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.	)	

REPLY IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS

INTRODUCTION

Plaintiffs essentially allege that they have a statutory entitlement to a government-funded windfall with every drug purchase they make through the 340B Program, and that the Secretary erred by decreasing the amount of the windfall in the final 2018 OPPS Rule. *See, e.g.*, Plaintiffs' Reply in Support of Their Motion for Preliminary and Permanent Injunction and Opposition to Defendants' Motion to Dismiss ("MTD Opp."),[1] Sept. 26, 2018, ECF No. 16, at 21-22. It is a startling claim. And it is wrong.

But the Court need not – indeed, cannot – reach the merits of the claim because Congress has precluded judicial review of the Secretary's decision to reduce the payment rate for drugs purchased through the 340B Program. *See* Memorandum in Support of Defendants' Motion to Dismiss and in Opposition to Plaintiffs' Motion for a Preliminary Injunction ("MTD"), Sept. 14,

[1] The Local Rules of Civil Procedure do not provide a right to file a reply brief to a motion for a preliminary injunction, LCvR 65.1(c), and plaintiffs did not move for leave to file a reply brief. Accordingly, the Court should consider plaintiffs' brief only in the context of resolving defendants' motion to dismiss.

2018, ECF No. 14, at 16-24. In fact, Congress has broadly precluded review of the Secretary's decisions regarding the establishment and adjustment of the components of the outpatient prospective payment system. The reason for this is simple enough: Adjustments by the Secretary are made in a budget neutral fashion, meaning that a decrease in the payment rate for one component is offset by an increase for the payment rate of another, and a *post hoc*, court-ordered change to a component could have significant effects throughout a system that handles over 100 million outpatient claims every year. *See* Ex. 1 to MTD.

In their brief, plaintiffs try to argue that the statutory preclusion provisions do not apply. But their arguments are unconvincing because, among other things, they depend on a misconception of how the statute's provisions, such as 42 U.S.C. § 1395*l*(t)(2) and § 1395*l*(t)(14), fit together, and a misunderstanding of the authority invoked by the Secretary. Plaintiffs also argue that the *ultra vires* exception to preclusion applies. This argument too comes up short: The Secretary did not exceed any clear and mandatory limit set by Congress when he decreased the windfall received by hospitals participating in the 340B program. Thus, the statute precludes review of plaintiffs' claims and the complaint should be dismissed for lack of jurisdiction.

The Court should also reject plaintiffs' claims on the merits, should it reach them. Plaintiffs allege that the Secretary could not, under 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II) (also "Subclause (II)"), rely on data related to drug acquisition prices to set the payment rate for drugs purchased through the 340B program. Compl. ¶¶ 35-36. Rather, plaintiffs contend, such data can be relied on only under § 1395*l*(t)(14)(A)(iii)(I) (also "Subclause (I)"). This argument is flawed. While Subclause I requires the consideration of certain acquisition-cost data, if it is available, nothing in Subclause I or II prohibits the consideration, under Subclause II, of any

other acquisition-cost related data if it is available. Nor, contrary to plaintiffs' arguments, was the Secretary's decision to adjust the payment rate downward inconsistent with the purposes of the 340B Program. That program is intended to provide drug discounts, not Medicare-funded windfall profits on drug purchases. Plaintiffs make other arguments, but they fare no better.

For the reasons stated in defendants' opening memorandum and this brief, the Court should dismiss plaintiffs' claims.[2]

ARGUMENT

I. The Statute Precludes Review of Plaintiffs' Claims

Review of plaintiffs' claims is precluded by statute. Specifically, three statutory provisions preclude review of plaintiffs' claims: first, 42 U.S.C. § 1395*l*(t)(12)(A), which precludes review of "the development of the [OPPS] classification system under paragraph (2), including . . . other adjustments"; second, § 1395*l*(t)(12)(C), which precludes review of the "periodic adjustments [to the OPPS] made under paragraph [9]"; and third, § 1395*l*(t)(12)(E), which precludes review of ". . .the portion of the medicare OPD fee schedule amount associated with particular devices, drugs, or biologicals, and the application of any pro rata reduction under

[2] The Local Rules provide that in a case "involving the judicial review of administrative agency actions, unless otherwise ordered by the Court, the agency must file a certified list of the contents of the administrative record with the Court . . . simultaneously with the filing of a dispositive motion." LCvR 7(n)(1). The apparent logic of the rule, however, presupposes the possibility of the court looking to the contents of the administrative record to resolve the motion. *See* LCvR 7(n) cmt.1 ("This rule is intended to assist the Court in cases involving a voluminous record . . . by providing the Court with copies of relevant portions of the record relied upon in any dispositive motion." (emphasis added)). Defendant's motion, however, does not depend upon the contents of any documents other than the final rule challenged by plaintiffs and other judicially noticeable materials. *See Carroll v. Office of Fed. Contract Compliance Programs, U.S. Dep't of Labor*, 235 F. Supp. 3d 79, 81 n.1 (D.D.C. 2017) (concluding that the "certified list" of administrative record contents was "'immaterial' to [the] resolution" of a motion to dismiss because documents appended to the complaint were "sufficient for determining whether the complaint states a claim upon which relief can be granted").

paragraph (6)." Defendants' opening brief explains in detail how each provision precludes review, and there's no need to plow that ground again. MTD at 16-24. It suffices to say this: Piecemeal review of the components of the outpatient prospective payment system – like the reimbursement rate at issue here – would wreak "havoc," given the interdependent nature of the components (a result of budget neutrality) and the number of claims that the Agency processes (100 million or so). *Amgen, Inc. v. Smith*, 357 F.3d 103, 112 (D.C. Cir. 2004) (noting that "judicially mandated changes in one payment rate would affect the aggregate impact of the Secretary's decisions by requiring offsets elsewhere, and thereby interfere with the Secretary's ability to ensure budget neutrality in each fiscal year").

Predictably, plaintiffs disagree. But their arguments fall flat. Take, for example, their argument that § 1395*l*(t)(12)(A) does not preclude review. As noted above, § 1395*l*(t)(12)(A) precludes review of "the development of the [OPPS] classification system under paragraph (2), including . . . other adjustments." Plaintiffs' response to this argument is the following: Subsection (t)(12)(A) mentions "paragraph (2)," not paragraph 14 – the paragraph specifically addressing "Drug APC Payment Rates" and invoked by the Secretary – and, given the requirement that there be "clear and convincing evidence that Congress intended to preclude the suit," *Amgen*, 357 F.3d at 111, review should be allowed to go forward. Not so. The argument fails because it proceeds from the false premise that adjustment of drug payment rates are not part of the "development of the [OPPS] classification system under paragraph (2)," but they are.

Paragraph 14 (§ 1395*l*(t)(14)) does not describe a new payment authority. Rather, it contains instructions from Congress about how to exercise authority granted in paragraph 2 (§ 1395*l*(t)(2)) for the setting and adjustment of payments with respect to "Drug APC Payment

Rates." There is "clear and convincing evidence" of this point. Paragraph (t)(2) establishes general "[s]ystem requirements" for the entire OPPS. The paragraph begins as follows:

> (2) System requirements
> Under the payment system--
> (A) the Secretary shall develop a classification system for covered OPD [*i.e.*, outpatient department] services

42 U.S.C. § 1395*l*(t)(2)(A). Section (t)(1)(B), in turn, defines "covered OPD services" to include all "hospital outpatient services designated by the Secretary." *Id.* § 1395*l*(t)(1)(B). "In implementing this system, the Secretary groups outpatient services into classifications called Ambulatory Payment Classifications ("APCs"). 42 U.S.C. § 419.31" *Amgen, Inc. v. Scully*, 234 F. Supp. 2d 9, 11 (D.D.C. 2002), *aff'd on other grounds sub nom. Amgen, Inc. v. Smith*, 357 F.3d 103 (D.C. Cir. 2004). And when Congress added § (t)(14) to the Medicare statute in 2003, it made clear in several respects that it was adding a new payment methodology within the overall APC system described in § (t)(2)(A). First, Congress titled the new paragraph "Drug APC payment rates." 42 U.S.C. § 1395*l*(t)(14). Second, a drug is eligible for OPPS payment only if it is a drug "for which a separate ambulatory payment classification group (APC) has been established." *Id.* § 1395*l*(t)(14)(B)(i). Third, the APC system described in § (t)(2)(A) applies to all "covered OPD services," and the specified covered outpatient drugs ("SCODs") subject to payment under § (t)(14)(A) are, by definition, drugs that are "furnished as part of a covered OPD service." Thus, action taken under (t)(14) is necessarily action taken under (t)(2). Accordingly, review is precluded by (t)(12)(A).

Plaintiffs make two other points in an attempt to prop up their arguments, but they are to no avail. First, plaintiffs argue that "when Congress amended the statute in 1999 to include other new components of the OPPS system (Paragraphs (5) and (6), 42 U.S.C. § 1395*l*(t)(5)–(6)), it amended Paragraphs (2) and (12) to refer explicitly to actions taken 'under paragraph (5)' and

'under paragraph (6).' 42 U.S.C. § 1395*l*(t)(2)(E), (12)(E)." MTD Opp. at 5-6. But, plaintiffs argue, Congress did not do so when it added paragraph 14. *Id.* at 5. While that may be true, Congress had no need to amend the statute to extend the preclusion provisions to paragraph 14 (§ 1395*l*(t)(14)) because, as explained above, paragraph 14 simply contains specific instructions about how to exercise the authority provided under paragraph 2. As for paragraphs 5 and 6, they were establishing new, separate payment authorities, rather than providing instructions for how to exercise an existing one. They specify additional payment amounts over and above the otherwise-applicable payment rates, so Congress needed to add specific references to them in the statute to shield these additional payment determinations from administrative and judicial review. *See* 42 U.S.C. §§ 1395*l*(t)(5) (providing for "an additional payment for each covered OPD service (or group of services)" for high-cost outlier services); §§ 1395*l*(t)(6) (providing for "an additional payment under this paragraph for any following services . . ." that relate to additional costs of innovative medical devices, drugs, and biologicals).[3]

Second, plaintiffs ague that "the clear implication" of this Court's decision in *Organogenesis Inc. v. Sebelius*, 41 F. Supp. 3d 14 (D.D.C. 2014), "was that if the product [at issue] has been reimbursed under Paragraph (14), as is indisputably the case here, the preclusion provision in Paragraph (12)(A) would not apply." MTD Opp. at 6-7. But in *Organogenesis* this Court did not specifically address whether action taken under paragraph 14 is covered under

[3] Plaintiffs make a similar argument with respect to § 1395*l*(t)(13)'s reference to § 1395*l*(t)(2)(E)'s adjustment authority. MTD Opp. at 5-6. But Paragraph 14's failure to explicitly mention Paragraph 2 does *not* establish that Paragraph 14 is an independent source of authority, separate and apart from Paragraph 2. Rather, it demonstrates that Congress can say the same thing – here, that authority derives from Paragraph 2 – in different ways. *Potocnik v. Carlson*, 2016 WL 3919950, at *11 (D. Minn. July 15, 2016) ("Congress often says the same thing in different ways."). Moreover, given that the adjustment discussed under Paragraph 13 is mandatory, rather than discretionary (which is the norm under Paragraph 2(e)), it made sense for Congress to make clear that Paragraph 2(e) nonetheless provides the basis for the adjustment.

paragraph 12(a)'s preclusion provision, *see Organogenesis Inc. v. Sebelius*, 41 F. Supp. 3d at 20-21, so the decision is not authority for that point, *see United States v. L.A. Tucker Truck Lines, Inc.*, 344 U.S. 33, 38 (1952) (issue not "raised in briefs or argument nor discussed in the opinion of the Court" cannot be taken as "a binding precedent on th[e] point"). What that decision does do, however, is recognize that under paragraph 12(a), Congress "preclu[ded] [ ] judicial review of CMS's authority to set prospective payment methodologies." *Organogenesis*, 41 F. Supp. 3d at 20. And as previously explained, this is precisely the authority that plaintiffs improperly seek to challenge.

Plaintiffs dispute not only that paragraph 12(a) precludes review of their claims, but also that paragraph 12(c) (§ 1395*l*(t)(12)(C)), precludes review of their claims. Again, their arguments do not hold water. Paragraph 12(c) precludes review of the "periodic adjustments [to the OPPS] made under paragraph [9][4]." § 1395*l*(t)(12)(C). Plaintiffs argue that the "'other adjustments' in Paragraph (9) are the same as the 'other adjustments' in Paragraph (2) – i.e., equitable adjustments – which HHS did not claim to be invoking when it made the payment reduction at issue here." MTD Opp. at 8. But the Secretary did invoke his power under Paragraph 9 when issuing the final 2018 OPPS rule. Paragraph 9 states that the "Secretary shall review not less often than annually and revise the groups, the relative payment weights, and the wage and other adjustments described in paragraph (2) to take into account changes in medical practice, changes in technology, the addition of new services, new cost data, and other relevant information and factors." 42 U.S.C. § 1395*l*(t)(9). And at the outset of the final 2018 OPPS Rule, the Secretary explicitly invoked paragraph 9 when explaining the purpose of the rule:

[4] The Statute references "adjustments made under paragraph 6," but plaintiffs agree that this was the result of a scrivener's error and that the provision should refer to paragraph 9. MTD Opp. at 7 n.6.

> In this final rule with comment period, we are updating the payment policies and payment rates for services furnished to Medicare beneficiaries in hospital outpatient departments . . . . Section 1833(t) of the Social Security Act (the Act) requires us to annually review and update the payment rates for services payable under the Hospital Outpatient Prospective Payment System (OPPS). Specifically, section 1833(t)(9)(A) of the Act requires the Secretary to review certain components of the OPPS not less often than annually, and to revise the groups, relative payment weights, and other adjustments that take into account changes in medical practices, changes in technologies, and the addition of new services, new cost data, and other relevant information and factors.

82 Fed. Reg. 52361-52362. Thus, as paragraph 12(c) bars review of periodic adjustments made under paragraph 9, review of plaintiffs' claims is precluded. [5]

As explained at the outset of this section, the purpose of the preclusion provisions demonstrate that defendants have the better of the statutory interpretation dispute with plaintiffs. Many courts – the D.C. Circuit included – have identified the harm that would be caused by the piecemeal review of components of the OPPS, given (1) the interdependence of the components that results from the budget neutrality requirements and (2) the large number of claims processed by Medicare. *Amgen*, 357 F.3d at 112; *Skagit Cty. Pub. Hosp. Dist. No. 2 v. Shalala*, 80 F.3d 379, 386 (9th Cir. 1996); *Am. Soc'y of Cataract & Refractive Surgery v. Thompson*, 279 F.3d 447, 454 (7th Cir. 2002)); *accord Paladin Cmty. Mental Health Ctr. v. Sebelius*, 684 F.3d 527, 531 n.3 (5th Cir. 2012). Plaintiffs' claims implicate these very concerns: The savings gained from reducing the previously bloated Medicare reimbursements paid for drugs purchased through the 340B Program were reapportioned to other services within OPPS. 82 Fed. Reg.

[5] Plaintiffs also contest the argument that Paragraph 12(e) (42 U.S.C. § 1395*l*(t)(12)(E)) precludes review of their claims. MTD Opp. at 8-10. But there's little to add to the parties' arguments over its application (and, by extension, the niceties of the last-antecedent rule) other than this: Interpreting that provision to preclude review would serve the salutary purpose that all of the preclusion provisions are intended to serve, namely, prevention of the serious mischief that follows from second guessing the Secretary's decisions regarding components of the OPPS.

52,623 (noting that because CMS made the payment adjustment "in a budget neutral manner within the OPPS, the reduced payments for separately payable drugs purchased through the 340B Program will increase payment rates for other non-drug items and services paid under the OPPS by an offsetting aggregate amount"). John Donne famously said no man is an island. Well, no drug is an island in the OPPS. For that reason, interpreting the preclusion provisions as defendants do makes more sense in view of the purposes of the statute. Accordingly, review is precluded.

Hedging their bets about the applicability of the preclusion provisions, plaintiffs argue that, even if the provisions apply to the Agency's actions, review is not precluded because the Agency acted in an ultra vires fashion. MTD Opp. at 10-11. But "[t]hat argument stretches the definition of *ultra vires* action too far. An agency only acts *ultra vires* when it exceeds a clear and mandatory limit on its regulatory jurisdiction." *Baxter Healthcare Corp. v. Weeks*, 643 F. Supp. 2d 111, 115 n.2 (D.D.C. 2009); *see Indep. Cosmetic Mfrs. & Distributors, Inc. v. U. S. Dep't of Health, Ed. & Welfare*, 574 F.2d 553, 555 (D.C. Cir. 1978) (a party urging jurisdiction based on ultra vires action must show a patent violation of agency authority). No such clear limit is implicated here (as demonstrated more fully below). Plaintiffs challenge the Secretary's discretionary decision to set the payment rate for drugs purchased through the 340B Program at a level that better aligns the rate with the prices the 340B hospitals actually pay for the drugs, but no statute clearly precludes the Secretary's consideration of acquisition costs. Rather, this is "a routine 'dispute over statutory interpretation' that does not rise to the level of an ultra vires claim." *Baxter Healthcare Corp.*, 643 F. Supp. 2d at 115 n.2 (citing *Dart v. United States*, 848 F.2d 217, 231 (D.C. Cir. 1988)).

In the course of arguing that their claims fit within the narrow *ultra vires* exception, plaintiffs also contend that "[d]enying preclusion under [the] circumstances" of this case will not wreak havoc on the OPPS because "facial" challenges are "infrequent" and "need only be resolved by the courts once." Opp. at 10-11. This argument fails because whether the *ultra vires* exception applies does not depend on an analysis of just how bad it would be to allow the claim. Rather, a court simply asks whether the agency's actions violate a clear and mandatory limit on its authority. HHS's actions here violate no such limit, as already explained above and will be more fully explained below. And, further, plaintiffs' argument that, in the abstract, facial challenges fare better from a cost-benefit perspective than do as-applied challenges, *i.e.*, that they may provide system-wide benefits offsetting their disruptiveness, says nothing about whether the text of the statute precludes plaintiffs' challenges here – it does.[6]

II. The Secretary Properly Exercised His Adjustment Authority

With respect to the kind of drugs at issue in this case, the Secretary may (as is relevant here) set the reimbursement rate equal to "the average price for the drug in the year established under . . . section 1395w-3a of this title [i.e., the average sales price plus six percent] . . . as calculated and adjusted by the Secretary as necessary for purposes of this paragraph." 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II) (also "Subclause (II)"). In the final 2018 OPPS Rule, the Secretary did just what this statute allows. He calculated the average sales price (ASP) and adjusted the reimbursement rate for drugs purchased through the 340B program to ASP minus 22.5 percent. 82 Fed. Reg. at 52,362. He adjusted the reimbursement rate for a couple of reasons. First, the Secretary reasoned that the payment adjustment will "better, and more appropriately, reflect the

[6] Defendants have nothing further to add with respect to the arguments that the adjustment is committed to agency discretion by law and that plaintiffs have not exhausted their administrative remedies.

resources and acquisition costs that [340B] hospitals incur," *id.*, given that "on average, hospitals in the 340B Program receive a minimum discount of 22.5 percent of the [ASP] for drugs paid under the [OPPS]," *id.* at 52,494 (quotation omitted). Second, the Secretary concluded that adjusting the rate downward would "lower drug costs for Medicare beneficiaries for drugs acquired by hospitals under the 340B Program," ensuring that beneficiaries would "share in the savings on drugs acquired through the 340B Program." 82 Fed. Reg. at 52,495-97. CMS estimated that this payment adjustment would save Medicare $1.6 billion. 82 Fed. Reg. at 52,509. As noted earlier, these savings were redistributed within the OPPS system. 82 Fed. Reg. at 52,623

Plaintiffs believe that the Secretary violated his adjustment authority under § 1395*l*(t)(14)(A)(iii)(II), arguing that "the Secretary cannot use his "Adjustment" authority under Subclause (II) [42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II)] to use acquisition costs in a manner that would be forbidden under subclause (I) [§ 1395*l*(t)(14)(A)(iii)(I)]."[7] MTD Opp. at 16 (capitals omitted). They continue, "[i]f Congress had intended for Subclause (II) sales price 'adjustments' to enable the Secretary to set reimbursement rates based on acquisition costs, as he has done here, it would not have enacted Subclause (I), imposing rigorous data requirements on HHS." *Id.* at 16-17. To that end, plaintiffs add, HHS's interpretation of the statute is flawed because, if the Secretary can consider acquisition data under Subclause (II), then Subclause (I) has been rendered superfluous. *Id.* at 17.

[7] Subclause I permits the Secretary to set payment rates for the drugs at issue in this case at "(I) . . . the average acquisition cost for the drug for that year (which, at the option of the Secretary, may vary by hospital group (as defined by the Secretary based on volume of covered [outpatient department ("OPD")] services or other relevant characteristics)), as determined by the Secretary taking into account the hospital acquisition cost survey data under subparagraph (D)." 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(I).

Plaintiffs' argument is incorrect. Interpreting Subclause (II) to allow the Secretary to use available information to more closely align reimbursement rates to acquisition costs does not violate the statute. Nothing in Subclause (II) prevents the Secretary from using acquisition-related data when making an adjustment to the ASP. 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II). And Congress clearly thought that acquisition costs can be a relevant factor in determining reimbursement rates, given the presence of Subsection (I). Moreover, the statute affords the Secretary broad discretion to make adjustments, as it does not cabin the bases on which adjustments may be made, but rather permits the Secretary to make any adjustments "necessary for purposes of this paragraph." 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II). And contrary to plaintiff's suggestion otherwise, interpreting the statute in this fashion does not render Subclause (I) a dead letter. Subclause (I) serves a useful purpose: It *requires* the Secretary to use acquisition cost data when he has it. *See* 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II) (stating that the ASP-based methodology can be used "if hospital acquisition cost data [referenced in Subclause (I)] are not available"). If the Secretary had the more specific acquisition cost data under Subclause (I), he could set Medicare payment rates to reflect the actual payment reductions 340B hospitals receive – far in excess of the 22.5% reduction here. As it is though, the Secretary estimated the minimum discount such providers receive, and no entity (including plaintiffs here) commented during the rulemaking that this estimated adjustment in fact exceeds the discount such providers receive on these drugs. But, in any event, neither Subclause (I) nor Subclause (II) *prohibits* the Secretary from using other acquisition-related data when the data described in Subclause I is not available.

Plaintiffs also argue that HHS violated the text of the statute because HHS did not "adjust" the payment rate for 340B drugs. More specifically, plaintiffs insist that "[a] reduction

of nearly 30% that is explicitly designed to approximate a measure of drug value *other than ASP* constitutes a 'total elimination' of the requirement to set the payment rate based on ASP." MTD Opp. at 18 (emphasis in the original). This argument builds off the Court of Appeals' statement in *Amgen* that the word "adjustment" prohibits the "elimination or severe restructuring of the statutory scheme." *Amgen*, 357 F.3d at 117.

This argument fails because the payment rate adopted by the Secretary in the final 2018 OPPS Rule is still "based on ASP." The Secretary did not ignore ASP; he calculated the ASP and used that as the starting point from which he set the payment rate. Thus, the payment rate is "based on" the ASP. Of course, after calculating the ASP baseline, he modified the payment rate downward (by 22.5 %) for 340B-acquired drugs to better align it with acquisition costs. This 22.5% change does not exceed the scope of action permitted by the word "adjustment." Plaintiffs cite no case establishing that it does. And usage of the term "adjustment" in case law is not to the contrary: Numerous cases describe changes of 30% as "adjustments." *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").

Plaintiffs dispute that the adjustments are indeed "necessary for purposes of this paragraph" because, in their view, the only adjustments allowed are for "overhead and related expenses, such as pharmacy services and handling costs," 42 U.S.C. § 1395*l*(t)(14)(E)(i), because those are the only adjustments explicitly listed in under Paragraph (14) – albeit in a

different subsection. This argument is unconvincing. If the Congress wanted to similarly limit the Secretary's adjustments under Subclause II to "overheard and related expenses," it would have used the same language. *See Persinger v. Islamic Republic of Iran*, 729 F.2d 835, 843 (D.C. Cir. 1984) (concluding that the use of different language in different parts of the same statute creates a strong inference that different meanings are intended). Rather, by providing for adjustment "necessary for purposes of this paragraph," Congress, through the breadth of this language, necessarily endowed the Secretary with broader discretion to make adjustments than it did in § 1395*l*(t)(14)(E)(i)[8]. And the Secretary has reasonably interpreted this language to permit an adjustment to the reimbursement rate to better align it with the acquisition costs, an interpretation in line with the "purposes of th[e] paragraph," as reflected in the text of Subclause (I).

Plaintiffs also object that the 340B Program-related adjustment was improper because it "target[ed]" some hospitals, but excluded others from the payment decrease, namely, "[r]ural sole community hospitals (SCHs), children's hospitals, and [prospective payment system]-exempt cancer hospitals." 82 Fed. Reg. at 52,362. They argue that if Congress intended for the Secretary to consider differences in hospitals, then it would have explicitly permitted the practice, as it did in Subclause (I). MTD Opp. at 20-21. In other words, Plaintiffs' argument is a version of an *expressio unius* argument, i.e., the specific reference to "vary[ing]" payments by "hospital groups" in Subclause (I), impliedly precludes the practice under Subclause (II). MTD Opp. at 20-21.

[8] In any case, the Secretary separately had the authority to make the adjustment under Paragraph 9.

Plaintiffs' argument improperly treats the Secretary as an automaton and ignores significant discretion conferred on the Secretary by the Medicare statute. Congress cannot by statute address every situation that will arise in the operation of the sprawling Medicare system, which is not only huge, but constantly buffeted by changing conditions. *See, e.g.*, *Hosp. de Area de Carolina v. Sullivan*, 735 F. Supp. 432, 434-35 (D.D.C. 1990) ("It is well established that Congress has granted the Secretary broad discretion to develop regulations under the Medicare statute[.]"); 42 U.S.C. § 1395*l*(t)(9) (authorizing the Secretary to "revise the groups, the relative payment weights, and the wage and other adjustments described in paragraph (2) to take into account changes in medical practice, changes in technology, the addition of new services, new cost data, and other relevant information and factors"). And, more specifically, the provision at issue here affords the Secretary the discretion to treat rural, children, and cancer hospitals differently by not decreasing payments to them: Calibrating the adjustment to exclude these hospitals – because of concerns about access to care and the different payment model employed in some of them, 82 Fed. Reg. at 52,505- 52,506 – served the "purposes of the paragraph," which logically include setting appropriate prices for drugs in view of all relevant considerations, including access to care. Indeed, tellingly plaintiffs do not argue that the distinctions are unreasonable. Rather, they argue that the Secretary lacks the authority to make them (because of their crabbed interpretation of the "purposes of the paragraph"). But as explained, plaintiffs' narrow interpretation of the Secretary's authority is flawed.

In any event, the D.C. Circuit has rejected the sort of *expressio unius* argument that plaintiffs rely on here. In a case in which a group of hospitals objected to the HHS Secretary's decision to apply a statutory change to a category of hospitals not specifically covered by the statute, the D.C. Circuit wrote the following: "The *expressio unius* canon is a feeble helper in an

administrative setting, where Congress is presumed to have left to reasonable agency discretion questions that it has not directly resolved. . . It offers too thin a reed to support the conclusion that Congress has clearly resolved an issue. . . And when countervailed by a broad grant of authority contained within the same statutory scheme, the canon is a poor indicator of Congress' intent." *Adirondack Med. Ctr. v. Sebelius*, 740 F.3d 692, 697 (D.C. Cir. 2014) (internal quotations and citations omitted). The same holds true here. The adjustment provision leaves the Secretary broad discretion to calibrate his adjustment to meet the purposes of the paragraph (and the program as a whole). Plaintiffs' argument fails.

Plaintiffs' final argument on the merits is that Secretary's adjustment is improper because it violates the purpose of the 340B Program. Opp. at 21-22. Defendants explained in their opening brief that reducing the payment rate does not undermine the 340B Program's purpose because it is a drug discount program that is not meant to determine Medicare reimbursement levels. MTD at 36-37. In their reply brief, plaintiffs respond that "this argument completely ignores Congress's stated purpose in enacting the 340B Program." Opp. at 21. The core purpose, plaintiffs announce, "is to enable hospitals serving underserved populations 'to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.'" *Id.* (Citing H.R. 102-384(II), at 12 (1992)).

Plaintiffs' argument is self-refuting. "Stretch[ing]" resources – including federal resources – means getting more for a fixed amount of money, such as through discounts. *See, e.g.*, "Stretch," Merriam Webster Online, ("stretch: . . .10(b)[:] to expand (as by improvisation) to fulfill a larger function //stretching a dollar"); *Lipscomb By & Through DeFehr v. Simmons*, 962 F.2d 1374, 1382–83 (9th Cir. 1992) ("The cases of Sheri Lipscomb and the Scalfs. . . are illustrative of only a part of the complex task faced by Oregon and other states in stretching finite

resources to provide social services to everyone deserving of them in as fair and efficient a manner as possible."). The phrase "[s]tretching scarce federal resources" does not mean getting more money, as through inflated Medicare reimbursement rates for drugs purchased through the 340B Program. Indeed, the full sentence from the House Report excerpted by plaintiffs makes clear that the purpose of the program is allow entities participating in 340B to get more drugs for less money, not to get more money: "In giving these 'covered entities' *access to price reductions* the Committee intends to enable these entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. 102-384(II), at 12 (emphasis added). Plaintiffs also argue that Congress reaffirmed "that purpose" by expanding the program. *Id.* at 21. But this argument does not help plaintiffs' cause. Expansion indicates that Congress liked the program; it says nothing about what the purpose is. But as noted above, the purpose is clear: It is a drug discount program, not a program designed to provide windfall profits on drug purchases.

* * * * *

Defendants' arguments on the merits are correct. But in any case, plaintiffs have not demonstrated, as they must to obtain judicial review under the ultra vires exception to preclusion, that HHS violated a clear, mandatory limit on its authority. Moreover, even if the Court finds that the statute does not clearly support the Agency's interpretation, the Agency is entitled to *Chevron* deference and would prevail under *Chevron* step two. *See* MTD at 28, 38.

CONCLUSION

For the reasons stated above and in defendants' opening brief, the Court should dismiss plaintiffs' complaint.

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Respectfully submitted,

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