IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

THE AMERICAN HOSPITAL ASSOCIATION, *et al.*,	)	
Plaintiffs,	)	
v.	)	No. 1:18-cv-02084-RC
ALEX M. AZAR II, in his official capacity as Secretary of Health and Human Services, *et al.*,	)	
Defendants.	)	

DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION FOR A FIRM DATE BY WHICH DEFENDANTS MUST PROPOSE A REMEDY

INTRODUCTION

The Court determined that Defendants erred in setting the payment rate for drugs purchased through the 340B Program too low in the 2018 and 2019 Outpatient Prospective Payment System rules. Following briefing on the appropriate remedy, the Court remanded the matter to the Agency – the U.S. Department of Health and Human Services – without vacatur. The Court also noted that it "expects that the agency will act expeditiously to resolve the [ ] issues" identified by the Court, and required the agency to file a status report on or before August 5, 2019. Order, ECF No. 49 (May 6, 2019). In issuing this remedy, the Court did all that it could do. *County of Los Angeles v. Shalala*, 192 F.3d 1005, 1011 (D.C. Cir. 1999) ("Under settled principles of administrative law, when a court reviewing agency action determines that an agency made an error of law, the court's inquiry is at an end: the case must be remanded to the agency for further action consistent with the corrected legal standards.").

But Plaintiffs want more. Accordingly, they ask the Court to reconsider its order and instruct Defendants to file a proposed remedy by June 28, 2019, which the Court, in Plaintiffs' view, should then either accept or reject. Plaintiffs' Motion for a Firm Date By Which Defendants Must Propose a Remedy for Violations of the Medicare Act (Mtn.), ECF No. 51,

May 10, 2019. Plaintiffs' motion is flawed. Plaintiffs effectively are seeking reconsideration of the Court's May 6 Order, but never address the standard for doing so, which they cannot meet. Also, as noted above, establishing a firm deadline for Defendants to act on remand would run contrary to D.C. Circuit precedent regarding a court's role following remand. Moreover, Plaintiffs' proposal that the Court accept or reject a proposed remedy from the Agency runs aground on the text of the Administrative Procedure Act, 5 U.S.C. § 704, under which only "final agency action" may be reviewed by the Court. Finally, the arguments in support of selecting June 28 in particular as the deadline for the Agency to propose a remedy fare no better.[1]

For these and other reasons, as more fully explained below, the Court should deny Plaintiffs' motion.

ARGUMENT

Plaintiffs "request a modification [of] the Court's" order regarding the appropriate remedy. Mtn. at 2. The request should be denied. After considering four briefs (running almost 50 pages) devoted to the question of remedy, the Court decided to remand the matter to the Agency to enable it to take the "first crack at crafting appropriate remedial measures." ECF No. 50 at 2. Plaintiffs want the Court to modify – reconsider, really – this remedial decision, as they believe the Court should also "establish a firm date, June 28, 2019, by which HHS must propose a remedy to the Court." Mtn. at 2.

Plaintiffs never address the standard for reconsidering an interlocutory court order. And there is a good reason for that: Plaintiffs cannot satisfy the applicable standard.[2] Under Federal Rule of Civil Procedure 54(b), the Court has discretion to reconsider an interlocutory order." *Lewis v. District of Columbia*, 736 F. Supp. 2d 98, 102 (D.D.C. 2010). But "[t]he burden is on

[1] The Solicitor General has authorized appeal.

[2] The standard is the same for modification and reconsideration, *see Zalduondo v. Aetna Life Ins. Co.*, 845 F. Supp. 2d 146, 157 (D.D.C. 2012); this brief will use the term "reconsideration" because it is a more apt description of Plaintiffs' request, given that this Court has already issued an order on the appropriate remedy after full briefing.

the moving party to show that reconsideration is appropriate and that harm or injustice would result if reconsideration were denied." *United States ex rel. Westrick v. Second Chance Body Armor, Inc*., 893 F. Supp. 2d 258, 268 (D.D.C. 2012). "In general, a court will grant a motion for reconsideration of an interlocutory order only when the movant demonstrates: (1) an intervening change in the law; (2) the discovery of new evidence not previously available; or (3) a clear error in the first order." *Zeigler v. Potter*, 555 F. Supp. 2d 126, 129 (D.D.C. 2008), *aff'd*, No. 09-5349, 2010 WL 1632965 (D.C. Cir. Apr. 1, 2010) (quotation marks omitted). This stringent standard makes sense because "where litigants have once battled for the court's decision, they should neither be required, nor without good reason permitted, to battle for it again." *Singh v. George Washington Univ*., 383 F. Supp. 2d 99, 101 (D.D.C. 2005) (quotation marks omitted).

Plaintiffs' motion offers no "good reason" why Defendant should have to "battle . . . again" for the Court's decision. *Id.* at 101. It makes no explicit mention of any of the three factors ordinarily considered by courts when determining whether reconsideration is appropriate. *See* Mtn. The only ground (arguably) implicitly raised by their motion is "a clear error in the first order." *Zeigler*, 555 F. Supp. 2d at 129. But assuming that the Court had correctly determined that the agency made an error of law, the Court's remedial order did not err by failing to include a deadline for submitting a proposed remedy.

By remanding the matter to the Agency for it to determine the appropriate remedy in the first instance, the Court followed D.C. Circuit precedent. Again, that precedent holds that "[u]nder settled principles of administrative law, when a court reviewing agency action determines that an agency made an error of law, the court's inquiry is at an end: the case must be remanded to the agency for further action consistent with the corrected legal standards." *County. of Los Angeles*, 192 F.3d at 1011. Indeed, by asking the Court to issue an injunction ordering a specific remedial step after remand – i.e., the filing of a proposed remedial plan by June 28 – Plaintiffs seek to introduce error into the order. *See id*. ("Not only was it unnecessary for the court to retain jurisdiction to devise a specific remedy for the Secretary to follow, but it was error

to do so."); *see also Palisades Gen. Hosp. Inc. v. Leavitt*, 426 F.3d 400, 403 (D.C. Cir. 2005) ("Thus, under settled principles of administrative law, when a court reviewing agency action determines that an agency made an error of law, the court's inquiry is at an end: the case must be remanded to the agency for further action consistent with the correct legal standards. Accordingly, the district court had jurisdiction only to vacate the Secretary's decision rejecting the hospital's revised wage data and to remand for further action consistent with its opinion. It did not, as the hospital contends, have jurisdiction to order either reclassification based upon those adjusted wage data or an adjusted reimbursement payment that would reflect such a reclassification.") (quotation marks and citation omitted from parenthetical); *Bennett v. Donovan*, 703 F.3d 582, 589 (D.C. Cir. 2013) (making similar holding); *Northern Air Cargo v. U.S. Postal Serv.*, 674 F.3d 852, 861 (D.C. Cir. 2012) (making similar holding in non-APA case). Thus, there is no basis for reconsideration. That fact alone suffices to justify denial of Plaintiffs' motion.

But not only does Plaintiffs' motion misunderstand the Court's role following remand in an APA case, it also ignores the limits on the Court's authority to review agency action. Plaintiffs assert that Defendants should "propose a remedy" that "the Court can rule on." Mtn. at 2. Under the APA, however, the Court may review only "final agency action[s]." 5 U.S.C. § 704. A final agency action is one which marks the consummation of the agency's decision making process and is "one by which rights or obligations have been determined, or from which legal consequences will flow." *Bennett v. Spear*, 520 U.S. 154, 178 (1997). A *proposed* remedy is not final agency action. The proposed remedy here would not mark the consummation of the Agency's decision making process: Any remedy here likely would need to be instituted by rule after notice and the consideration of comments, and the proposed remedy would not have gone through that process. Moreover, a proposed remedy would not be an action that determines rights or obligations, nor would any legal consequences flow from it. Thus, the Court could not "rule on" (Mtn. at 2) the proposed remedy. *See, e.g., Holistic Candlers & Consumers Ass'n v.*

Food & Drug Admin., 664 F.3d 940, 943 (D.C. Cir. 2012) (holding that final agency action is a prerequisite to judicial review under the APA).

Another judge in this Court highlighted the limits imposed by § 704 in the context of a similar request to superintend an agency's crafting of a remedy after remand. In *Baystate Medical Center v. Leavitt*, the Court noted that the plaintiffs' requests to "assess[ ] the adequacy of the remand proceedings as they progress . . . comes perilously close to involving the Court in reviewing non-final agency actions." 587 F. Supp. 2d 37, 41–43 (D.D.C.), judgment entered, 587 F. Supp. 2d 44 (D.D.C. 2008). Here, the request goes beyond that in *Baystate Medical Center* by inviting the Court to reject, if it chooses to, the Agency's proposed (non-final) remedy. Mtn. at 2. As the D.C. Circuit has noted, however, on remand, "courts are not charged with general guardianship against all potential mischief in the complicated tasks of government," but instead may review only final actions under the APA. *PPG Indus., Inc. v. United States*, 52 F.3d 363, 365 (D.C.Cir.1995). This defect in Plaintiffs' position also independently supports denial of the motion. But there is more.

Plaintiffs make several arguments in support of selecting a date on or around June 28, 2019 as the deadline for Defendants to offer a proposed remedy. The fundamental substantive problem with these arguments, as explained above, is that there is no basis for requiring *any* specific deadline for the submission of a proposed remedy to the court. But there are other flaws.

Plaintiffs argue that June 28 is an appropriate deadline because "unless there is a Court order on the remedy in this case this summer, Defendants may issue a 2020 OPPS rule reducing reimbursements for 340B drugs by nearly 30% in violation of law, just as they did in 2018 and 2019." Mtn at 2. This argument is a nonstarter. For one thing, the Court already issued its order on remedy – it remanded the matter to the Agency. Given D.C. Circuit precedent on the limitations on remedies in APA cases, there is no reason to think that another remedial order is – or even can be – forthcoming. *See Countyof Los Angeles*, 192 F.3d at 1011. In addition, the forthcoming 2020 OPPS rule is not a subject of this case. *See* Am. Compl. In fact, the proposed

2020 OPPS rule has not been issued yet, much less the final one. And under the APA, as explained above, Plaintiffs cannot challenge a non-final agency action, such as a proposed rule. *See, e.g., In re Murray Energy Corp*., 788 F.3d 330, 334 (D.C. Cir. 2015) ("Proposed rules meet neither of the two requirements for final agency action."). What is more, as the D.C. Circuit held in *American Hospital Association v. Azar*, 895 F.3d 822, 826 (D.C. Cir. 2018), Plaintiffs cannot challenge the OPPS rule without first satisfying the Medicare statute's presentment requirement, which can be done only after implementation of the final rule. In short, Plaintiffs' complaints about a proposed rule that has not been issued or implemented yet, much less challenged in this case, should not affect this Court's decisions about the appropriate remedy with respect to the matters actually before the Court.[3]

CONCLUSION

For the reasons stated above, Plaintiffs' motion, which seeks reconsideration of the Court's remedial order, should be denied.

[3] Plaintiffs also argue that setting the deadline for the submission of a proposed remedy on or before June 28 could help the Medicare Trust Funds save money. Mtn. at 3. There are a number of problems with this argument, but it suffices here to say the following: 1) Defendants are keenly aware of the Government's duty to expend Trust Fund dollars carefully, as demonstrated by Defendants' decision to reduce the payment rate for drugs purchased through the 340B Program to eliminate an unnecessary windfall accruing to hospitals; and 2) federal law creates Boards of Trustees for the Medicare Trust Funds whose duty it is to "hold" the trust funds, 42 U.S.C. §§ 1395i(b), 1395t(b), and those Boards include Defendant Secretary Azar, but they do not include Plaintiffs.

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Respectfully submitted,

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