UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

THE AMERICAN HOSPITAL ASSOCIATION, *et al.*, *Plaintiffs,* –v– ERIC D. HARGAN, *et al.*, *Defendants.*	**Case No. 1:17-CV-02447-RC**

PLAINTIFFS' REPLY BRIEF IN SUPPORT OF MOTION FOR PRELIMINARY INJUNCTION AND OPPOSITION TO DEFENDANTS' MOTION TO DISMISS

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Plaintiffs the American Hospital Association ("AHA"), the Association of American Medical Colleges ("AAMC"), America's Essential Hospitals ("AEH"), Eastern Maine Healthcare Systems ("EMHS"), Henry Ford Health System ("Henry Ford"), and Fletcher Hospital, Inc. d/b/a Park Ridge Health ("Park Ridge") (collectively, "Plaintiffs")[1] respectfully submit this reply in support of their motion for a preliminary injunction and memorandum in opposition to Defendants' motion to dismiss.[2]

INTRODUCTION

Defendants' arguments opposing the requested preliminary injunction and supporting their motion to dismiss share a common theme: when it comes to implementing the Outpatient Prospective Payment System ("OPPS"), the Department of Health and Human Services ("HHS") and its Centers for Medicare and Medicaid Services ("CMS") are not subject to judicial review and, if review is available, should be granted virtually unlimited discretion. Defendants are wrong on both counts.

As we demonstrate in Sections I-III, the Court can address the merits in this case. Defendants' preclusion arguments principally rely on two provisions of the Social Security Act ("SSA"), but the text of both provisions makes clear that they do not apply to the rule challenged in this case. Indeed, one of these provisions was the subject of a decision by this Court holding that preclusion would not apply in a case involving the very statutory provision at issue here. *Organogenesis, Inc. v. Sebelius*, 41 F. Supp. 3d 14 (D.D.C. 2014). Defendants' arguments that

[1] Plaintiffs AHA, AAMC, and AEH are also referred to in this memorandum as the "Association Plaintiffs" and Plaintiffs EMHS, Henry Ford, and Park Ridge are referred to as the "Hospital Plaintiffs."

[2] Defendants' memorandum jointly supporting dismissal and opposing the requested preliminary injunction is hereafter cited as "Opp."

the issues in this case are committed to agency discretion by law and that Plaintiffs have failed to exhaust administrative remedies also should be rejected.

On the merits, we demonstrate in Section IV that CMS's nearly-30% reduction of the Medicare reimbursement rate for separately payable drugs purchased through the 340B Program[3] far exceeds Defendants' statutory authority under the SSA to "adjust" this reimbursement rate. Plaintiffs' reading of "adjust" is strongly supported by the D.C. Circuit's interpretation of that term in *Amgen Inc. v. Smith*, 357 F.3d 103 (D.C. Cir. 2004), as well as by the structure of the two (related) statutory frameworks at issue here – the Medicare reimbursement system under 42 U.S.C. § 1395*l*(t)(14)(A)(iii) *and* the 340B drug discount program codified at 42 U.S.C. § 256b. Defendants' reading of the term "adjust" as unlimited has no basis in ordinary meaning or statutory structure. Accordingly, Defendants' motion to dismiss should be denied, and the Court should find that Plaintiffs are likely to succeed on the merits of their claims.

Finally, we demonstrate in Section V that the Plaintiffs would suffer irreparable harm if the 340B Provisions of the OPPS Rule were to take effect as scheduled on January 1, 2018, and that the balance of equities between the parties and the public interest favor suspending implementation of those provisions until final resolution of this legal challenge. Thus, in addition to denying Defendants' motion to dismiss, this Court should grant Plaintiffs' motion for a preliminary injunction.

At the outset, we note that Defendants devote much of their brief to explaining why the 340B Provisions of the OPPS Rule are desirable as a matter of policy. Opp. at 1-3, 8-13. Plaintiffs strongly disagree with Defendants' policy positions, but those concerns in any event,

[3] This reduction is set forth in CMS' OPPS rule for Calendar Year 2018 (82 Fed. Reg. 52,356, 52,493-52,511, 52,622-52,625 (Nov. 13, 2017)) and is hereafter referred to as the "340B Provisions of the OPPS Rule."

like Defendants' actions challenged here, lie within Congress's domain. They are irrelevant to the question of Defendants' *legal* authority to take the actions Plaintiffs challenge.

ARGUMENT

I. THE SSA DOES NOT PRECLUDE REVIEW OF PLAINTIFFS' CHALLENGE TO THE 340B PROVISIONS OF THE OPPS RULE.

Defendants' argument that the 340B Provisions of the OPPS Rule challenged by Plaintiffs are not subject to judicial review (Opp. 14-21) has no support in the two SSA provisions relied on by Defendants. Defendants correctly identify the key cases on these issues – the D.C. Circuit's decision in *Amgen Inc., v. Smith*, 357 F.3d 103 (D.C. Cir. 2004), and this Court's decision in *Organogenesis, Inc. v. Sebelius*, 41 F.Supp.3d 14 (D.D.C. 2014). But both cases *support* judicial review here.

As an initial matter, the D.C. Circuit in *Amgen* made clear (and Defendants fail to mention) that "'[t]here is a strong presumption that Congress intends judicial review of administrative action.'" 357 F.3d at 111 (*quoting Bowen v. Mich. Academy of Family Physicians*, 476 U.S. 667, 670 (1986)). The *Amgen* court added (and again Defendants ignore) that this presumption can only be overcome by "clear and convincing evidence that Congress intended to preclude the suit" and that "[t]he presumption is particularly strong that Congress intends judicial review of agency action taken in excess of delegated authority." 357 F.3d at 111-12 (citations omitted). Plaintiffs' lawsuit alleges that the Defendants exceeded their congressionally-delegated authority to set Medicare reimbursement rates under 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II) when they reduced by nearly 30 percent reimbursements paid to hospitals for separately payable drugs purchased through the 340B Program. Thus, this case is entitled to the strongest possible presumption in favor of review.

Also, even if one of the preclusion provisions cited by Defendants applies (as demonstrated below, neither does), in deciding whether it can review a challenge to agency action, a court must first decide whether the agency had the authority to take the action it claims is unreviewable. *Amgen*, 357 F.3d at 113 (noting that a court must "'merge[] consideration of the legality of the [agency's] action with consideration of [the court's] jurisdiction'" where, as here, the legal challenge "'raises the question of the [agency's] authority to enact a particular amendment.'") (quoting *COMSAT Corp. v. FCC*, 114 F.3d 223, 226-227 (D.C. Cir. 1997)). Thus, under *Amgen*, which also involved the issue of preclusion in connection with OPPS, this Court must review Defendants' exercise of their congressionally-delegated authority under 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II) to adopt the 340B Provisions of the OPPS Rule before deciding the issue of preclusion. Plaintiffs therefore incorporate into this section the arguments made in Section IV that the 340B Provisions of the OPPS Rule violate the Administrative Procedure Act ("APA").

A. 42 U.S.C. § 1395*l*(t)(12)(A) ("(t)(12)(A)") Does Not Preclude Judicial Review of the 340B Provisions of the OPPS Rule.

Subsection (t)(12)(A) precludes judicial review of:

> The development of the [OPPS] *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).

42 U.S.C. § 1395*l*(t)(12)(A) (emphasis added). This provision does not preclude review of the 340B Provisions of the OPPS Rule because those provisions are not part of the "classification system under paragraph (2)." The "classification system under paragraph (2)" (42 U.S.C. § 1395*l*(t)(2)) is a specific methodology used by HHS to establish payment rates under the OPPS. Importantly, as is clear on their face, the 340B Provisions of the OPPS Rule implement

and rely on Defendants' authority under the *separate* reimbursement methodology that is set forth in *paragraph (t)(14)* of the OPPS provisions (42 U.S.C. § 1395*l*(t)(*14*), hereafter "the paragraph 14 system"). CMS expressly relied only on its authority to "adjust" the statutory reimbursement formula under the paragraph 14 methodology (specifically, its authority under 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II)) to promulgate the 340B Provisions of the OPPS Rule.[4] Nowhere does either the proposed or final version of the rule mention authority under paragraph (2). This alone is dispositive of Defendants' (t)(12)(A) preclusion argument.

Moreover, this Court has recognized that review of decisions under paragraph (14) is not precluded under (t)(12)(A). *Organogenesis*, 41 F. Supp. 3d at 20-21. In *Organogenesis*, this Court explained the important differences between the paragraph (2) and paragraph (14) reimbursement methodologies. The OPPS "classification system under paragraph (2)" was created in 1997. *Id.* at 16. This approach assigns outpatient items – including most outpatient drugs – and services to particular payment categories. *Id.* Under this methodology, "payments are calculated through a formula, setting payment weights for the provision of certain services, or groups of clinically similar services, as determined by the agency." *Id.* (citing 42 U.S.C. § 1395*l*(t)(2)(C)). These calculations "are based on the mean or median cost of providing such services, with adjustments for regional cost variations." *Id.* (citing 42 U.S.C. § 1395*l*(t)(2)(C)-(D)). In other words, payments for items/services within the paragraph (2) classification methodology are based on the category the item/service is assigned and collective cost data for all the items/services in that category.

[4] *See, e.g.*, 82 Fed. Reg. at 52,499 ("We believe our authority *under Section 1833(t)(14)(A)(iii)(II)* to 'calculate and adjust' drug payments as 'necessary *for purposes of this paragraph*' gives the Secretary broad discretion to adjust payments for drugs, which includes an ability to adjust Medicare payment rates according to whether or not certain drugs are acquired at a significant discount.") (emphasis added); *id.* at 52,500 (same).

In 2003, however, Congress created the "separate" (*Organogenesis*, 41 F. Supp. 3d at 17) paragraph 14 methodology for certain drugs and biological products as part of the Medicare Modernization Act. *It is this payment methodology − not the paragraph (2) methodology – that is at issue in this case.* As this Court explained, "Congress . . . specified the methodology for determining the payment rates for [drugs covered under the paragraph 14 system] *in a separate provision*." 41 F. Supp. 3d at 17 (emphasis added). This separate methodology sets payment rates (starting in 2006) based on either (1) acquisition costs for the *individual drug* (not as under the paragraph 2 system aggregated data for a category of items and services) or (2) a statutory formula. 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(I)-(II). This is a completely different methodology from the paragraph (2) system, and it is Defendants' application of this methodology – not any determination under paragraph (2) − that is at issue here.

This distinction was dispositive in *Organogenesis*, where this Court considered the reviewability under (t)(12)(A) of a drug manufacturer's challenge to CMS's decision to reimburse one of its products, Apligraf, under the paragraph (2) methodology instead of under the paragraph (14) methodology. This Court determined that if Apligraf were properly subject to the paragraph (14) methodology, "for which Congress has required a separate, unpackaged payment mechanism" (*id*. at 20), review was not precluded, but if it were properly handled under the paragraph (2) classification methodology, the preclusion provision in paragraph (t)(12)(A) applied. *Id.* at 20-21. In other words, this Court treated the paragraph (14) and paragraph (2) regimes as distinct and held that paragraph (14), unlike paragraph (2), was *not* covered under the (t)(12)(A) preclusion language. *This case* is indisputably about the specific, "separate" payment methodology set forth in (t)(14). Thus, under the plain text of (t)(12)(A) and this Court's decision in *Organogenesis*, there is no obstacle to judicial review of Plaintiffs' claims – and

certainly no "clear and convincing" evidence to rebut the strong presumption that challenges to agency authority like this one are reviewable. *Amgen*, 357 F.3d at 111-12 (citations omitted).

Defendants assert that because (t)(12)(A) mentions "other adjustments," review of Defendants' "adjustment" authority under the paragraph 14 methodology – a key issue in this case − is precluded. Opp. 17. But (t)(12)(A) precludes review of "[t]he development of the [OPPS] classification system *under paragraph (2), including* . . . other adjustments . . . ." 42 U.S.C. § 1395*l*(t)(12)(A) (emphasis added). The use of the word "including" demonstrates that "other adjustments" in (t)(12)(A) expressly refers only to "other adjustments" *under paragraph (2)*, *i.e.*, "*other adjustments* as determined [by the Secretary of 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) (emphasis added). *See also Amgen*, 357 F.3d at 113 (use of the common term "other adjustments" in (t)(12)(A) review preclusion provision and (t)(2)(E) indicated Congress's intent that preclusion apply to "other adjustments" under *(t)(2)(E)*). As noted, Defendants did not rely on or even mention its authority under (t)(2)(E) (or under any other part of paragraph (2)) in the 340B Provisions of the OPPS Rule.

Paragraph (t)(12)(A) on its face does not apply to "adjustments" that are *not* "includ[ed]" in paragraph (2). *See Rai v. WB Imico Lexington Fee, LLC*, 802 F.3d 353, 362 (2d Cir. 2015) (noting that the canon of construction that mention of one thing excludes others applies "when the items expressed are members of an associated group or series, justifying the inference that items not mentioned were excluded by deliberate choice, not inadvertence") (citing *Barnhart v. Peabody Coal Co.*, 537 U.S. 149, 168 (2003)). And that paragraph certainly does not preclude review of adjustments allegedly authorized under the separate paragraph (14) payment regime that this Court in *Organogenesis* held was not immunized from judicial review.

Even if this were a plausible argument, it certainly would fail to provide clear and convincing evidence, as *Amgen* requires, of Congress's intent to preclude review.

Defendants' reliance on the title of the paragraph 14 payment system ("Drug APC Payment Rates") (Opp. 17) also gets it nowhere. Defendants' argument is that because both paragraph (2) and paragraph (14) relate to CMS's overall "Ambulatory Payment Classification" ("APC") regime, (t)(12)(A) precludes review of *any* aspect of that regime. But (t)(12)(A) says nothing of the sort. It specifically precludes review only of matters relating to paragraph (2). The fact that the paragraph (2) and paragraph (14) payment regimes are both part of the overall APC/OPPS system does not mean that Congress intended to preclude review of paragraph (14) matters when it only expressly precluded review of paragraph (2) matters.

B. 42 U.S.C. § 1395*l*(t)(12)(E) ("(t)(12)(E)") Does Not Preclude Judicial Review of the 340B Provisions of the OPPS Rule.

This subparagraph precludes judicial review of:

> (E) 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). Defendants contend that (t)(12)(E)'s reference to "the portion of the medicare OPD fee schedule amount associated with particular devices, drugs, or devices" precludes judicial review. Opp. 18-19. They are wrong again.

Subparagraph (t)(12)(E) does not apply here because the only matters "relating to the OPD fee schedule amounts associated with particular devices, drugs, or biologicals" that Congress sought to immunize from review under that provision were those that arose "*under*

paragraph (6)" – *i.e.*, 42 U.S.C. § 1395*l*(t)(6) – and not those that arose under paragraph (14). 42 U.S.C. § 1395*l*(t)(12)(E) (emphasis added). The structure of (t)(12)(E) makes this clear. The first part of (t)(12)(E) immunizes from review a series of items covered "under paragraph (5)," *i.e.*, 42 U.S.C. § 1395*l*(t)(5); the second part of (t)(12)(E) sets forth an even longer list of items "under paragraph (6)" that are also unreviewable, including the "medicare OPD fee schedule" language. Again, CMS relied exclusively on its authority under paragraph (14) to make "adjust[ments]" to the formula in that paragraph. *See* n. 4. Nowhere in the 340B Provisions of the OPPS Rule does CMS rely on or even mention authority under paragraphs (5) or (6).

Defendants completely ignore the "under paragraph (6)" modifier that limits which "OPD fee schedule" issues are precluded from review. And lest there be any doubt, "paragraph 6" does in fact extensively address payments for certain drugs, devices and biologic medicines under the paragraph (2) classification system − completely independent, once again, of the paragraph 14 system that this Court found to be judicially reviewable. *See* 42 U.S.C. § 1395*l*(t)(6) (titled "Transitional Pass-through for additional costs of innovative medical devices, drugs and biologicals."); *Organogenesis*, 41 F. Supp. 3d at 17 (noting that as part of the paragraph (2) classification system, "[h]ospitals can also receive supplemental payments, called 'pass-through' payments, to help cover the cost of providing certain treatments, including new drugs, biologicals, and medical devices" and specifically citing 42 U.S.C. § 1395*l*(t)(6)).

Once again, if Congress had intended to specifically immunize from review matters under paragraph (14) in addition to matters "under paragraph (6)," it would have expressly done so in (t)(12)(E). But it did not, and the statutory text in no way supports – and certainly does not provide clear and convincing evidence favoring – preclusion of review under this provision.

C. Concerns About Piecemeal Litigation *Support* Review Here.

In *Amgen*, the D.C. Circuit considered the preclusion issue in the context of Congress's serious concern that "piecemeal review of individual [OPPS] payment determinations could frustrate the efficient operation of the complex prospective payment system." 357 F.3d at 112. The *Amgen* court noted and shared concerns expressed by other courts that "havoc [would result from] piecemeal review of OPPS payments . . . ." *Id.* (citing decisions from other courts of appeals). The D.C. Circuit then noted that while such piecemeal review had significant negative effects, "the interference with the administration of the [Medicare] program that would result from judicial review pertaining to the overall scope of the Secretary's . . . 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] program." *Id.* at 113 (emphasis added).

In this case, associations representing *thousands* of hospitals, along with three of those member hospitals, are challenging Defendants' authority to reduce by nearly 30% Medicare reimbursements for drugs purchased through the 340B Program. This challenge does not involve "case-by-case review of . . . the Secretary's individual applications," but rather a challenge to the "overall scope of the Secretary's authority" (*id*.) to adopt these across-the-board reductions – exactly the kind of broad challenge that the D.C. Circuit in *Amgen* explained was desirable to ensure efficient operation of the Medicare program. This case stands in stark contrast to both

Amgen and *Organogenesis*, each of which involved a *single* drug company's challenge to CMS's treatment of *one* of its products under the paragraph (2) methodology.[5]

Defendants parrot *Amgen*'s concerns about "piecemeal review" (Opp. 16), but their suggestion that *this case* raises the specter of the review that Congress sought to avoid is absurd. If a challenge to the Secretary's authority to enact an *across-the-board* reduction of Medicare reimbursement payment rates cannot be asserted by associations representing *thousands* of affected hospitals because it involves "piecemeal review," it is hard to imagine *any* challenge to Defendants' authority under the OPPS system generally, or any challenge to the 340B Provisions of the OPPS Rule specifically, that could be reviewed by the courts. Defendants' interpretation therefore effectively vitiates the distinction drawn by the D.C. Circuit in *Amgen* between "case-by-case review of . . . the Secretary's individual applications" and challenges to the "overall scope of the Secretary's authority." If any challenge falls within the latter category, this one does, and judicial review is therefore appropriate and in the interests of efficient operation of the Medicare system. *Amgen*, 357 F.3d at 112 (citation, internal quotation omitted).

Finally, an overarching theme of Defendants' preclusion arguments is that judicial review of this lawsuit would "wreak havoc" on the OPPS system because it might force CMS to recalculate revised payment rates to ensure budget neutrality. Opp. 19. But Defendants' concerns about the impact of a favorable decision for Plaintiffs cannot substitute for the clear lack of textual support for precluding review of this case. If Congress had wanted to preclude any review whatsoever of any OPPS reimbursement determination, it could have easily done so.

[5] *Amgen* involved a challenge by the drug manufacturer Amgen to CMS's decision not to make "pass-through" reimbursements to providers under 42 U.S.C. § 1395*l*(t)(2)(E) for Amgen's product Aranesp. *Organogenesis*, as discussed above, involved a challenge to CMS's decision to reimburse Organogenesis's drug product Apligraf as part of a drug/procedure package under the paragraph (2) classification system instead of under the paragraph (14) system.

However, as the D.C. Circuit in *Amgen* and this Court in *Organogenesis* each determined, that is not what it did, and this lawsuit does not fall within any of the express exemptions in (t)(12)(A). Moreover, as discussed in Section V in connection with Plaintiffs' request for a preliminary injunction, far greater havoc would be wrought on the OPPS system if the 340B Provisions of the OPPS Rule were allowed to be implemented on January 1, 2018, only to then be invalidated.

II. THE ISSUE OF THE LEGALITY OF THE 340B PROVISIONS OF THE OPPS RULE IS NOT COMMITTED TO AGENCY DISCRETION BY LAW.

Defendants argue that their payment decisions under § 1395*l*(t)(A)(14)(iii)(II) are "committed to agency discretion by law," and are thus unreviewable under the APA. Opp. 21 (quoting 5 U.S.C. § 701(a)(2)). But that argument runs headlong into the first case cited by Defendants, which holds that review is only precluded under the APA where "statutes are drawn in such broad terms that in a given case there is no law to apply." *Heckler v. Chaney*, 470 U.S. 821, 830 (1985) (citations omitted). The OPPS reimbursement provisions at issue in this case have no such breadth. And in fact, courts in this Circuit have regularly reviewed whether HHS decisions have complied with similar statutory provisions. *See, e.g.*, *Amgen*, 357 F.3d at 107-08 (reviewing the Secretary's authority to adjust pass-through payment rate for a drug under § 1395*l*(t)(2)(E)); *Shands Jacksonville Med. Ctr. v. Burwell*, 139 F. Supp. 3d 240, 251 (D.D.C. 2014) (reviewing authority to adjust compensation for inpatient services under §1395ww(d)(5)(*l*)(i)). As discussed in Section I, in *Amgen* and *Organogenerisis*, respectively, the D.C. Circuit and this Court considered whether the Secretary had properly exercised his authority under similar statutory provisions in the context of deciding the applicability of a preclusion provision, an exercise which would have been unnecessary if the Secretary's decisions were unreviewable under the APA.

The D.C. Circuit has explained 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." *Delta Air Lines, Inc. v. Export-Import Bank of the U.S.*, 718 F.3d 974, 977 (D.C. Cir. 2013); *see also Amador Cty. v. Salazar*, 640 F.3d 373, 381 (D.C. Cir. 2011) (review available because the statute imposes mandatory obligations on the agency). That exactly describes the situation here. The key question in this case is whether the 340B Provisions of the OPPS Rule exceed the bounds of Defendants' authority to adjust reimbursement rates by nearly 30%, to ASP minus 22.5%, given the statute's express reference to the statutory default rate of ASP plus 6%. Policing the bounds of agency discretion under these circumstances is "standard judicial fare." *Delta Air Lines*, 718 F.3d at 977.

The cases Defendants cite for their "committed to agency discretion" argument are either inapposite or directly undermine their position. The agency action in *Sierra Club v. Jackson* was 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). The same is not true of a challenge to an agency's reimbursement rate-setting authority within a complex regulatory program like Medicare. *See Heckler*, 470 U.S. at 831 (explaining this distinction and why it matters). Defendants' other two cases both involved provisions authorizing agencies to take action that it "*deemed* necessary," and both courts specifically called attention to the word "deem," a word absent from subclause (II), as the key textual indicator that the decision at issue was committed to agency discretion. *See Webster v. Doe*, 486 U.S. 592, 600 (1988); *Wendland v. Gutierrez*, 580 F. Supp. 2d 151, 153 (D.D.C. 2008). In *Webster*, the Supreme Court indicated that the dismissal decision at issue *would* have been reviewable had the statute omitted the word "deem" and allowed the agency to act "simply when the dismissal *is*

necessary" in the interests of the United States, 486 U.S. at 600 (emphasis in original) − language strikingly similar to subclause (II). Thus the case law is clear that the Secretary's authority under § 1395*l*(t)(14)(A)(iii)(II) is clearly subject to judicial review.

III. PLAINTIFFS HAVE SATISFIED EXHAUSTION REQUIREMENTS.

Defendants argue that Plaintiffs' claims should be dismissed pursuant to 42 U.S.C. § 405(h), as incorporated into the Medicare statute by 42 U.S.C. § 1395ii, for failing to exhaust the Medicare statute's administrative procedures before filing suit. Under section 405, a party generally may not seek judicial review "without first receiving a final decision from the Secretary." *Nat'l Ass'n for Home Care & Hospice, Inc. v. Burwell*, 77 F. Supp. 3d 103, 109 (D.D.C. 2015). This exhaustion requirement has two components: "a non-waivable 'requirement that a claim for benefits shall have been presented to the Secretary[;]' and a waivable 'requirement that the administrative remedies prescribed by the Secretary be exhausted.'" *Id.* (quoting *Mathews v. Eldridge*, 424 U.S. 319, 328 (1976)). Together, these components serve the practical purpose of "assur[ing] the agency greater opportunity to apply, interpret, or revise policies, regulations, or statutes." *Shalala v. Ill. Council on Long Term Care, Inc.*, 529 U.S. 1, 13 (2000). Here, Plaintiffs have fully satisfied both prongs of the exhaustion requirement.

First, Plaintiffs satisfied the presentment requirement by submitting detailed comments during the notice-and-comment process for the 340B Provisions of the OPPS Rule. The presentment requirement affords the Secretary an opportunity to receive information sufficient to notify him of, and to decide, the issue presented. *See Ill. Council*, 529 U.S. at 24 (citing *Eldridge*, 424 U.S. at 330-31). In *Eldridge*, the Supreme Court rejected HHS's argument that section 405 required the plaintiff to request reconsideration and a hearing prior to judicial review and instead found that a letter from the plaintiff to the state social security agency constituted presentment. 424 U.S. at 329. More recently, in *Action Alliance of Senior Citizens v. Johnson*,

607 F. Supp. 2d 33, 37-40 (D.D.C. 2009), the court held that senior citizen organizations challenging the Secretary's policy decision to recover Medicare premium refunds erroneously sent to Medicare beneficiaries satisfied presentment by sending a letter to the agency setting forth the requested relief and its legal basis, which the agency considered and denied in a responsive letter. The court rejected HHS's argument that presentment required the formal submission and denial by the Commission of Social Security of a specific monetary claim. *See id.* at 38-39. The D.C. Circuit, which before the submission of plaintiffs' letter had found no presentment (*Action Alliance of Senior Citizens v. Leavitt*, 483 F.3d 852, 856-57 (D.C. Cir. 2007)), affirmed, holding that this subsequent letter to the agency "cured the jurisdictional defect." *Action Alliance of Senior Citizens v. Sebelius*, 607 F.3d 860, 862 n.1 (D.C. Cir. 2010).

These decisions confirm that the detailed comments submitted by Plaintiffs during the notice-and comment process fully satisfy the presentment requirement. These comments identify the arguments Plaintiffs raise in this action − *i.e.*, that the Secretary lacks authority under § 1395*l*(t)(14)(A)(iii)(II) to impose a nearly 30% payment reduction for 340B drugs, including by virtue of his limited authority to "adjust" the reimbursement rate under that section, in light of both the SSA's provisions and the intent of the 340B Program. They also identify the harms that would result from the reduction. *See, e.g.*, Pls.' Corrected Ex. C (AHA comments at 6-8); Pls.' Corrected Ex. D (AAMC comments at 7 and attached legal memorandum);[6] Pls.'Ex. E (AEH comments at 4-8); Pls.' Ex. F (EMHS comments at 1-2); Pls.' Ex. G (Henry Ford comments at 1-3); Pls.' Ex. H (Park Ridge comments at 2-3, 4-5). CMS considered and rejected Plaintiffs' arguments, relying on precisely the same legal authority for the 340B Provisions of the OPPS

[6] Plaintiffs inadvertently filed, with their motion for preliminary injunction, versions of the AHA and AAMC comments that omitted certain attachments submitted to CMS, and have attached the corrected versions of Exhibits C and D to this brief.

Rule that Defendants have relied on in this case. *See* 82 Fed. Reg. at 52,499-52,502 (asserting as authority for the 340B Provisions of the OPPS Rule the Secretary's authority to "adjust" reimbursement rates under 42 §1395*l*(t)(14)(A)(iii)(II) and rejecting Plaintiffs' claims that this authority does not support the Rule).[7]

The second exhaustion prong is the requirement that the Secretary's procedures be followed – a requirement that is waived if following the procedures would be futile. Here further exhaustion would have been entirely futile. The 340B Provisions of the OPPS Rule are final and will be applied as written starting on January 1, 2018. No HHS administrative review body would have the authority to alter or deviate from this regulation, which is binding on HHS and private parties until repealed or enjoined by a court. *See* 42 C.F.R. § 405.1063(a) ("All laws and regulations pertaining to the Medicare and Medicaid programs, including, but not limited to Titles XI, XVIII, and XIX of the Social Security Act and applicable implementing regulations, are binding on ALJs and attorney adjudicators, and the [Medicare Appeals] Council"). Put simply, Plaintiffs objected to the Secretary's action and provided the precise legal basis for that objection during the only decisional process that matters, in comments that explained in detail why the Secretary exceeded his authority, and those objections were rejected, leaving the agency administrative process without discretion to overturn that decision.

[7] The comments in this case differ from the "generalized" opposition to an agency action that the court found insufficient for presentment in *National Association for Home Care*, 77 F. Supp. 3d at 109 n.1. Here, Plaintiffs' comments raised both specific, legal objections to the agency's action and identified specific harms that would result from that action. The other cases cited by Defendants are also inapposite because plaintiffs in those cases *never* presented their claims to the agency. *See Ill. Council*, 529 U.S. at 24 (no presentment); *Three Lower Ctys. Cmty. Health Servs., Inc. v. HHS*, 317 F. App'x 1, 2 (D.C. Cir. 2009) (per curiam) (no presentment effected by sending a letter to administrative review board seeking only a jurisdictional ruling); *Heckler v. Ringer*, 466 U.S. 602, 609-10, 613, 617-18, 621 (1984) (holding that some claimants did not present, while others failed the futility test).

Compounding the problem of futility are the extreme delays inherent in the Medicare reimbursement review process. This process requires presentation of a claim to the Medicare Administrative Contractor, three levels of administrative appeal, *de novo* review by an administrative law judge, and finally de novo review by the Medicare Appeals Council. *See Am. Hosp. Ass'n v. Burwell*, 812 F.3d 183, 185-86 (D.C. Cir. 2016). And the administrative appeals process would add extreme delays. *Id.* at 187 (noting that as of February 2015, ALJ appeals were pending for an average 572 days before decision). *At no step along the way would any reviewing body have authority to deviate from the rule. See* 42 C.F.R. § 405.1063(a). Thus, this process merely delays review without affording the claimant any possibility of redress before judicial review.

In conclusion, the notice-and-comment process, rather than the administrative appeals process, was the only meaningful avenue to assure that the purposes of section 405 would be fulfilled, *i.e.*, to ensure that the agency has the "opportunity to apply, interpret, or revise policies, regulations, or statutes." *Ill. Council*, 529 U.S. at 13. Plaintiffs presented their arguments to HHS and their arguments were rejected. Further review by Defendants would be entirely futile.

IV. PLAINTIFFS ARE LIKELY TO SUCCEED ON THE MERITS OF THEIR CLAIMS.

Plaintiffs' Memorandum demonstrated that the nearly-30% Medicare payment reduction in the 340B Provisions of the OPPS Rule exceeds the Secretary's adjustment authority under subclause (II) of 42 U.S.C. § 1395*l*(t)(14)(A). Plaintiffs relied on the plain and ordinary meaning of the term "adjustment," the structure of 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(I)-(II), and the interplay between those provisions and the statutory 340B Program. Defendants respond that the Secretary's authority to make "adjust[ments] . . . as necessary" under subclause (II) is essentially limitless, allowing him to make dramatic changes to OPPS payment rates for 340B drugs that

have no connection to the statutorily required APS plus 6% rate, in order to remedy his policy concerns about 340B hospitals' allegedly "outsized profits." Opp. 26, 32-34. The Secretary also treats as irrelevant that Congress *specifically designed* the 340B Program to create a gap between (1) 340B drug discounts and (2) Medicare reimbursements that covered entities could rely on to provide vital services to their communities and vulnerable populations. Defendants' assertion of unfettered authority, untethered to either the specific statutory requirements of the SSA or Congress's intent in enacting the 340B Program, should be rejected by this Court.

A. The Nearly-30% Reduction Exceeds the Secretary's Authority.

Defendants do not dispute that the nearly-30% payment reduction for 340B drugs is a "dramatic departure" from the agency's prior payment rates. Opp. 31. Instead, Defendants make the remarkable assertion that the Secretary's authority to "adjust[] [the ASP plus 6% statutory default rate] as necessary" under subclause (II) does not impose "*any* restriction on the Secretary's discretionary 'adjustment' of OPPS drug payments." *Id.* 26 (emphasis added).

This argument, however, is foreclosed by *Amgen*, where the D.C. Circuit interpreted the term "adjust . . . as necessary" in another case involving OPPS. In *Amgen*, the D.C. Circuit evaluated the Secretary's authority to make "*other adjustments* as determined *to be necessary* to ensure equitable payments" under the OPPS "paragraph (2)" methodology relating to bundled hospital outpatient department services (as opposed to the separately payable drugs addressed in the paragraph (14) methodology at issue in this case). 42 U.S.C. § 1395*l*(t)(2)(E) (emphasis added). The D.C. Circuit recognized the limitations that "inhere" in the discretionary authority to make "adjustments," which the court found to encompass "similar limits . . . to those the Supreme Court found in the word 'modify'" in *MCI Telecommunications Corp. v. AT&T, Co.*, 512 U.S. 218, 225 (1994). *Amgen*, 357 F.3d at 117 (citing *MCI*, 512 U.S. at 225, which found

that the word "modify" has "a connotation of increment or limitation" and defined it to mean "to change moderately or in minor fashion"). The D.C. Circuit held that this "inhere[nt]" limitation in the meaning of "adjustment" meant 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[ ].'" *Id.* The D.C. Circuit contrasted changes that were mere "adjustment[s]" with changes that instead caused "total elimination or severe restructuring of the statutory scheme." *Id*.

Consistent with the clear limit of "adjust" that the D.C. Circuit found to "inhere" in that word's plain meaning, courts have only upheld the use of the authority to "adjust" to sustain minor changes that do not work basic and fundamental changes to the scheme created by Congress. *Id.* In *Amgen*, for instance, the Secretary sought to use the authority to modify the payment amount for a *single* drug. In *Shands, supra*, 139 F. Supp. 3d at 260, and *Adirondack Medical Center v. Sebelius*, 891 F. Supp. 2d 36, 41-42 (D.D.C. 2012), *aff'd*, 740 F. 3d 692, 695 (D.C. Cir. 2014), the Secretary adopted 0.2% and 2.9% reductions, respectively, in compensation for hospital inpatient services.[8] These examples of limited modification sharply contrast with the dramatic, nearly-*30%* reduction of the payment rate for 340B drugs at issue here. A circumscribed reading of "adjust" is especially appropriate where, as here and as discussed below, an agency's purported "adjustment" would in fact "severe[ly] restructure" (*Amgen*, 357 F.3d at 117) not one but two statutory schemes – the OPPS "paragraph (14)" payment scheme *and* the 340B Program. Amgen precludes treating as an "adjustment" agency actions with such dramatic effects. And indeed, Defendants have not identified a single case in which a court has

[8] In these cases, the relevant statute provides the Secretary with the authority to make "other exceptions and adjustments to such payment amount . . . as the Secretary deems appropriate." *See Shands*, 139 F. Supp. 3d at 251 (quoting 42 U.S.C. § 1395ww(d)(5)(*l*)(i)).

upheld the kind of dramatic departure from a statutory standard that Defendants claim here to be a proper exercise of the authority to "adjust."

The D.C. Circuit's recognition of the inherent limitations of the Secretary's adjustment authority is buttressed by the plain and ordinary meaning of "adjust," which is defined as "to alter or move (something) *slightly* in order to achieve the desired fit, appearance, or result." Mot. 12 (citing the Oxford Dictionaries (emphasis added)). Other dictionary definitions of "adjust" also cabin that word's meaning to include only "slight" changes.[9] Defendants point to dictionary definitions that do not use the word "slight." Opp. 27-28 & n.7. But these definitions use words other than "slight" that *also* connote moderate or incremental changes to bring about precision and refinement, consistent with the derivation of "adjust" from the root word *juste*, meaning "right, exact." *Adjust*, Webster's Third New International Dictionary (1961 ed.).[10] Thus,

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[9] *See also, e.g.*, *Adjust*, Cambridge Dictionary, https://dictionary.cambridge.org/dictionary/english/adjust ("to change something *slightly*, especially to make it more correct, effective, or suitable") (emphasis added); *Adjust*, Collins English Dictionary (12th ed. 2014) ("to alter *slightly*, esp to achieve accuracy; regulate") (emphasis added); *Adjust*, Longman Dictionary, https://www.ldoceonline.com/dictionary/adjust ("to gradually become familiar with a new situation"; "to change or move something *slightly* to improve it or make it more suitable for a particular purpose") (emphasis added). Tellingly, Merriam-Webster—one of the dictionaries Defendants rely on—also defines "adjust" as "to change (something) *in a minor way* so that it works better." *See Adjust*, Merriam-Webster, https://www.merriam-webster.com/dictionary/adjust (emphasis added). This definition, set out separately for English learners and children, presumably attempts to define the word in the most plain and understandable terms.

[10] For example, one of Defendants' chosen definitions defines "adjust" to mean "adapt," which is itself defined to mean ("to make fit (as for a new use) often by *modification*" (emphasis added)). *Adapt*, Merriam-Webster, https://www.merriam-webster.com/dictionary/adapt. Others use words like "fits," "conforms," and "corresponds," all of which also connote changes that remain faithful to a fixed reference point. *See Fit*, Merriam-Webster, https://www.merriam-webster.com/dictionary/conform ("to be similar or identical; "to be in agreement or harmony"); *Correspond*, Merriam-Webster, https://www.merriam-webster.com/dictionary/correspond ("to be in conformity or agreement"; "to compare closely"; match; to be equivalent or parallel"); *Conform*, Merriam-Webster, https://www.merriam-webster.com/dictionary/conform ("to give the same shape, outline, or contour to"; "to be similar or identical; *also* : to be in agreement or harmony").

Defendants' definitions of "adjust" *support* the limits the D.C. Circuit found to inhere in that term and do not allow for a meaning that encompasses significant, unlimited changes.[11]

Defendants attempt to avoid the plain meaning and inherent limitations of "adjust" by invoking the reference in subclause (II) to "adjustments *as necessary for purposes of this paragraph*" (42 U.S.C. § 1395*l*(14)(A)(iii)(II) (emphasis added)). Opp. 26. But as *Amgen* makes clear in interpreting similar authority under OPPS to make "adjustments . . . as determined to be necessary," the phrase "as necessary" grants the Secretary no additional authority than what is embedded within the power to "adjust." *See Amgen*, 357 F.3d at 117.

Defendants accuse Plaintiffs of looking at the term "adjust" "in isolation," Opp. 26. But if any party is guilty of ignoring context, it is Defendants, who assign the word "adjust" an unlimited meaning without any consideration for the many signs in the statute that Congress intended to limit the kinds of adjustments under the paragraph 14 system. By contrast, Plaintiffs' Motion demonstrated that both the structure of § 1395*l*(t)(14)(A)(iii) − which requires payment rates under subclause (II) to be made "subject to subparagraph (E)," which in turn confers authority on the Secretary to make adjustments *for overhead and related expenses* − and the overall structure of § 1395*l*(t)(14)(A) − which sets forth the payment rate scheme by year with specificity − reflect a congressional intent to confer the Secretary with limited authority to set payment rates. Mot. 13-15 & n.13.

[11] The D.C. Circuit also made clear that in reviewing the Secretary's adjustment authority, the relevant definition of "adjust" is the one that relates to making changes to something. *Amgen*, 357 F.3d at 117. The technical definition of the word in the insurance context − which Defendants invoke (Opp. 28) − is obviously inapposite in this context. Defendants cannot seriously contend that the Secretary is functioning like an insurance adjuster in the context of setting and modifying payment rates for an entire drug class pursuant to statute simply because this case implicates Medicare, a public insurance program.

Defendants assert that the reference in 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II) to "subparagraph (E)" (which provides for adjustments *for overhead and related expenses*) has no bearing on the Secretary's "adjustment" authority under subclause (A)(iii)(II) because subparagraph (E) authorizes "a *separate* adjustment specifically to account for 'overhead and related expense[s]'" and thus cannot be "coextensive" with the broader adjustment authority under subclause (II). Opp. 29-31 (emphasis in original). Plaintiffs, however, do not contend that the two adjustment authorities are coextensive. Rather, because subparagraph (E) sets forth this specific, limited adjustment authority *and* precedes the more general reference to the Secretary's authority to "adjust[] . . . as necessary" under subclause (II), subparagraph (E)'s limitations necessarily inform the meaning of the Secretary's adjustment authority under subclause (II). *Cf. Cement Kiln Recycling Coalition v. EPA*, 493 F.3d 207, 221 (D.C. Cir. 2007) ("[W]here general words follow specific words, the general words are construed to embrace only objects similar in nature to those objects enumerated by the preceding specific words.") (citation omitted). A reading of "adjust" under subclause (II) that is consistent with the limitations on that term in subparagraph (E) is also the only interpretation that makes sense given that in both cases, the term is part of a statutory payment rate scheme that carefully defines and limits the Secretary's authority at every turn. *See* Mot. 15 n.13.

B. The Secretary Impermissibly Invoked His Authority Under Subclause (II) to Circumvent Express Statutory Requirements Under Subclause (I).

As explained in Plaintiffs' motion, the Secretary's exercise of authority under subclause (II) is an improper attempt to circumvent the unambiguous requirements of subclause (I), which requires that rates based on average acquisition cost take into account statistically sound survey data that meets certain statutory requirements. Mot. 15-17. In response, Defendants merely reiterate their position that there is "no limit[ation]" to what methods or factors the Secretary

may use or consider in "adjusting" the ASP under subclause (II). Opp. 33. In other words, Defendants claim paradoxically that in circumstances where the Secretary lacks statutorily required, statistically sound, reliable data as required if he is to take into account acquisition costs under subclause (I), he enjoys the most discretion under subclause (II) to rely on what is inadequate information under subclause (I). This convoluted argument serves only one purpose − to remedy what the Secretary views, as a policy matter, as "outsized profits" received by 340B hospitals. It makes absolutely no sense given the structure of paragraph 14.

Specifically, Defendants' interpretation of "adjustment" authority under subclause (II) cannot be so boundless that it eliminates Congress's express distinction between the subclause (I) acquisition cost-based approach and the subclause (II) ASP plus 6%-based approach, and the clear statutory requirements for each. The 340B Provisions of the OPPS Rule are based on estimates of acquisition costs, which cannot be the basis for the paragraph (14) payment methodology in the absence of the statistical data required by subclause (I), which Defendants admit they do not have. *See* Opp. 32-35. If CMS could simply use estimated acquisition cost data instead of the data required under Paragraph (I) and thereby substantially depart from the ASP plus 6% benchmark in paragraph (II), there would be no reason for *either* the statute's subclause (I) data requirement or its subclause (II) ASP plus 6% benchmark. The Secretary's adjustment authority simply does not empower him to restructure Congress's carefully calibrated determination of what criteria are required under both subclause (I) and subclause (II) of the paragraph (14) payment methodology, so that he may discard what he might perceive as burdensome statutory requirements. Mot. 15.

C. The Unprecedented, Nearly-30% Reduction Unlawfully Undermines the 340B Program.

Even if the OPPS statute granted the Secretary the broad authority he claims here, it is impermissible for him to exercise that authority in a manner that undermines the 340B Program that he is also responsible for administering. Defendants are wrong that the devastating impact of the rate reduction on the 340B Program is irrelevant to the Secretary's authority under subclause (II) of § 1395*l*(t)(14)(A). To the contrary, an agency must apply a statute "insofar as possible, in a manner that minimizes the impact of its actions on the policies of . . . [an]other statute." *Can-Am Plumbing, Inc. v. NLRB*, 321 F.3d 145, 154 (D.C. Cir. 2003) (citation omitted). This is true even where there is genuine tension between two distinct statutory regimes. Here, where the two statutory regimes are related, this reasoning is even more compelling.

PBGC v. LTV Corp., 496 U.S. 633, 645-46 (1990), cited by Defendants, is not to the contrary. That case noted only that an agency need not account for every possible effect of its actions on areas of the law in which the agency "can claim no expertise" and that nobody brought to the agency's attention during the administrative process. 496 U.S. at 646. *LTV Corp.* also involved no indication that the agency's decision "*actually conflicted* with any provision" of the other statutory regimes at issue. *Id.* at 645-46 (internal quotations and alterations omitted). There is *every* indication here, by contrast, that the 340B Provisions of the OPPS Rule would significantly undercut the congressionally intended benefits of the 340B Program.

Defendants' principal argument is that "the 340B Program and Medicare are distinct programs, administered by separate agencies and governed by different statutory schemes." Opp. 35-36. Even if it were true that an agency could ignore how its application of a statute affects unrelated statutes, 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II) and the 340B Program are not only

related (as they are both administered by HHS), they are in fact *inextricably intertwined* pursuant to operation of the 340B Program.

Defendants do not and cannot dispute that the 340B Program's express purpose was to "stretch scarce Federal resources as far as possible, reach more eligible patients and provid[e] more comprehensive services." H.R. Rep. No. 102-384(II), at 12 (1992). This purpose can *only* be effectuated through the *joint* operation of two programs: one that provides covered entities with discounted drugs and another that reimburses the entities at a rate higher than the discounts, including under Medicare, which is responsible for providing reimbursements for a substantial percentage of 340B drugs. The 340B Program's objective is thus dependent, by design, on a particular approach to Medicare reimbursement – one that does not, as Defendants have done in the 340B Provisions of the OPPS Rule, closely "align" reimbursements with 340B discounts to dramatically reduce the differential envisioned by Congress.

Far from "amorphous," as Defendants claim, *see* Opp. 37, this dependence has been consistently recognized by the Health Resources and Services Administration ("HRSA"), the HHS agency that administers the 340B Program. *See* Mot. 3-4 (quoting HRSA manual explaining that the 340B Program operates through discounted acquisition cost and reimbursement rate maintained at a level higher than the discount). More critically, this dependence has been endorsed by Congress, which chose to expand significantly the type and number of "covered entity" hospitals in 2010 (from 1,365 to 2,140 hospitals) without imposing any limits on the Program. *See* 82 Fed. Reg. at 52,495, 52,502.

Thus, contrary to Defendants' claims, the Secretary had no authority to reconfigure Congress's chosen statutory scheme for the 340B Program by invoking its authority under the OPPS statute. That the 340B Program and the OPPS payment rate are codified in different

sections of Title 42 of the U.S. Code does not change this. *See POM Wonderful LLC v. Coca-Cola Co.*, 134 S. Ct. 2228, 2242 (2014) ("An agency may not reorder federal statutory rights without congressional authorization."). Under *Howard v. Pritzker*, 775 F.3d 430, 437-38 (D.C. Cir. 2015), 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.

Howard also demonstrates the flaw in Defendants' argument that the nearly-30% reduction does not exceed the Secretary's authority because it does not completely eliminate all financial benefits for 340B hospitals. Specifically, Defendants assert that because the reduced rate reflects the "lower bound" of the average discount received by 340B hospitals, it still allows the hospitals to retain an unspecified amount of "profit" on 340B drugs. Opp. 35-37. In *Howard*, however, two statute of limitations provisions were in "irreconcilable conflict" (*Howard*, 775 F.3d at 437) not because the application of the more general limitations provision necessarily or completely precluded the application of the more specific limitations provision, but because the application of the more general provision undermined "Congress's preferred manner of resolving federal employment discrimination complaints [administratively]." *Id.* at 439-40. Here, similarly, the Secretary's dramatic, nearly-30% reduction in payment rate for 340B drugs would significantly undermine the hospitals' ability to fulfill the express congressional purposes of stretching scarce federal dollars to serve more patients and provide more comprehensive services.

As detailed in comments submitted by Plaintiffs and other covered entities, the funds characterized by the Secretary as "outsized profits" (Opp. 33) received by 340B hospitals were used to support vital services to vulnerable populations—services that are endangered by the

nearly-30% reduction. *See, e.g.*, Pls.' Ex. G at 2 (Hospital Plaintiff Henry Ford's charity care, meds to beds, and reduced cost medical and behavioral health care programs, provided to the underserved communities of Jackson and Detroit, Michigan); Pls.' Ex. H at 4 (Hospital Plaintiff Park Ridge's free/discounted drug program in North Carolina); Pls.' Ex. L at 2-3 (University of California Health System's infusion and post-transplant centers, as well as its inner-city clinics); Pls.' Ex. M at 1 (MedStar Health's in-home services to Washington, D.C.'s most vulnerable elderly patients, an after-hours clinic that provides free healthcare at a Southeast DC homeless shelter, a no-charge clinic for uninsured patients in Baltimore). The nearly-30% reimbursement reduction will cripple these hospitals' ability to effect the 340B Program's express purposes, causing an "irreconcilable conflict" between the OPPS payment statute and that program.

Defendants also cryptically assert that Plaintiffs' challenge to the Secretary's authority is a "reasonableness challenge" in disguise. Opp. 34 (citing *Fla. Health Scis. Ctr., Inc. v. HHS*, 830 F.3d 515, 523 (D.C. Cir. 2016)). *Florida Health Sciences*, however, has no bearing whatsoever here. In that case, the court held that where a statute expressly precludes judicial review of certain funding "estimates" by the Secretary, a hospital cannot end-run preclusion by challenging the estimates' underlying data, essentially raising "the kind of case-by-case review of the reasonableness or procedural propriety of the Secretary's individual applications that Congress intended to bar." *Id.* at 522-23 (citation omitted). Plaintiffs here do not challenge the reasonableness or procedural propriety of an individual determination. Rather, they challenge agency action effecting significant, fundamental changes to both the paragraph (14) payment system and the 340B program. *See* Mot. 17-19.

V. PLAINTIFFS SATISFY THE OTHER FACTORS FOR A PRELIMINARY INJUNCTION.

In addition to arguing Plaintiffs are unlikely to succeed on the merits, Defendants also insist Plaintiffs have not demonstrated irreparable harm absent a preliminary injunction (Opp. 39-42) and that an injunction would not be in the public interest (*id*. at 43). They are wrong on both counts. Because Plaintiffs have satisfied all requirements for a preliminary injunction, this Court should preserve the *status quo* by suspending implementation of the 340B Provisions of the Proposed Rule pending resolution of this case – exactly the purpose for which preliminary injunctions are intended. Mot. 22; *Aamer v. Obama*, 742 F.3d 1023, 1043 (D.C. Cir. 2014) ("The primary purpose of a preliminary injunction is to preserve the object of the controversy in its then existing condition – to preserve the status quo.") (citation omitted).

A. Plaintiffs Satisfy the Irreparable Harm Requirement.

As a threshold matter, Defendants misstate what possibility of harm must be shown for an applicant to obtain a preliminary injunction. The Supreme Court in *Winter v. NRDC, Inc.*, 555 U.S. 7, 20 (2008), made clear that a party seeking a preliminary injunction "must establish that . . . he is *likely* to suffer irreparable harm in the absence of preliminary relief . . . ." (citations omitted) (emphasis added). Defendants' claims that Plaintiffs' multiple undisputed assertions of "likely" irreparable harm are legally insufficient (Opp. 41-42) ignore this clear precedent.[12]

As set forth in Plaintiffs' preliminary injunction motion and accompanying affidavits (Exs. I-K), the harm that the three Hospital Plaintiffs and members of the three Association Plaintiffs would suffer is not only (at minimum) likely, it is also both "imminent" and "actual."

[12] To the extent that the D.C. Circuit's over-30-year old decision in *Wisconsin Gas Company v. FERC*, 758 F.2d 669 (D.C. Cir. 1985), held, as Defendants suggest (Opp. at 41), that "likely" irreparable harm is not legally cognizable, that view has been superseded by the Supreme Court in *Winter*.

The 340B Provisions of the OPPS Rule are scheduled to go into effect on January 1, 2018, and, if effective, would reduce Medicare reimbursements for 340B drugs to the Hospital Plaintiffs and other members of the Association Plaintiffs by nearly 30%. The total cost of this reduction to affected hospitals, as calculated by CMS itself, would be $1.6 billion (82 Fed. Reg. at 52,623), and the net cost to each of the Hospital Plaintiffs would be $2.86 million or more.[13]

These concrete and imminent harms would not be, as Defendants claim (Opp. 39), "purely economic." The loss of funds would *immediately* jeopardize the ability of the Hospital Plaintiffs (as well as other members of the Association Plaintiffs) to provide essential services to their communities, including underserved populations in those communities – specific examples of which Plaintiffs' affidavits highlight. *E.g.*, Pls.' Ex. I (EMHS Aff. ¶¶ 15-16) (noting that EMHS' "oncology services," including specifically its Cancer Care of Maine program, as well as "dialysis services, services for immediate stroke treatment, osteoporosis services, and blood factor services" would "likely be impacted by [the 340B Provisions of the OPPS Rule], to at least some degree"); Pls.' Ex. K (Park Ridge Aff. ¶ 18) (noting that the 340B Provisions of the OPPS Rule would "threaten the continued health, or even the existence," of PR's four infusion centers and geriatric psychiatric program). In addition to its immediate effect on specific programs and service lines, the loss of funds caused by the 340B Provisions of the OPPS Rule would also *immediately* affect more generally the Hospital Plaintiffs' (and other Association Plaintiffs' members') financial and budgeting operations, including their loan covenants and other arrangements that allow these entities to provide essential health care to their communities. *E.g.*, Pls.' Ex. I (EMHS Aff. ¶ 19).

[13] *See* Pls.' Ex. I (EMHS Aff. ¶ 12) (estimating $2.86 million net cost to Hospital Plaintiff EMHS); Pls.' Ex. J (Henry Ford Aff. ¶ 14) (estimating $9.3 million net cost to Hospital Plaintiff Henry Ford); Pls.' Ex. K (Park Ridge Aff. ¶ 14) (estimating $3.3 million net cost to Hospital Plaintiff Park Ridge).

A healthcare provider's inability to provide essential healthcare services constitutes irreparable harm, even if it is only temporary and the provider is not driven out of business by the conduct it seeks to enjoin. As Judge Sullivan noted in *Texas Children's Hospital v. Burwell*, 76 F. Supp. 3d 224, 244 (D.D.C. 2014), the loss of funds threatening non-profit healthcare providers' essential services is "different in kind from economic loss suffered by a for-profit entity." The fact that hospital *programs* "*may* be" driven out of business – even temporarily – establishes irreparable harm even if the hospital as a whole will survive. *Id.* at 224 n.7 (emphasis added). *See also Arkansas Med. Soc'y v. Reynolds*, 834 F. Supp. 1097, 1101-02 (E.D. Ark. 1992) (granting preliminary injunction and finding irreparable harm based on, *inter alia*, healthcare providers' inability to provide services to Medicaid beneficiaries). Similarly, the fact that an affected hospital could, if Plaintiffs prevail in this case, theoretically recover the lost reimbursement amounts at some later point in time and reinstate any programs curtailed or terminated in the interim in no way obviates the harm of not being able to provide essential services to those who need those services *now*. Defendants do not cite a single case, and we know of no case, in which a healthcare provider was denied a preliminary injunction where the action sought to be enjoined was likely to cause the provider to deny *anyone* medical services.

Defendants also argue that Plaintiffs do not face imminent harm from the 340B Provisions of the OPPS Rule going into effect on January 1, 2018, because hospitals have one year to submit claims for reimbursement to CMS. Opp. 42. This is absurd on several levels.

First, a regulation that sets hospitals' legal rights to Medicare reimbursements clearly causes harm to hospitals before they actually seek/are denied reimbursement. *E.g., Lapeer Cty. Med. Care Facility v. Michigan*, 765 F. Supp. 1291, 1300 (W.D. Mich. 1991) (finding irreparable harm before plaintiffs' receipt of check reflecting challenged Medicaid

reimbursement reduction). As set forth in Plaintiffs' affidavits and above, hospitals (understandably) rely on the Medicare reimbursement rules in effect at the time they engage in their financial planning (*e.g.*, Pls.' Ex. I, EMHS Aff. ¶ 19), especially because as noted above in connection with the exhaustion issue, a regulation is binding on HHS and private parties unless/until it is repealed or enjoined by a court. 42 C.F.R. § 405.1063(a). To ignore the 340B Provisions of the OPPS Rule in the hopes of eventually having it invalidated by a court would be irresponsible. Thus, it is the promulgation of a regulation setting hospitals' legal rights, not just the later actual payment reduction receipt pursuant to the regulation, that causes the complained-of harm here.

Second, Defendants' implication that the Hospital Plaintiffs and other members of the Association Plaintiffs could afford to wait a full year before full reimbursement for drugs purchased under the 340B Program is puzzling, given the undisputed affidavits and other evidence showing the harms that the Hospital Plaintiffs and other members of the Association Plaintiffs would suffer from the 340B Provisions of the OPPS Rule and their general dependence on Medicare reimbursements to provide essential services to their communities.

Third, as a matter of fact, hospitals of course do not wait one year to file reimbursement claims, but rather maintain necessary cash flow by seeking reimbursement weeks or even days after the reimbursable drug has been provided. Any harm caused by actual claims under the regime created by the 340B Provisions of the OPPS Rule would begin shortly after January 1, 2018, if the rule were to take effect as scheduled − not sometime in January 2019.

Defendants then proceed to argue that a preliminary injunction would not redress any uncertainty arising out of whether the 340B Provisions of the OPPS Rule will eventually take effect. This argument is of course applicable to *every* preliminary injunction. Preliminary

injunctions do not resolve anything. Rather, they maintain the *status quo* pending full judicial consideration of the controversy. *Aamer*, 742 F.3d at 1043. In this case, the requested injunction, if granted, would temporarily redress the Plaintiffs' harms by suspending operation of a regulation that would deny them Medicare reimbursements to which they claim to be entitled. Such temporary relief is all that preliminary injunctions ever afford. For Defendants to require that Plaintiffs' requested injunction afford certainty regarding Medicare reimbursements for separately payable drugs is to completely ignore the very purpose and design of that remedy. Put another way, if a preliminary injunction should be denied because it affords no ultimate certainty to the movant, no preliminary injunction would ever be granted.

B. The Balance of Equities and Public Interest Favor a Preliminary Injunction.

Defendants claim that the "balance of equities" and the public interest both favor denying the requested injunction. Opp. 43-44.[14] Again, they are wrong.

Defendants' argument centers on their earlier assertion, in the context of discussing preclusion of judicial review (Opp. 16), that this case creates "piecemeal" review of Defendants' Medicare payment determinations. As noted earlier, this case does not generate piecemeal review. It does the opposite. *See* Section I.C.

Defendants also argue that the requested injunction would disrupt the Medicare reimbursement system. Opp. 44. But the system would be *most* disrupted if the 340B Provisions

[14] Defendants contend that where the government is the defendant, the "balance of equities" and "public interest" prongs collapse into one. *Id.* But this ignores both that important elements of the public – specifically patients who receive services from 340B hospitals under programs that face extinction or downsizing as a result of the 340B Provisions of the OPPS Rule – would be significantly harmed by denial of the requested injunction, and that there is a strong public interest in the "faithful application of the laws." *Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1066 (D.C. Cir. 1998). Neither of these interests is congruent with the public interests Defendants point to in their papers. Both the public interest and the "balance of harms" between the parties favor an injunction preserving the *status quo* here. *See also* Mot. 21-23.

of the OPPS Rule (1) took effect on January 1, 2018, and (2) were then subsequently invalidated. This would result in *two* changes to the reimbursement system and would require CMS to reprocess claims that it first paid under the 340B Provisions of the OPPS Rule. By comparison, preserving the legally valid *status quo* and then allowing CMS to adopt those provisions if they withstood judicial scrutiny would result at most in one round of changes to the system, causing as little disruption as possible.

Finally, Defendants do not consider as part of the public interest analysis the segment of the public most affected by the public interest analysis – the patients who have benefited from the services that the 340B Provisions of the OPPS Rule threaten.[15] Courts have held that denial of medical services constitutes irreparable harm entitling patients to preliminary injunctions that would allow them to continue to receive those services. *E.g., Arkansas Med. Soc'y*, 834 F. Supp. at 1101-1102 (granting preliminary injunction and finding irreparable harm based on, *inter alia*, Medicaid beneficiaries' loss of services)**.** In this case, where the patients are not parties, the harms caused to them from the 340B Provisions of the Proposed Rule is part of the public interest equation and strongly supports granting the requested injunction.

[15] Defendants suggest in the background section of their brief that Medicare beneficiary cost sharing would be reduced by the 340B Provisions of the OPPS Rule. Opp. 12-13. While cost-sharing on the affected drugs would be reduced, Defendants ignore that its budget-neutral proposal would raise reimbursement rates and related beneficiary cost-sharing for other Medicare services. Thus, while the impact on beneficiary cost-sharing burden is unknowable, the impact on patients from the likely loss of vital services from 340B hospitals is indeed at risk.

CONCLUSION

For the foregoing reasons, this Court should grant Plaintiffs' motion for preliminary injunction and deny Defendants' motion to dismiss.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this 8th day of December, 2017, I electronically filed the foregoing PLAINTIFFS' REPLY BRIEF IN SUPPORT OF MOTION FOR PRELIMINARY INJUNCTION AND OPPOSITION TO DEFENDANTS' MOTION TO DISMISS by using the CM/ECF system. All parties to the case have been served through the CM/ECF system.

/s/ Carlos T. Angulo
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