IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

THE AMERICAN HOSPITAL ASSOCIATION, *et al.*,	)	
Plaintiffs,	)	
v.	)	No. 1:17-cv-02447-RC
ERIC D. HARGAN, Acting Secretary of Health and Human Services, and	)	
THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,	)	
Defendants.	)	

REPLY IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases **Page(s)**

Statutes

Other Authorities

INTRODUCTION

Nothing in Plaintiffs' opposition changes the fact that the plain text of 42 U.S.C. § 1395*l*(t)(12) "'clearly preclude[s] judicial review of the Secretary's adjustments to prospective payment amounts,'" or that "the legislative history comports with a preclusion of judicial review of CMS's authority to set prospective payment methodologies." *Organogenesis Inc. v. Sebelius*, 41 F. Supp. 3d 14, 20 (D.D.C. 2014) (Contreras, J.) (quoting *Amgen, Inc. v. Smith*, 357 F.3d 103, 112 (D.C. Cir. 2004)). Plaintiffs do not dispute that this suit is a challenge to "the Secretary's adjustments to prospective payment amounts." They instead engage in textual gymnastics that distort both § 1395*l*(t)(12)'s plain meaning and its context within the Outpatient Prospective Payment System ("OPPS"). Under Plaintiffs' convoluted reading, § 1395*l*(t)(12) inexplicitly forbids judicial review of ***some*** of the Secretary's payment adjustments within the OPPS, but not others—even though ***any*** such review threatens to wreak "havoc" on the carefully-calibrated OPPS, which is precisely why Congress enacted the preclusion-of-review provision. Plaintiffs' position cannot be squared with the totality of the Medicare statute's OPPS provisions, the legislative history, or the governing case law. Their APA claim is precluded by § 1395*l*(t)(12).

Plaintiffs also fail to refute Defendants' position that the Secretary's payment adjustment under § 1395*l*(t)(14)(A)(iii)(II) is "committed to agency discretion by law" and thus unreviewable. In disputing this point, Plaintiffs cite only inapposite case law and, critically, fail to identify any "meaningful standard" that this Court could apply to determine whether the Secretary's adjustment was "necessary for purposes of this paragraph." 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II).

Even if Plaintiffs' APA claim were reviewable, Plaintiffs' opposition confirms that they have failed to satisfy the Medicare statute's exhaustion requirements. Before filing suit, Plaintiffs did not adequately "present" their claims to the agency, nor did they "exhaust" agency procedures.

Plaintiffs concede the latter point, but seek to excuse that failure by claiming that exhaustion would have been "futile." But they fall far short of satisfying the demanding "futility" exception.

Nor do Plaintiffs refute Defendants' position that their APA claim—asserting that the Secretary exceeded his statutory adjustment authority—fails on the merits. Unable to point to anything in the Medicare statute's text or legislative history supporting their strained reading, Plaintiffs continue to invoke cherry-picked dictionary definitions and inapplicable case law. They also take the Secretary's payment adjustment out of context by characterizing it as "dramatic" and "severe," overlooking that it reduced what was itself an ***enormous*** disparity (of up to 58%) between Medicare payment rates and 340B providers' acquisition costs—a disparity that led to outsized payments to 340B providers at the expense of other OPPS participants and Medicare beneficiaries. Moreover, Plaintiffs do not dispute that if there is any material statutory ambiguity concerning the Secretary's adjustment authority, Defendants' reading is entitled to *Chevron* deference, and likewise passes muster under the narrow *ultra vires* review doctrine.[1]

ARGUMENT

I. Section 1395*l*(t)(12) Precludes Judicial Review

A. The D.C. Circuit's Decision in *Amgen* Supports Preclusion

Plaintiffs cite *Amgen* as recognizing a "strong presumption that Congress intends judicial review of administrative action." Pls.' Reply Br. in Supp. of Mot. for Prelim. Inj. & Opp. to Defs.' Mot. to Dismiss [ECF No. 20] ("Pls.' Opp") at 3. But *Amgen* goes on to recognize that this presumption may be overcome by "'clear and convincing evidence' that Congress intended to preclude the suit." 357 F.3d at 111. And the Circuit found such evidence in § (t)(12): "That

[1] Hereinafter, references to 42 U.S.C. § 1395*l*(t)—the OPPS provisions of the Medicare statute—will be abbreviated as "§ (t)" followed by the relevant paragraph number (e.g., "§ (t)(2)").

Congress intended to preclude judicial review of the ***Secretary's adjustments to prospective payment amounts*** is 'clear and convincing' from the plain text of § (t)(12) alone," and "the legislative history reflects this stipulation." *Id.* at 112 (emphasis added); *see also id.* at 118 (holding that "the court lacks jurisdiction under § (t)(12)(A) to consider Amgen's complaint challenging the Secretary's exercise of the equitable adjustment authority under § (t)(2)(E)."). This suit is precisely what *Amgen* recognized is barred by § (t)(12): a challenge to the "Secretary's adjustments to prospective payment amounts."

Plaintiffs do not address this crucial language from *Amgen*. Nor do they address the extensive legislative history undermining their position, cited both in *Amgen* and Defendants' memorandum. *See* Mem. in. Supp. of Defs.' Mot. to Dismiss & in Opp. to Pls.' Mot. for Prelim. Inj. [ECF No. 17] ("Defs.' Mem.") at 15 (citing H.R. Rep. No. 108-391, 599 (2003) (Conf. Rep.), *as reprinted in* 2003 U.S.C.C.A.N. 1808, 1965 (the "provisions concerning Medicare's determination of payment amounts . . . or adjustments . . . will not be subject to . . . judicial review," and the "provisions concerning Medicare's . . . adjustments to . . . other drug administration services will not be subject to . . . judicial review."); H.R. Rep. No. 105-149, 724 (1997) ("The provision would prohibit administrative or judicial review of the prospective payment system.")).

Plaintiffs also misconstrue *Amgen* as holding that where, as here, a plaintiff alleges that the Secretary acted *ultra vires* in administering the OPPS, the Court must fully evaluate the merits of that claim before deciding whether § (t)(12) precludes judicial review. Pls.' Opp. at 4. As Defendants' memorandum explained (at 19-20), although review under the narrow *ultra vires* doctrine entails *some* evaluation of the merits, *see Amgen*, 357 F.3d at 113, this is not a full-blown review—if it were, then the preclusion provision would be rendered meaningless. Rather, "[c]ourts will exercise their power to review alleged *ultra vires* agency action when an agency

'patently misconstrues a statute, disregards a specific and unambiguous statutory directive, or violates a specific command of a statute.'" *Organogenesis*, 41 F. Supp. 3d at 23; *accord Fla. Health Sci. Ctr. v. Sec'y of Health & Human Servs.*, 830 F.3d 515, 522 (D.C. Cir. 2016). Because Plaintiffs fail to show that the Secretary violated any "specific and unambiguous statutory directive," they cannot prevail under the narrow *ultra vires* doctrine.

B. Section 1395*l*(t)(12)(A) Precludes Judicial Review

Defendants explained that § (t)(12)(A) broadly precludes judicial review of the Secretary's "development of" the OPPS "classification system under paragraph [(t)](2)," including any "adjustments" to that system. Defs.' Mem. at 17-18. Plaintiffs respond that § (t)(12)(A) does not preclude judicial review of adjustments made under § (t)(14), because § (t)(12)(A)'s reference to the "classification system under paragraph [(t)](2)" concerns a "specific methodology used by HHS to establish payment rates under the OPPS," which Plaintiffs argue is "separate" from the drug payment methodology of § (t)(14). Pls.' Opp. at 4-5.

Plaintiffs are mistaken. 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) (emphasis added). 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). Thus, § (t)(2)(A)'s reference to the "classification system for covered OPD services" plainly refers to the ***overall*** payment classification system for the OPPS, better known as the "APC system." Defs.' Mem. at 17-18. By contrast, the remaining subsections of § (t)(2)—

subsections (B) through (H)—describe specific types of payment methodologies and adjustments ***within*** the overall APC system. *See* 42 U.S.C. § 1395*l*(t)(2)(B)-(H).

Because § (t)(2)(A) refers to the overall APC system within which ***all*** OPPS payment rates are established, Plaintiffs are wrong when they claim that § (t)(12)'s reference to § (t)(2) concerns a "separate" payment methodology from the one outlined in § (t)(14). To the contrary, 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) (emphasis added). 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." Viewed together, then, these provisions make clear that a drug's payment rate is necessarily part of the overall APC system described in § (t)(2)(A). It follows that the Secretary's adjustment here of the 340B drug payment rate under § (t)(14)(A)(iii)(II) was part of his "development of" the overall APC system described in § (t)(2)(A), and was likewise an "other adjustment[]" to that system, meaning that judicial review is barred by § (t)(12)(A).

Plaintiffs' reading finds no support in *Organogenesis*, 41 F. Supp. 3d at 14. There, the plaintiff challenged the Secretary's payment methodology for a product called Apligraf. *Id.* at 18. Pursuant to his authority under § (t)(2)(B) to "establish groups of covered OPD services," the Secretary "grouped" Apligraf together "with its corresponding surgical procedure, instead of reimbursing for Apligraf separately using the [specified covered outpatient drug ("SCOD")]

methodology" of § (t)(14)(A)(iii). *Id.* at 19. The plaintiff argued that the Secretary "improperly group[ed] and reimburse[d] for Apligraf as a part of a procedure package" under § (t)(2)(B), "instead of paying for Apligraf separately as a SCOD" under § (t)(14)(A)(iii). *Id.* The Secretary responded that this claim fell within § (t)(12)(A)'s bar on review of the Secretary's "establishment of groups . . . for covered OPD services" under § (t)(2)(B). *Id.* at 19-20.

This Court dismissed the complaint. *Id.* at 23. In so ruling, the Court framed the issue as "whether Apligraf properly qualifie[d] as a SCOD" for which separate payment was required under § (t)(14), or whether it qualified as an OPD service that the Secretary could "group" with other OPD services per § (t)(2)(B). *Id.* at 20-21. If Apligraf qualified as a SCOD, review would be available under the narrow "*ultra vires* doctrine of review" because the Secretary plainly would have exceeded his statutory authority by failing to apply the SCOD payment methodology of § (t)(14)(A)(iii). *Id.* If, however, Apligraf did not qualify as a SCOD, judicial review would be precluded by § (t)(12)(A)'s bar on claims challenging the Secretary's "establishment of groups . . . for covered OPD services" under § (t)(2)(B). *Id.* at 20. The Court concluded, for reasons not pertinent here, that Apligraf did not "meet the statutory definition of a SCOD," and was instead "governed by the general OPD grouping provisions" of § (t)(2). *Id.* at 21-23. The plaintiff's claim was therefore precluded by § (t)(12)(A). *Id.* at 23.

Plaintiffs contend that *Organogenesis* held that § (t)(2) and § (t)(14) establish "completely different" payment methodologies, which, they contend, shows that a payment adjustment under § (t)(14) could not qualify as an adjustment to the "classification system for covered OPD services" described in § (t)(2)(A). Pls.' Opp. at 5-7. But Plaintiffs are conflating subsections (A) and (B) of § (t)(2). As noted, Defendants here are relying on ***subsection (A)***, which refers to the ***overall*** "classification system for covered OPD services." 42 U.S.C. § 1395*l*(t)(2)(A). *Organogenesis*,

by contrast, concerned ***subsection (B)***, which refers to a ***specific*** methodology by which "the Secretary may establish groups of covered OPD services, within the classification system described in subparagraph (A)." *Id.* § 1395*l*(t)(2)(B) (emphasis added). Defendants do not dispute that the "grouping" of covered OPD services under ***§ (t)(2)(B)*** is indeed a different payment methodology than the SCOD methodology of § (t)(14). But that has no bearing on whether ***§ (t)(2)(A)*** refers to the overall APC system.[2]

Plaintiffs also mischaracterize *Organogenesis* as holding that "paragraph (14), unlike paragraph (2), [is] *not* covered under the (t)(12)(A) preclusion language." Pls.' Opp. at 6, 9. That is incorrect. The Court did not hold that § (t)(12)(A)'s preclusion provision categorically does not apply to the Secretary's actions under § (t)(14). Rather, the Court recognized that judicial review would have been available ***in that case*** under the narrow *ultra vires* doctrine if Apligraf plainly and unambiguously met the statutory definition of a SCOD, because in that instance, the Secretary would have clearly erred in applying the "grouping" methodology of § (t)(2)(B), rather than the SCOD payment methodology of § (t)(14)(A)(iii). *Organogenesis*, 41 F. Supp. 3d at 21-23; *see id.* at 23 ("ultra vires" review only available when "agency 'patently misconstrues a statute, disregards a specific and unambiguous statutory directive, or violates a specific command of a statute.'").

Plaintiffs further argue that § (t)(12)(A)'s bar on judicial review of "other adjustments" does not apply here, because "other adjustments" refers to adjustments under § (t)(2)(E) ("the Secretary shall establish . . . other adjustments as determined to be necessary to ensure equitable payments . . ."), not adjustments under § (t)(14). Pls.' Opp. at 7. In support of this reading, Plaintiffs note that § (t)(12)(A) precludes review of "development of the [OPPS] classification

[2] Moreover, as the statutory language makes plain, § (t)(2)(B)'s "grouping" methodology is merely a component "within" the overall OPPS "classification system" described in § (t)(2)(A)—just as the § (t)(14) payment methodology is a component of that overall system.

system *under paragraph (2), including* . . . other adjustments." 42 U.S.C. § 1395*l*(t)(12)(A) (emphasis added). Plaintiffs claim that "use of the word 'including' demonstrates that 'other adjustments' in (t)(12)(A) expressly refers only to 'other adjustments' under paragraph (2)."

Plaintiffs are wrong again. First, as explained above, the reference in § (t)(12)(A)'s prefatory clause to the "classification system under paragraph (2)" concerns the ***overall*** APC system described in § (t)(2)(A), not the particular adjustments or payment methodologies set forth in § (t)(2)(B)-(H).[3] This prefatory language thus does not suggest that § (t)(12)(A) only bars judicial review of adjustments made under § (t)(2). Second, while it is true that the "other adjustment" language in § (t)(12)(A) and § (t)(2)(E) is similar, that does not mean that § (t)(12)(A) is ***limited*** to adjustments under § (t)(2)(E). The statute contains no such express limitation or cross-reference and, contrary to Plaintiffs' contention, Congress's use of the term "including" does not imply such a limitation. "[U]nder traditional rules of statutory construction, the term 'including' is not one of all-embracing definition, but connotes simply an illustrative application of the general principle." *Pub. Citizen, Inc. v. Lew*, 127 F. Supp. 2d 1, 23 (D.D.C. 2000). Third, the legislative history for the 2003 amendment that added § (t)(14) to the Medicare statute confirms that Congress contemplated that adjustments under § (t)(14) would be subject to the already-existing preclusion provisions of § (t)(12). *See* H.R. Rep. No. 108-391 at 599. Earlier legislative history from 1997 similarly indicates that Congress intended to broadly immunize judicial review of adjustments to prospective payment amounts. *See* H.R. Rep. No. 105-149 at 724.

Plaintiffs' reading of § (t)(12) would, moreover, lead to incongruous and arbitrary results. *See Winkelman ex rel. Winkelman v. Parma City Sch. Dist.*, 550 U.S. 516, 531 (2007) (construing

[3] Moreover, § (t)(14)(H) makes clear that (after 2005) expenditures under § (t)(14) are considered in calculating revisions under § (t)(9) to components of the APC system described in § (t)(2).

statute to avoid "incongruous results"). In Plaintiffs' view, the Secretary's adjustments under § (t)(2) are judicially reviewable, but his adjustments under § (t)(14) are not. Plaintiffs offer no explanation for why Congress would have decided to insulate some adjustments from judicial review, but not others. That is because Congress had no such intent. Indeed, judicial review of *either* type of payment adjustment implicates the same concerns regarding disrupting the OPPS and the Secretary's budget neutrality obligations. Rather than allowing such incongruities, the statutory text and legislative history confirm that Congress intended to *uniformly* preclude review of the Secretary's administration of the OPPS.

C. Section 1395*l*(t)(12)(E) Precludes Judicial Review

Defendants explained that Plaintiffs' APA claim is separately barred by subsection (E) of § 1395*l*(t)(12). Defs.' Mem. at 18. That provision 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).***

42 U.S.C. § 1395*l*(t)(12)(E) (emphasis added). Pointing to the "under paragraph (6)" qualifier at the end of this provision, Plaintiffs contend that § (t)(12)(E) only precludes review of "the portion of the medicare OPD fee schedule amount associated with particular . . . drugs" *within the meaning of § (t)(6)*. Pls.' Opp. at 8.

Plaintiffs' reading disregards the "last antecedent rule" of statutory construction, under which "qualifying words or phrases modify the words or phrases ***immediately preceding them*** and not words or phrases more remote, unless the extension is necessary from the context or the spirit of the entire writing." *Lockhart v. United States*, 136 S. Ct. 958, 962-63 (2016) (quoting Black's

Law Dictionary 1532-1533 (10th ed. 2014)) (emphasis added). Applying that rule here, 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." *See id.* at 962-69 (applying last antecedent rule). This reading makes sense in light of the rest of the statutory scheme, because the only place in § 1395*l*(t) where a "pro rata reduction" is mentioned is indeed in § (t)(6). *See* 42 U.S.C. § 1395*l*(t)(6)(E). By contrast, the "medicare OPD fee schedule" is mentioned repeatedly throughout § 1395*l*(t),[4] undermining any inference that § (t)(12)(E)'s reference to the "medicare OPD fee schedule" is somehow limited to § (t)(6) alone. Indeed, it would be nonsensical for Congress to have barred review of "the portion of the medicare OPD fee schedule amount associated with particular . . . drugs" in some contexts, but not in others; there is only ***one*** OPD fee schedule in the OPPS system, and thus a claim, such as Plaintiffs, that challenges fee schedule amounts necessarily implicates each of the provisions in § 1395*l*(t) referencing the OPD fee schedule.

D. Congress's Concerns That Judicial Review Would Wreak Havoc On The OPPS Are Directly Implicated Here.

Defendants emphasized that Congress's rationale for precluding review of the Secretary's administration of the OPPS—to avoid "wreaking havoc" on the carefully-calibrated payment system—is directly implicated here. Defs.' Mem. at 16, 19. Plaintiffs opine that concerns of "piecemeal review" actually *support* judicial review here, because Plaintiffs are challenging not individual determinations, but an "across-the-board reduction of Medicare reimbursement payment rates" on behalf of 'thousands of affected hospitals." Pls.' Opp. at 10-11.

Plaintiffs are again mistaken. First, Congress's concerns regarding the disruptive effect of judicial review on the OPPS are still implicated even where, as here, a large group of affected

[4] *See, e.g.*, 42 U.S.C. §§ 1395*l*(t)(3)(C)(i)(II)-(III), (t)(3)(C)(ii), (t)(3)(C)(iv), (t)(3)(D), (t)(3)(E)(i)-(ii), (t)(3)(F), (t)(4)(A), (t)(5)(A)(i)(I), (t)(5)(D)(i), (t)(6)(D)(i)-(ii), (t)(8)(B).

parties bring a facial challenge to a Medicare rule. *See Am. Soc'y of Cataract & Refractive Surgery v. Thompson*, 279 F.3d 447, 448-49, 454 (7th Cir. 2002) (judicial review of Medicare rule creating a "new system for calculating a component of the Medicare physician fee schedule" brought by "[e]leven national medical societies and associations" would be "disruptive" to OPPS).[5] Second, as Defendants have noted and Plaintiffs do not dispute, Defs.' Mem. at 19, a court order granting Plaintiffs' requested relief would have significant repercussions throughout the OPPS, including forcing CMS to recalculate the "budget neutral" adjustments it made to the payment rates for non-drugs items and services in the 2018 OPPS Rule. This is precisely the outcome Congress sought to avoid in precluding review of the Secretary's administration of the OPPS.

II. The Secretary's Payment Adjustment Under § 1395*l*(t)(14)(A)(iii)(II) Is Not Reviewable Because It Is Committed To Agency Discretion By Law

Defendants explained that the Secretary's adjustment is "committed to agency discretion by law" and thus unreviewable. Defs.' Mem. at 21-22. Plaintiffs' responses are unavailing.

Plaintiffs first assert that courts have "regularly reviewed whether HHS decisions have complied with similar statutory provisions." Pls.' Opp. at 12 (citing *Amgen*, 357 F.3d at 107-08; *Shands Jacksonville Med. Ctr. v. Burwell*, 139 F. Supp. 3d 240, 251 (D.D.C. 2014); *Organogenesis*, 41 F. Supp. 3d at 23). But these cases are plainly inapposite, because none of them addressed arguments that agency action was "committed to agency discretion by law." Let alone did these cases address the *specific* question presented here—i.e., whether the Secretary's

[5] *Amgen* is not to the contrary. There, the Circuit construed § (t)(12) "to prevent review only of those 'other adjustments' that the Medicare Act authorizes the Secretary to make." *Amgen*, 357 F.3d at 112. It reasoned that any disruption caused by *ultra vires* review was outweighed by the "likely gains of reducing the risk of systematic misinterpretation in the administration of the Medicare B program." *Id.* at 113. The Circuit did not hold that concerns of disruption are categorically irrelevant, or that there was a need for full-blown judicial review. Defendants do not dispute that § (t)(12) likewise allows review here under the narrow *ultra vires* doctrine, which as Defendants have explained, Plaintiffs fail to satisfy.

decision to "adjust[]" OPPS drug payment rates "as necessary for purposes of this paragraph" under § (t)(14)(A)(iii)(II) is committed to agency discretion by law.

Plaintiffs next argue that "agency action is reviewable whenever a statute directs that the agency 'shall' take action and cabins any discretion regarding what action to take by 'identif[ying] factors that the [agency] must consider.'" Pls.' Opp. at 13 (citing *Delta Air Lines, Inc. v. Export-Import Bank of the U.S.*, 718 F.3d 974, 977 (D.C. Cir. 2013); *Amador Cty. v. Salazar*, 640 F.3d 373, 381 (D.C. Cir. 2011)). But here again, Plaintiffs' cases are inapposite. In *Delta*, the statute provided that the agency "'shall take into account any serious adverse effect' a guarantee might have on certain U.S. industries or U.S. jobs," and "'shall implement such regulations and procedures as may be appropriate to insure that full consideration is given to the extent to which any loan or financial guarantee is likely to have an adverse effect' on U.S. industries and U.S. jobs." 718 F.3d at 977. The court found that these provisions "identifie[d] factors that the [agency] must consider—namely, the adverse effects on U.S. industries and U.S. jobs," and noted that "[e]nsuring that agencies follow commands of this sort is of course standard judicial fare." *Id.* But unlike the statute in *Delta*, the Medicare statute does not "identif[y] factors" that the Secretary "must consider" in making adjustments under § (t)(14)(A)(iii)(II). It merely states that the Secretary must set the payment rate for SCODs at "the average price for the drug . . . 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) (emphasis added). The language "as necessary for the purposes of this paragraph" stands in stark contrast to the concrete criteria in *Delta* mandating consideration of the "adverse effects on U.S. industries and U.S. jobs."

Amador County, 640 F.3d at 373, is even further afield. There, the statute provided that the agency "may disapprove a compact . . . only if such compact violates—(i) any provision of

this chapter, (ii) any other provision of Federal law . . . , or (iii) the trust obligations of the United States to Indians." *Id.* at 380-81. The Circuit read this provision as requiring the agency to "disapprove a compact if it would violate any of the three limitations in that subsection," and held that "those limitations provide the 'law to apply.'" *Id.* at 381. Here, by contrast, there are no such limitations on the Secretary's authority to "adjust[]" OPPS drug payment rates "as necessary for purposes of this paragraph," and thus there is no "law to apply" to that adjustment decision.

Plaintiffs' attempts to distinguish Defendants' cases are likewise unpersuasive. Pls.' Opp. at 13-15. Although it is true that the statutes in *Webster v. Doe*, 486 U.S. 592 (1988), and *Wendland v. Gutierrez*, 580 F. Supp. 2d 151 (D.D.C. 2008), authorized agency action when "***deemed*** necessary," the absence of the word "deemed" in § (t)(14)(A)(iii)(II) does not make the Secretary's authority any less discretionary. Just as the statutes in *Webster* and *Wendland* "exude[d] deference" to the agencies, so too does the Medicare statute, by authorizing adjustments "as necessary for purposes of this paragraph." Whether action is "necessary for purposes of" § (t)(14) is a question that draws on the Secretary's specialized expertise concerning the complex and interdependent OPPS; it is not a matter fit for judicial resolution. The legislative history confirms this conclusion. *See* H.R. Rep. No. 108-391 at 599; H.R. Rep. No. 105-149 at 1323; H.R. Rep. No. 105-217 at 785 (1997) (Conf. Rep.), *as reprinted in* 1997 U.S.C.C.A.N. 176, 406.

Although *Sierra Club v. Jackson*, 648 F.3d 848 (D.C. Cir. 2011), concerned an agency decision not to take enforcement action, it is still relevant here. Indeed, the Circuit held that the statutory phrase "as necessary"—the exact phrase used in § (t)(14)(A)(iii)(II)—provided "no guidance to the Administrator or to a reviewing court as to what action is 'necessary,'" and instead left it "to the Administrator's discretion to determine what action is 'necessary.'" *Id.* at 856. Courts have reached similar conclusions outside the "non-enforcement" context. *See Ctr. for*

Biological Diversity v. Zinke, 260 F. Supp. 3d 11, 27 (D.D.C. 2017) (statutory "requirement that agencies 'shall continue . . . to revise" certain procedures "'***as necessary***' confers upon agencies so much discretion regarding whether and how to act that it lacks the mandatoriness that is required . . . under § 706(1)" of the APA) (emphasis added).

III. Plaintiffs Failed To Satisfy The Medicare Statute's Exhaustion Requirements

Defendants explained that Plaintiffs failed to satisfy the Medicare statute's exhaustion requirements before filing suit. Defs.' Mem. at 22-24. In response, Plaintiffs acknowledge that Medicare exhaustion has two components: (1) a non-waivable requirement of "'presentment' (i.e., initiation of administrative review)," and (2) a waivable requirement of "'exhaustion' (i.e., completion of that review) of claims." *Am. Med. Techs. v. Johnson*, 598 F. Supp. 2d 78, 81 (D.D.C. 2009). Plaintiffs claim they satisfied the first requirement, and ask the Court to waive the second requirement on "futility" grounds. Pls.' Opp. at 14-17. Both arguments fail.

1. Plaintiffs have not "presented" their claims to the agency. To satisfy the presentment requirement under 42 U.S.C. § 405, a plaintiff must submit a "concrete claim for reimbursement" to the agency. *Heckler v. Ringer*, 466 U.S. 602, 622 (1984); *see also Mathews v. Eldridge*, 424 U.S. 319, 328 (1976) ("a claim for benefits shall have been presented to the Secretary. Absent such a claim there can be no 'decision' of any type."). Presentment is an "absolute" jurisdictional "prerequisite" to judicial review. *Action All. of Senior Citizens v. Leavitt*, 483 F.3d 852, 857 (D.C. Cir. 2007). Here, Plaintiffs indisputably have not presented a "concrete claim for reimbursement" to the Secretary—they instead raise an anticipatory challenge to a Medicare payment methodology that has not even been applied yet. The Court thus lacks jurisdiction.

Plaintiffs argue that they "satisfied the presentment requirement by submitting detailed comments during the notice-and-comment process for the 340B Provisions of the [2018] OPPS

Rule." Pls.' Opp. at 14. But numerous courts have recognized that such comments are no substitute for an actual "claim for benefits" and thus fail to satisfy the presentment requirement. *See Three Lower Ctys. Cmty. Health Servs. v. HHS*, 317 F. App'x 1, 2 (D.C. Cir. 2009) (per curiam) (presentment not satisfied by plaintiff's "letter to the [Provider Reimbursement Review Board] requesting a jurisdictional ruling," because "[t]he Medicare Act . . . requires that parties present all such challenges to the agency in the context of a fiscal year reimbursement claim"); *Am. Orthotic & Prosthetic Ass'n v. Sebelius*, 62 F. Supp. 3d 114, 123 (D.D.C. 2014) (presentment not satisfied by plaintiff's "detailed critiques" of agency's "'Dear Physician letter,'" because critiques "were not tied to any concrete claims" for reimbursement). Even one of the cases cited by Plaintiffs recognizes as much. *See Nat'l Ass'n for Home Care & Hospice, Inc. ("NAHC&H") v. Burwell*, 77 F. Supp. 3d 103, 109 n.1 (D.D.C. 2015) (presentment not satisfied by association's submission of "comments to the agency and . . . meeting with agency officials to voice disagreement with the [Medicare] rule").[6]

Plaintiffs contend that *Eldridge*, 424 U.S. at 329, held that a "letter from the plaintiff to the state social security agency constituted presentment." Pls.' Opp. at 14. But the correspondence in *Eldridge* was tantamount to a "concrete claim for reimbursement," and the agency processed it as such. In particular, "[t]hrough his answers to the state agency questionnaire, and his letter in

[6] Plaintiffs attempt to head off this unfavorable language from *NAHC&H* by noting that the plaintiff's comments to the agency in that case constituted "generalized opposition to agency action," *NAHC&H*, 77 F. Supp. 3d at 109 n.1, whereas here, "Plaintiffs' comments raised both specific, legal objections to the agency's action and identified specific harms that would result from that action," Pls.' Opp. at 16 n.7. Plaintiffs misconstrue *NAHC&H*. By "generalized opposition," the court was referring not to the *level of detail* in Plaintiffs' comments to the agency, but to the fact that the comments were not tied to a specific claim for benefits. This conclusion is bolstered by later language in the same paragraph, where the court stated that a party may not challenge "regulations in the abstract on the basis that its members are likely to confront those regulations in the future." *NAHC&H*, 77 F. Supp. 3d at 109 n.1.

response to the tentative determination that his disability had ceased," the plaintiff "specifically presented the claim that his benefits should not be terminated because he was still disabled. This claim was denied by the state agency and its decision was accepted by the SSA." *Eldridge*, 424 U.S. at 329. Plaintiffs here presented no comparable claim for benefits to the Secretary.

Plaintiffs also cite *Action Alliance of Senior Citizens v. Johnson*, 607 F. Supp. 2d 33 (D.D.C. 2009), and *Action Alliance of Senior Citizens v. Sebelius,* 607 F.3d 860 (D.C. Cir. 2010). Pls.' Opp. at 14-15. But as Judge Lamberth has explained, those cases are of little value here:

> [In] *Action Alliance of Senior Citizens v. Johnson*, 607 F. Supp. 2d 33, 40 (D.D.C. 2009)[,] . . . the district court, without explanation, declared that an association's letters to the agency established presentment. *Id.* In affirming the district court's decision, the Circuit summarily noted that a prior jurisdictional defect had been cured but offered no opinion on whether and why generalized letters were sufficient. *Action Alliance of Senior Citizens v. Sebelius*, 607 F.3d 860, 862 n.1 (D.C. Cir. 2010). The lack of explanation in both cases is likely because the precise question presented here—whether generalized grievance letters rather than discrete claims are sufficient to satisfy presentment—was not raised by the parties in *Action Alliance*, and the Court therefore questions the precedential value of those opinions. *See, e.g.*, *Arizona Christian Sch. Tuition Org. v. Winn*, 563 U.S. 125, 144 (2011) ("When a potential jurisdictional defect is neither noted nor discussed in a federal decision, the decision does not stand for the proposition that no defect existed.").

Am. Orthotic & Prosthetic Ass'n,, 62 F. Supp. 3d at 123. Following Judge Lamberth's reasoning, this Court should reject Plaintiffs' reliance on *Action Alliance*. The Court should instead look to the cases cited above, which squarely held that presentment is not satisfied by letters and comments that are not tied to concrete claims for reimbursement.[7]

[7] *Action Alliance* is distinguishable in any event, because "the letters relied upon by Action Alliance presented HHS with factually detailed letters regarding discrete claims on behalf of individuals," and thus "were closer to the 'concrete claim for reimbursement' that the Supreme Court has held is required for proper presentment." *Am. Orthotic & Prosthetic Ass'n*, 62 F. Supp. 3d at 123. Here, while Plaintiffs' letters critiqued the proposed 2018 OPPS Rule, *see* Pls.' Exs. C-H, they did ***not*** provide detailed information on "discrete claims [for reimbursement] on behalf of individuals."

2. Plaintiffs also fail the second exhaustion prong, which requires that the Secretary's procedures be followed to completion. They admit that they did not exhaust agency procedures, but urge the Court to excuse that failure on the ground that exhaustion would have been "futile." Pls.' Opp. at 16-17. The "futility" standard is particularly "stringent" and applies only in "exceptional cases," because "'the bar of § 405(h) reaches beyond ordinary administrative law principles [such as] exhaustion of administrative remedies' and 'demands the channeling of virtually all legal attacks through the agency.'" *Am. Orthotic & Prosthetic Ass'n*, 62 F. Supp. 3d at 123 (quoting *Shalala v. Ill. Council on Long Term Care*, 529 U.S. 1, 13 (2000)).

This is not one of the "exceptional cases" fitting the futility exception. Assuming that administrative and judicial review of Plaintiffs' claim were not statutorily precluded (which it is, *see supra* Part I), Plaintiffs have administrative avenues through which this action could be "channeled," as Plaintiffs themselves recognize, Pls.' Opp. at 17 (describing administrative process). Plaintiffs contend that no HHS administrative review body would have authority to "alter or deviate from" the 2018 OPPS Rule, *id.* at 16, but the Supreme Court has made clear that this is no excuse for refusing to channel claims through the agency, *see Ill. Council*, 529 U.S. at 23 (channeling required even where agency lacks authority to consider certain questions, because plaintiffs "remain free . . . after following the special review route that the statutes prescribe, to contest in court the lawfulness of any regulation or statute upon which an agency determination depends. The fact that the agency . . . may lack the power to" resolve certain questions "is beside the point because it is the 'action' arising under the Medicare Act that must be channeled through the agency."). So long as Plaintiffs can channel the "action" through the agency, a court may later consider "any statutory . . . contention that the agency . . . cannot decide." *Id.*

Plaintiffs also complain of "extreme delays inherent in the Medicare reimbursement review process." Pls.' Opp. at 17. But any "delay-related hardship" is simply the "price" of the agency review process established by Congress. *Ill. Council*, 529 U.S. at 13; *see also id.* at 22-23 ("added inconvenience or cost" is no excuse for failing to exhaust); *Heckler*, 466 U.S. at 619 (claimants "must adhere to the administrative procedure which Congress has established for adjudicating their Medicare claims" even when they "would clearly prefer an immediate appeal to the District Court rather than the often lengthy administrative review process").

IV. Plaintiffs' APA Claim Fails On The Merits

A. The Secretary Did Not Exceed His Authority To "Calculate And Adjust" OPPS Payment Rates Under § 1395*l*(t)(14)(A)(iii)(II)

Plaintiffs continue to argue that the Court should read § (t)(14)(A)(iii)(II) to say that the OPPS drug payment rate may be "adjusted by the Secretary as necessary," so long as that adjustment is only "slight," even though no such limitation appears in the statutory text. Pls.' Opp. at 18-20.[8] Plaintiffs now argue that this position is supported by *Amgen*. *Id.* That is incorrect. In *Amgen*, the court held that "[o]n the merits, Amgen's statutory claim" challenging the Secretary's exercise of his equitable adjustment authority under § (t)(2)(E) was "defeated by the text of" the statute.[9] *Amgen*, 357 F.3d at 114. After making that ruling, the Circuit went on to reject Amgen's slippery-slope argument that the court's reading of § (t)(2)(E) would "give the

[8] Plaintiffs do not dispute Defendants' positions that (1) their APA claim raises purely legal questions that may be resolved on a Rule 12(b)(6) motion, without an administrative record, Defs.' Mem. at 25 n.6; and (2) the *Chevron* framework applies to the parties' competing readings of the Medicare statute, *id.* at 24-25, 37-38. These points are therefore conceded. *See Potter v. Toei Animation Inc*., 839 F. Supp. 2d 49, 53 (D.D.C. 2012) ("In the District of Columbia Circuit, it is established that an argument in a dispositive motion that the opponent fails to address in an opposition may be deemed conceded."), *aff'd*, 2012 WL 3055990 (D.C. Cir. July 18, 2012).

[9] Section (t)(2)(E) provides "the Secretary shall establish . . . other adjustments as determined to be necessary to ensure equitable payments, such as adjustments for certain classes of hospitals."

Secretary the absurdly broad power to make drastic adjustments, such as the elimination of the entire pass-through program." *Id.* at 117. The court stated that "[l]imitations on the Secretary's equitable adjustment authority inhere in the text of § (t)(2)(E), which only authorizes 'adjustments,' not total elimination or severe restructuring of the statutory scheme." *Id.* But the court made clear that it had "no occasion to engage in line drawing to determine when 'adjustments' cease being 'adjustments,'" because the Secretary's adjustment in *Amgen* did "not work 'basic and fundamental changes in the scheme' Congress created in the Medicare Act." *Id.*

Amgen does not support Plaintiffs' position. The Secretary's payment adjustment here was consistent with the Circuit's reasoning, because it came nowhere near resulting in "total elimination or severe restructuring" of the Medicare Part B statutory scheme. To the contrary, the Secretary's reduction of the OPPS payment rate for 340B drugs, in tandem with the Secretary's offsetting increase in the OPPS payment rate for all non-drug items and services, reflect a permissible reallocation of Medicare funds designed to ***preserve***, not "eliminate" the OPPS. As the 2018 OPPS Rule noted, Medicare spending on 340B drugs has been growing at a rapid and substantial rate. *See* 82 Fed. Reg. 52,356, 52,494 (Nov. 13, 2017). The Secretary found that "drug spending increases that are correlated with participation in the 340B Program" called "into question whether Medicare's current policy to pay for separately payable drugs at ASP+6 percent is appropriate in light of the discounted rates at which 340B hospitals acquire such drugs," *id.*, particularly since Medicare overpayments to 340B providers have come at the expense of non-340B providers participating in the OPPS and Medicare beneficiaries. The Secretary therefore deemed the adjustment necessary to efficiently allocate Medicare funding to ***all*** OPPS participants.

Plaintiffs thus mischaracterize the revised ASP minus 22.5% payment rate as a "dramatic" adjustment, which "severely restructure[es]" the statutory scheme. Pls.' Opp. at 18-20. To

understand the relative significance of the payment adjustment, one cannot look at the rate reduction in isolation—context is critical. As noted, the Secretary identified an enormous disparity between Medicare payment rates and 340B drug acquisition costs when the ASP plus 6% payment rate was employed. Defs.' Mem. at 9-10 (summarizing studies relied upon in 2018 OPPS Rule). By one measure, providers received Medicare payments for 340B drugs that were on average ***58% more*** than what they paid for the drug. *Id.* To reduce (but not eliminate) this substantial disparity, the Secretary adjusted the payment rate for 340B drugs to ASP minus 22.5%—a "conservative" rate that reflected the "lower bound" or "minimum" "average discount received by 340B hospitals for drugs paid under the [OPPS]"—and made an offsetting increase to the OPPS payment rate for all non-drug items and services. 82 Fed. Reg. at 52,496.

The Secretary's goal was to bring payment rates for 340B drugs closer in line with 340B providers' acquisition costs. Since § (t)(14) itself identifies "acquisition cost[s]" as a valid reference point for drug payment rates, 42 U.S.C. § 1395*l*(t)(14)(A)(iii), it is not plausible for Plaintiffs to claim that the Secretary's adjustment was anything close to a "total elimination or severe restructuring of the statutory scheme," *Amgen*, 357 F.3d at 117. Rather, the adjustment was well within the Secretary's authority under § (t)(14)(A)(iii)(II) to "adjust[]" drug payment rates "as necessary for purposes of this paragraph."

Plaintiffs also cite cases where courts *upheld* adjustments under various Medicare adjustment provisions (but not the provision at issue here, § (t)(14)(A)(iii)(II)), in an attempt to show that adjustments that courts have deemed permissible entailed a smaller number of drugs, or a smaller rate reduction, than the Secretary's adjustment here. Pls.' Opp. at 19. But these cases do not define the outer boundaries of the Secretary's adjustment authority under the various Medicare provisions evaluated, let alone under § (t)(14)(A)(iii)(II). In fact, the courts made clear

that they were *not* doing that. *See Amgen*, 357 F.3d at 117 (court had "no occasion to engage in line drawing to determine when 'adjustments' cease being 'adjustments'"); *Shands Jacksonville Med. Ctr.*, 139 F. Supp. 3d at 260 (same). In any event, Plaintiffs' comparison of rate reductions is apples to oranges, because, again, the relative significance of a rate reduction is context dependent, and thus varies from case to case. That is particularly true here, where the Secretary reduced the payment rate for 340B drugs specifically to account for deep, below-market discounts that providers obtain on those drugs.

Plaintiffs continue to invoke dictionary definitions that they claim show that the Secretary's adjustments under § (t)(14)(A)(iii)(II) must be "slight." Pls.' Opp. at 20-21. As the parties' briefing makes clear, some dictionary definitions use the word "slight" and others do not, so it cannot be said that the prevailing definition of "adjust" includes the "slight" qualifier. However, a common thread among *both* parties' dictionary definitions is that "adjust" means to change something to make it more "correct," "effective," or "suitable for a particular purpose," so that it better "conforms" with a "fixed reference point." *See id.* at 20 & n. 9-10; *Adjust*, Merriam-Webster, https://www.merriam-webster.com/dictionary/adjust ("a: to bring to a more satisfactory state . . . b: to make correspondent or conformable . . . c: to bring the parts of to a true or more effective relative position."). That is precisely what the Secretary's payment adjustment did—it altered the payment rate for 340B drugs to better "conform" with 340B providers' drug acquisition costs, and to bring it to a "more effective relative position." Thus, the Secretary's adjustment was fully consistent with the prevailing dictionary definition of "adjust."

Plaintiffs initially argued that the Secretary's adjustment authority under § (t)(14)(A)(iii)(II) must be read as "limited" to "overhead and related expenses," in light of a different provision, § (t)(14)(E), which authorizes a ***separate*** "[a]djustment in payment rates for

overhead costs." They now halfheartedly attempt to walk back this argument, asserting that they are not claiming that the "two adjustment authorities are coextensive." Pls.' Opp. at 22. But that is the logical conclusion of their argument, which fails for the reasons outlined in Defendants' memorandum (at 29-31).[10]

B. The Secretary Did Not Exceed His Authority Under § 1395*l*(t)(14)(A)(iii) By Applying A Payment Methodology Not Specified In The Statute

Citing no authority and without substantively responding to Defendants' arguments, Plaintiffs continue to assert that the Secretary may not make payment adjustments under subclause (II) of § (t)(14)(A)(iii) based on "estimated acquisition cost data," because that would "circumvent" the payment methodology in subclause (I) of § (t)(14)(A)(iii). Pls.' Opp. at 22-23. As Defendants have explained, however, subclause (II) does not mandate payment based strictly on ASP, nor does it (or any other part of the statute) forbid the Secretary from considering any type of acquisition cost data in adjusting payment rates. Defs.' Mem. at 32-34. The Secretary permissibly considered both providers' acquisition costs and Medicare beneficiaries' drug costs in exercising his adjustment authority under § (t)(14)(A)(iii)(II).

C. The Secretary Did Not Exceed His Authority Under § 1395*l*(t)(14)(A)(iii)(II) By Allegedly Undermining The 340B Program

Finally, Plaintiffs continue to press their misguided claim that the Secretary exceeded his adjustment authority under § (t)(14)(A)(iii)(II) by purportedly undermining the 340B Program, Pls.' Opp. at 24-27, a program separate from Medicare, governed by a different statute,

[10] Plaintiffs fail altogether to respond to Defendants' arguments that (1) the "surrounding statutory text" supports Defendants' reading of § (t)(14)(A)(iii)(II), Defs.' Mem. at 27; (2) Plaintiffs have not identified any action in excess of the Secretary's statutory authority to "calculate[]" OPPS payment rates, *id.* at 28-29; and (3) CMS has, in prior OPPS rules that Plaintiffs explicitly endorse, recognized that adjustments under § (t)(14)(A)(iii)(II) may entail consideration of drug acquisition costs, *id.* at 32 n.9. These points are therefore conceded. *See Potter*, 839 F. Supp. 2d at 53.

administered by a different HHS component. Plaintiffs' claim is, in actuality, not that specific statutory text contradicts the Secretary's reading of the statute, but rather that the Secretary acted unreasonably in adopting the 2018 OPPS Rule. Such an "arbitrariness" claim has no bearing on the Secretary's statutory authority, and is outside the scope of the narrow *ultra vires* review doctrine. *See Fla. Health Scis. Ctr.*, 830 F.3d at 523.

Defendants challenged Plaintiffs to "identify anything in the text or legislative history of either the Medicare statute or the 340B statute reflecting a 'clear [congressional] purpose' to 'separate . . . hospitals' costs of purchasing 340B prescription drugs' from the 'Medicare payment[]' rate for those drugs." Defs.' Mem. at 35. Tellingly, Plaintiffs' opposition identifies no such proof. They instead continue to parrot a single line from a House Report noting that one of the 340B Program's purposes was to "stretch scarce Federal resources as far as possible, reach more eligible patients and provid[e] more comprehensive services." Pls.' Opp. at 25. This general policy statement has nothing to do with the Medicare statute, nor does it provide evidence that Congress specifically intended that OPPS payment rates for 340B drugs would be substantially higher (up to 58% higher, in some cases) than providers' drug acquisition costs. And in any event, the Secretary's payment adjustment ***furthers*** the goal of "stretch[ing] scarce Federal resources as far as possible," insofar as it allocates federal funds throughout the OPPS more efficiently, rather than allowing 340B providers to continue receiving outsized Medicare payments at the expense of other OPPS participants and Medicare beneficiaries.

Defendants further challenged Plaintiffs to cite any "authority supporting their claim that the Secretary could exceed his authority under one statute . . . by purportedly 'undermining' the purposes of a different statute." Defs.' Mem. at 36. Again, Plaintiffs fail to deliver. They continue to rely on *Howard v. Pritzker*, 775 F.3d 430 (D.C. Cir. 2015), but as Defendants explained, that

case is readily distinguishable, Defs.' Mem. at 36-37. Plaintiffs nonetheless try to recast *Howard* as holding that "where there are two interrelated statutory schemes and one provides a comprehensive scheme to target specific problems with specific solutions, ***an agency has no authority to invoke more general authority from the other statutory scheme to undo the specific solution***." Pls.' Opp. at 26 (emphasis added). This characterization is far off the mark. *Howard* says nothing about the scope of "agency . . . authority"—it was not even an agency review case. It was a Title VII case where the Circuit declined to apply the general six-year statute of limitations of 28 U.S.C. § 2401(a), due to a direct conflict between the two statutes. Nothing in *Howard* remotely suggests that the Secretary could have "exceeded his authority" under the Medicare statute by allegedly undermining the 340B statute.

Plaintiffs also fail to identify any genuine conflict—let alone an "irreconcilable" one—between the Secretary's exercise of his adjustment authority and the 340B statute. As Defendants explained, the Secretary's payment adjustment does nothing to modify the core purpose of the 340B Program, which is achieved not through Medicare reimbursement, but through the significantly discounted ceiling prices that 340B providers obtain from drug manufacturers. Defs.' Mem. at 35-36. The payment adjustment does not even eliminate the overpayments that 340B providers obtain through Medicare reimbursement; to the contrary, the ASP minus 22.5% payment rate is designed to "allow[] hospitals to retain a profit on [340B] drugs." 82 Fed. Reg. at 52,497. Plaintiffs complain that they will reap less profits under the 2018 OPPS Rule, but, again, that does not establish that the Secretary exceeded his authority under § (t)(14)(A)(iii)(II).

Can-Am Plumbing, Inc. v. NLRB, 321 F.3d 145 (D.C. Cir. 2003), on which Plaintiffs rely, is off point. There, the Circuit held that the National Labor Relations Board erred in failing to adequately consider and explain the potential conflict its decision would create between its statute

and another federal law, noting that the Board "made ***no effort*** to engage in . . . careful balancing of conflicting [statutory] policies." *Id.* at 153-54 (emphasis added). Here, by contrast, the 2018 OPPS Rule carefully considered and explained the effect of the drug payment reduction on the 340B Program.[11] Moreover, unlike the petitioner in *Can-Am Plumbing*, Plaintiffs make no claim that the Secretary failed to adequately explain his decision; they allege only that he exceeded his statutory authority, a theory not addressed in *Can-Am Plumbing*.

D. If The Court Finds Any Material Statutory Ambiguity, It Is Undisputed That Plaintiffs' APA Claim Fails

As Defendants explained, even if the Court deems the statute ambiguous, it should accord *Chevron* deference to the Secretary's reasonable interpretation and reject Plaintiffs' *ultra vires* claim, as there would be no "patent" or "obvious" violation of agency authority. Defs.' Mem. at 37-38. Plaintiffs do not respond to these points, so they are conceded. *See Potter*, 839 F. Supp. 2d at 53.

CONCLUSION

Defendants' motion to dismiss should be granted.

[11] *See, e.g.*, 82 Fed. Reg. at 52,502 ("We . . . disagree with commenters who believe that implementing the OPPS payment methodology for 340B-acquired drugs as proposed will 'eviscerate' or 'gut' the 340B Program. . . . [T]he findings from several 340B studies conducted by the GAO, OIG, and MedPAC show a wide range of discounts that are afforded to 340B hospitals, with some reports finding discounts of up to 50 percent. . . . [W]e believe ASP minus 22.5 percent is a conservative estimate of the discount for 340B-acquired drugs and that even with the reduced payment, hospitals will continue to receive savings that can be directed at programs and services to carry out the intent of the 340B Program. . . . [And] we proposed to redistribute the savings in an equal and offsetting manner to all hospitals paid under the OPPS, including those in the 340B Program, in accordance with the budget neutrality requirements.").

Date: December 15, 2017

Respectfully submitted,

BRIAN R. STIMSON
Acting General Counsel

KELLY M. CLEARY
Deputy General Counsel &
Chief Legal Officer
Centers for Medicare and Medicaid Services

JANICE L. HOFFMAN
Associate General Counsel

SUSAN MAXSON LYONS
Deputy Associate General Counsel for Litigation

ROBERT W. BALDERSTON
Attorney, Office of the General Counsel
U.S. Department of Health & Human Services

Of Counsel to Defendants

CHAD A. READLER
Acting Assistant Attorney General

JESSIE K. LIU
United States Attorney

JOEL McELVAIN
Assistant Branch Director

/s/ Nikhel S. Sus
Nikhel S. Sus (D.C. Bar No. 1017937)
Trial Attorney
U.S. Department of Justice
Civil Division, Federal Programs Branch
20 Massachusetts Avenue N.W.
Washington, D.C. 20530
Tel.: (202) 514-2071
Fax: (202) 616-8470
Email: nikhel.s.sus@usdoj.gov

Counsel for Defendants