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.	)	

MEMORANDUM IN SUPPORT OF MOTION TO DISMISS NEW CLAIM AND OPPOSITION TO MOTION FOR PERMANENT INJUNCTION WITH RESPECT TO 2019 OPPS RULE

The Court concluded that the defendants – the U.S. Department of Health and Human Services and its Secretary (referred to collectively throughout as "the Agency") – acted in an *ultra vires* fashion by reducing the payment rate for drugs purchased through the 340B Program in the 2018 Outpatient Prospective Payment System ("OPPS") Rule, 82 Fed. Reg. at 52, 362. Memorandum Opinion ("Op."), Dec. 27, 2018, ECF No. 25. Plaintiffs have supplemented their complaint to challenge the analogous payment reduction in the 2019 OPPS Rule, Supplemental Compl., Feb. 8, 2019, ECF No. 34-3, and have filed a motion for a permanent injunction with respect to that rule, Motion for A Permanent Injunction Covering the 2019 OPPS Rule, Feb. 11, 2019, ECF No. 35.

The Court should deny plaintiffs' motion and dismiss the claims related to the 2019 OPPS Rule. The arguments provided in defendants' motion to dismiss and opposition to plaintiffs' motion for a preliminary injunction with respect to the 2018 OPPS Rule provide ample bases for rejecting plaintiffs' current motion and for dismissing their new claim, *see* Defendants'

Motion to Dismiss and Opposition to Plaintiffs' Preliminary Injunction Motion, Sept. 14, 2018, ECF Nos. 14-15; Reply in Support of Defendants' Motion to Dismiss, Oct. 10, 2018, ECF No. 20, and defendants incorporate those arguments as if stated here. Defendants recognize that the Court has rejected those arguments in the context of the 2018 OPPS Rule, but respectfully request that the Court reconsider its conclusion in the context of the 2019 OPPS Rule.

For example, with respect to the 2019 OPPS Rule, the Court should not find that that the Agency acted in an *ultra vires* manner. "To challenge agency action on the ground that it is *ultra vires*, [plaintiffs] must show a *patent* violation of agency authority." *Fla. Health Scis. Ctr., Inc. v. Sec'y of Health & Human Servs.*, 830 F.3d 515, 522 (D.C. Cir. 2016) (emphasis added).[1] To that end, the D.C. Circuit has explained that non-statutory "review may be had only when the agency's error is patently a misconstruction of the Act . . . or when the agency has disregarded a specific and unambiguous statutory directive . . . or when the agency has violated some specific command of a statute . . . . Garden-variety errors of law or fact are not enough." *Griffith v. Fed. Labor Relations Auth.*, 842 F.2d 487, 493 (D.C. Cir. 1988).

There has been no violation of Agency authority, as Defendants explained in their earlier motion to dismiss, *see* Motion to Dismiss at 27-39, but at a minimum, any such violation was not dramatic enough to warrant relief under the *ultra vires* doctrine. The Court's decision that the Agency exceeded its "adjustment" authority and, therefore, acted in an *ultra vires* fashion rests on two conclusions: 1) the Agency cannot consider cost of acquisition unless it has the data specified in 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(I) ("Section I"), and 2) the term "adjustment" does not countenance a reduction in the reimbursement rate as large as 30%. Op. at 27-30. But the statute does not explicitly preclude the consideration of the cost of acquisition in 42 U.S.C.

[1] "A violation is patent if it is obvious or apparent." *Id.* (quotation marks and brackets omitted).

§ 1395*l*(t)(14)(A)(iii)(II) ("Section II"), and it is reasonable to read the statute to mean that the cost of acquisition *must* be considered, under Section I, if the Agency possesses the data specified in the statute, but *may* be considered, under Section II, even if it does not. In other words, the Agency's reduction of the payment rate for drugs purchased through the 340B Program was, at a minimum, based on a colorable interpretation of the statute and, therefore, is not a patent violation of Agency authority. Moreover, as the Agency demonstrated in earlier briefing, MTD Reply at 13, it is common in the law to use the term "adjustment" to refer to changes as large as 30%. *See, e.g., Asbun v. Resende*, 2017 WL 24781, at *1 (S.D. Fla. Jan. 3, 2017) (referring to a report and recommendations "30% downward adjustment to the lodestar calculation" of attorney's fees); *Davis v. Comm'r IRS*, 109 T.C.M. (CCH) 1450 (T.C. 2015) (discussing "30% adjustment[s]" to property appraisals); *ASARCO LLC v. Americas Mining Corp.*, 396 B.R. 278, 352 (S.D. Tex. 2008) (discussing a "30% downward adjustment" made to a corporate valuation "to account for size and foreign risk"). Thus, the Court should reject the argument that the Agency acted in an *ultra vires* fashion and should, instead, conclude that judicial review of the plaintiffs' challenge is precluded by statute. Motion to Dismiss at 16-24. Dismissal of the 2019 OPPS Rule claims and the related request for permanent injunction is warranted.

Plaintiffs address not only the merits of their claims, but also the nature of the relief they seek. Specifically, they ask the Court to issue a mandatory injunction requiring "Defendants to issue an interim final rule within 30 days of the Court's order, effective no more than 30 days later, providing that 340B drugs will be reimbursed using the methodology based on the statutory default rate of ASP plus 6%—that is, the same rate that Defendants applied in 2017 . . . ." Motion for Permanent Injunction at 3-4. But, as defendants have demonstrated in their briefing

with regard to the remedy for the 2018 OPPS Rule, such an injunction would contradict D.C. Circuit precedent. Defendants' Opposition Brief on Remedy, Feb. 14, 2019, ECF No. 36, at 3-6. This precedent establishes that a district court that has identified a flaw in a rule should not issue an injunction imposing specific duties on the agency, *see Northern Air Cargo v. U.S. Postal Serv.*, 674 F.3d 852, 861 (D.C. Cir. 2012), but should instead remand the matter to the agency for it "to decide in the first instance how best to provide relief," *Bennett v. Donovan*, 703 F.3d 582, 589 (D.C. Cir. 2013). Thus, if the Court identifies a flaw in the 2019 OPPS Rule, it should remand the matter to the Agency for it to craft an appropriate remedy. *See* Defendants' Brief on Remedy, Jan. 31, 2019, ECF No. 31.

Accordingly, the Court should dismiss the claims related to the 2019 OPPS Rule and should also deny plaintiffs' motion for a permanent injunction as to those claims. But if the Court determines that the 2019 OPPS Rule suffered from the same legal flaw as the one that it identified in the 2018 OPPS Rule, it should remand the matter to the Agency for it to determine in the first instance how best to provide relief. If the Court grants any of plaintiffs' remedial requests, then defendants request that the Court stay the order to afford the Solicitor General sufficient time to decide whether to pursue appeal. 28 C.F.R. § 0.20(b); 28 U.S.C. § 2107(b).[2]

[2] If an appeal is authorized, defendants may seek a stay of this Court's judgment pending resolution of the appeal.

Date: February 22, 2019

Respectfully submitted,

JOSEPH H. HUNT
Assistant Attorney General

JEAN LIN
Acting Deputy Branch Director, Federal Programs

s/ Justin M. Sandberg
Justin M. Sandberg (Ill. Bar No. 6278377)
Senior Trial Counsel
U.S. Department of Justice
Civil Division, Federal Programs Branch
1100 L Street, NW, Room 11004
Washington, DC 20005
Tel.: (202) 514-5838
Fax: (202) 616-8460
Email: justin.sandberg@usdoj.gov

Counsel for Defendants