IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

THE AMERICAN HOSPITAL ASSOCIATION, *et al.*,	)	
Plaintiffs,	)	
v.	)	No. 1:18-cv-02084-RC
ALEX M. AZAR II, in his official capacity as Secretary of Health and Human Services, *et al.*,	)	
Defendants.	)	

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

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INTRODUCTION

Congress granted the Secretary of Health and Human Services (the "Secretary") broad authority to administer Medicare Part B's system for prospective payment of hospital outpatient services (known as the "Outpatient Prospective Payment System" or "OPPS"). That authority extends to setting payment rates for certain outpatient drugs, and making annual adjustments that are budget neutral. *See* 42 U.S.C. § 1395l(t)(2), (9) The Medicare statute provides that, once the Secretary calculates an OPPS drug payment rate, that rate may be "adjusted by the Secretary as necessary for purposes of this paragraph." *Id.* § 1395*l*(t)(14)(A)(iii)(II). This broad and unequivocal grant of discretion reflects Congress's judgment that the Secretary needs flexibility to effectively administer the OPPS. Further demonstrating this congressional intent, the Medicare statute expressly precludes "administrative or judicial review" of the Secretary's development of the OPPS, including adjustments within that system. *See id.* § 1395*l*(t)(12). Both the D.C. Circuit and this Court have construed § 1395*l*(t)(12) to "clearly preclude judicial review of the Secretary's adjustments to prospective payment amounts." *Organogenesis Inc. v. Sebelius*, 41 F. Supp. 3d 14, 20 (D.D.C. 2014) (Contreras, J.) (citing *Amgen, Inc. v. Smith*, 357 F.3d 103, 112 (D.C. Cir. 2004)).

At issue here is the OPPS payment rate for drugs procured under the 340B Program, a program separate from Medicare that allows certain health care providers to obtain drugs at significantly discounted prices. From 2013 to 2017, the Centers for Medicare & Medicaid Services ("CMS") within Health and Human Services ("HHS") used a payment rate of average sale price ("ASP") plus 6% for all OPPS drugs, including drugs purchased under the 340B Program. Recent reports, however, have highlighted that providers have been receiving remarkably deep discounts on outpatient drugs under the 340B Program and, consequently, have reaped substantial profits on each drug they prescribe. By one measure, providers received Medicare payments for drugs

acquired under the 340B Program that were on average *58% higher* than what the provider paid for the drug.

This discrepancy is troubling for several reasons. First, because the Secretary administers the OPPS in a budget-neutral manner, providers outside the 340B Program have subsidized drug payments to 340B Program participants that bear no actual relation to the participants' acquisition costs. Second, Medicare beneficiaries' out-of-pocket payments, such as copayments or coinsurance, are tied to the amount that Medicare—not the provider—pays for the drug. As a result, beneficiaries have been paying artificially high rates for drugs that their providers received at a significant discount. Third, perhaps quite predictably, reports show that 340B hospitals tend to prescribe more drugs, or more expensive drugs, than hospitals outside the program – and they do so at the government's and beneficiaries' expense.

To address this issue, the Secretary issued a final rule that exercises his authority under § 1395*l*(t)(14)(A)(iii)(II) to "adjust[] . . . as necessary" the OPPS payment rate for 340B drugs. *See* 82 Fed. Reg. 52,356, 52,362 (Nov. 13, 2017) ("2018 OPPS Rule"). The Rule reduces the OPPS payment rate for 340B drugs to ASP minus 22.5%, which reflects the "minimum" or "lower bound of the average discount received by 340B hospitals," thus allowing 340B providers to retain some profit margin. *Id.* at 52,496. The payment adjustment is intended to "better, and more appropriately, reflect the resources and acquisition costs that [340B] hospitals incur," as well as "lower drug costs for Medicare beneficiaries for drugs acquired by hospitals under the 340B Program," ensuring that beneficiaries "share in the savings on drugs acquired through the 340B Program." *Id.* at 52,362, 52,495-97. The Rule exempts from the payment adjustment "[r]ural sole community hospitals (SCHs), children's hospitals, and [prospective payment system]-exempt cancer hospitals." *Id.* at 52,362. The payment adjustment also does not affect 340B providers that

are paid under a separate payment scheme outside of the OPPS, such as critical access hospitals. In total, at least 52% of the 340B providers are not affected by the payment adjustment, either because they are specifically exempted, or because they are not paid under the OPPS. The Secretary estimated that the payment adjustment would save Medicare $1.6 billion on OPPS drug expenditures for 2018. *Id.* at 52,509. In accordance with the Medicare statute's budget neutrality requirements, these savings already have been and will continue to be "redistributed in an equal offsetting amount to all hospitals paid under the OPPS," *id.*, including Plaintiffs.

Plaintiffs brought this suit under the Administrative Procedure Act ("APA"), seeking the extraordinary remedy of a preliminary injunction to enjoin the application of the 2018 OPPS Rule, among other things. Compl.; Plaintiffs' Memorandum in Support of their Motion for a Preliminary and Permanent Injunction ("Pls.'Mem."), ECF No. 2, Sept. 5, 2018. They claim that the Secretary's payment adjustment exceeded his authority under the Medicare statute. Compl. ¶¶ 67-78.

Plaintiffs' Complaint should be dismissed for four independent reasons. First, as indicated above, judicial review of the Secretary's adjustment of OPPS payment rates under § 1395*l*(t)(14)(A)(iii)(II) is expressly precluded by § 1395*l*(t)(12). Second, the Secretary's payment adjustment is an agency action that is "committed to agency discretion by law" and thus unreviewable under the APA. Third, Plaintiffs failed to exhaust their administrative remedies. Fourth, Plaintiffs' claim fails on the merits because their various theories as to why the Secretary's actions exceeded his statutory authority rest on misinterpretations of the Medicare statute.

Plaintiffs also fall far short of the extraordinary showing necessary to obtain a preliminary injunction. For the reasons outlined in support of Defendants' motion to dismiss, Plaintiffs are not likely to succeed on the merits. Moreover, the requested injunction would significantly disrupt

operation of the Medicare system, to the detriment of its participants and Defendants. Indeed, the Agency has processed millions of claims under the 2018 OPPS rule, and a preliminary injunction increasing the payment rate for drugs purchased through the 340B program would raise significant and difficult questions about how to handle claims related to other components of the OPPS that, as a result of the budget neutrality requirement, were paid under rates that were increased to offset the decrease to the payment rate for drugs acquired through the 340B program.

For all these reasons, Defendants respectfully request that the Court grant Defendants' motion to dismiss, and deny Plaintiffs' motion for a preliminary injunction.

BACKGROUND

I. The Medicare Outpatient Prospective Payment System

Medicare is a federal health insurance program for the elderly and disabled. *See* 42 U.S.C. § 1395 *et seq.* (the "Medicare statute"). HHS administers Medicare through CMS. Part A of Medicare provides insurance coverage for inpatient hospital care, home health care, and hospice services. *Id.* § 1395c. Part B of Medicare, at issue here, provides supplemental coverage for other types of care, including outpatient hospital care. *Id.* §§ 1395j, 1395k.

A component of Medicare Part B is the OPPS, which pays hospitals directly to provide outpatient services to beneficiaries. *See* 42 U.S.C. § 1395*l*(t) (establishing the OPPS). Under the OPPS, hospitals are paid on prospectively-determined rates for their services in each upcoming year, thus requiring payments for outpatient hospital care to be determined in advance. *See id.* The Medicare program currently processes more than 100 million outpatient hospital claims per year. *See, e.g.*, 2016 CMS Statistics, at 42, Table V.6 (outpatient hospital claims represent 59.7% of 214.1 million total claims received) (attached as Exh. 1).

The Medicare statute confers broad authority on the Secretary to make adjustments to the OPPS. For instance, the Secretary is charged with annually updating the OPPS payment

classifications, relative payment weights, and other components of the OPPS, "to take into account changes in medical practice, changes in technology, the addition of new services, new cost data, and other relevant information and factors." *Id.* § 1395*l*(t)(9)(A). Such adjustments must be made in a "budget-neutral" manner—*i.e.*, "the adjustments for a year may not cause the estimated amount of expenditures . . . for the year to increase or decrease from the estimated amount of expenditures . . . that would have been made if the adjustments had not been made." *Id.* § 1395*l*(t)(9)(B). Further demonstrating the flexibility Congress intended to confer upon the Secretary in administering the OPPS, the Medicare statute expressly precludes "administrative or judicial review" of the Secretary's "development of" and "adjustments" to the OPPS system, including payment adjustments. *See id.* § 1395*l*(t)(12) (subsection titled "Limitation on review").

In 2003, Congress amended the Medicare statute to require the Secretary to set Medicare payment rates for "specified covered outpatient drugs" ("SCODs"). *Id.* § 1395*l*(t)(14). SCODs are a category of "separately payable" drugs—*i.e.*, drugs that are not bundled with other outpatient services, and for which a "separate ambulatory payment classification group" has been established. *Id.* § 1395*l*(t)(14)(B). Of particular relevance here, SCODs include some outpatient drugs that are subject to discounts under the 340B Program.

For 2004 and 2005, the Medicare statute gave the Secretary specific instructions on how to set payment rates for SCODs. *Id.* § 1395*l*(t)(14)(A)(i)-(ii). But for 2006 and beyond, Congress eschewed these specific instructions and instead expressed a preference for payment rates to align with acquisition costs. Specifically, Congress directed the Secretary to set payment rates for SCODs to be equal to either:

> (I) . . . the average acquisition cost for the drug for that year (which, at the option of the Secretary, may vary by hospital group (as defined by the Secretary based on volume of covered [outpatient department ("OPD")] services or other relevant

> characteristics)), as determined by the Secretary taking into account the hospital acquisition cost survey data under subparagraph (D); *or*
>
> (II) if hospital acquisition cost data are not available, the average price for the drug in the year established under . . . section 1395w-3a of this title . . . *as calculated and adjusted by the Secretary as necessary for purposes of this paragraph.*

Id. § 1395*l*(t)(14)(A)(iii)(I)-(II) (emphasis added).[1] For purposes of subclause (II) of § 1395*l*(t)(14)(A)(iii), the cross-referenced statute establishes that the default payment rate shall be "106 percent" of "average sales price," or "ASP+6%." *See id.* § 1395w-3a(b)(1). As subclause (II) provides, however, this rate may be "adjusted by the Secretary as necessary for purposes of this paragraph." *Id.* § 1395*l*(t)(14)(A)(iii)(II).

As explained in detail below, judicial review of the Secretary's payment adjustments under § 1395*l*(t)(14)(A)(iii)(II) is expressly precluded by three subsections of § 1395*l*(t)(12). First, § 1395*l*(t)(12)(A) provides that "there shall be no . . . 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)." (emphasis added). This provision bars suits challenging the Secretary's adjustment of payment rates under § 1395*l*(t)(14)(A)(iii)(II), because such action is part of the Secretary's "development of" the OPPS, and is likewise an "adjustment[]" to that system. Second, § 1395l(t)(12)(C) states that there shall be no administrative or judicial review of "the periodic adjustments made under paragraph [9]"[2];

[1] Not all separately payable drugs qualify as statutory SCODs to which the payment methodologies of § 1395*l*(t)(14)(A)(iii) apply. Nonetheless, CMS applies these statutory payment methodologies to *all* separately payable drugs, even those that are *not* SCODS. 77 Fed. Reg. 68,210, 68,383 (Nov. 15, 2012). This "is a policy choice rather than a statutory requirement." *Id.*

[2] Although subsection 1395*l*(t)(12)(C) refers to "periodic adjustments made under paragraph (6)," the statutory history makes clear that Congress in fact meant the Secretary's authority to make periodic adjustments under paragraph (9). *Compare* Pub L. No. 105-33, 111 Stat. 251, 448-49

paragraph nine addresses periodic adjustments to "components of [the] prospective payment system" to "take into account changes in medical practice, changes in technology, the addition of new services, new cost data, and other relevant information and factors." 42 U.S.C.A. § 1395l(t)(9)(A). Third, § 1395*l*(t)(12)(E) provides that "there shall be no . . . judicial review . . . of" the "portion of the medicare [outpatient department] *fee schedule amount associated with particular . . . drugs*" (emphasis added). Because a payment adjustment under § 1395*l*(t)(14)(A)(iii)(II) necessarily alters the "fee schedule amount associated with particular … drugs," such an adjustment falls within § 1395*l*(t)(12)(E)'s bar on judicial review.

II. The 340B Program

Enacted by Congress in 1992, the 340B Program allows participating healthcare providers, known as "covered entities," to purchase "covered outpatient drugs" at discounted prices from drug manufacturers. *See* Public Health Service Act, § 340B, 42 U.S.C. § 256b. The Program initially applied to federal health care grant recipients and to hospitals that met a threshold disproportionate share hospital ("DSH") percentage. In 2010, Congress amended the Program to include additional types of hospitals. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 7101, 124 Stat. 119, 821 (2010). Currently, about 40% of all U.S. hospitals participate in the 340B Program. U.S. Gov't Accountability Off., GAO-15-442, *Medicare Part B Drugs: Action*

(Aug. 5, 1997), *with* 42 U.S.C. § 1395*l*(t)(9) & (12). In the 1997 statutes at large, the preclusion-of-review provision—which was then in subsection (t)(9)—expressly precluded administrative and judicial review of "periodic adjustments made under paragraph (6)." 111 Stat. at 449. The provision providing for "periodic review and adjustments [to] components of [the] prospective payment system" was then found at subsection (t)(6) and was materially identical to the provision that is now in subsection 1395*l*(t)(9). *Id.* at 448. In 1999, Congress added what are now provisions (t)(5) through (t)(8). *See* Pub. L. No. 106-113, div. B., 113 Stat. 1501, 1501A-336-342 (Nov. 29, 1999). Although it "redesignat[ed]" the other provisions in section 1395*l*(t), Congress neglected to update the number of the provision cross-referenced in what is now (t)(12)(C). *Id.* at 1501A-336, 1501A-342.

Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals at 1 (June 2015), https://www.gao.gov/assets/680/670676.pdf ("GAO-15-442").

Participating drug manufacturers must agree to offer covered outpatient drugs to covered entities at or below a "maximum" or "ceiling" price, which is calculated pursuant to a statutory formula. 42 U.S.C. § 256b(a)(1)-(2). The program is designed to insure that participating grant recipients and hospitals obtain drugs at affordable prices. *See* Public Health Service Act, § 340B; *see also* H.R. Rep. No. 102-384, pt. 2, at 12 (explaining that the 340B Program allows participating grant recipients to "stretch scarce Federal resources as far as possible" by enabling them to purchase drugs at discounted prices). Nowhere in the enacting legislation does it indicate that a purpose of the Program is to allow providers to generate large profits on drug purchases, through differentials between purchase prices and reimbursement rates, which will subsidize other aspects of the grant recipient's or hospital's activities. *See* Public Health Service Act, § 340B. Indeed, reimbursements are not ever addressed under the § 340B program. Medicare payment amounts, for drugs administered to Medicare patients, are addressed through the OPPS. The 340B Program is distinct from Medicare: it is governed by a separate statutory scheme, and is administered by the Health Resources and Services Administration ("HRSA"), a component within HHS that is separate from CMS.

Notably, covered entities are often able to obtain outpatient drugs below the already-discounted 340B ceiling price. For instance, through the Prime Vendor Program, covered entities may contract with a prime vendor, which may negotiate even steeper, "subceiling" discounts from drug manufacturers. 82 Fed. Reg. 52,356, 52,494 (Nov. 13, 2017). By the end of FY 2015, this program "had nearly 7,600 products available to participating entities below the 340B ceiling price, including 3,557 covered outpatient drugs with an estimated average savings of 10 percent

below the [already-discounted] 340B ceiling price." *Id.* Participation in the Prime Vendor Program is voluntary and free. *Id* .

III. CMS's Prior OPPS Drug Payment Methodologies

CMS publishes an annual rule addressing the outpatient prospective payment system. In the OPPS rules for 2006 through 2012, CMS used what is called "standard drug payment methodology" to determine OPPS payment rates for separately payable drugs and biologicals. 77 Fed. Reg. 68,210, 68,383 (Nov. 15, 2012). Under this methodology, CMS paid the average sales price plus a fixed, add-on percentage, which was intended to reflect "hospitals' acquisition costs for drugs and biologicals while taking into account relevant pharmacy overhead and related handling expenses." *Id.* at 68,385. Application of this methodology between 2006 and 2012 "yielded a finalized payment rate in the range of ASP+4 percent to ASP+6 percent." *Id.* at 68,386.

In CMS's 2013 OPPS Rule, the agency noted that there was "continuing uncertainty about the full cost of pharmacy overhead and acquisition cost, based in large part on the limitations of the submitted hospital charge and claims data for drugs." *Id.* In light of these concerns, CMS decided that for 2013, it would invoke the payment methodology set forth in subclause (II) of § 1395*l*(t)(14)(A)(iii) and "pay for separately payable drugs and biologicals at ASP+6 percent," which is the "statutory default" under § 1395*l*(t)(14)(A)(iii)(II). *Id.* CMS found it appropriate "at this time" to use the ASP+6% statutory default rate because, among other things, it yielded "increased predictability in payment for separately payable drugs and biologicals under the OPPS." *Id.* CMS applied this ASP+6% rate from 2013 until 2017, when it issued the 2018 OPPS Rule.

IV. The 2018 OPPS Rule

In its proposed OPPS rule for 2018, CMS noted recent studies indicating wide discrepancies between the amounts that 340B Program participants paid for covered outpatient

drugs and the amounts that Medicare reimbursed hospitals for those drugs, and proposed to adjust OPPS drug payment rates to correct these discrepancies. 82 Fed. Reg. 33,558, 33,632-33 (July 20, 2017). CMS adopted this proposal in its final 2018 OPPS Rule, at the outset of which the Secretary made clear that he was relying on his authority under 42 U.S.C.A. § 1395l(t)(9)(A) to "review certain components of the OPPS not less often than annually, and to revise the groups, relative payment weights, and other adjustments that take into account changes in medical practices, changes in technologies, and the addition of new services, new cost data, and other relevant information and factors." 82 Fed. Reg. 52,356, 52,356 (Nov. 13, 2017). The 2018 OPPS Rule also announced that CMS was exercising the Secretary's authority under § 1395*l*(t)(14)(A)(iii)(II) "to adjust the applicable payment rate as necessary for separately payable drugs and biologicals (other than drugs on pass-through payment status and vaccines) acquired under the 340B Program from average sales price (ASP) plus 6 percent to ASP minus 22.5 percent." 82 Fed. Reg. at 52,356.

In explaining this payment adjustment, CMS highlighted recent data showing that Medicare reimbursements for 340B drugs have substantially exceeded providers' costs for those drugs as a result of deep discounts providers receive from drug manufacturers, thus allowing providers to reap significant profits from the 340B Program discounts. For example, the Rule cites:

- A report by the Medicare Payment Advisory Commission ("MedPAC"),[3] citing data showing that "discounts across all 340B providers (hospitals and certain clinics) average *33.6 percent* of ASP, allowing these [340B] providers to generate significant profits when they administer Part B drugs." *Id.* at 52,494 (emphasis added).

[3] MedPAC is an independent congressional agency established by the Balanced Budget Act of 1997 to advise Congress on issues affecting the Medicare program.

- A report by the Government Accountability Office ("GAO"), titled "Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals," finding that "the amount of the 340B discount ranges from an estimated *20 to 50 percent discount*, compared to what the entity would have otherwise paid to purchase the drug." *Id.* (emphasis added).
- A MedPAC report estimating that, "on average, hospitals in the 340B Program receive a *minimum discount* of *22.5 percent* of the [ASP] for drugs paid under the [OPPS]." *Id.* (emphasis added). MedPAC emphasized this was a "minimum" discount that reflected the "lower bound of the average discount received by 340B hospitals." *Id.* at 52,496.
- HRSA's FY 2018 Budget Justification, which notes that 340B providers participating in the HRSA's Prime Vendor Program "often . . . pay[] a subceiling price on some covered outpatient drugs." *Id.* at 52,494. As previously noted, by the end of FY 2015, the Prime Vendor Program "had nearly 7,600 products available to participating entities below the 340B ceiling price, including 3,557 covered outpatient drugs with an estimated average savings of 10 percent below the 340B ceiling price." *Id.*
- An HHS Office of Inspector General ("OIG") report, finding that Medicare payments "were *58 percent more than* 340B ceiling prices, which allowed covered entities to retain approximately *$1.3 billion* in 2013." *Id.* at 52,495 (emphasis added).

The 2018 OPPS Rule also notes the rapid and substantial growth of Medicare spending for 340B drugs. It highlights MedPAC's findings in its May 2015 report that "the number of hospitals participating in the [340B] program has grown from 583 in 2005 to 1,365 in 2010 and 2,140 in 2014." *Id.* at 52,495. In other words, the number of hospitals participating in the program more than tripled over a nine year period. MedPAC added that "Medicare spending grew faster among

hospitals that participated in the 340B Program for all five years than among hospitals that did not participate in the 340B Program." *Id.* at 52,494. CMS cited this as "just one example of drug spending increases that are correlated with participation in the 340B Program and calls 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.*

CMS also emphasized GAO's finding in its June 2015 report that "in both 2008 and 2012, per beneficiary Medicare Part B drug spending … was substantially higher at 340B DSH than at non-340B hospitals." *Id.* In 2012, for example, GAO found that the "average per beneficiary spending at 340B DSH hospitals was $144, compared to approximately $60 at non-340B hospitals"—*i.e.*, per beneficiary spending was more than double at 340B hospitals. *Id.* These "differences did not appear to be explained by the hospital characteristics GAO examined or patients' health status"; rather, the data indicated that, "on average, beneficiaries at 340B DSH hospitals were either prescribed more drugs or more expensive drugs than beneficiaries at the other non-340B hospitals in GAO's analysis." *Id.*

CMS also explained that higher Medicare payment rates for 340B drugs results in higher drug costs for beneficiaries, because a beneficiary's copayment is tied to the Medicare payment rate, not the drug's actual purchase price. The Rule notes that "Medicare beneficiaries are liable for a copayment that is equal to 20 percent of the OPPS payment rate, which is currently ASP+6 percent (regardless of the 340B purchase price for the drug)." *Id.* at 52,495. It adds that "[b]ased on an analysis of almost 500 drugs billed in the hospital outpatient setting in 2013, the [HHS] OIG found that, for 35 drugs . . . in at least one quarter of 2013, the beneficiary's coinsurance alone … was greater than the amount a covered entity spent to acquire the drug.'" *Id.* CMS further explained that it is not possible to tie a beneficiary's copayment to the drug's 340B ceiling price,

because "ceiling prices are confidential" and CMS is thus "unable to publicly disclose those prices or set payment rates in a way that would allow the public to determine the ceiling price for a particular drug." *Id.* at 52,496.

In light of these findings, the 2018 OPPS Rule announced that CMS was exercising the Secretary's authority under § 1395*l*(t)(14)(A)(iii)(II) "to adjust the applicable payment rate as necessary for separately payable drugs and biologicals (other than drugs on pass-through payment status and vaccines) acquired under the 340B Program from average sales price (ASP) plus 6 percent to ASP minus 22.5 percent." *Id.* at 52,362. CMS arrived at the ASP minus 22.5% figure based on MedPAC's 2015 report, which, as noted above, found that "on average, hospitals in the 340B Program 'receive a *minimum* discount of 22.5 percent of the [ASP] for drugs paid under the [OPPS].'" *Id.* at 52,494 (emphasis added). CMS noted that this figure was "conservative" because it estimated the "lower bound" or "minimum" "average discount received by 340B hospitals for drugs paid under the [OPPS]" and found that it is "likely that the average discount is higher, potentially significantly higher, than the average minimum of 22.5 percent that MedPAC found through its analysis." *Id.* at 52,496. Thus, even after the payment adjustment, 340B providers would be able "to retain a profit on these drugs." *Id.* at 52,497. CMS reasoned that the payment adjustment will "better, and more appropriately, reflect the resources and acquisition costs that [340B] hospitals incur," as well as "lower drug costs for Medicare beneficiaries for drugs acquired by hospitals under the 340B Program," ensuring that beneficiaries "share in the savings on drugs acquired through the 340B Program." *Id.* at 52,362, 52,495-97. CMS expressly exempted from the payment adjustment "[r]ural sole community hospitals (SCHs), children's hospitals, and [prospective payment system]-exempt cancer hospitals," *id.* at 52,362, because of concerns about access to care and the different payment model employed in children's hospitals and PPS-exempt

cancer hospitals, *id.* at 52,505-52,506. The payment adjustment also does not affect covered entities that are paid under a separate payment scheme outside of the OPPS, such as critical access hospitals. *Id.* at 52,495. In total, at least 52% of the 340B covered entities are not affected by the payment adjustment, either because they are specifically exempted, or because they are not paid under the OPPS.[4]

CMS estimated that this payment adjustment would save Medicare $1.6 billion. 82 Fed. Reg. at 52,509. Critically, these savings are being redistributed within the OPPS system (including to Plaintiffs). That is because the CMS made the payment adjustment pursuant to § 1395*l*(t)(9)(B), which requires that adjustments be made in a "budget-neutral" manner within OPPS. As CMS explains in the Rule, "the reduced payments for separately payable drugs purchased through the 340B Program w[ould] *increase* payment rates for other non-drug items and services paid under the OPPS by an offsetting aggregate amount." *Id.* at 52,623 (emphasis added). CMS "project[ed] that reducing payment for 340B drugs to ASP minus 22.5 percent will increase OPPS payment rates for non-drug items and services by approximately 3.2 percent in CY 2018." *Id.*

The 2018 OPPS Rule became effective January 1, 2018.

V. This Case

Plaintiffs—three hospital associations and three of their member hospitals[5]— challenge, under the APA, 5 U.S.C. § 706(2), the 340B-related provisions of the 2018 OPPS Rule. The Complaint includes four counts, all of which are premised on the assertion that the 2018 OPPS

[4] *See* MedPac Report to Congress, *Overview of the 340B Drug Pricing Program*, at 20 n.22 & 10, Figure 1 (May 2015), http://www.medpac.gov/docs/default-source/reports/may-2015-report-to-the-congress-overview-of-the-340b-drug-pricing-program.pdf.

[5] The three hospital association plaintiffs are the American Hospital Association, the Association of American Medical Colleges, and America's Essential Hospitals. The three hospital plaintiffs are Eastern Maine Healthcare Systems, Henry Ford Health System, and Fletcher Hospital, Inc.

Rule's reduction of the payment rate for drugs purchased through the 340B Program was arbitrary and capricious and contrary to law, in violation of the APA. Compl. ¶¶ 67-78. More specifically, Count 1 challenges the OPPS Rule itself, while Counts 2 through 4 attack payment decisions made under the Rule with respect to Medicare claims submitted by the Plaintiff hospitals. *Id.*

As relief, Plaintiffs seek a declaration that the reduction of the payment rate for drugs purchased under the 340B program is unlawful, and an injunction requiring the Agency to: (i) use the payment rate from the 2017 OPPS Rule for drugs purchased through the 340 Program, (ii) reimburse the hospital Plaintiffs for their supposed underpayment with respect to the claims for payment referenced in Counts 2 through 4, (iii) reimburse the hospital Plaintiffs and any other members of the association Plaintiffs for any other alleged underpayments that occurred as a result of the agency's adherence to the 340B-related provisions of the 2018 OPPS; and (iv) follow the law (namely the Social Security Act) in the 2019 OPPS and beyond, and not rely on the payment approach adopted in the 2018 OPPS with regard to the 340B-related provisions. Compl., Prayer for Relief, ¶¶ A-E. Together with their Complaint, Plaintiffs moved for a preliminary injunction. Pls.' Mem. at 1. It seeks all of the relief sought in the Complaint. Pls.' Memo. at 35.

At bottom, this suit is a near carbon copy of a suit Plaintiffs filed last year in this Court. *See AHA v. Hargan*, 17-cv-2447 (DDC) (RC). The Court dismissed that case for lack of subject matter jurisdiction because Plaintiffs had not presented their claims to the agency as required under 42 U.S.C. § 405(g), *Am. Hosp. Ass'n v. Hargan*, 289 F. Supp. 3d 45, 55 (D.D.C. 2017), and the D.C. Circuit affirmed the decision, *Am. Hosp. Ass'n v. Azar*, 895 F.3d 822 (D.C. Cir. 2018).[6]

[6] Defendants do not dispute that the hospital Plaintiffs have now presented claims to the Agency, though they have not otherwise exhausted their administrative remedies.

ARGUMENT

I. Defendants' Motion To Dismiss Should Be Granted

Defendant moves to dismiss the Complaint for lack of subject-matter jurisdiction under Rule 12(b)(1), and failure to state a claim under Rule 12(b)(6). Dismissal for lack of subject-matter jurisdiction is appropriate when a statute precludes judicial review. *See Amgen, Inc. v. Smith*, 357 F.3d 103, 118 (D.C. Cir. 2004) (court "lack[ed] jurisdiction" where § 1395*l*(t)(12) precluded review); *Organogenesis Inc. v. Sebelius*, 41 F. Supp. 3d 14, 20 (D.D.C. 2014) (same). To survive a Rule 12(b)(1) motion, the plaintiff bears the burden of establishing that the court has subject matter jurisdiction over its claim. *Moms Against Mercury v. FDA*, 483 F.3d 824, 828 (D.C. Cir. 2007). The Court may "consider the complaint supplemented by undisputed facts evidenced in the record, or the complaint supplemented by undisputed facts plus the court's resolution of disputed facts." *Coal. for Underground Expansion v. Mineta*, 333 F.3d 193, 198 (D.C. Cir. 2003). To survive a Rule 12(b)(6) motion, "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

A. The Medicare Statute Expressly Precludes Judicial Review Of The Secretary's Payment Adjustments Under § 1395*l*(t)(14)(A)(iii)(II)

The Medicare statute expressly precludes judicial review of Plaintiffs' APA claims challenging the Secretary's exercise of his payment adjustment authority under § 1395*l*(t)(14)(A)(iii)(II). Although the "APA generally establishes a cause of action for those suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action," the "APA does not apply . . . to the extent that . . . statutes preclude judicial review." *Tex. All. for Home Care Servs. v. Sebelius*, 681 F.3d 402, 408 (D.C. Cir. 2012); *see* 5 U.S.C. § 701(a)(1). To determine "[w]hether and to what extent a particular statute precludes judicial

review," a court must look to the statute's "express language . . . the structure of the statutory schemes, its objectives, its legislative history, and the nature of the administrative action involved." *Block v. Cmty. Nutrition Inst.*, 467 U.S. 340, 345 (1984).

Subsection (t)(12) of 42 U.S.C. § 1395*l* establishes strict limitations on judicial review of the Secretary's administration of the OPPS. Most pertinent here, the statute provides:

> ***There shall be no*** administrative or ***judicial review*** under section 1395ff of this title, 1395oo, of this title, or otherwise ***of***—
>
> > (A) ***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);
> >
> > * * *
> >
> > (C) ***periodic adjustments*** made under paragraph [9];
> >
> > * * *
> >
> > (E) . . .***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)(A), (C), (E) (emphasis added). The legislative history confirms that Congress intended § 1395*l*(t)(12) to broadly preclude judicial review—under the Medicare statute "or otherwise"—of the Secretary's "adjustment" of OPPS payments. *See* H.R. Rep. No. 108-391, at 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,* methods or *adjustments . . . will not be subject to* administrative or *judicial review*," and the "provisions concerning *Medicare's determination of the budget neutral adjustments, adjustments to* the practice expense relative value units for certain drug administration services and *other drug administration services* will not be subject to administrative or judicial review." (emphasis added)); *see also* H.R. Rep. No. 105-149

at 724 (1997) ("The provision would prohibit administrative or judicial review of the prospective payment system.").

In *Amgen, Inc. v. Smith*, 357 F.3d 103 (D.C. Cir. 2004), the D.C. Circuit construed § 1395*l*(t)(12), and concluded that the fact that "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*." *Id.* at 112 (emphasis added). The Circuit found "unsurprising" Congress's preclusion of review, given that "piecemeal review of individual payment determinations could frustrate the efficient operation of the complex prospective payment system."[7] *Id.* The court recognized that "judicially mandated changes in one payment rate would affect the aggregate impact of the Secretary's decisions by requiring offsets elsewhere, and thereby interfere with the Secretary's ability to ensure budget neutrality in each fiscal year." *Id.* Moreover, as the court explained, "[p]ayments to hospitals are made on a prospective basis, and given the length of time that review of individual payment determinations could take, review could result in the retroactive ordering of payment adjustments after hospitals have already received their payments for the year." *Id.*

The D.C. Circuit is not alone in recognizing "the havoc that piecemeal review of OPPS payments could bring about." *Id.* (citing *Skagit Cty. Pub. Hosp. Dist. No. 2 v. Shalala*, 80 F.3d 379, 386 (9th Cir. 1996); *Am. Soc'y of Cataract & Refractive Surgery v. Thompson*, 279 F.3d 447, 454 (7th Cir. 2002)); *accord Paladin Cmty. Mental Health Ctr. v. Sebelius*, 684 F.3d 527, 531 n.3 (5th Cir. 2012). And this Court has acknowledged *Amgen*'s breadth, describing the decision as

[7] Recall, the Medicare program currently processes more than 100 million outpatient hospital claims per year. Since we are already three-quarters of the way through 2018, this means that Medicare providers have already furnished services related to tens of millions of claims that have been or will be reimbursed based on interdependent rates set in the 2018 OPPS.

holding that § 1395*l*(t)(12) "clearly preclude[s] judicial review of the Secretary's adjustments to prospective payment amounts." *Organogenesis Inc.*, 41 F. Supp. 3d at 20 (citing *Amgen*, 357 F.3d at 112).

The bottom line is this: subsections (A), (C) and (E) of § 1395*l*(t)(12) foreclose judicial review of Plaintiffs' APA claims.

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

As explained above, subsection (A) of § 1395*l*(t)(12) broadly precludes judicial review of the Secretary's "development of" the OPPS "classification system under paragraph (2)," including any "adjustments" to that system. This "classification system" refers to the general system of "classification for covered [outpatient department] services" that the Secretary is required to "develop" under § 1395*l*(t)(2)(A), which is better known as the ambulatory payment classification ("APC") system. *See* 42 C.F.R. § 419.60 (parallel regulation to § 1395*l*(t)(12), which forbids judicial review of the "development of the APC system"). When Congress added the OPPS drug payment provision at issue here—subsection (t)(14)—in 2003, it made clear that it was adding to the APC system by titling the new subsection "Drug *APC* payment rates." 42 U.S.C. § 1395*l*(t)(14) (emphasis added); *see also id.* § 1395*l*(t)(14)(B)(i) (drug is eligible for OPPS payment only if it is a drug "for which a separate ambulatory payment classification group (APC) has been established"). Thus, it is beyond dispute that the setting of drug payment rates under subsection (t)(14) is a component of the APC system, and the broader OPPS. It follows that the Secretary's *adjustment* of those rates for 340B drugs was part of his "development of" the APC system, and likewise qualifies as an "adjustment" to that system. In particular, it was an adjustment to the fee schedule amounts associated with particular drugs within the APC system. In light of this, as well as the case law holding that § 1395*l*(t)(12)(A) "clearly preclude[s] judicial review of the

Secretary's adjustments to prospective payment amounts," *Organogenesis*, 41 F. Supp. 3d at 20 (citing *Amgen*, 357 F.3d at 112), Plaintiffs' claims are statutorily barred by § 1395*l*(t)(12)(A).

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

Subsection (C) of § 1395*l*(t)(12) bars judicial review of the "periodic adjustments made under paragraph [9]." 42 U.S.C. § 1395*l*(t)(12)(C). The reference to "periodic adjustments made under paragraph [9]" is a reference to the statute's requirement that the Secretary make periodic adjustments to the components of the prospective payment systems. *Id.* § 1395l(t)(9)(A) ("The Secretary shall review not less often than annually and revise the groups, the relative payment weights, and the wage and other adjustments described in paragraph (2) to take into account changes in medical practice, changes in technology, the addition of new services, new cost data, and other relevant information and factors."). The reimbursement rate for drugs purchased through the 340B program is a component of the prospective payment system, as explained in the previous paragraph. And the Secretary invoked this authority when promulgating the final 2018 OPPS Rule, noting that "the Act requires the Secretary to review certain components of the OPPS not less often than annually, and to revise the groups, relative payment weights, and other adjustments that take into account changes in medical practices, changes in technologies, and the addition of new services, new cost data, and other relevant information and factors." 82 Fed. Reg. at 52,356. Accordingly, this provision also precludes review of Plaintiffs' claims.

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

Plaintiffs' APA claims are separately barred by subsection (E) of § 1395*l*(t)(12). That subsection provides that "there shall be no . . . judicial review . . . of" the "portion of the medicare [outpatient department ("OPD")] fee schedule amount associated with particular . . . drugs." The "OPD fee schedule" is a listing of Medicare payment rates for "each covered OPD service (or

group of such services), furnished in a year," including separately payable drugs. 42 U.S.C. § 1395*l*(t)(3)(D). Here, in exercising his authority under § 1395*l*(t)(14)(A)(iii)(II) to adjust the payment rate for 340B drugs, the Secretary necessarily changed the "fee schedule amount associated with" those "particular . . . drugs." *See* 82 Fed. Reg. at 52,503 (noting that hospitals can discern reduced payment rates for 340B drugs by using the fee schedule in Addendum B to the 2018 OPPS Rule). Thus, Plaintiffs' claim that the Secretary's adjustment of the payment rate for 340B drugs violates the APA, *see, e.g.*, Compl. ¶ 69, is necessarily a challenge to the "fee schedule amount associated with" those drugs. Based on § 1395*l*(t)(12)(E)'s plain statutory text, and the governing precedent, *see Amgen*, 357 F.3d at 112; *Organogenesis*, 41 F. Supp. 3d at 20, Plaintiffs' APA claims are also barred by § 1395*l*(t)(12)(E).

It bears emphasizing that Congress's rationale for precluding judicial review of the Secretary's administration of the OPPS—*i.e.*, to avoid "wreaking havoc" on the carefully-calibrated and interdependent system—is directly implicated here. *See Amgen*, 357 F.3d at 112. To achieve budget neutrality, the 2018 OPPS Rule offsets the savings from the 340B drug payment reduction by "increas[ing] OPPS payment rates for non-drug items and services by approximately 3.2 percent in CY 2018." 82 Fed. Reg. at 52,623 (noting that revised payment rates for non-drug items and services were reflected in the Addenda to the Rule). So, if the Court were to grant Plaintiffs' requested relief and require CMS to revert to its prior OPPS payment rate for 340B drugs (ASP+6%), *see* Compl. at 23, this could have repercussions throughout the OPPS, including perhaps forcing CMS to recalculate the revised payment rates for all non-drug items and services to ensure budget neutrality. (And as set forth earlier, the Medicare program currently processes more than 100 million outpatient claims pre year.) Permitting review here would, moreover, open the floodgates for other providers to challenge the OPPS payment rates for any number of drugs

or biologics, creating instability and uncertainty in the payment system. Congress did not intend such a "severe[] disrupt[ion of] this complex and delicate administrative scheme," and so it included statutory language expressly precluding judicial review to avoid such disruption. *Block*, 467 U.S. at 348; *see Amgen*, 357 F.3d at 112; *Paladin*, 684 F.3d at 531 n.3; *Skagit County*, 80 F.3d at 386; *Am. Soc'y of Cataract*, 279 F.3d at 454. This Court's review of Plaintiff's APA claims accordingly is precluded by statute.

4. The Preclusion Provisions Apply to Plaintiffs' Claims

Plaintiffs argue in support their motion for a preliminary injunction that "neither [§ 1395l(t)(12)(A) nor §1395l(t)(12)(E)] applies to agency action under subsection (t)(14), which is the authority HHS relied on in adopting its near 30% reduction in reimbursements." Pls.' Mem. at 20. Plaintiffs continue: "Subsection (t)(12)(A) precludes judicial review under paragraph (2) of subsection (t), but does not bar judicial review of agency action under (t)(14). Similarly, (t)(12)(E) only precludes judicial review of agency action under (t)(5) and (t)(6)." *Id.* at 20.

This argument lacks merit. As an initial matter, Plaintiffs do not address preclusion under § 1395*l*(t)(12)(C). In any case, Plaintiffs' argument fails to demonstrate the inapplicability of the two preclusion provisions that it addresses. By Plaintiffs' own admission, subsection (t)(12)(A) bars judicial review of the Secretary's action under Paragraph (t)(2). As explained above, 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."[8] And when Congress added § (t)(14) to the Medicare statute in 2003, it made clear in several respects that it was adding a new payment methodology ***within*** the overall APC system described in § (t)(2)(A). First, Congress titled the new paragraph "Drug *APC* payment rates." 42 U.S.C. § 1395*l*(t)(14) (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." *Id.* § 1395*l*(t)(14)(A). 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, subject to the judicial review preclusion provision of § (t)(12)(A).

Subsection (t)(12)(E) also precludes judicial review. 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

[8] 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).

> 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). As is relevant to this case, Plaintiffs contend that the provision precludes review only under paragraph 6. But 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)). 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), 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.

B. 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

The Secretary's exercise of his payment adjustment authority is unreviewable for an additional reason: it is "committed to agency discretion by law" and thus exempt from judicial review under the APA. *See* 5 U.S.C. § 701(a)(2). A matter is "committed to agency discretion" where "the statute is drawn so that a court would have no meaningful standard against which to judge the agency's exercise of discretion." *Heckler v. Chaney*, 470 U.S. 821, 830 (1985).

Such is the case here. The Medicare statute provides that, if sufficient hospital acquisition cost data are not available, 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 statute imposes no limitation on the Secretary's "adjust[ment]" of the payment rate for SCODs. It instead allows the Secretary to adjust that rate "as necessary for purposes of this paragraph," without imposing any "meaningful standard against which to judge the agency's exercise of discretion." *Heckler*, 470 U.S. at 830. The legislative history, moreover, confirms what the statute's text makes plain: that Congress wished to confer unreviewable discretion on the Secretary to adjust OPPS payment rates. *See* H.R. Rep. No. 108-391, at 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, methods or adjustments…will not be subject to administrative or judicial review"); *see also* H.R. Rep. No. 105-149, at 1323 (1997) ("The Committee has given the Secretary discretion in determining the adjustment factors that will be applied to the OPD prospective rates."); H.R. Rep. No. 105-217, at 785 (1997) (Conf. Rep.), *as reprinted in* 1997 U.S.C.C.A.N. 176, 406 (same).

Consistent with this reasoning, courts routinely hold that where, as here, a statute authorizes an agency to take certain action whenever deemed "necessary" by the agency, such

action is committed to agency discretion by law. *See, e.g.*, *Webster v. Doe*, 486 U.S. 592, 600 (1988) (action unreviewable where statute allowed termination of employee whenever the agency Director "'shall deem such termination necessary or advisable in the interests of the United States,' not simply when the dismissal is necessary or advisable to those interests."); *Sierra Club v. Jackson*, 648 F.3d 848, 856 (D.C. Cir. 2011) (action unreviewable where "Congress's mandate to the Administrator is that she shall 'take such measures, including issuance of an order, or seeking injunctive relief, as necessary. . . ."); *Wendland v. Gutierrez*, 580 F. Supp. 2d 151, 153 (D.D.C. 2008) (action unreviewable where directive provided that agency director shall convene Record Examination Board "[a]t such times as he/she may deem necessary"). This Court should reach the same conclusion.

C. Plaintiffs Failed To Exhaust Administrative Remedies Under The Medicare Statute

The Court lacks jurisdiction for an additional reason: Plaintiffs have not exhausted their administrative remedies as required by 42 U.S.C. § 405(g). *See Tataranowicz v. Sullivan*, 959 F.2d 268, 272 (D.C. Cir. 1992). Exhaustion may be excused, but "only under rather limited conditions." *National Kidney Patients Ass'n v. Sullivan*, 958 F.2d 1127, 1130 (D.C. Cir. 1992). As the Supreme Court has explained, Section 405(g)'s final decision requirement is "more than simply a codification of the judicially developed doctrine of exhaustion, and may not be dispensed with merely by a judicial conclusion of futility." *Weinberger v. Salfi*, 422 U.S. 749, 766 (1975). Thus, Plaintiffs' contention that administrative review would be futile, Pls.' PI Mem. at 17-20, does not excuse compliance with the exhaustion requirement, *Shalala v. Illinois Council on Long Term Care, Inc*. ("*Illinois Council"*), 529 U.S. 1, 23 (2000) (channeling required even where agency lacks authority to consider certain questions). "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." *Id.*

Congress provided a "special review route," *Illinois Council*, 529 U.S. at 23, in Section 1395ff(b) which sets out an abbreviated administrative review process that establishes a path to expedited judicial review for those cases in which the administrative appeals tribunal "does not have the authority to decide the question of law or regulation relevant to the matters in controversy and that there is no material issue of fact in dispute." 42 U.S.C. § 1395ff(b)(2)(A).[9] (Plaintiffs have not received a determination that their claims are fit for expedited review.) Plaintiffs are not entitled to forgo administrative review and go straight to court merely because they wish to "resolve [a] statutory or constitutional contention that the agency . . . cannot[] decide." *Illinois Council*, 529 U.S. at 23. 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.* (citing *Thunder Basin Coal Co. v. Reich*, 510 U.S. 200, 215 & n. 20 (1994); *Heckler v. Ringer*, 466 U.S. 602, 617 (1984); *Salfi*, 422 U.S. at 762).

D. Plaintiffs' APA Claims Fail On The Merits

Even assuming Plaintiffs' APA claims were not statutorily precluded and Plaintiffs had exhausted their administrative remedies, the claims fail on the merits and thus should be dismissed

[9] Section 1395ff(b) provides that "[t]he Secretary shall establish a process under which a provider of services or supplier that furnishes an item or service or an individual entitled to benefits under part A or enrolled under part B of this subchapter, or both, who has filed an appeal . . . may obtain access to judicial review when a review entity . . . , on its own motion or at the request of the appellant, determines that the Departmental Appeals Board does not have the authority to decide the question of law or regulation relevant to the matters in controversy and that there is no material issue of fact in dispute." 42 U.S.C. § 1395ff(b)(2)(A); *see also* 42 C.F.R. § 405.990 (expedited access to judicial review). Once that determination has been made, or if it is not made within 60 days after receipt of the request, "the appellant may bring a civil action" within 60 days in district court either in the judicial district in which the appellant is located or in the District Court for the District of Columbia. *Id.* § 1395ff(b)(2)(C).

under Rule 12(b)(6). In evaluating the merits, the Court must assess the parties' competing readings of the Medicare statute under the familiar two-step *Chevron* framework, under which the court first determines whether the statute is ambiguous, and if it is, upholds the agency's interpretation if reasonable. *Chevron, U.S.A., Inc. v. NRDC*, 467 U.S. 837, 842-43 (1984). Plaintiffs advance three theories for why the Secretary's payment adjustment exceeded his statutory authority under 1395*l*(t)(14)(A)(iii)(II), but each theory is foreclosed by the statute's unambiguous text. Insofar as the Court finds any relevant ambiguity in § 1395*l*(t)(14)(A)(iii)(II), however, the Secretary's interpretation is, at minimum, a reasonable one that is entitled to *Chevron* deference.[10]

1. The Secretary Did Not Exceed His Authority Under § 1395*l*(t)(14)(A)(iii) By Considering Acquisition Costs

Plaintiffs first argue that the Secretary is precluded from considering "acquisition costs" in adjusting the payment rate pursuant to subsection 1395*l*(t)(14)(A)(iii)(II). Pls.' Mem. at 22. Plaintiffs point to subclause (II)'s cross-reference of Section 1395w-3a to argue that the statute obligates the Secretary to set the payment rate based only on average sales price when exercising his authority under subclause (II). Pls.' Mem. at 22. Plaintiffs contend that the agency can rely on acquisition costs "only if" it has certain statutorily defined acquisition cost data, and is thus, exercising authority to set payment rates under subsection 1395*l*(t)(14)(A)(iii)(I). *Id.*

[10] Because Plaintiffs' APA claims raise pure legal questions regarding the scope of the Secretary's statutory authority, the Court may reach the merits of those claims on a Rule 12(b)(6) motion. *See Marshall Cty. Health Care Auth. v. Shalala*, 988 F.2d 1221, 1226 (D.C. Cir. 1993) (noting in Medicare case that "a court can fully resolve any purely legal question on a motion to dismiss," and thus "there is no inherent barrier to reaching the merits at the 12(b)(6) stage"). Relatedly, it is unnecessary for the Court to consider the administrative record in evaluating Plaintiffs' claim, since the claims present pure questions of statutory interpretation.

Plaintiffs are mistaken in two respects. First, subclause (II)'s text does not mandate "payment" based on ASP. While it requires that the Secretary "calculate[]" ASP, it also authorizes the Secretary to "adjust[]" that calculation "as necessary"—which is what the Secretary did here. So it is not accurate to say that the ultimate "payment" must be based strictly on ASP. If that were true, then the Secretary's adjustment authority would be rendered meaningless. *See Corley*, 556 U.S. at 314 ("[O]ne of the most basic interpretive canons . . . [is] that '[a] statute should be construed so that effect is given to all its provisions, so that no part will be inoperative or superfluous, void or insignificant.'").

Second, and relatedly, nothing in subclause (II) or elsewhere in the Medicare statute precludes the Secretary from considering "acquisition cost" in adjusting the payment rate. As noted, the statute imposes no limitation on what the Secretary may consider in exercising his adjustment authority under subclause (II); it instead vests him with discretion to make such adjustments "as necessary for purposes of this paragraph." Moreover, subsection 1395l(t)(14)(A)(iii) itself specifically identifies "acquisition cost[s]" as a valid reference point for drug payments, 42 U.S.C. § 1395l(t)(14)(iii)(I). Even under the prior payment methodology that Plaintiffs endorse and request that the Secretary reinstate, CMS recognized that adjustments might be necessary to account for "acquisition" costs. *See* 77 Fed. Reg. at 68,383. Plaintiffs apparently believe that the Secretary is powerless to adjust OPPS payment rates for 340B drugs to account for evidence showing (1) providers are reaping substantial profits from Medicare payment amounts from the program, and (2) beneficiaries are paying unduly high copayments tied to Medicare payment rates. But that is an overly restrictive view of the Secretary's adjustment authority. The

Secretary permissibly considered both providers' acquisition costs and Medicare beneficiaries' copayments in exercising his adjustment authority under § 1395*l*(t)(14)(A)(iii)(II).[11]

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

Plaintiffs' next argument is that "Defendants' near-30% reduction in payments is not an 'adjustment' to ASP [under § 1395*l*(t)(14)(A)(iii)(II)] because it is too large to be an 'adjustment' and because it bears no coherent relationship to Average Sales Price, the thing being 'adjusted.'" Pls.' Mem. at 24. As to the relationship point, Plaintiffs explain that "[t]he adjustment to the average sales price must more accurately reflect that price. The Secretary may not 'adjust' the ASP to more closely reflect another way of valuing the drug, such as acquisition costs." *Id.* at 26. Lastly, Plaintiffs contend, citing § 1395*l*(t)(14)(E), that the adjustment can take account only of overhead costs. Pls.' Mem. at 26-27. None of these arguments is persuasive.

Plaintiffs' argument that the reduction of the payment is too large to qualify as an "adjustment" is foreclosed by the statute's text. The statute does not impose any restriction on the Secretary's discretionary "adjustment" of OPPS drug payment rates under § 1395*l*(t)(14)(A)(iii)(II), including any restriction on the *amount* of that adjustment. Plaintiffs contend that the Secretary's adjustments must be "minor," Pls.' Mem. at 24, but no such qualifier

[11] Plaintiffs also claim that GAO agrees with this limited view of CMS's authority. Pls.' Mem. at 30. But GAO's interpretation of the Secretary's statutory authority is not binding on this Court (or the Secretary), and, in any event, provides little support for Plaintiffs' position. The 2015 GAO report cited by Plaintiffs—which, it bears emphasizing, is titled "Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals" and was one of the bases for the Secretary's decision to adjust the OPPS payment rate for 340B drugs—simply stated that "Medicare uses a statutorily defined formula to pay hospitals at set rates for drugs, regardless of their costs for acquiring them, which CMS cannot alter based on hospitals' acquisition costs." GAO-15-442 at 29. The report also opines that CMS and HRSA lack "statutory authority" to "limit[] hospitals' Medicare Part B reimbursement for 340B discounted drugs." *Id.* at 30. GAO did not engage in any substantive statutory analysis to support these conclusions, nor did it address the Secretary's adjustment authority under § 1395*l*(t)(14)(A)(iii).

appears in the statutory text. To the contrary, Congress stated that adjustments will be made "by the Secretary *as necessary* for purposes of this paragraph." 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II) (emphasis added). Congress's inclusion of this language explicitly vesting the Secretary with discretion to make payment adjustments "as necessary" negates any inference that Congress intended to *implicitly* limit the Secretary's payment adjustment authority. Plaintiffs are, in essence, reading the statute to say that the payment rate may be adjusted by the Secretary as necessary "so long as that adjustment is only slight." Congress included no such express limitation on the Secretary's discretion, and this Court should not write one into the statute.

This conclusion is bolstered by the surrounding statutory text. In subsection (A) of § 1395*l*(t)(14), Congress provided specific instructions for how the Secretary should calculate drug payments rates for the years 2004 and 2005, and did not include any provision granting the Secretary discretion to adjust those rates. *See id.* § 1395*l*(t)(14)(A)(i)-(ii). By contrast, for 2006 and beyond, Congress eschewed these specific instructions and instead directed the Secretary to set payment rates for SCODs using one of the methodologies set forth in subclauses (I) and (II) of § 1395*l*(t)(14)(A)(iii). Thus, Congress demonstrated in § 1395*l*(t)(14)(A)(i)-(ii) that it knew how to impose express restrictions on the Secretary's setting of OPPS drug payment rates. But Congress omitted such restrictions in § 1395*l*(t)(14)(A)(iii)(II), and instead authorized the Secretary to make such adjustments "as necessary." This supports an inference that Congress did not intend to restrict the Secretary's payment adjustment authority under § 1395*l*(t)(14)(A)(iii)(II). *See King v. St. Vincent's Hosp.*, 502 U.S. 215, 220-21 (1991) ("Given the examples of affirmative limitations on reemployment benefits conferred by neighboring provisions, we infer that the simplicity of subsection (d) was deliberate, consistent with a plain meaning to provide its benefit without conditions on length of service.").

Plaintiffs cite *Amgen v. Smith*, 357 F.3d 103, 117 (D.C. Cir. 2004), and *MCI Telecommunications Corp. v. AT&T*, 512 U.S. 218, 225 (1994), in support of their argument that the Secretary's rate reduction does not qualify as an adjustment. *Amgen* and *MCI* stand for the proposition that the Secretary may not rely upon his adjustment authority to eliminate payments altogether, or "severe[ly] restructur[e] . . . the statutory scheme" in a manner that would "violate the Secretary's statutory obligation to make such payments and cease to be an 'adjustment.'" *Amgen*, 357 F.3d at 117 (alteration omitted).

These decisions do not support Plaintiffs' argument. The adjustment at issue here does not remotely approximate a "total elimination or severe restructuring of the statutory scheme." *Amgen*, 357 F.3d at 117. To understand the relative significance of the payment adjustment, one cannot look at the rate reduction in isolation—context is critical. The Secretary adjusted the payment rate for 340B drugs from average sales price plus six percent to average sales price minus 22.5% in order to "better, and more appropriately, reflect the resources and acquisition costs that [340B] hospitals incur," as well as "allow the Medicare program and Medicare beneficiaries to pay less for drugs . . . that are purchased under the 340B Program," ensuring that beneficiaries "share in the program savings realized by hospitals and other covered entities that participate in the 340B Program." 82 Fed. Reg. at 52,495. Although Plaintiffs characterize this adjustment as substantial, they overlook that it was intended to address an enormous disparity between Medicare payment rates and 340B drug acquisition costs when the average sales price plus six percent payment rate was employed. *See id.* (noting that the HHS Inspector General Report found that the Medicare payments "were 58 percent more than [already-discounted] 340B ceiling prices"). Indeed, in establishing the 340B Program and in granting the Secretary authority to set payment rates for what Medicare pays for drugs, Congress did not demonstrate an intent for 340B providers to reap

huge profits from the Medicare program. In fact, Congress specifically contemplated that where "average acquisition cost" data is available, the Secretary would rely on that data to set payment rates, likely resulting in little to no profit for providers participating in the 340B program. *See* 42 U.S.C. § 1395l(t)14(A)(iii)(I). Thus, the Secretary plainly did not exceed his authority in considering acquisition costs in adjusting the payment rate in the 2018 OPPS Rule.

Nor did the Secretary eliminate entirely the disparity between acquisition costs and Medicare payment rates. As the Secretary explained, 22.5% below the average sales price represented, on average, the highest amount that 340B providers were paying for drugs. *See* 82 Fed. Reg. at 52,496. In the majority of cases, "the average discount is higher, potentially significantly higher, than . . . 22.5 percent." *Id.* The Secretary chose a "conservative" number in order to ensure both that beneficiaries "share in the savings on drugs acquired through the 340B Program" and also that 340B providers would "retain a profit on these drugs." *Id.* at 52,496-97, 52,502. [12]

[12] Plaintiffs' reliance on dictionary definitions, Pls.' Mem. at 25 n.23, is unpersuasive because numerous dictionaries define "adjust" without using the word "slight" or any other term that could be construed to impose a quantitative limitation. *See, e.g.*, *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 … 3: to determine the amount to be paid under an insurance policy in settlement of (a loss)."); *Adjust*, American Heritage Dictionary, https://ahdictionary.com/word/search.html?q=adjust ("1.a. To move or change (something) so as to be in a more effective arrangement or desired condition … b. To change so as to be suitable to or conform with something else… 3. To decide how much is to be paid on (an insurance claim)."); *Adjust*, Random House Dictionary, http://www.dictionary.com/browse/adjust ("1. to change (something) so that it fits, corresponds, or conforms; adapt; accommodate … 2. to put in good working order; regulate; bring to a proper state or position … 4. *Insurance*. to determine the amount to be paid in settlement of (a claim)."); *Adjust*, Black's Law Dictionary Free (2d ed.), https://thelawdictionary.org/adjust/ ("To bring to proper relations; to settle; to determine and apportion an amount due.").

Plaintiffs' argument that the adjustment is inadequately connected to the ASP is also unconvincing. Under the 2018 OPPS Rule, the Secretary continues to "calculate[]" ASP in the same manner as in calendar years 2013 through 2017—the difference is that *after* calculating ASP, the Secretary "adjusts" the payment rate to ASP minus 22.5%. *See* 82 Fed. Reg. at 52,496 (CMS will "*continue to pay for these drugs* under our authority at section [1395*l*](t)(14)(A)(iii)(II) of the Act *at ASP, and then . . . adjust that amount* by applying a reduction of 22.5 percent") (emphasis added). And as discussed earlier, the statute does not prohibit the Secretary from considering acquisition costs when making adjustments under this provision. *See* § I.D.1.

Plaintiffs' reliance on subparagraph (E) of § 1395*l*(t)(14) is similarly unpersuasive. Section 1395*l*(t)(14)(A)(iii) provides that the Secretary's determination of OPPS payment rates for SCODs is "subject to subparagraph (E)." Subparagraph (E), in turn, authorizes a separate "[a]djustment in payment rates for overhead costs." 42 U.S.C. § 1395*l*(t)(14)(E). Specifically, subparagraph (E) directs MedPAC to "submit to the Secretary, not later than July 1, 2005, a report on adjustment of payment for ambulatory payment classifications for specified covered outpatient drugs to take into account overhead and related expenses, such as pharmacy services and handling costs." *Id.* § 1395*l*(t)(14)(E)(i). Subparagraph (E) further provides, in a provision titled "Adjustment authorized," that the "Secretary may adjust the weights for ambulatory payment classifications for specified covered outpatient drugs to take into account" MedPAC's recommendations. *Id.* § 1395*l*(t)(14)(E)(ii). Because subparagraph (E) concerns adjustments to account for "overhead costs and related expenses," and because § 1395*l*(t)(14)(A)(iii) incorporates subparagraph (E), Plaintiffs assert that the term "adjusted" as used in § 1395*l*(t)(14)(A)(iii)(II) must be limited to alterations for "overhead costs.'" Pls.' Mem. at 27.

Plaintiffs' convoluted statutory analysis overlooks that subparagraph (E) of § 1395*l*(t)(14) "authorize[s]" a *separate* adjustment specifically to account for "overhead and related expense" based on MedPAC's findings. This adjustment authority is wholly distinct from the Secretary's broader authority to adjust OPPS drug payment rates "as necessary" under § 1395*l*(t)(14)(A)(iii)(II). Indeed, whereas Congress titled subparagraph (E) "[a]djustment in payment rates *for overhead costs*," 42 U.S.C. § 1395*l*(t)(14)(E) (emphasis added), it included no similar qualifying language in describing the Secretary's adjustment authority under § 1395*l*(t)(14)(A)(iii)(II). Congress's omission of such language in § 1395*l*(t)(14)(A)(iii)(II) indicates that the "adjustments" described in the two provisions are distinct. *See Am. Forest & Paper Ass'n v. FERC*, 550 F.3d 1179, 1181 (D.C. Cir. 2008) ("Where Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion."); *see also Knapp Med. Ctr. v. Hargan*, 875 F.3d 1125, 1130 (D.C. Cir. 2017) (rejecting argument that the term "process" had same meaning throughout section of Medicare statute, because "there is more than one 'process' in [42 U.S.C] section 1395nn(i)(3)"). Moreover, if Plaintiffs were correct that the adjustment authority conferred by § 1395*l*(t)(14)(A)(iii)(II) and § 1395*l*(t)(14)(E) are coextensive, then it would have been unnecessary for Congress to separately "authorize" adjustment authority in § 1395*l*(t)(14)(E)(ii), because such authority would have already been available under § 1395*l*(t)(14)(A)(iii)(II).

3. The Secretary Did Not Exceed His Authority Under § 1395*l*(t)(14)(A)(iii)(II) By Limiting Application of the Rate Reduction or by Allegedly Undermining The 340B Program

Plaintiffs' final argument is that the Secretary exceeded his authority under § 1395*l*(t)(14)(A)(iii)(II) because he exempted certain providers from the adjustment and because

the 2018 OPPS Rule "undermines the basic purposes of the 340B Program." Pls.' Mem. at 27-30. Both parts of Plaintiffs' argument are flawed.

First, the 2018 OPPS Rule exempted certain providers from the rate reduction because other parts of the Medicare statute treat those types of providers differently. For example, subsection 1395*l*(t)(13) provides that the Secretary can treat rural hospitals differently, and the Secretary relied on this authority to exempt rural sole community hospitals from the 340B payment adjustment. *See* 42 U.S.C. § 1395*l*(t)(13); *see also* 82 Fed. Reg. at 52,505-06 (explaining differential treatment of rural sole community hospitals, and setting forth statutory basis). Likewise, children's hospitals and cancer hospitals are treated differently under subsection (t)(7)(D)(ii). *See* 42 U.S.C. § 1395*l*(t)(7)(D)(ii). And there are good reasons for treating these sorts of hospitals differently, including reasons related to access-to-care concerns. 82 Fed. Reg. at 52,505-52,506. Plaintiffs point to no statutory provision that would require the Secretary to ignore his authority to treat different types of providers differently merely because they might also have 340B agreements in place.

Second, the 2018 OPPS Final Rule does not undermine the purpose of the 340B Program. As Plaintiffs state, "[t]hat Program envisioned that eligible hospitals and clinics – i.e., those that served a disproportionately large share of persons who cannot afford to pay medical bills – would receive drug price discounts from pharmaceutical companies." Pls.' Mem. at 28. Of course, nothing in the 2018 OPPS Rule prohibits 340B Program participants from receiving drug price discounts. Indeed, the 2018 OPPS Rule addresses only the amount 340B participants will be reimbursed for these drugs (with respect to the treatment of covered Medicare patients). And nothing in the statute creating the 340B Program indicates that it was designed to make drug purchasing a huge profit center from which other activities could be subsidized. *See* Public Health

Service Act, § 340B.[13] Indeed, contrary to such a purpose, the law creating the 340B Program prohibited the resale of drugs by program participants to non-patients, cutting off an obvious source of such profits. *Id.* § 340B(a)(5)(B). Finally, the structure for reimbursing providers for drugs contemplates that there may be no profits from drug purchases, as Congress permits CMS to reimburse providers for the actual acquisition costs of the drugs. 42 U.S.C.A. § 1395*l*(t)(14)(A)(iii)(I).

In any case, the Rule was not intended (and is not likely) to *eliminate* providers' profit margin on 340B drugs, but was intended to make Medicare payment for these drugs "more aligned" with providers' acquisition costs. Indeed, CMS set the payment rate at ASP minus 22.5% because it determined (and several commenters agreed) that this was "an amount that allows hospitals to retain a profit on [340B] drugs." 82 Fed. Reg. at 52,497; *see id.* at 52,496 (noting that ASP minus 22.5% is a "conservative" payment rate because it reflects the "lower bound" or "minimum" "average discount received by 340B hospitals for drugs paid under the [OPPS]," and it is "likely that the average discount is higher, potentially significantly higher, than the average

[13] Plaintiffs cite a 2005 HRSA manual for the proposition that Congress intended for the 340B Program to become a profit center for providers. Pls.' Mem. at 28 (citing HRSA, Hemophilia Treatment Center Manual for Participating in the Drug Pricing Program Established by Section 340B of the Public Health Service Act 14 (July 2005) (attached as Exh. 2)). But what the manual actually says is "The *purpose of the 340B Program is to lower the cost of acquiring covered outpatient drugs* for selected health care providers so that they can stretch their resources in order to serve more patients or improve services. *Additional program* resources are generated if drug acquisition costs are lowered but revenue from grants or health insurance reimbursements are maintained or not reduced as much as the 340B discounts or rebates." HRSA Manual at 14. Thus, HRSA recognizes that the purpose of 340B is facilitate the acquisition of low cost drugs, not to create a profit – that is an ancillary benefit to providers of a misalignment between acquisition costs and reimbursements, rather than a purpose of the 340B Program.

minimum of 22.5 percent that MedPAC found through its analysis."). Thus, Plaintiffs' assertion that the 340B drug payment reduction "undermines" the 340B Program is flawed.[14]

* * *

For all these reasons, the Medicare statute's plain text unambiguously forecloses each theory Plaintiffs assert in support of their APA claim. But even if there were any ambiguity in the statutory text, the Secretary's interpretation of the statute is eminently reasonable, was extensively explained in the 2018 OPPS Rule, *see* 82 Fed. Reg. at 52,493-511, and is bolstered by the legislative history, *see* H.R. Rep. No. 108-391, at 599 (2003) (Conf. Rep.), *as reprinted in* 2003 U.S.C.C.A.N. 1808, 1965; H.R. Rep. No. 105-149, at 1323 (1997); H.R. Rep. No. 105-217, at 785 (1997) (Conf. Rep.), *as reprinted in* 1997 U.S.C.C.A.N. 176, 406. Thus, if the Court deems it necessary to reach *Chevron* step two, the Court should defer to the Secretary's reasonable reading of § 1395*l*(t)(14)(A)(iii). Plaintiffs' APA claims should therefore be dismissed.

II. Plaintiffs' Motion For A Preliminary Injunction Should Be Denied

If the Court deems it necessary to reach Plaintiffs' motion for a preliminary injunction, that motion should be denied. "A preliminary injunction is 'an extraordinary remedy that may only be awarded upon a clear showing that the plaintiff is entitled to such relief.'" *Sherley v. Sebelius*, 644 F.3d 388, 392 (D.C. Cir. 2011) (quoting *Winter v. NRDC*, 555 U.S. 7 (2008)). "A plaintiff seeking a preliminary injunction must establish [1] that he is likely to succeed on the merits, [2] that he is likely to suffer irreparable harm in the absence of preliminary relief, [3] that the balance of equities tips in his favor, and [4] that an injunction is in the public interest." *Id.* Moreover, a plaintiff

[14] Plaintiffs make much of the fact that in the Patient Protection and Affordable Care Act of 2010, Congress expanded the "covered entities" under the 340B Program. Pls.' Mem. at 30. But this has no bearing on the scope of the Secretary's adjustment authority under § 1395*l*(t)(14)(A)(iii)(II). That Congress wanted to increase access to low-cost drugs says nothing about its desire to make the purchasing of drugs a profit center for some providers under the Medicare program.

seeking an injunction that would alter the status quo – as Plaintiffs do here – must satisfy a heightened standard. *Paleteria La Michoacana, Inc. v. Productos Lacteos Tocumbo S.A. de C.V.*, 901 F. Supp. 2d 54, 56 (D.D.C. 2012) ("If the requested relief would alter, not preserve, the status quo, the court must subject the plaintiff's claim to a somewhat higher standard . . . [D]efendant thus seeks to alter—not preserve—the status quo. Accordingly, the court will exercise extreme caution in assessing the defendant's invitation to invoke the court's extraordinary equitable powers."). Plaintiffs would not satisfy the standard that applies to a request for a preliminary injunction that seeks to maintain the status quo, as they cannot establish that they are likely to succeed on the merits, that the equities tip in their favor, or that an injunction is in the public interest. And since Plaintiffs seek to alter the status quo, their arguments fall even further short of the mark.

A. Plaintiffs Are Unlikely To Succeed On The Merits

For the reasons outlined above in support of Defendants' motion to dismiss, Plaintiffs are not likely to succeed on their APA claims because: (1) they are statutorily precluded by § 1395*l*(t)(12); (2) they challenge agency action that is "committed to agency discretion by law" and thus unreviewable under the APA; (3) Plaintiffs have failed to exhaust administration remedies; and (4) the claims fail on the merits. Thus, Plaintiffs' motion for a preliminary injunction should be denied. *See U.S. Ass'n of Reptile Keepers, Inc. v. Jewell*, 103 F. Supp. 3d 133, 153 (D.D.C. 2015) (even if likelihood of success on the merits is not "an independent, free-standing requirement for a preliminary injunction," it is at least "a key issue and often the dispositive one"). At minimum, this factor weighs heavily against granting a preliminary injunction.

B. The Balance Of Equities And The Public Interest Weigh Strongly Against Granting A Preliminary Injunction

A party seeking a preliminary injunction must also demonstrate "that the balance of equities tips in [its] favor, and that an injunction is in the public interest." *Winter*, 555 U.S. at 20. "These factors merge when the Government is the opposing party." *Nken v. Holder*, 556 U.S. 418, 435 (2009). These factors weigh heavily against granting a preliminary injunction here.

As explained above, the D.C. Circuit and other courts have repeatedly recognized that "piecemeal review of individual [OPPS] payment determinations could frustrate the efficient operation" of the Medicare scheme, and "judicially mandated changes in one payment rate would affect the aggregate impact of the Secretary's decisions by requiring offsets elsewhere, and thereby interfere with the Secretary's ability to ensure budget neutrality in each fiscal year." *Amgen Inc.*, 357 F.3d at 112; *see, e.g.*, *Paladin*, 684 F.3d at 531 n.3 ("Judicial determinations forcing the Secretary to retroactively alter payment rates for various covered services—e.g., payment rates that are adjusted annually and are required to remain budget neutral—would likely wreak havoc on the already complex administration of Medicare Part B's outpatient prospective payment system."); *Skagit*, 80 F.3d at 386 (judicially mandated change in one payment rate would affect the "aggregate impact" of the Secretary's decisions and make it impossible for the Secretary to comply with his "duty to ensure budget neutrality in each fiscal year"); *see also Methodist Hosp. of Sacramento v. Shalala*, 38 F.3d 1225, 1233 (D.C. Cir. 1994) (noting "significant, if not debilitating, disruption" that would be caused by retroactive corrections under the prospective payment system for inpatient care under Medicare Part A). Moreover, numerous payments have already been made under the 2018 OPPS Rule for drugs purchased under the 340B Program – and for other components of the OPPS that had their reimbursement rates altered to render the changes to the drug reimbursement rate budget neutral. Thus, a preliminary injunction increasing the

payment rate for drugs purchased through the 340B program would raise significant and difficult questions about how to handle claims related to other components of the OPPS that, as a result of the budget neutrality requirement, were paid under rates that were increased to offset the decrease to the payment rate for drugs acquired through the 340B Program. And it is precisely because of the interdependence of the Secretary's determinations, and dependence on payments already made by CMS, that Congress precluded judicial review of the Secretary's OPPS payment rate determinations. *See* 42 U.S.C. § 1395*l*(t)(12). Such concerns caution strongly against *any* judicial involvement—let alone the extraordinary remedy of a status-altering preliminary injunction—in the Secretary's administration of the OPPS.

In sum, each of the preliminary injunction factors weighs strongly against granting injunctive relief. Plaintiffs' motion for a preliminary injunction should therefore be denied.

CONCLUSION

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

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Respectfully submitted,

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