UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

THE AMERICAN HOSPITAL ASSOCIATION, *et al.*,

Plaintiffs,

–v–

ALEX M. AZAR II, in his official capacity as the Secretary of Health and Human Services, *et al.*,

Defendants.

Civil Action No. 18-2084 (RC)

PLAINTIFFS' RESPONSE BRIEF ON REMEDIES

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

STATUTES

OTHER AUTHORITIES

REGULATIONS AND FEDERAL REGISTER NOTICES

INTRODUCTION

On December 27, 2018, this Court found that the Secretary of HHS had exceeded his authority under 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II) in setting the 340B drug reimbursement rates in the 2018 OPPS Rule and ordered the parties to, within 30 days, submit supplemental briefs on the appropriate remedy. Defendants sought and were granted an extension of time to file their remedies brief, but, even with that extension, instead of filing a brief proposing an appropriate remedy, as this Court had ordered, Defendants filed a brief challenging the Court's holding and asking the Court to simply remand the case to HHS. Defendants claim that the Court should allow them unilaterally, on their own time schedule, to decide what remedy they should provide, if any. As Plaintiffs have demonstrated, however, there is a straightforward method by which HHS can make whole the Hospital Plaintiffs and member hospitals of Association Plaintiffs (hereinafter 340B hospitals) that received the reimbursement reductions that this Court found to be *ultra vires*.

This Court should reject Defendants' attempt to re-litigate the merits of the case or, alternatively, to decide on their own if the 340B hospitals are entitled to relief and if so what that relief might be. Defendants' proposal is nothing more than an attempt to further delay resolution of this matter, which Plaintiffs have been attempting to resolve since the illegal reductions in reimbursements for 340B drugs were first proposed 19 months ago. Instead this Court should direct Defendants to make 340B hospitals whole in the simple and expeditious manner proposed in Plaintiffs' opening brief.

ARGUMENT

I. An Open-Ended Remand Is Not the Appropriate Remedy in this Case.

In their opening brief on remedies, Defendants argue that the Court has only two options – to vacate the 2018 OPPS Rule or to remand to HHS so that HHS may determine a remedy – and because, according to Defendants, vacatur is not appropriate, the Court must remand to HHS. ECF No. 31 at 2-3. Defendants proposed approach should be rejected.

Although Plaintiffs are not urging this Court to vacate the portions of the 2018 OPPS Rule that the Court held unlawful, Defendants are wrong in arguing that vacatur of those portions of the rule is not supported by the facts of the case. Defendants correctly state that the determination is based on the two part test adopted in *Allied-Signal, Inc. v. U.S. Nuclear Regulatory Comm'n*, 988 F.2d 146, 150-51 (D.C. Cir. 1993). Likewise, Defendants correctly acknowledge that a party need not prevail on both factors. ECF No. 31 at 5, *citing Shands Jacksonville Med. Ctr. v. Burwell*, 139 F. Supp. 3d 240, 270 (D.D.C. 2015).

Plaintiffs, however, do not agree with Defendants' analysis of those factors. Contrary to Defendant's assertion (ECF No. 31 at 5), in this case there does not "remain[] 'doubt about whether the agency chose correctly.'" Rather, in finding the agency's action "*ultra vires*," this Court found that the agency definitely did not choose correctly. Moreover, as described in its opening brief and again below, the remedy Plaintiffs are proposing would not disrupt the Medicare program. In fact, it is a simplified way of achieving the same compensation that Plaintiffs are entitled to under HHS's own regulations, except it avoids a cumbersome process that would benefit no one.[1]

[1] Although this court has ruled that the almost 30% reduction in the 2018 OPPS Rule violates the statute, Defendants continue to process 2018 340B claims in accordance with that reduction, and are processing 2019 340B drug claims in accordance with the same reduction.

Defendants are also wrong in arguing that the Court's only option is to remand the case to HHS with no direction. In their opening remedies brief, Defendants state that the "proper remedy, *assuming plaintiffs are entitled to one*, is for the Court to remand the matter to the Agency" so that the Agency has "an opportunity to craft a remedy in the first instance." ECF No. 31 at 1, 3 (emphasis added). The court-ordered briefing provided HHS the very opportunity to "craft a remedy" that it is now arguing it should be permitted to develop on remand. But Defendants instead took that time to re-litigate the case by writing a brief challenging the Court's holding and asking the Court to allow HHS, in its own time, to decide on whatever remedy it chooses which may or may not include actual relief for Plaintiffs. (*See, e.g.*, ECF No. 31 at n.1: "Plaintiffs are not entitled to relief.")

As the Court noted in *Oglala Sioux Tribe v. U.S. Nuclear Regulatory Comm'n*, 896 F.3d 520, 537 (D.C. Cir. 2018), the D.C. Circuit has "never turned merely to a remand remedy when an agency refused to adhere to a statutory command in … an across-the-board fashion," and Defendants have cited no case in which the court simply remanded the matter to the agency after finding that the agency had violated the underlying statute, as the Court found here. Instead, in the cases cited by Defendants for the proposition that remand is appropriate, the government's actions were flawed, but potentially reparable. For example, in *Shands Jacksonville Med. Ctr. v. Burwell*, 139 F. Supp. 3d 240, the court found that HHS had violated the Administrative Procedure Act by adopting a 0.2 percent cut in payments for hospital inpatient services without providing the opportunity for meaningful comment on the Department's actuarial assumptions which HHS claimed supported that cut. *Id.* at 265. The court remanded the matter to give the Secretary the opportunity to remedy that error. *Id.* at 270-71. Apparently recognizing that it could not defend its methodology, HHS ultimately did an about face, abandoned the cut and

proposed a one-time increase to address the impact of the reduction. *Shands Jacksonville Med. Ctr. v. Azar,* CV 14-1477, 2018 U.S. Dist. LEXIS 217391, at *45 (D.D.C. Dec. 28, 2018).

Similarly, in *Am. Great Lakes Ports Ass'n v. Zukunft,* 301 F. Supp. 3d 99, 102 (D.D.C. 2018), this Court found that the Coast Guard had failed to justify its decision, not that the Coast Guard's decision violated the underlying statute. Thus, this Court remanded the case to the Coast Guard so that it would have the opportunity to supply the justification that the Court found lacking. *Id.* at 105. Likewise in *N. Air Cargo v. U.S. Postal Serv.*, 674 F.3d 852, 861 (D.C. Cir. 2012), the court remanded the case to the Postal Service to give it the opportunity to "advance reasonable interpretations of the provisions at issue." Even in *Allied-Signal,* the error was not that the rule violated the statute but that it was "inadequately supported," 988 F.2d at 150, and the court remanded the matter to the Nuclear Regulatory Commission so that the Commission would have the opportunity to substantiate its decision. *Id.* at 151. In each of those cases, there was something the agency could do to rectify its illegality – *e.g.*, better explain its decision/rationale or provide an opportunity to comment and respond. In the present case, on the other hand, there is no claim that HHS failed to provide an opportunity to comment or inadequately explain its decision, but rather, as the Court found, HHS imposed an almost 30% reduction that was *ultra vires:* the only remedy for this violation is for the agency to cease imposing the reductions in payments and to make the hospitals whose payments were cut under the 2018 OPPS rule whole.

The most comparable case cited by either party is *Cape Cod Hosp. v. Sebelius,* 630 F.3d 203 (D.C. Cir. 2011), which resulted in CMS recalculating payments due to hospitals using a formula that removed a statutory violation. Specifically, the court in *Cape Cod* found that HHS had incorrectly implemented a statutory provision regarding how certain wage indices should be

calculated. Because the calculation was cumulative, the error was carried forward each year, and as a result it had progressively reduced Medicare payments for inpatient services at affected hospitals. *Id.* at 214-216. Although HHS had corrected the calculation in 2008, it made it non-cumulative and made a one-time adjustment that accounted only for the error made in 2007. The court vacated the portions of the 2007 and 2008 regulations that were challenged and remanded to CMS to explain why it had not undone all of its prior errors, and, if it could not provide an explanation beyond its desire for finality, to recalculate the payments due to hospitals under a formula that removed all of the prior, progressive errors. *Id.* at 216. HHS corrected the errors that the hospitals had identified and settled past claims where hospitals had been underpaid by paying the hospitals corrected amounts going back several years.[2] If anything, Plaintiffs' proposed remedy in this case is simpler than the remedy in *Cape Cod*: this case involved a single error over a single year (although it is now extending to a second year) rather than the compounding errors over multiple years at issue in *Cape Cod.* Accordingly, the court should order CMS to revise its reimbursement rate for 340B drugs to eliminate the unlawful adjustment and instead use the method of reimbursement in the statute, which appears in the 2017 OPPS rule.

This case is also similar to a recent case in this district, *H. Lee Moffitt Cancer Ctr. & Res. Inst. Hosp., Inc. v. Azar*, 324 F. Supp. 3d 1 (D.D.C. 2018), *appeal voluntarily dismissed* Jan. 19, 2019 (No. 18-5277), in which the court ordered HHS to pay a cancer hospital an adjustment it had failed to pay in a prior year. A provision of the Affordable Care Act, 42 U.S.C. § 1395*l*(t)(18), had directed HHS to institute adjustments for cancer hospitals for services furnished beginning in 2011, but HHS had not made this adjustment until 2012. The court found

[2] *See* Rich Daly, *CMS may owe $3 billion; Payments to settle lawsuits in Medicare pay deals*, MODERN HEALTHCARE, Apr. 14, 2012, https://www.modernhealthcare.com/article/20120414/MAGAZINE/304149931.

that this decision was inconsistent with the statute and ordered HHS to adjust the cancer hospital's OPPS payments for the 2011 calendar year. *Id.* at 19. Similarly, here HHS's actions were inconsistent with the statute, and here the Court should order HHS to correct the payments to the 340B hospitals so that the hospitals receive the reimbursements required by law.

II. The Remedy Proposed by Plaintiffs Is Straightforward and Would Not Wreak Havoc.

As stated in our opening brief, this Court should order HHS to recalculate the payments due to 340B hospitals for 2018 claims to ensure that those hospitals receive payment based on the default rate of ASP plus 6% provided by the OPPS statute and the 2017 OPPS rule. 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II); 42 U.S.C. § 1395w-3a; 81 Fed. Reg. 79,562, 79,718 (Nov. 14, 2016). Hospitals that have already received payment for 340B claims using the 2018 methodology should receive a supplemental payment for those claims in an amount that equals the difference between the amount they received and the amount they are entitled to (based on the ASP plus 6% methodology) under this Court's order, plus interest. Claims that have not yet been paid should be paid in the full amount (the amount they would have received under the statutory default, ASP plus 6%, which is the rate set forth in the 2017 OPPS rule).[3]

Defendants argue against applying the statutory default/2017 OPPS rate to 2018 340B drug claims because according to Defendants "that rule was designed to last for only a year" (EFC No. 31 at 7), but in fact the 2017 OPPS rate of ASP plus 6% is the statutory default formula, which Defendants applied not only from 2013 until 2017, but also in 2018 and again in 2019 for all separately payable drugs other than non-exempted 340B Drugs. 42 U.S.C. §§ 1395*l*(t)(14)(A)(iii)(II), 1395w-3a; 77 Fed. Reg. 68,210, 68,386 (Nov. 15, 2012); 78 Fed.

[3] Plaintiffs opening brief explains how easily this can be accomplished using CMS's own National Claims History database. ECF No. 32 at 9-10.

Reg. 74,826, 75,010 (Dec. 10, 2013); 79 Fed. Reg. 66,770, 66,874 (Nov. 10, 2014); 80 Fed. Reg. 70,298, 70,439 (Nov. 13, 2015); 81 Fed. Reg. 79,562, 79,661 (Nov. 14, 2016); 82 Fed. Reg. 52,356, 52,490 (Nov. 13, 2017); 83 Fed. Reg. 58,818, 58,974 (Nov. 21, 2018).[4]

Defendants also argue that even though this Court rejected the reimbursement cut that HHS made in 2018, the Court recognized that HHS has the authority to make some adjustments under the statute and that this means Defendants may decide what that adjustment can be when deciding on a remedy. ECF No. 31 at 12. There is nothing in the administrative record, however, that supports any adjustment to the statutory default rate of ASP plus 6%. The administrative record is clear that the reduction Defendants made in the 2018 OPPS was based on acquisition costs of 340B hospitals, which this Court determined is not a legal basis for adjusting average sales price. HHS should not be permitted to go back in time and conjure up support for an adjustment it did not propose in 2017 when the 2018 OPPS Rule was published for comment.

Even though this Court had held that the near 30% reduction in reimbursements for 340B drugs was illegal, Defendants stunningly accuse Plaintiffs of seeking "windfall payments" (ECF No. 31 at 2). The Court should reject Defendants' arguments and instead issue an order requiring that the Hospital Plaintiffs and the members of the Association Plaintiffs be made whole, and that they receive the payments which they could obtain by going through a cumbersome

[4] In their opening brief, Defendants cite to several cases that discuss decisions that address whether a court should reinstate a rule that was previously in effect or remand to the agency to draft a replacement. ECF Mo. 31 at 7. As Defendants point out, *citing Oceana, Inc. v. Evans*, 389 F. Supp. 3d 4, 6 (D.D.C. 2005), the choice depends on the facts of the case. Plaintiffs are not asking the Court to vacate the 2018 OPPS rule and reinstate the 2017 OPPS rule but rather to direct HHS to reimburse 340B hospitals so that they are receiving (for 2018 340B claims) the amount that they would have received under the statute had the illegal cut to reimbursement not been implemented, which is equivalent to the statutory default amount that was in the 2017 OPPS rule.

administrative appeals process, which as Plaintiffs described in their opening brief (ECF No. 32 at pp. 7-8) is not in the best interest of Plaintiffs or Defendants.[5]

Making Plaintiffs whole would not, contrary to Defendant's assertion, be a retroactive application of the 2017 OPPS Rule, which Defendants argue would wreak havoc on the Medicare system by disrupting the administration of the processing and payment of Medicare claims and by imposing potential delays on payments for OPPS services and providers. ECF No. 30 at 2, 3, 9. As noted above, Plaintiffs proposed remedy is simple and straightforward: Plaintiffs are asking that HHS be required to pay 340B hospitals the full amount to which they are entitled under the statutory default.

Such a payment would also not cause the type of disruption that Defendants predict, and it is precisely the type of remedy that was found to be appropriate in *Cape Cod* and *Moffitt Cancer Ctr*. Moreover, while concerns about wreaking havoc may appropriately be considered when an agency's action is procedurally flawed, agencies should not be permitted to argue havoc to block a remedy when an agency failed to follow the law. *Moffitt Cancer Ctr.*, 324 F. Supp. 3d at 16 (concerns about judicial "meddling," or that requiring retroactive payments would "wreak havoc" in a fundamentally prospective payment system, are no reason to ignore congressional mandates in the OPPS statute).[6]

[5] Defendants have previously conceded that Plaintiffs would be entitled to reimbursement if they prevailed on the merits. Def.'s Mem. In Supp. Of Mot. To Dismiss, *Am. Hosp. Ass'n v. Hargan*, No. 17-cv-02447 (D.D.C.), ECF. No. 18 (citing 42 C.F.R. § 405.942(a); 42 C.F.R. § 405.980(a)(1)). The remedy Plaintiffs are requesting is a more efficient way of getting what Defendants said they could get under the administrative appeals processes to which they cited. It also would ensure that Defendants actually stop paying claims using the illegal method they adopted in the 2018 OPPS Rule.

[6] Defendants repeatedly claim that going back to correct their illegal behavior would wreak havoc, yet they continue to process claims in the illegal manner that will require them to go back and undo the error. Defendants should not be permitted to create the situation that results in the so-called havoc they fear and then argue that that very havoc blocks a remedy that would make Plaintiffs whole.

III. Budget Neutrality Does Not Preclude Providing an Appropriate Remedy.

Defendants claim that if the Court orders HHS to reimburse 340B hospitals for the 2018 OPPS Rule's unlawful reductions in reimbursements for 340B drugs, then all payments under the 2018 OPPS would have to be recalculated so that HHS can recoup the 3.2% increase it provided to all hospitals when it illegally cut the 340B reimbursement rates. There are several problems with this argument.

First, as set forth in our opening brief (ECF No. 32 at 8-9), there is a serious question as to whether HHS's budget neutrality authority applies to adjustments under Paragraph (14), which contains no budget neutrality authority. Now, after two proposed rules, two final rules, six briefs on the merits and 15 months in litigation, Defendants have for the first time cited to subparagraph (H) of Paragraph (14), 42 U.S.C. § 1395l(t)(14)(H), as their authority for imposing budget neutrality when HHS imposed the severe cut in payments for 340B drugs. Subparagraph (H), however, does not confer this authority. Instead it states that (after 2005) the Secretary shall consider "*additional* expenditures" resulting from payments under paragraph (14) (*i.e.*, payments for outpatient drugs) in establishing the conversion weighting and other adjustment factors under Paragraph (9). 42 U.S.C. § 1395*l*(t)(14)(H) (emphasis added). In the case at hand, however, the Secretary made cuts, not additions in expenditures. Moreover, Defendants never suggest that in the entire history of the OPPS program HHS has ever used subparagraph (H) to make additional expenditures budget neutral, and HHS did not rely on this subparagraph in its Federal Register notices explaining the 2018 OPPS rule. Thus, even if this were an additional expenditure, which it is not, it is unclear as to whether budget neutrality would apply directly to a paragraph (14) adjustment. The lawyer for the government admitted as much when she expressed doubt about

whether budget neutrality applies to all adjustments under paragraph (14). Oral Arg. Tr. 34:6-7, *Am. Hosp. Ass'n v. Azar*, No. 18-5004 (D.C. Cir. May 4, 2018), Doc. No.1770299.[7]

Second, to recoup the 3.2% increase on the basis of budget neutrality Defendants would have to undertake rulemaking and retroactively apply that rule. But section 1395hh(e)(1)(A) of Title 42 of the U.S. Code, cited by Defendants (ECF No. 31 at 8), bars retroactive application of a "substantive change in regulation" unless the Secretary can demonstrate that (i) such retroactive application is necessary to comply with statutory requirements or (ii) failure to apply the change retroactively would be contrary to public interest.

Here retroactive application is not necessary to comply with a statutory requirement since there is nothing in the OPPS statute that authorizes, much less requires, the Secretary to ensure that payments it makes to correct illegal cuts are budget neutral. Nor would retroactive application of such a regulation be in the public interest. As Defendants themselves assert, the retroactive application of the 2017 OPPS Rule would create "confusion and anxiety among Medicare beneficiaries," "require tens of thousands of hours of work, take at least a year," "add between $25-30 million in administrative costs, and significantly disrupt the administration of the processing and payment of Medicare claims," and could "impose potential delays in payments of OPPS services and providers," thereby affecting "the ability of Medicare beneficiaries to get needed service." ECF No. 31at 8-9.

Third, even if HHS had authority to apply budget neutrality to the reimbursement cuts in the 2018 OPPS Rule and even if the bar to retroactivity does not apply here, there is no authority in the statute to use the budget neutrality authority where payments are made as a result of a

[7] Plaintiffs are not suggesting that HHS's authority to recoup the 3.2% it paid to hospitals depends on whether or not HHS had the authority to impose budget neutrality in the first place. Regardless of whether they had that authority, as explained below, Defendants do not have the authority to recoup the 3.2%.

court order to remedy a violation of law. Just as HHS would not be able to ask hospitals to pay back some of what they were paid in a prior year to make up for the fact that HHS inaccurately estimated payments in one of its prospective payment rules (because there is no specific, statutory authority for such a payment), the budget neutrality provisions in the statute do not give HHS authority to require hospitals to pay back money they have already been paid as a result of HHS's erroneous reimbursement reductions.

IV. To the Extent that the Balance of Equities Should be a Consideration in Fashioning a Remedy, the Equities Here Strongly Favor Plaintiffs.

Relying on *Oglala Sioux Tribe v. U.S. Nuclear Regulatory Comm'n,* 896 F.3d 520, Defendants argue that, under the APA, equitable considerations require the open ended remand they seek. ECF No. 31 at n.2. In that case, the Oglala Sioux Tribe challenged the Nuclear Regulatory Commission's (NRC's) issuance of a license to mine uranium on the grounds that the NRC had failed to ensure that issuance of the license complied with the National Environmental Policy Act (NEPA). In deciding whether to remand the case without any direction, the court stated that "remand practice is informed by the APA" and that the NRC failed to identify any statute that authorized it not to comply with NEPA on equitable grounds. *Oglala,* 896 F.3d at 536. Likewise, there is nothing in the Medicare Act that authorizes HHS to ignore the statutory requirements, as it did here, on equitable grounds.

In *Oglala,* the court did not vacate the license the NRC had granted because it determined that the NRC could correct its failure to comply with NEPA without vacatur. *Id.* at 538. The court thus remanded the case to allow the NRC to correct its error consistent with the court's opinion. As noted above, HHS's action cannot stand because there is nothing HHS can do to make legal its 30% cut to 340B providers.

To the extent this Court considers the balance of equities in fashioning a remedy, that balance strongly favors Plaintiffs. First, as this Court found, HHS violated the law: its almost 30% cut to reimbursement for 340B drugs was *ultra vires*. This is an equitable consideration that counts against Defendants.

Second, Plaintiffs have taken every possible step to expedite the matter to mitigate any disruption that might be associated with Defendants' imposition of illegal pay cuts. Plaintiffs filed comments to the regulation at issue in August 2017. Plaintiffs filed a complaint before the 2018 OPPS final rule went into effect. That case was dismissed but then Plaintiffs filed a new case in September 2018. As soon as a claim was presented for 2019, Plaintiffs amended its complaint. Thus, Plaintiffs have tried to get this issue resolved as quickly as possible. HHS, on the other hand, has resisted every step of the way.

Defendants have continuously sought to delay a decision on the merits of this case, and they are doing the same thing now regarding a decision on an appropriate remedy. Equitable considerations do not favor HHS when, despite seeking to delay resolution, it now claims that it is too difficult to undo the illegal cuts to reimbursement because time has passed. In fact, it is undeniable that there is a strong interest on both sides in getting the case resolved. Defendants should not be permitted further delay at great costs to both Plaintiffs and themselves.

CONCLUSION

For the reasons set forth herein, this Court should order HHS to recalculate the payments due to Hospital Plaintiffs and hospital members of Association Plaintiffs for 2018 340B drug claims to ensure that those hospitals receive payment based on the statutory rate of ASP plus 6%, the same rate provided in the 2017 OPPS rule (and in the 2018 OPPS Rule for all separately payable drugs other than non-exempted 340B drugs). Hospitals that have received payment for

340B claims using the 2018 methodology prior to the Court's order should receive payment for those claims in an amount that equals the difference between the amount to which they are entitled (based on the ASP plus 6% methodology) under this Court's order and the amount they received, plus interest. Hospitals that have not received payment prior to the Court's order for 2018 340B claims should receive the full amount to which they are entitled (based on the ASP plus 6% methodology).

Date: February 14, 2019

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this 14th day of February, 2019, I electronically filed the foregoing Plaintiffs' Response Brief on Remedies by using the CM/ECF system. All parties to the case have been served through the CM/ECF system.

/s/ *Margaret M. Dotzel*
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