Center, Inc. v. Azar*, 959 F.3d 1113 (D.C. Cir. 2020), in which it increased rates for 2017 to offset a challenged reduction in 2014–2016, HHS argues that "[s]imilarly, here, a prospective rate increase would be an option for 2022." HHS Opp'n at 8. But the suggestion of an offsetting rate increase in a future year *presumes* underpayments for the rest of 2022; it does not avoid them. Making up for past underpayments—whether through future rate increases or otherwise—has nothing to do with stopping the unlawful underpayments for the remainder of this year. In putting forth this supposed "option for 2022," HHS is simply asking for permission to continue violating the law for the remainder of the year and make up for it later.

HHS further demonstrates that it has no serious plan to stop its statutory violations before the end of 2022 when it suggests that it could "conduct a survey of hospital acquisition costs," which "could validate the rates at issue in this litigation or otherwise inform the appropriate remedy." HHS Opp'n at 9. It is fanciful for HHS to suggest that it could design a survey, issue it to hospitals, receive responses, analyze the cost survey data, and propose and finalize payment rates based on the data, all before the end of 2022. The last time HHS attempted to collect cost-survey data, the process took *over a year*, and the flawed survey did not meet the requirements of

the statute.[1] Currently, HHS has not even proposed a survey methodology, let alone issued a survey or received responses. In May 2019, upon holding the 2019 OPPS Rule unlawful, this Court observed that it would be "nearly impossible" for the Secretary to re-implement the same payment rates on remand using cost survey data under 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(I), "given the Secretary's lack of relevant data." ECF 50 at 17. That is equally true now—if not more so—given that we are in August instead of May.

A review of HHS's Opposition demonstrates that it has not actually identified "multiple ways" to stop violating the law going forward. HHS Opp'n at 8. Instead, each of its supposed options reveals that HHS has no real plan to stop underpaying 340B claims for the remainder of 2022 and will continue violating the law unless this Court orders it to stop. Because there is "only one rational course for the agency to follow upon remand," *see* Order, ECF 50 at 15, the Court should vacate the 2022 OPPS Rule's unlawful 340B exception to the generally applicable drug reimbursement rate of ASP plus 6%.

II. HHS has not demonstrated that significant disruption would result from complying with the law.

In resisting vacatur, HHS invokes this Court's prior observation that vacating the 2018 and 2019 OPPS Rules could "be highly disruptive." HHS Opp'n at 10 (quoting ECF 50 at 18). But HHS is on much weaker footing now to complain of disruption than when the parties last briefed remedies issues in 2019. HHS has had ample time to consider possibilities and to prepare for this

[1] HHS first published its proposed survey methodology on September 30, 2019, and it proposed to set a payment rate based on the survey data in the 2021 OPPS Final Rule, which was published over a year later on December 29, 2020. *See* 2021 OPPS Final Rule, 85 Fed. Reg. 85,866, 86,044–045 (Dec. 29, 2020) (describing the survey timeline). HHS ultimately chose *not* to rely on this survey in setting reimbursement rates for 2021 and 2022, and, as several commenters pointed out at the time, HHS could not have relied on the survey because it was fundamentally flawed. *See* 2021 OPPS Rule, 85 Fed. Reg. 85,866, 86,050–52 (Dec. 29, 2020). Notably, although HHS now suggests that it could "conduct a survey of hospital acquisition costs," HHS Opp'n at 9, it never suggests that it could rely on the survey it previously conducted to set rates for the remainder of 2022.

situation in a manner that might reduce disruption. It has been *more than three years* since HHS first solicited comments on possible remedies in the 2020 OPPS Proposed Rule. *See* 2020 OPPS Proposed Rule, 84 Fed. Reg. 39,398, 39,504–05 (Aug. 9, 2019). And once the Supreme Court granted certiorari in July 2021, HHS knew that a decision finding its policy to be unlawful was at least possible and would require a mid-year change. Put simply, HHS has had more than enough time to consider what to do in this circumstance. It cannot legitimately complain about any disruption that might be caused by vacating the unlawful exception for 340B drugs for the remainder of 2022, and the Court should not incentivize this kind of apparent failure to appropriately prepare for an entirely foreseeable scenario. *See Environmental Def. Fund v. FERC*, 2 F.4th 953, 976 (D.C. Cir. 2021) (vacating FERC certificate that authorized construction of a natural gas pipeline, even though vacatur would disrupt the already-operational pipeline, because "remanding without vacatur under these circumstances would give the Commission incentive to allow building first and conducting comprehensive reviews later," and the court "certainly d[id] not wish to encourage such an approach given the significant powers that accompany" the challenged pipeline certificate).

Significantly, HHS has not suggested that vacatur could cause disruption of the type described in *Allied Signal*—disruption caused by "an interim change *that may itself be changed*." 988 F.2d at 150–51 (emphasis added); *see also Long Island Power Auth. v. FERC*, 27 F.4th 705, 717 (D.C. Cir. 2022) ("[D]isruptive consequences matter only insofar as the agency may be able to rehabilitate its rationale." (citation omitted)). This type of disruption is not a possibility here, because, as already discussed, there is only one way for HHS to comply with the law for the remainder of 2022—reimburse 340B hospitals at a rate of ASP plus 6%. In this important respect, the circumstances have changed since the Court last considered remedies in 2019 (and even then,

the Court viewed vacatur as "a close question"). Order, ECF 50 at 16. Where "the controlling [statutory] provision is unambiguous, [an agency] cannot rehabilitate its preferred interpretation on remand," and vacatur is ordinarily the appropriate remedy. *Long Island Power*, 27 F.4th at 717.

Instead, HHS appears to be warning about disruption from *any* change of an OPPS payment rate in the middle of the year. But HHS never details what the administrative difficulty would be, other than to note that an offsetting budget-neutrality adjustment would be required, which Plaintiffs address below. And in any event, HHS has offered no convincing explanation of why it should be allowed to continue violating the law simply because it would be difficult to stop.

Nevertheless, if the Court concludes that HHS has demonstrated that vacating the unlawful payment rate reduction for 340B drugs will cause disruption, Plaintiffs have suggested as an alternative that Defendants could be given 30 days within which to stop underpaying for 340B drugs. Similarly, it is well established that the Court could vacate the rule while staying its vacatur for a short period. *See, e.g.*, *Bauer v. DeVos*, 332 F. Supp. 3d 181, 186 (D.D.C. 2018) (staying vacatur order for a period of 30 days). But ultimately, concerns about the difficulty in coming into compliance with the law are not a legitimate basis to excuse HHS from promptly meeting its statutory obligations going forward. And with each passing day that HHS's unlawful policy remains in effect, Plaintiffs and their members continue to miss out on crucial funds that they rely on to provide important medical services to underserved communities.

III. The Court need not decide anything about budget neutrality in vacating the unlawful payment reduction for 340B drugs in the 2022 OPPS Rule.

Throughout this litigation, HHS has wielded the specter of budget neutrality as a shield against judicial intervention of any kind. Again here, HHS argues that it should not be ordered to do anything because "[a]bruptly increasing payments for drugs purchased through the 340B

Program for the remainder of 2022 would raise complicated questions regarding budget neutrality." HHS Opp'n at 2; *see id.* at 9 (invoking "the need to resolve complicated questions relating to budget neutrality").

First, HHS never describes with any specificity what the complications would be with making a budget neutrality adjustment to offset increased payments to 340B hospitals for the remainder of 2022. Instead it makes blanket assertions that a budget neutrality adjustment will be complicated. Moreover, many of the "complicated questions regarding budget neutrality" that HHS has previously identified relate to *retrospective* relief and would not be implicated by vacating the unlawful 340B payment policy going forward. For example, HHS previously warned that "accounting for th[e] budget neutrality requirement would set the Agency on a course to recoup funds paid under a previous rule, and therefore unsettle the expectations of beneficiaries and those who had been paid, and raise the serious logistical problems of recoupment." ECF 31 at 10. There would of course be no such concerns with a *prospective* budget neutrality adjustment. It should come as little surprise that budget neutrality raises fewer complications when applied prospectively, because, as Plaintiffs have explained, budget neutrality is *designed* to apply prospectively under the OPPS. *See* Pls.' Mot. to Hold Unlawful and Set Aside Defendants' Past Underpayment of 340B Drugs, ECF 69 at 7–9. For the same reason, HHS's citation (at 11) to *Citrus HMA, LLC v. Becerra*, 2022 WL 1062990 (D.D.C. Apr. 8, 2022) is inapposite because, in denying vacatur in that case, the court cited possible budget-neutrality consequences of a

retrospective change. *See id.* at *10 (noting HHS's concern that vacatur "could require revising interdependent budget-neutral reimbursement decisions *already made*" (emphasis added)).[2]

Second, even if it is true that applying budget neutrality to the remainder of 2022 would be complicated, the Court need not deal with that issue in ordering vacatur. Whatever budget neutrality adjustment HHS may decide to make to offset the cost of restoring proper payments to 340B hospitals for the remainder of 2022, it can make that determination independently, on a completely separate track from an order vacating the relevant portion of the 2022 OPPS Rule. HHS could choose to make an offsetting adjustment immediately, or it could solicit public comments if it concludes that doing so would reduce litigation risk. *See* HHS Opp'n at 10 (raising concern that HHS could face litigation if it made budget neutrality adjustments without opportunity for public comment).

Ultimately, budget neutrality cannot be used as an all-purpose excuse for delay. HHS should not be permitted to invoke budget neutrality as a basis for continuing to act illegally going forward. HHS is obligated to cease violating the law by applying the general OPPS drug payment rate to 340B hospitals, and any other adjustments are for HHS to address independently. The fact that it will need to address additional issues does not counsel against immediately vacating the 2022 OPPS Rule, especially given how long HHS has had to prepare for the possibility that its policy of reducing payments for 340B drugs could be held unlawful.

[2] It is precisely because budget neutrality applies prospectively, not retrospectively, that Plaintiffs have explained elsewhere that HHS has no authority to retrospectively recoup prior OPPS payments in the name of budget neutrality. *See* Pls.' Mot. to Hold Unlawful and Set Aside Defendants' Past Underpayment of 340B Drugs, ECF 69 at 7–11.

IV. None of the cases HHS cites supports its argument that the Court should decline to vacate the unlawful payment reduction for 340B drugs.

It is bedrock administrative law that "[w]hen a rule is contrary to law, the ordinary practice is to vacate it." *Am. Bankers Ass'n v. Nat'l Credit Union Admin.*, 934 F.3d 649, 673 (D.C. Cir. 2019) (citation omitted); *accord, e.g.*, *Standing Rock Sioux Tribe v. U.S. Army Corps of Engineers*, 985 F.3d 1032, 1050 (D.C. Cir. 2021); *United Steel v. Mine Safety & Health Admin,*, 925 F.3d 1279, 1287 (D.C. Cir. 2019). That is what Plaintiffs ask for here: that the Court vacate the portion of the 2022 OPPS Rule that even HHS concedes is unlawful "insofar as it varies the reimbursement rate for 340B hospitals from ASP plus six percent." HHS Br. at 5.

HHS argues that there are other requirements that are a prerequisite to vacatur in this case—the four traditional injunctive relief factors, and "[i]n particular, . . . irreparable harm." HHS Opp'n at 6–7. But "[t]he irreparable harm standard . . . derives from the standard courts must apply in granting injunctive relief," and "*is not the standard for the less drastic APA remedy of vacatur*." *Oglala Sioux Tribe v. U.S. Nuclear Regulatory. Comm'n*, 896 F.3d 520, 535 (D.C. Cir. 2018) (emphasis added).

HHS cites a number of cases as supposedly supporting application of the injunction factors, *see* HHS Opp'n at 6–7, but a careful reading reveals that those cases differ markedly from this case, in that in each of them, a district court was asked to direct an agency to do something specific—not to simply vacate an existing rule. *See Ramirez v. U.S. Immigration and Customs Enforcement*, 568 F. Supp. 3d 10, 35–47 (D.D.C. 2021) (discussing specific steps plaintiffs had asked court to order agency to take to ensure future compliance with statutory requirements, in a case that did not involve vacatur); *Nat. Res. Defense Council v. U.S. Army Corps of Engineers*, 457 F. Supp. 2d 198, 203 (S.D.N.Y. 2006) (describing plaintiffs' request, in NEPA case, that

agency be enjoined from entering into future contacts related to the challenged project, in a case that did not involve vacatur). Indeed, in some of the government's cases, the district court's more limited step of *vacating* unlawful agency action was either directly affirmed or noted approvingly by the D.C. Circuit. *See Allina Health Servs. v. Sebelius*, 746 F.3d 1102, 1111 (D.C. Cir. 2014) ("The district court thus correctly concluded that vacatur was warranted."); *Palisades Gen. Hosp. Inc. v. Leavitt*, 426 F.3d 400, 403 (D.C. Cir. 2005) (affirming district court remedy ruling because "the district court had jurisdiction only to vacate the Secretary's decision . . . and to remand for further action consistent with its opinion. It did not . . . have jurisdiction to order" specific new action via injunction).

Here the unlawful payment reduction for 340B hospitals was *an exception*, carved out from the generally applicable payment rate of ASP plus 6% that remains in effect. *See* 2022 OPPS Rule, 86 Fed. Reg. 63,458, 63,640 (Nov. 15, 2021) (announcing policy "to pay for separately payable drugs and biologicals, *with the exception of 340B-acquired drugs*, at ASP+6%," but to pay for 340B drugs "at a rate of ASP minus 22.5%" (emphasis added)). Vacating the 340B exception to the general payment policy would amount to an order that 340B hospitals be reimbursed at a rate of ASP plus 6% only because HHS *already* applies a reimbursement rate of ASP plus 6% to hospitals not subject to the 340B exception.

Plaintiffs are asking *only* that the concededly unlawful exception in the 2022 OPPS Rule be vacated, which is "[t]he ordinary practice" when an agency has acted unlawfully. *United Steel*, 925 F.3d at 1287. Neither of the *Allied Signal* factors counsels against vacatur, and timeworn appeals to budget neutrality are no excuse for delay. Accordingly, the 2022 OPPS Rule should be vacated insofar as it sets a payment rate for 340B hospitals that is lower that the generally applicable payment rate of ASP plus 6%.

CONCLUSION

The Court should vacate the 2022 OPPS Rule insofar as it sets a payment rate for 340B hospitals that is lower that the generally applicable payment rate of ASP plus 6%.

Dated: August 17, 2022

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that, on August 17, 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