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.*	**Case No. 18-cv-2084 (RC)**

PLAINTIFFS' REPLY IN SUPPORT OF THEIR MOTION FOR A PRELIMINARY AND PERMANENT INJUNCTION AND OPPOSITION TO DEFENDANTS' MOTION TO DISMISS

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INTRODUCTION

On the merits, this is a straightforward case of statutory construction. Subclause (I) of Subsection (t)(14)(A)(iii) of the Medicare Act, 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(I), directs the Secretary to use acquisition costs to calculate the reimbursement rate for separately payable drugs *if* data are available that meet the rigorous statistical standards of the statute. *See* Pls.' Mem., ECF No. 2-1, at 22–24. Acquisition cost data meeting this standard are not, and have never been, available. *Am. Hosp. Ass'n v. Azar*, 895 F.3d 822, 824 (D.C. Cir. 2018). Thus the Secretary's only authority to set the reimbursement rates for separately payable drugs is under Subclause (II) of Paragraph (14)(A)(iii), which requires that the rate be set at average sales price (ASP) plus 6%. This rate may be adjusted, but, as the Secretary acknowledges, the reduction at issue here was imposed to better align the reimbursement with acquisition costs; it was not a refinement or adjustment to average sales price. *See* Defs.' Mem., ECF No. 15, at 37. Moreover, under *Amgen Inc. v. Smith*, 357 F.3d 103, 111 (D.C. Cir. 2004), CMS's near-30% cut in reimbursements is not an "adjustment" within the meaning of the statute. In any event, Paragraph (14)(E) of Subsection 1395*l*(t) demonstrates that the only permissible adjustments are to the 6% portion of allowable reimbursements which covers overhead and related expenses, such as pharmacy services and handling costs, which is the only circumstance for which CMS has previously used its Subclause (II) adjustment authority. Finally, CMS may not use the adjustment authority to undermine the 340B Program, which it essentially acknowledges was its intent here.

On preclusion, this Circuit requires "clear and convincing evidence that Congress intended to preclude the suit." *Amgen*, 357 F.3d at 111. Although Paragraph (12) of the OPPS statute expressly precludes review of numerous specific decisions under enumerated paragraphs of the statute, no provision of Paragraph (12) references Paragraph (14), which is the authority

invoked by CMS for the action challenged here. In the absence of any provision that expressly precludes judicial review, HHS has offered strained arguments that preclusion is required by three separate provisions of Paragraph (12), one of which it did not identify until oral argument in the D.C. Circuit. Even if its statutory arguments had some validity, and they do not, HHS has plainly not satisfied the D.C. Circuit's "clear and convincing evidence" standard. In any event, even if review of agency action under Paragraph (14) were precluded, the Court would still need to determine whether CMS acted outside its authority under that Paragraph (14). *Amgen*, 357 F.3d at 112–13. CMS's lack of authority for the action that it took means both that judicial review is not precluded and that Defendants lose on the merits.

HHS continues to raise arguments that Plaintiffs must fully exhaust all administrative review procedures and that the challenged decisions are committed to agency discretion, but those arguments fare no better. HHS concedes that Plaintiffs have now presented claims for payment to the Secretary, and it does not dispute that any further review would be futile. Moreover, the boundaries of HHS's statutory authority dictate that the challenged decision is not committed to agency discretion.

This is the third occasion on which the parties have fully briefed all the issues in this case. There are no factual disputes to be resolved and HHS has had more than an ample opportunity to brief the legal issues in this case. The Court should reach the merits and enter final judgment in favor of Plaintiffs.

ARGUMENT

I. THE MEDICARE ACT DOES NOT PRECLUDE REVIEW OF THE RATE CHANGE AT ISSUE IN THIS CASE.

A. The Medicare Act Does Not Preclude Judicial Review of Administrative Action Taken Under Section 1395*l*(t)(14).

HHS argues that Paragraph (12) of section 1395*l*(t) of title 42 prohibits judicial review of agency actions under Paragraph (14) of section 1395*l*(t)(14) of title 42, under which the outpatient reimbursement rule at issue here was promulgated. However, the provisions on which HHS relies – Subparagraphs (A), (C) and (E) of Paragraph (12) − reference other parts of the Outpatient Prospective Payment System ("OPPS") for covered outpatient services, *not Paragraph (14)*. HHS's own regulation implementing Paragraph (12) references the same other provisions of the OPPS system, and likewise makes no reference to Paragraph (14). *See* 42 C.F.R. § 419.60 ("Limitations on Administrative and Judicial Review"). To explain the lack of any reference to Paragraph (14), HHS has argued that the Secretary's authority under Paragraph (14) is "mushed together" with other authorities that *are* precluded from review under Paragraph (12). Oral Argument at 41:00–41:20, *Am. Hosp. Ass'n v. Azar*, 895 F.3d 822 (D.C. Cir. 2018) (No. 18-5004), https://www.cadc.uscourts.gov/recordings/recordings2018.nsf/651CFD131E722 35285258283005D50B4/$file/18-5004.mp3.

HHS's construction cannot be reconciled with the "strong presumption that Congress intends judicial review of administrative action." *Amgen*, 357 F.3d at 111 (citation omitted). The presumption can be overcome only by "clear and convincing evidence that Congress intended to preclude the suit." *Id.* As the D.C. Circuit has held, Congress must speak plainly to preclude judicial review, and in Paragraph (12) Congress was careful to preclude review of agency action under certain specific paragraphs but not others. HHS's brief does not attempt to

reconcile its strained statutory analysis – reading in a reference to Paragraph (14) where none exists – with the strong presumption of reviewability.

1. Subsection (t)(12)(A)

Section 1395*l*(t)(12)(A) of title 42 ("Paragraph (12)(A)") precludes judicial review of:

> [T]he *development of the classification system under paragraph (2)*, including the establishment of groups and relative payment weights for covered OPD services, of wage adjustment factors, *other adjustments*, and methods described in paragraph (2)(F).

(Emphasis added). When Congress directed CMS to switch the payment of outpatient department services from a system based on reasonable costs to a system where the payments were established prospectively based on historical data, it instructed CMS in Paragraph (2) to develop a classification system for covered services, specifying, for example, that the Secretary "may establish groups of covered OPD services" (Subparagraph (B)), "shall . . . establish relative payment weights" (Subparagraph (C)), "shall determine a wage adjustment factor" (Subparagraph (D)), and "shall establish . . . other adjustments as determined to be necessary to ensure equitable payments" (Subparagraph (E)). This system was developed and announced in the Federal Register in 2000. HHS Office of Inspector General, *Medicare Program; Prospective Payment System for Hospital Outpatient Services*, 65 Fed. Reg. 18,434 (Apr. 7, 2000).

Relying on the words "development of the classification system under paragraph (2)," HHS argues that Paragraph (12)(A) precludes review of the outpatient reimbursement rule at issue here because the rule pertains to the OPPS classification system. This is incorrect. While the outpatient rule is part of the OPPS system and the ambulatory payment classification (APC) system, it is *not* part of the system "develop[ed] . . . under paragraph (2)." The new rule for separately payable drugs at issue here was promulgated under Paragraph (14), a separate part of

OPPS. Paragraph (14), unlike Paragraph (2), is not referenced in Paragraph (12)(A). HHS's argument fails to give effect to the "under paragraph (2)" limitation in the statute.[1]

HHS also argues that Paragraph (12)(A)'s reference to "other adjustments" precludes review of the 340B Provisions of the OPPS Rule because "the Secretary's *adjustment* of [payment rates for 2018 under paragraph (14)] was part of his 'development of' the APC system." Defs.' Mem. at 18 (emphasis in original). This reading likewise overlooks the statutory text. Paragraph (12)(A) precludes review of "the development of the [OPPS] classification system *under paragraph (2)*, *including* . . . other adjustments. . . ." (Emphasis added). Paragraph (12)(A) limits preclusion of "other adjustments" to those made under "paragraph (2)" and thus does not reach the Secretary's actions here under Paragraph (14). *See* note 1, *supra*.[2]

HHS's argument effectively amends Paragraph (2) to include a reference to Paragraph (14) that does not exist. Moreover, this reading flies in the face of what Congress actually did in 2003, when it added Paragraph (14) to the OPPS statute but did *not* amend either Paragraph (12) or Paragraph (2) to include any reference to Paragraph (14). By contrast, 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

[1] HHS does not dispute that, when it promulgated the new rule, it invoked its authority under Paragraph (14), not under Paragraph (2). *See* 82 Fed. Reg. at 52,499 (relying on "authority *under section 1833(t)(14)(A)(iii)(II)* to 'calculate and adjust' drug payments" (emphasis added)); *id.* at 52,500 (same).

[2] The "other adjustments" authorized under "paragraph (2)" and precluded from review under Paragraph (12)(A) are "other adjustments as determined [by HHS] to be necessary to ensure equitable payments, such as adjustments for certain classes of hospitals." 42 U.S.C. § 1395*l*(t)(2)(E). HHS did not invoke its equitable adjustment authority under Paragraph (2)(E) in the 340B Provisions of the OPPS Rule. *See* 82 Fed. Reg. at 52,506–07.

actions taken "under paragraph (5)" and "under paragraph (6)." 42 U.S.C. § 1395*l*(t)(2)(E), (12)(E).[3] Similarly, when Congress amended the statute in 2003 to add the text codified at section § 1395*l*(t)(13) of title 42, it specifically authorized "an appropriate adjustment under paragraph (2)(E)" with respect to rural hospitals, thereby subjecting them to preclusion under Paragraph (12).[4] In short, Congress made clear that actions taken under these new provisions were "under paragraph (2)" and therefore within Paragraph (12)(A)'s text precluding actions taken "under paragraph (2)." *See also* 42 U.S.C. § 1395*l*(t)(3)(D) (referring to "relative payment weight (determined *under paragraph (2)(C)*)" (emphasis added)). Actions taken under Paragraph (14), which is referenced nowhere in Paragraph (2) *or* Paragraph (12)(A), are not precluded from review.[5] HHS has certainly not satisfied the clear and convincing evidence standard.

HHS's reliance on this Court's decision in *Organogenesis Inc. v. Sebelius*, 41 F. Supp. 3d 14 (D.D.C. 2014), is also misplaced. In *Organogenesis*, the issue was whether a product (Apligraf) was "properly considered a regular OPD service under § (t)(2)" or whether it "should properly be considered a [drug] under . . . (t)(14)." *Id.* at 20. The Court ruled that, because Apligraf was appropriately classified as a surgical procedure rather than as a drug, HHS had had properly classified it under Paragraph (2), which meant that preclusion applied under Paragraph (12)(A). The clear implication of the decision was that if the product has been reimbursed under

[3] Consol. Appropriations Act, App'x F, Sec. 1, § 201(c), 113 Stat. 1501, 1501A-339 (1999).

[4] Medicare Prescription Drug, Improvement, & Modernization Act, Sec. 1, § 411(b), 117 Stat. 2066, 2274 (2003).

[5] Although HHS argues that *Amgen* recognized Paragraph (12)'s preclusion of review of Paragraph (14) adjustments, *see* Defs.' Mem. at 18–19, in fact *Amgen* concerned the reviewability of adjustments under Paragraph (2)(E), which are expressly referenced in Paragraph (12).

Paragraph (14), as is indisputably the case here, the preclusion provision in Paragraph (12)(A) would not apply.

2. Subsection (t)(12)(C)

HHS also invokes Subsection (t)(12)(C) of the Medicare Act, which precludes review of "periodic adjustments made under paragraph [9]." 42 U.S.C. § 1395*l*(t)(12)(C).[6] HHS did not invoke Subsection (t)(12)(C) when this case was previously before this Court or in its brief on appeal; it first argued that preclusion is required under Paragraph (12)(C) during oral argument in the D.C. Circuit. Oral Argument at 34:20–36:00, *Am. Hosp. Ass'n v. Azar*, 895 F.3d 822 (D.C. Cir. 2018) (No. 18-5004), https://www.cadc.uscourts.gov/recordings/recordings2018.nsf/651CFD131E72235285258283005D50B4/$file/18-5004.mp3.

Adjustments under Paragraph (9) are separate and apart from agency action under Paragraph (14) such as the payment reduction at issue in this case. As previously explained, CMS established the classification system under the authority granted in Paragraph (2). After the system was established, in Paragraph (9), Congress directed HHS to "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)(A). In other words after CMS used its authority under Paragraph (2)(B)–(E) to establish groups, relative payment weights, wage and other adjustments, Paragraph (9) requires it to update those factors at least annually.

[6] As HHS points out, as a result of a scrivener's error, Subsection (t)(12)(C) refers to "periodic adjustments made under paragraph (6)" but should refer to Paragraph (9). *See* Defs.' Mem. at 6 n.2.

Setting payment amounts under Paragraph (14) is not the same as, or an example of, making periodic adjustments under Paragraph (9). In particular, "adjustments" under Paragraph (14) are not among the "other adjustments" referenced in Paragraph (9); the "other adjustments" in Paragraph (9) are the same as the "other adjustments" in Paragraph (2) – *i.e.*, equitable adjustments – which the HHS did not claim to be invoking when it made the payment reduction at issue here. *See supra* note 2.

Paragraph (12)(C) only applies to agency action under Paragraph (9), and it does not constitute clear and convincing evidence of congressional intent to preclude review of action under Paragraph (14).

3. Subsection (t)(12)(E)

HHS also asserts preclusion based on Subsection (t)(12)(E) of the Medicare Act, but that preclusion provision only applies to certain "determination[s]" made "under paragraph (5)" or "under paragraph (6)," and not to actions taken under paragraph (14) like the payment reduction at issue in this case. 42 U.S.C. § 1395*l*(t)(12)(E). Paragraph (12)(E) precludes review of:

> ***the determination of*** the fixed multiple, or a fixed dollar cutoff amount, the marginal cost of care, or applicable percentage ***under paragraph (5) or the determination of*** insignificance of cost, the duration of the additional payments, the determination and deletion of initial and new categories (consistent with subparagraphs (B) and (C) of paragraph (6)), *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 paragraph (6)***.

Id. (emphasis added). This provision is plainly inapplicable to the agency action at issue in this case.

HHS isolates Paragraph (12)(E)'s reference to "the portion of the medicare OPD fee schedule amount associated with particular . . . drugs," and argues that this phrase extends to and includes the Paragraph (14) "adjustments" at issue here. Defs.' Mem. at 20–24. In an attempt to circumvent the obvious textual limitation on the scope of (t)(12)(E) to "determination[s]" made

"under paragraph (5)" or "under paragraph (6)," HHS argues that "the 'under paragraph (6) language in § (t)(12)(E) only modifies the phrase immediately preceding it – *i.e.*, 'the application of any pro rata reduction'" – *not* the phrase regarding the Medicare OPD fee schedule that Defendants believe applies here. *Id.* at 24.

The structure of (t)(12)(E) makes plain that *all* of the listed types of determinations are made "under paragraph (5)" or "under paragraph (6)"—not just the types that immediately precede those phrases. Each of the types of determinations listed in the first part of (t)(12)(E) refers to a specific provision of Paragraph (5), and each of the types of determinations listed in the second part of (t)(12)(E), which follow the word "or," refers to a specific provision of Paragraph (6). *Compare* 42 U.S.C. § 1395*l*(t)(12)(E), *with id.* § 1395*l*(t)(5), (6). Critically, this includes the language that Defendants focus on in (t)(12)(E) regarding "the determination of . . . the portion of the medicare OPD fee schedule amount associated with particular . . . drugs." *See* Defs.' Mem. at 20–24. That phrase is obviously a reference to action under Paragraph (6) that must be based on "the portion of the otherwise applicable medicare OPD fee schedule that the Secretary determines is associated with the drug." 42 U.S.C. § 1395*l*(t)(6)(D)(i). Agency action under Paragraph (6) has nothing to do with agency action under Paragraph (14), which in fact specifically *excludes* drugs that receive payments under Paragraph (6). *See id.* § 1395*l*(t)(14)(B)(ii)(I).

HHS suggests that its reading is required by "the 'last antecedent rule' of statutory construction." Defs.' Mem. at 24. But HHS's argument takes the "last antecedent rule" much too far, and paragraph (12)(E) is a prime example of the precept that "structural or contextual evidence may rebut the last antecedent inference." *Lockhart v. United States*, 136 S. Ct. 958, 965 (2016) (citation omitted).

Reading Paragraph (12)(E) to refer exclusively to types of agency action under paragraphs (5) and (6) makes perfect sense because Congress added all of Paragraph (12)(E) to the OPPS law in 1999 at the same time that it added Paragraphs (5) and (6).[7] Congress did not enact Paragraph (14) until 2003 and, tellingly, did not amend Paragraph (12)(E) to include a reference to Paragraph (14). There is no evidence that Congress intended for Paragraph (12)(E) to preclude review of agency action under Paragraph (14), let alone the requisite clear and convincing evidence.

B. Even if Preclusion Applies to Section 1395*l*(t)(14), Agency Action that Exceeds the Secretary's Authority Under that Provision is Reviewable.

HHS floats a grab bag of preclusion arguments, and its approach amounts to throwing spaghetti at a wall, hoping something will stick. But even if one of Paragraph (12)'s preclusion provisions applied to agency action under Paragraph (14), those provisions do not bar review of agency action under the OPPS system "for which [statutory] authority is lacking." *Amgen*, 357 F.3d at 113. Accordingly, "the determination of whether the court has jurisdiction is intertwined with the question of whether the agency has authority for the challenged action, and the court must address the merits to the extent necessary to determine whether the challenged agency action falls within the scope of the preclusion on judicial review." *Id.*; *accord Organogenesis*, 41 F. Supp. 3d at 20–21; *H. Lee Moffitt Cancer Ctr. & Research Inst. Hosp., Inc. v. Azar*, No. 16-cv-2237 (TJK), 2018 WL 3459916, at *6–7 (D.D.C. July 18, 2018), *appeal filed*, No. 18-5277, 2018 WL 3459916 (D.C. Cir. Sept. 19, 2018). Denying preclusion under such circumstances does not implicate concerns about piecemeal review because facial challenges to an agency's statutory authority "are infrequent and typically raise issues—unrelated to the facts

[7] *See supra* note 3, at § 201(a), (b), and (d), 113 Stat. at 1501A-336 to 339 (adding Paragraphs (5), (6), and (12)(E) to OPPS law).

of the particular cases—that need only be resolved by the courts once." *H. Lee Moffitt*, 2018 WL 3459916, at *6 (citation omitted); *see also Amgen*, 357 F.3d at 113 ("[T]he interference with the administration of the Medicare B program that would result from judicial review pertaining to the overall scope of the Secretary's statutory adjustment authority, as opposed to case-by-case review of the reasonableness or procedural propriety of the Secretary's individual applications, would be sufficiently offset by the likely gains from reducing the risk of systematic misinterpretation in the administration of the Medicare B program."). Thus, there is no preclusion if HHS exceeded its "adjustment" authority in reducing reimbursements for 340B drugs by almost 30%. As explained below, HHS did exceed its authority. *See infra* § IV.

II. PLAINTIFFS EMHS AND PARK RIDGE HAVE SATISFIED THE EXHAUSTION REQUIREMENT, AND IN ANY EVENT, EXHAUSTION SHOULD BE WAIVED AS FUTILE.

HHS concedes, as it must, that all Plaintiffs have satisfied the jurisdictional presentment requirement by submitting claims for payment to the Secretary for drugs covered by the 340B Program. Defs.' Mem. at 15 n.6. But HHS contends that, in light of the waivable exhaustion requirement, Plaintiffs cannot bring their claims to the Court until they have completed every stage of administrative review set forth in HHS regulations. *See id.* at 26–27.

As an initial matter, after Plaintiffs filed their Motion for a Preliminary and Permanent Injunction but before Defendants filed their Motion to Dismiss, Plaintiffs Eastern Maine Healthcare Systems ("EMHS") and Park Ridge Health ("Park Ridge") *did* obtain decisions that HHS regulations treat as final. A Qualified Independent Contractor ("QIC") issued letters in three of EMHS's appeals and in one of Park Ridge's appeals stating as follows:

> [B]ecause administrative review is not available for this issue, there is not sufficient cause to reverse the [Medicare Administrative C]ontractor's dismissal. Therefore, the contractor's original dismissal stands. In accordance with 42 CFR Section 405.974(b)(3), **a QIC's reconsideration of a contractor's dismissal of a**

> **redetermination request is final and not subject to any further review. You have no further appeal rights on this case.**

Suppl. Ex. L at 6; Suppl. Ex. N at 6; Suppl. Ex. P at 7; Suppl. Ex. R at 9 (emphasis added). The regulation cited in the letters provides that "[a] QIC's review of a contractor's dismissal of a redetermination request is binding and not subject to further review." 42 C.F.R. § 405.974(b)(3). Plaintiffs EMHS and Park Ridge have fully exhausted the review procedures set forth in HHS regulations and have obtained decisions that those regulations treat as final.[8]

As for the other Plaintiffs (and for EMHS's and Park Ridge's other pending appeals), any further administrative review would be manifestly futile, as Plaintiffs demonstrated in their Motion for a Preliminary and Permanent Injunction. *See* Pls.' Mem. at 16–20. Perhaps the most striking evidence is that HHS itself has stated in another lawsuit that, in light of its position that administrative and judicial review of OPPS adjustments is statutorily precluded, any administrative appeals that reach the Administrative Law Judge stage *will be dismissed as unreviewable*. Ex. U to Pls.' Mem., ECF No. 2-24 ("If AHA member hospitals attempt to challenge non-reviewable [340B] determinations by filing administrative appeals with the Office of Medicare Hearings and Appeals (OMHA), then OMHA *will flag those filings and dismiss them promptly*." (emphasis added)). HHS was similarly blunt in a letter that it submitted to the D.C. Circuit in the prior iteration of the instant lawsuit: "providers cannot challenge the reimbursement rate for [340B] drugs within the current Medicare administrative appeals process." Ex. Y. HHS does not suggest there is any chance it will change its position during the administrative review process. Nor does it suggest that the administrative review process might

[8] Out of an abundance of caution, EMHS has submitted requests for administrative law judge review of the three QIC decisions it has received. *See* Suppl. Ex. L at 8–13; Suppl. Ex. N at 8–13; Suppl. Ex. P at 9–14. Park Ridge will do likewise shortly. EMHS has not received any responses to its requests.

yield a helpful factual record; in fact, HHS flatly acknowledges that the Court need not even "consider the administrative record in evaluating Plaintiffs' claim[s], since the claims present pure questions of statutory interpretation." Defs.' Mem. at 28 n.10. In other words, HHS does not dispute the premise that further administrative review would be entirely futile.

HHS argues instead that "Plaintiffs' contention that administrative review would be futile does not excuse compliance with the exhaustion requirement." *Id.* at 26 (citation omitted). HHS displays considerable audacity in insisting on exhaustion of administrative procedures that HHS believes Plaintiffs "cannot" pursue. Ex. Y. In any event, HHS's argument is squarely foreclosed by binding precedent and is based on a misreading of the authorities that HHS cites. The D.C. Circuit has squarely held that futility of further administrative review is a valid basis for judicial waiver of the exhaustion requirement. *Tataranowicz v. Sullivan*, 959 F.2d 268, 273–75 (D.C. Cir. 1992); *see also Nat'l Ass'n for Home Care & Hospice, Inc. v. Burwell* ("*NAHC*"), 77 F. Supp. 3d 103, 110–12 (D.D.C. 2015). Although it cites *Tataranowicz*, HHS makes no attempt to distinguish it (or *NAHC*).

Instead, HHS relies on a misreading of the Supreme Court's decision in *Weinberger v. Salfi*, 422 U.S. 749 (1975), in suggesting that that case supports an argument that futility does not excuse compliance with the exhaustion requirement. *See* Defs.' Mem. at 26. *Salfi* did hold that, where there had been no exhaustion *or presentment*, § 405(g)'s "final decision" requirement cannot be discarded on grounds of futility. *Id.* at 764. But for the plaintiffs in *Salfi* who had presented their claims, as HHS concedes Plaintiffs have here, the Court allowed judicial review to proceed because further administrative review would be futile. *See id.* at 764–67. And although the agency in *Salfi* did not contest exhaustion, *id.* at 767, the Supreme Court and the D.C. Circuit have repeatedly affirmed that courts can determine that exhaustion should be

waived even in cases where the agency disagrees. *See Shalala v. Ill. Council on Long Term Care, Inc.*, 529 U.S. 1, 24 (2000); *Matthews v. Eldridge*, 424 U.S. 319, 330–31 (1976); *Tataranowicz*, 959 F.2d at 274.

Finally, HHS argues that the Supreme Court's *Illinois Council* decision held that even where the agency "lack[s] the power to resolve certain questions," claims against it must nevertheless undergo "an abbreviated administrative review process that establishes a path to expedited judicial review." Defs.' Mem. at 26–27. But the Court in *Illinois Council* stated, citing *Eldridge,* that "a court can deem [many of the procedural steps set forth in § 405(g)] waived in certain circumstances." 529 U.S. at 24. This authority derives both from the agency's authority to waive certain procedural steps, *see* 42 U.S.C. § 1395ff(b) (authorizing agencies to establish a process for expedited access to judicial review) and from the court's independent authority to determine whether waiver of the exhaustion requirement is appropriate. *Eldridge*, 424 U.S. at 330–32 ("denial of Eldridge's request for benefits constitutes a final decision for purposes of § 405(g) jurisdiction" even where Eldridge "did not exhaust the full set of internal-review procedures provided by the Secretary"); *Tataranowicz*, 959 F.2d at 274.

All three Hospital Plaintiffs have proceeded through multiple stages of administrative review to no avail, and any further review would be demonstrably futile. That is grounds for the Court to determine that the Secretary has reached a "final decision" for purposes of § 405(g) and to waive any requirement of further exhaustion.

III. THE SECRETARY'S EXERCISE OF "ADJUSTMENT" AUTHORITY IS NOT COMMITTED TO AGENCY DISCRETION BY LAW.

HHS's argument that the Secretary's exercise of "adjustment" authority is "committed to agency discretion by law" is foreclosed by the D.C. Circuit's decision in *Amgen*. That case holds that "a more substantial departure from the default amounts would, at some point violate the

Secretary's statutory obligation to make such payments and cease to be an 'adjustment'" and would therefore be subject to judicial review. 357 F.3d at 117. In other words, *Amgen* holds there *is* a "meaningful standard" against which to measure the Secretary's exercise of "adjustment" authority.

Further, regarding the statutory provision at issue here, Paragraph (14)(A)(iii), the Secretary's authority is limited not only by the meaning of the term "adjustment," but also by the Subclause (II) requirement that the adjustment be consistent with the average sales price of drugs and the Subclause (I) requirement that reimbursement may be based on acquisition cost only if the Secretary has certain rigorous data. These "statutory obligations," to use *Amgen*'s language, also provide meaningful standards by which to assess the legality of the 340B Provisions of the OPPS Rule. 357 F.3d at 117.

HHS's cases are inapposite. *Sierra Club v. Jackson* involved an "agency decision[] not to take enforcement action," and in that unique context courts "begin with the presumption that the agency's action is unreviewable." 648 F.3d 848, 855 (D.C. Cir. 2011). *Webster v. Doe*, 486 U.S. 592 (1988), and *Wendland v. Gutierrez*, 580 F. Supp. 2d 151 (D.D.C. 2008) both involved statutory language authorizing an agency to take action it "*deem[ed]* necessary." *Doe*, 486 U.S. at 600; 580 F. Supp. 2d at 153 (emphasis added). Indeed, in *Doe*, the Supreme Court indicated that the agency decision at issue *would* have been reviewable had the statute omitted the word "deem" and authorized action "simply when [it] *is* necessary" in the interests of the United States. 486 U.S. at 600 (emphasis in original). The language that *Doe* concluded would permit review is analogous to the adjustment language here. *See* 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II) (authorizing adjustment "as necessary for purposes of this paragraph"). That language provides meaningful constraints on agency action that a court can enforce. *See Amgen*, 357 F.3d at 117.

IV. ON THE MERITS, THE SECRETARY EXCEEDED HIS "ADJUSTMENT" AUTHORITY UNDER SECTION 1395*l*(t)(14).

We have previously demonstrated that the Secretary exceeded his authority to adjust the statutory rate for separately payable drugs for three reasons: (1) the Secretary cannot use his statutory adjustment authority to set payment amounts based on acquisition costs; (2) the almost 30 percent reduction was not an "adjustment" of the average sales price; and (3) the adjustment authority may not be used for the purpose of undermining the 340B Program. Pls.' Mem. at 21–30. HHS's response on each point is unpersuasive.[9]

A. The Secretary Cannot Use His "Adjustment" Authority Under Subclause (II) to Use Acquisition Costs in a Manner that Would Be Forbidden Under Subclause (I).

As we explained in our opening brief, Congress limited the acquisition-cost methodology for calculating reimbursements for separately payable drugs to circumstances in which the Secretary has "survey data" drawn from "a large sample of hospitals that is sufficient to generate a statistically significant estimate of the average hospital acquisition cost for each specified covered outpatient drug." 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(I), (D)(iii). Undaunted by the fact that he "does not have acquisition cost survey data," *Am. Hosp. Ass'n*, 895 F.3d at 824, the Secretary calculated the payment amount based on an estimate of average acquisition cost anyway, framing his calculation as an "adjustment" of Average Sales Price under Subclause (II), claiming he could avoid the limitations of Subclause (I). *See* 82 Fed. Reg. at 52,498. If the Secretary had set the exact same payment rate based on the exact same information and cited Subclause (I) as authority for his action, he would obviously have been violating Subclause (I)'s data requirement. If Congress had intended for Subclause (II) sales price "adjustments" to

[9] Because HHS's interpretation of its authority is clearly foreclosed by the OPPS statute, deference under *Chevron U.S.A. Inc v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984), has no application.

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.

HHS's arguments to the contrary are unpersuasive. HHS claims that "the Secretary's adjustment authority would be rendered meaningless" if "the ultimate 'payment' must be based strictly on ASP" and that there must be some content to the Secretary's authority to "adjust" ASP so as to adhere to "one of the most basic interpretive canons, that a statute should be construed so that effect is given to all its provisions, so that no part will be inoperative or superfluous, void or insignificant." Defs.' Mem. at 29. But the Secretary's adjustment authority would not be "rendered meaningless" under Plaintiffs' reading: the Secretary may "adjust" ASP in a manner that bears a coherent relationship to ASP plus 6 percent, and that attempts to refine the national average sales price so it is more accurate, or better approximates pharmacy services and handling costs. *See* Pls.' Mem. at 26–27. The Secretary has made this type of adjustment in the past. *See id.* at 25–26.

Indeed it is *HHS's* reading that would render an entire provision of the statute superfluous. If the Secretary were correct that he may "adjust" ASP under Subclause (II) by whatever percentage is necessary to approximate acquisition cost, without the data required under Subclause (I), then Subclause (I) is superfluous in its entirety. HHS could simply use its "adjustment" authority under Subclause (II) to set the payment rate based on acquisition cost, whether it had statistically significant survey data or not. That is not how Congress writes statutes; if the Secretary does not have the requisite data for considering acquisition costs pursuant to Subclause (I), he may not do so anyway pursuant to Subclause (II) under the guise of "adjusting" ASP.

B. The Payment Reduction in the OPPS Rule Was Not an "Adjustment" of ASP.

We explained in our opening brief that the Secretary's near-30% reduction in payment rate was not an "adjustment" of ASP because (1) it was too large to be an "adjustment" and (2) it bore no coherent relationship to ASP, the thing supposedly being "adjusted." Pls.' Mem. at 24–27.

None of HHS's responses holds water. First, HHS argues that "[t]he statute does not impose any restriction on the Secretary's discretionary 'adjustment' of OPPS drug payment rates . . . , including any restriction on the *amount* of that adjustment." Defs.' Mem. at 30 (emphasis in original); *see also id.* at 1 (claiming that the Secretary's adjustment authority is a "broad and unequivocal grant of discretion"). But that argument ignores the "[l]imitations . . . [that] inhere in the text" of a statutory provision that "only authorizes 'adjustments,' not a total elimination or severe restructuring of the statutory scheme." *Amgen*, 357 F.3d at 117.

HHS breezily dismisses this limitation, arguing that the challenged payment reduction "does not remotely approximate a 'total elimination or severe restructuring of the statutory scheme.'" Defs.' Mem. at 32 (quoting *Amgen*, 357 F.3d at 117). But the statute commands that the payment rate "shall be equal . . . [to] the average price of the drug in the year [ASP] . . . , 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). 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. Furthermore, HHS's boundless interpretation of its "adjustment" authority effectively rewrites Congress's chosen structure in two ways, allowing HHS: (1) to use its Subclause (II) "adjustment" authority to end-run the Subclause (I) data requirement; *and* (2) to adopt a rate under Subclause (II) that bears no meaningful relationship to

the ASP plus 6% default rate. By any measure, that approach "severe[ly] restructure[s]" Congress's chosen statutory scheme. *Amgen*, 357 F.3d at 117.[10]

Second, HHS argues that the adjustments referenced in Paragraph (14)(E) for "overhead and related expenses, such as pharmacy services and handling costs," 42 U.S.C. § 1395*l*(t)(14)(E)(i), are "wholly distinct from the Secretary's broader authority to adjust OPPS drug payment rates 'as necessary'" under Subclause (II). Defs.' Mem. at 35. HHS contends that while Paragraph (14)(E) expressly authorizes only a limited set of adjustments, Subclause (II) "include[s] no similar qualifying language." *Id.* This argument ignores the fact that, under Subclause (II), the Secretary may only adjust ASP "as necessary for purposes of this paragraph." 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II). The only type of adjustments referenced in Paragraph (14) are the ones in Subparagraph (E), and the Secretary has no competing explanation for which adjustments are "necessary for purposes of this paragraph." The Secretary's view that "[t]he statute does not impose *any* restriction on the Secretary's discretionary 'adjustment' of OPPS drug payment rates under [Subclause (II)]," Defs.' Mem. at 30, reads this limiting language out of the statute.

Finally, HHS attempts to rebut Plaintiffs' argument that the payment reduction was "inadequately connected to the ASP" by contending that "the Secretary continues to 'calculate' ASP" in the same manner that it did before the 2018 OPPS Rule. Defs.' Mem. at 34. That response is plainly insufficient; the statute requires that the payment be equal to ASP, "as calculated *and adjusted* by the Secretary as necessary for purposes of this paragraph."

[10] This case contrasts with *Amgen* itself, which involved a rate change for a single drug product made by a single company that quite clearly "[did] not work 'basic and fundamental changes in the scheme Congress created in the Medicare Act.'" 357 F.3d at 117 (citation omitted). Here, in contrast, the Secretary has expanded the scope of his adjustment authority in a manner that affects hundreds of hospitals and millions of patients.

§ 1395*l*(t)(14)(A)(iii)(II). ASP is the thing being "adjusted," not just the thing being "calculated," and so any adjustment must coherently relate to ASP. Defendants' dictionary definitions agree. *See* Defs.' Mem. at 33 n.12 (citing dictionaries that define "adjust" to mean, for example, "a: to bring to a more satisfactory state . . . b: to make correspondent or comfortable . . . c: to bring the parts of to a true or more effective relative position" (alterations by Defendants)). The default ASP-plus-6% statutory rate is meaningless as a baseline if *any* departure from it is acceptable. *See Amgen*, 357 F.3d at 117 (noting that "a more substantial departure from the default amounts would, at some point, . . . cease to be an 'adjustment'").

C. The Secretary May Not Use His "Adjustment" Authority to Target 340B Hospitals and to Undermine the 340B Program.

HHS argues that it is permitted to treat different hospital groups differently when setting payment rates for separately payable drugs under Subclause (II) "because other parts of the Medicare statute treat those types of providers differently." Defs.' Mem. at 36. As examples, HHS points to provisions that authorize special treatment for rural hospitals, children's hospitals, and cancer hospitals. *See id.* (citing 42 U.S.C. § 1395*l*(t)(7)(D)(ii), (t)(13)). If anything, the fact that *other* parts of the Medicare statute authorize differential treatment for *other* groups of hospitals undercuts HHS's argument that the Secretary may specifically target 340B hospitals, for which Subclause (II) does not authorize differential treatment. Indeed, as Plaintiffs pointed out in their opening brief, Pls.' Mem. at 27–28, Subclause (I) expressly authorizes the Secretary to "vary" payments "by hospital group," and Subclause (II) has no similar authority. *See* 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(I), (II); *see also id.* § 1395*l*(t)(2)(E) (authorizing the Secretary to "establish . . . other adjustments as determined to be necessary to ensure equitable payments, such as adjustments for certain classes of hospitals"). ASP is a nationwide measure of drug

value, *see* 42 U.S.C. § 1395w-3a, and, unlike other provisions of the OPPS statute, Subclause (II) contains no authority for the Secretary to adjust ASP differently for different hospital groups.

HHS also protests that the 340B Provisions of the OPPS Rule were not designed to undermine the purposes of the 340B Program. HHS contends that is so, first, because the 340B Program implements drug discounts, and the 2018 OPPS Rule affects only the amount that hospitals are reimbursed—not the discounts they receive when acquiring drugs. Defs.' Mem. at 36–37. HHS argues that any difference between the discounted drug prices and the amount reimbursed "is an ancillary benefit to providers of a misalignment between acquisition costs and reimbursements, rather than a purpose of the 340B Program." *Id.* at 37 n.13. This argument completely ignores Congress's stated purpose in enacting the 340B Program. Much as HHS may disagree with the 340B Program on policy grounds, the core purpose of that Program 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." H.R. Rep. No. 102-384(II), at 12 (1992). In 2010, Congress reaffirmed that purpose by expanding the Program to additional groups of hospitals. *See* Pls.' Mem. at 30 (discussing 42 U.S.C. § 256b(a)(4)(M)–(O)). HHS cannot seriously deny that it is undermining the purpose of the Program by drastically reducing the difference between reimbursements and discounted prices.[11]

[11] Many of HHS's policy objections to the 340B Program rest on inaccurate factual statements. For example, HHS asserted that reducing reimbursements for 340B Drugs would result in lower patient copays. Ex. A, 82 Fed. Reg. at 52,495–96, 52,498. But as several commenters pointed out, most Medicare beneficiaries do not cover their own copays and would not benefit from this reduction. *See, e.g.*, Ex. C at 12 (AHA Comment); Ex. E at 10 (AEH Comment). Commenters also pointed out that HHS's drastic reimbursement cuts in the 340B Provisions of the 2018 OPPS Rule would likely *raise* copays for the majority of Medicare beneficiaries because of corresponding budget-neutrality adjustments. *See* Ex. C at 12 (AHA Comment); Ex. E at 9–10 (AEH Comment). And more fundamentally, HHS may not target and undermine a congressionally mandated program based on its own policy disagreements with that program.

Second, HHS argues that the 340B Provisions of the OPPS Rule were not intended to undermine the purposes of the 340B Program because they sought only to make Medicare reimbursements "more aligned" with providers' acquisition costs, not to "*eliminate*" the difference between the two. Defs.' Mem. at 37 (emphasis in original). That is, at best, a purely semantic distinction, and in any event, when an agency has specifically attempted to undermine a program enacted by Congress, it is no answer that the agency did not *entirely* eliminate the program's benefits, but only *mostly* so.

V. THE COURT SHOULD GRANT PLAINTIFFS FINAL JUDGMENT UNDER RULE 65(a)(2).

Plaintiffs have previously demonstrated that they meet each of the four preliminary injunction factors. *See* Pls.' Mem. at 21–33. Plaintiffs reaffirm the arguments in their Motion regarding each factor. Notably, Defendants have conceded the "irreparable harm" factor by failing to address it. *See* Defs.' Mem. at 39–41 (addressing likelihood of success on the merits, balance of equities, and public interest, but not irreparable harm); *see also Texas v. United States*, 798 F.3d 1108, 1115 (D.C. Cir. 2015) (noting that, under D.D.C. Local Rule 7(b), the district court may "deem[] as conceded any of a movant's arguments to which the opposing party fails to respond").

As Plaintiffs noted in their Motion for a Preliminary and Permanent Injunction, if the Court consolidates the merits with the hearing on the preliminary injunction, it need not consider the four preliminary injunction factors. Pls.' Mem. at 34–35 (citing, *e.g*, *March for Life v. Burwell*, 128 F. Supp. 3d 116, 124 (D.D.C. 2015)). While Plaintiffs have satisfied the

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See Utility Air Reg. Grp. v. EPA, 134 S. Ct. 1427, 2445 (2014) ("An agency has no power to 'tailor' legislation to bureaucratic policy goals by rewriting unambiguous statutory terms.").

requirements for a preliminary injunction, the Court should reach the merits and issue a final judgment in favor of Plaintiffs.

CONCLUSION

The parties have fully briefed all of the issues in this case three times. As Defendants acknowledge, "this suit is a near carbon copy of [the] suit Plaintiffs filed last year in this Court." Defs.' Mem. at 15. HHS has had more than an ample opportunity to brief the legal issues in this case, and there are no factual issues to be resolved. Plaintiffs respectfully ask that the Court deny Defendants' Motion to Dismiss, advance its determination of the merits under Rule 65(a)(2), enter judgment for the Plaintiffs, and award the relief requested in the Complaint.

Dated: September 26, 2018

Respectfully submitted,

/s/ William B. Schultz

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CERTIFICATE OF SERVICE

I hereby certify that on September 26, 2018, I caused the foregoing to be electronically served on counsel of record via the Court's CM/ECF system.

/s/ William B. Schultz
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