IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

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

DEFENDANTS' MOTION TO DISMISS

Pursuant to Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6), Defendants Eric D. Hargan and Department of Health and Human Services respectfully move to dismiss Plaintiffs' Complaint. In support of this Motion, Defendants respectfully refer the Court to the attached Memorandum of Points and Authorities. A proposed order is submitted herewith.

Date: December 1, 2017

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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. 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." 42 U.S.C. § 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 and 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.

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 covered entities that are paid under a separate payment scheme outside of the OPPS, such as critical access hospitals.

In total, at least 52% of 340B covered entities would not be affected by the payment adjustment, either because they are specifically exempted, or because they are not paid under the OPPS. The Secretary estimates that the payment adjustment will 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 will be "redistributed in an equal offsetting amount to all hospitals paid under the OPPS." *Id.*

Plaintiffs brought this suit under the Administrative Procedure Act ("APA"), seeking the extraordinary remedy of a preliminary injunction blocking implementation of the 2018 OPPS Rule. Plaintiffs do not assert that the 2018 OPPS Rule was procedurally flawed or inadequately justified. They claim only that the Secretary's payment adjustment exceeded his authority under the Medicare statute.

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 administrative remedies under the Medicare statute. 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. Nor have Plaintiffs made an adequate showing of irreparable harm, because their alleged injury is purely economic, and is not sufficiently great, certain, or imminent.

Meanwhile, the requested injunction would significantly disrupt operation of the Medicare system, to the detriment of its participants and Defendants.

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 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 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). And 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* .

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.

II. 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 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 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 purchased 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 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

[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

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 two 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, § 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 pay 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.

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 it called its "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 ASP plus a fixed,

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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.*

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 was 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, which 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. 52,356, 52,362 (Nov. 13, 2017).

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

- A March 2016 report by the Medicare Payment Advisory Commission ("MedPAC"),[2] 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).
- A June 2015 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 May 2015 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.
- A November 2015 HHS Office of Inspector General ("OIG") report, finding that Medicare payments "were ***58 percent more than*** [already-discounted] 340B ceiling prices, which

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

allowed covered entities to retain approximately ***$1.3 billion*** in 2013." *Id.* at 52,495 (emphasis added).

- 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 [already-discounted] 340B ceiling price." *Id.*

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, the 'difference between the Part B [payment] amount and the 340B ceiling price was so large that, 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]"; indeed, 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 will 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. 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 340B covered entities would not be affected by the payment adjustment, either because they are specifically exempted, or because they are not paid under the OPPS.[3]

CMS estimates that this payment adjustment will save Medicare $1.6 billion. 82 Fed. Reg. at 52,509. Critically, these savings will be redistributed within the OPPS system. That is because the CMS made the payment adjustment, per § 1395*l*(t)(9)(B), "in a budget neutral manner within the OPPS," and thus "the reduced payments for separately payable drugs purchased through the

[3] *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

340B Program will *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[s] 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.*

Although the 2018 OPPS Rule becomes effective January 1, 2018, providers have twelve months after the date of service to timely file a claim for payment for 340B drugs. *See* 42 U.S.C. § 1395n(a); 42 C.F.R. § 424.44. Thus, 340B providers have up to a year after the 2018 OPPS Rule takes effect before they must submit a claim using the adjusted 340B drug payment rate.

V. This Case

Plaintiffs—three hospital associations and three of their member hospitals[4]—brought this action on November 13, 2017, challenging the 340B provisions of the 2018 OPPS Rule under the APA, 5 U.S.C. § 706(2). Count 1 of the Complaint asserts the Secretary's exercise of his statutory payment adjustment authority to reduce the rate for 340B drugs is "arbitrary and capricious and contrary to law and in excess of the Secretary's authority under 42 U.S.C. § 1395*l*(t)(14)(A)(iii)," in violation of the APA. Compl. ¶¶ 47-49. Plaintiffs do not allege that the 2018 OPPS Rule was procedurally flawed or inadequately justified; they claim only that the Secretary exceeded his statutory authority. *See id.*; Pls.' Mem. in Supp. of Mot. for Prelim. Inj. [ECF No. 2-1] ("Pls.' Mem.") at 10-20. Count 2 of the Complaint is a claim for interim injunctive relief under 5 U.S.C. § 705. Compl. ¶¶ 50-51. Together with their Complaint, Plaintiffs moved for a preliminary injunction blocking implementation of the 340B provisions of the OPPS Rule pending resolution of this suit. Pls.' Mem. at 1.

[4] 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.

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). 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 claim 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). But the first step is "to determine whether the language at issue has a plain and unambiguous meaning with regard to the particular dispute

in the case. Our inquiry must cease if the statutory language is unambiguous and the statutory scheme is coherent and consistent." *Robinson v. Shell Oil Co.*, 519 U.S. 337, 340 (1997).

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);
> >
> > * * *
> >
> > (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)(A), (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). Focusing on subsection (A), the Circuit emphasized that the plain text of this provision "stipulates that 'there shall be no administrative or judicial review' of 'other adjustments,'" and the "the legislative history reflects this stipulation." *Id.* (citing H.R. Rep. No. 105-149 at 724). "That Congress would use such language of prohibition is unsurprising," the Circuit noted, "for piecemeal review of individual payment determinations could frustrate the efficient operation of the complex prospective payment system." *Id.* 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 court added 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.* Indeed, "[o]ther circuits have noted 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). This Court has acknowledged *Amgen*'s breadth, describing the decision as holding that § 1395*l*(t)(12) "clearly preclude[s] judicial review of the Secretary's adjustments to prospective payment amounts," and that "the legislative history comports with a preclusion of judicial review of CMS's

authority to set prospective payment methodologies." *Organogenesis Inc. v. Sebelius*, 41 F. Supp. 3d 14, 20 (D.D.C. 2014) (Contreras, J.) (citing *Amgen*, 357 F.3d at 112).

At bottom, this case law reflects an understanding that § 1395*l*(t)(12)'s sweeping language, "combined with the broad range of subjects expressly immunized from review, manifest the Congress's intent to 'proceed with these initial administrative processes without risk of litigation blocking the execution of the program.'" *Tex. All. for Home Care Servs.*, 681 F.3d at 409; *see also Carolina Med. Sales, Inc. v. Leavitt*, 559 F. Supp. 2d 69, 77 (D.D.C. 2008) ("The scope of the other areas of preclusion indicate a scheme to insulate the entire program from review, as does the broad, general language used."). Applying these principles here leads to the conclusion that both subsections (A) and (E) of § 1395*l*(t)(12) foreclose judicial review of Plaintiffs' APA claim.

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' claim is statutorily barred by § 1395*l*(t)(12)(A).

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

Plaintiffs' APA claim is 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* Compl. ¶ 49, 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 claim is 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 16, this would have repercussions throughout the OPPS, including forcing CMS to recalculate the revised payment rates for all non-drug items and services to ensure budget neutrality. 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.

3. Plaintiffs' APA Claim Does Not Fit The Narrow *Ultra Vires* Exception To Statutory Preclusion Provisions

In *Amgen*, the court explained that "[i]f a no-review provision shields particular types of administrative action, a court may not inquire whether a challenged agency decision is arbitrary, capricious, or procedurally defective, but it must determine whether the challenged agency action is *of the sort* shielded from review." *Amgen*, 357 F.3d at 113 (emphasis added). "Otherwise," the court explained, "agencies could characterize reviewable or unauthorized action as falling within

the scope of no-review provisions whose application to such action Congress did not intend." *Id.* As this Court recognized in *Organogenesis*, however, review under this "*ultra vires* doctrine" is not and cannot be a full-blown review on the merits—if it were, then the statutory preclusion provision would be rendered meaningless. *See* 41 F. Supp. 3d at 23. Rather, "[c]ourts will exercise their power to review alleged *ultra vires* agency action when an agency 'patently misconstrues a statute, disregards a specific and unambiguous statutory directive, or violates a specific command of a statute.'" *Id.*; *see Fla. Health Sci. Ctr. v. Sec'y of Health & Human Servs.*, 830 F.3d 515, 522 (D.C. Cir. 2016) ("To challenge agency action on the ground that it is *ultra vires*, [the plaintiff] must show a patent violation of agency authority. … A violation is 'patent' if it is 'obvious' or 'apparent.'"); *see also Griffith v. FLRA*, 842 F.2d 487, 493 (D.C. Cir. 1988) (*ultra vires* doctrine is an "implicit but narrow exception").

Here, the Secretary's statutory authority to "adjust[]" OPPS payment rates "as necessary" under § 1395*l*(t)(14)(A)(iii)(II) is clear, unequivocal, and not subject to any express statutory limitation. And the challenged action here—the Secretary's adjustment of the OPPS payment rate for 340B drugs—is indisputably "of the sort shielded from review." *Amgen*, 357 F.3d at 113. As explained *infra* in Part I.D, Plaintiffs' theories as to why the Secretary's adjustment of 340B payment rates exceeded his statutory authority under § 1395*l*(t)(14)(A)(iii)(II) are based not on any violation of a "specific and unambiguous statutory directive," but on Plaintiffs' idiosyncratic and unsupported interpretation of the Medicare statute. Plaintiffs thus cannot show that their claim fits the narrow *ultra vires* doctrine.[5]

[5] Insofar as the Court deems it necessary to consider the merits of Plaintiffs' claims in evaluating whether to permit review under the narrow *ultra vires* exception, Defendants incorporate by reference *infra* Part I.D, which explains why Plaintiffs' APA claim fails on the merits.

In sum, Plaintiffs' APA claim is statutorily precluded by both subsections (A) and (E) of § 1395*l*(t)(12), and thus should be dismissed for lack of subject-matter jurisdiction. *See Amgen*, 357 F.3d at 118 (court "lack[ed] jurisdiction" where § 1395*l*(t)(12) precluded review); *Organogenesis*, 41 F. Supp. 3d at 23 (same).

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 the 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. This standard fairly exudes deference to the Director, and appears to us to foreclose the application of any meaningful judicial standard of review"); *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. . . .' There is no guidance to the Administrator or to a reviewing court as to what action is '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.

For all these reasons, the Secretary's exercise of his payment adjustment authority under § 1395*l*(t)(14)(A)(iii)(II) is committed to agency discretion by law and thus unreviewable, providing yet another ground for dismissal of Plaintiffs' APA claim.

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

If the Secretary's payment adjustment under § 1395*l*(t)(14)(A)(iii)(II) were reviewable, the proper vehicle for review would not be in this anticipatory suit, but instead in a suit brought only

after Plaintiffs had first satisfied the Medicare statute's exhaustion requirements. Plaintiffs have not met those requirements, so this Court lacks jurisdiction.

Under 42 U.S.C. § 405(h), "[n]o action against the United States, the [Secretary of Health and Human Services], or any officer or employee thereof shall be brought under section 1331 . . . of title 28 [i.e., the general federal question statute] to recover on any claim arising under" the Medicare statute. 42 U.S.C. § 405(h); *see also* 42 U.S.C. § 1395ii (incorporating § 405(h)). Rather, such claims must be "channeled" through the Medicare statute's administrative procedures. *Shalala v. Ill. Council on Long Term Care, Inc.*, 529 U.S. 1, 12 (2000). Only after exhausting those procedures can a claimant seek judicial review under the Medicare statute, which contains its own jurisdictional provision separate from § 1331's grant of general federal question jurisdiction. *See* 42 U.S.C. § 1395ff(a)(1)(C), (b), (d); 42 U.S.C. § 405(b), (g)-(h).

The Supreme Court has made clear that "the bar of § 405(h) reaches beyond ordinary administrative law principles of 'ripeness' and 'exhaustion of administrative remedies,'" and "demands the 'channeling' of virtually all legal attacks through the agency." *Ill. Council*, 529 U.S. at 12-13. Even where, as here, a party brings a "facial challenge" to a "Medicare rule[]," it "must exhaust the agency review process regardless of whether the matter involves a direct constitutional, statutory, or regulatory challenge." *Three Lower Ctys. Cmty. Health Servs., Inc. v. HHS*, 317 F. App'x 1, 2 (D.C. Cir. 2009) (per curiam); *see Ill. Council*, 529 U.S. at 5 (explaining that anticipatory challenges to the lawfulness of a provision that might later bar recovery of benefits must proceed "through the special review channel that the Medicare statutes create"); *see also Nat'l Ass'n for Home Care & Hospice, Inc. v. Burwell*, 77 F. Supp. 3d 103, 109 (D.D.C. 2015) ("A challenge that arises under the Medicare [statute] must be brought via Section 405 irrespective of whether it may be equally framed as a challenge under other laws or the Constitution."). Mere

"added inconvenience or cost" is no excuse for failing to exhaust administrative remedies. *See Heckler v. Ringer*, 466 U.S. 602, 619 (1984) (claimants "must adhere to the administrative procedure which Congress has established for adjudicating their Medicare claims" even when they "would clearly prefer an immediate appeal to the District Court rather than the often lengthy administrative review process"); *Ill. Council*, 529 U.S. at 22-23 (claimant may not avoid the administrative process even when postponement "would mean added inconvenience or cost").

Here, the Complaint describes no effort by Plaintiffs to exhaust the Medicare statute's administrative procedures before filing suit. Plaintiffs instead seek to bypass those procedures altogether by invoking this Court's federal question jurisdiction under 28 U.S.C. § 1331. *See* Compl. ¶ 24. But as Plaintiffs themselves acknowledge, "[t]his action arises under … [the Medicare statute], 42 U.S.C. § 1395 *et seq.*" *Id.* ¶ 23. Thus, federal question jurisdiction is plainly barred by 42 U.S.C. § 405(h). Because Plaintiffs failed to exhaust Medicare's administrative procedures before filing suit, their Complaint must be dismissed for lack of subject-matter jurisdiction. *See Three Lower Ctys.*, 317 F. App'x at 3 (failure to exhaust in Medicare case "forecloses subject matter jurisdiction").

D. Plaintiffs' APA Claim Fails On The Merits

Even assuming Plaintiffs' APA claim were not statutorily precluded and Plaintiffs had exhausted their administrative remedies, the claim fails on the merits and thus should be dismissed 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. "First, always, is the question whether Congress has directly spoken to the precise question at issue. If the intent of Congress is clear, that is the end of the matter." *Chevron, U.S.A., Inc. v. NRDC*, 467 U.S. 837, 842-43 (1984). But if the "statute is silent or ambiguous with respect to the specific issue," the

Court proceeds to *Chevron* step two, under which the agency's interpretation of the statute will be upheld so long as it is "reasonable." *Id.* at 843-44.

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 plain 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.[6] And Plaintiffs certainly have not identified any "patent violation of agency authority," *Fla. Health Sci. Ctr.*, 830 F.3d at 522, as they must do to satisfy the even more deferential standards of *ultra vires* review.

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

Plaintiffs' primary argument is that "CMS's authority under subclause (II) [of 1395*l*(t)(14)(A)(iii)] to 'calculate[] and adjust[] … as necessary' is a limited authority to determine mathematically any appropriate, slight alterations that should be applied to the ASP plus 6% statutory default rate in a given year." Pls.' Mem. at 12-13. This is so, according to Plaintiffs, because "[t]he plain and ordinary meaning of 'calculate' is to 'determine (the amount or number of something) *mathematically*' while 'adjust' is to 'alter or move (something) *slightly* in order to achieve the desired fit, appearance, or result.'" *Id.* at 12 (quoting Oxford Dictionary). Plaintiffs claim that the 2018 OPPS Rule is contrary to the statute's "plain and ordinary meaning," because

[6] Because Plaintiffs' APA claim raises pure legal questions regarding the scope of the Secretary's statutory authority, the Court may reach the merits of that claim 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 claim presents a pure question of statutory interpretation.

the new 340B payment rate "is neither slight nor mathematically derived from any calculation of ASP." *Id.* at 12-13.

Plaintiffs' reading of § 1395*l*(t)(14)(A)(iii)(II) is foreclosed by the statute's plain text. As noted, 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 "slight," but no such qualifier appears in the statutory text. In support of their reading, Plaintiffs point to a single dictionary definition of "adjust" that includes the word "slight." But "a reviewing court should not confine itself to examining a particular statutory provision in isolation. The meaning—or ambiguity—of certain words or phrases may only become evident when placed in context." *Am. Coal Co. v. Fed. Mine Safety & Health Review Comm'n*, 796 F.3d 18, 23 (D.C. Cir. 2015). Indeed, Plaintiffs themselves acknowledge that "statutory provisions 'cannot be construed in a vacuum' and that [it is] a 'fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme.'" Pls.' Mem. at 13 (quoting *Roberts v. Sea-Land Servs.*, 566 U.S. 93, 101 (2012)).

Contrary to this "fundamental canon," Plaintiffs analyze the word "adjusted" in isolation, and overlook the subsequent text providing 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, through use of the term "adjusted," 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' reliance on dictionary definitions is unpersuasive for an additional reason: numerous other dictionaries define "adjust" *without* using the word "slight" or any other term that could be construed to impose a quantitative limitation.[7] These other definitions are, moreover,

[7] *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,

fully consistent with the Secretary's interpretation of the statutory phrase "adjusted by the Secretary as necessary." Indeed, some of the definitions explicitly refer to "adjust" as that term is used in the insurance context, which is particularly relevant here since Medicare is, after all, a federal health insurance program. *See*, *e.g.*, *Adjust*, American Heritage Dictionary, https://ahdictionary.com/word/search.html?q=adjust ("To decide how much is to be paid on (an insurance claim)."). Plaintiffs' reliance on a single, outlier definition of "adjust" is unavailing.

Equally unconvincing is Plaintiffs' claim that by reducing the OPPS payment rate for 340B drugs, the Secretary exceeded his statutory authority to "calculate[]" OPPS payment rates. While Plaintiffs' theory is not entirely clear, they appear to assert that the Secretary's calculation was improper because it was not "mathematically derived from any calculation of ASP." Pls.' Mem. at 13. But 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). Plaintiffs offer no basis for challenging the Secretary's calculation of ASP as "mathematically" unsound. And they would be hard pressed to do so, since one form of relief they request is an order directing Defendants to revert to "the methodology used in calendar year 2017,"

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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.").

Compl. at 16—a methodology that, as noted, used the same ASP calculation that Defendants continue to employ under the 2018 OPPS Rule. Alternatively, insofar as Plaintiffs mean to challenge the Secretary's 22.5% *adjustment* (rather than the ASP *calculation*) as "mathematically unsound," they are improperly conflating the terms "calculate" and "adjust." While "calculate" suggests application of a mathematically-defined formula, "adjust" does not; to the contrary, in this context, "adjust" means a *discretionary* change made by the Secretary "as necessary."

Nor is Plaintiffs' reliance on subparagraph (E) of § 1395*l*(t)(14) persuasive. 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 "similarly limited to alterations for 'overhead and related expenses.'" Pls.' Mem. at 14.

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*, --- F.3d ---, 2017 WL 5579508, at *4 (D.C. Cir. Nov. 21, 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).").[8]

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). *See Corley v. United States*, 556 U.S. 303, 314 (2009) ("one 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.'"). In addition, the phrase on which

[8] Plaintiffs invoke the canon of statutory construction that "a term appearing in several places in a statutory text is generally read the same way each time it appears." Pls.' Mem. at 14 (quoting *Ratzlaf v. United States*, 510 U.S. 135, 143 (1994)). But this canon applies only when the statutory phrases are "identical." *Estate of Cowart v. Nicklos Drilling Co.*, 505 U.S. 469, 479 (1992). The statutory phrases here are *not* identical: § 1395*l*(t)(14)(E) concerns "[a]djustment[s] in payment rates for overhead costs," while § 1395*l*(t)(14)(A)(iii)(II) concerns "adjust[ments] by the Secretary as necessary for purposes of this paragraph."

Plaintiffs rely provides that the amounts of payment are "subject to ***subparagraph*** (E)." 42 U.S.C. § 1395*l*(t)(14)(A)(iii) (emphasis added). But the separate adjustment authority on which the Secretary relied here provides that he may make adjustments "as necessary for purposes of this ***paragraph***." *Id.* § 1395*l*(t)(14)(A)(iii)(II) (emphasis added). By its terms, then, this adjustment authority is broader than that strictly required to give effect to one particular subparagraph within paragraph (14). *See Koons Buick Pontiac GMC, Inc. v. Nigh*, 543 U.S. 50, 60 (2004) ("Congress ordinarily adheres to a hierarchical scheme in subdividing statutory sections … [including] paragraphs (starting with (1)) … [and] subparagraphs (starting with (A))."); *see also Knapp*, 2017 WL 5579508, at *4.

Plaintiffs also make much of the fact that the 340B drug payment reduction is a "dramatic departure" from the agency's prior payment rates. Pls.' Mem. at 12, 14-15. But "[a]gencies are free to change their existing policies as long as they provide a reasoned explanation for the change." *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2125 (2016). Plaintiffs have not alleged that Defendants failed to provide such a "reasoned explanation" here—nor could they, since the 2018 OPPS Rule provides a thorough explanation for why the agency deemed it necessary to adjust the OPPS payment rate for 340B drugs. *See* 82 Fed. Reg. at 52,493-511. Nor does it matter that this is the first time the Secretary has exercised his payment adjustment authority under § 1395*l*(t)(14)(A)(iii)(II). As CMS explained in the 2018 OPPS Rule, "the fact that we have not historically utilized our adjustment authority . . . to adjust payment amounts for separately payable 340B-acquired drugs" does not "mean[] we are permanently barred from adjusting these payments where, as here, we have provided a reasoned explanation for doing so." 82 Fed. Reg. at 52,501. While Plaintiffs may disagree with the Secretary's discretionary decision to make the

payment adjustment, they have failed to show that the Secretary's decision exceeded his statutory authority.[9]

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

Plaintiffs' next theory is that the Secretary exceeded his authority under § 1395*l*(t)(14)(A)(iii) by failing to apply one of the payment methodologies set forth in subclauses (I) and (II) of § 1395*l*(t)(14)(A)(iii), and instead using a "third, hybrid method of his own design for setting payment rates." Pls.' Mem. at 15. That is false. Defendants do not dispute that § 1395*l*(t)(14)(A)(iii) requires that the Secretary use either the payment methodology set forth in subclause (I) ("the average acquisition cost for the drug . . . as determined by the Secretary taking into account the hospital acquisition cost survey data under subparagraph (D)"), or subclause (II) ("if hospital acquisition cost data are not available, the average price for the drug . . . as calculated and adjusted by the Secretary as necessary for purposes of this paragraph"). As explained in the 2018 OPPS Rule, CMS did "not have hospital acquisition cost data for 340B drugs" sufficient to rely on subclause (I), so it relied on subclause (II) to calculate ASP, and then "adjust[ed] that amount by applying a reduction of 22.5 percent," to "more closely align" the OPPS payment rate

[9] Plaintiffs incorrectly assert that CMS previously understood the Secretary's payment adjustment authority under § 1395*l*(t)(14)(A)(iii)(II) "to be limited to changes to overhead and similar expense calculations." Pls.' Mem. at 14-15. CMS has never taken that position. Rather, the 2013 OPPS Rule cited by Plaintiffs recognized that the "statutory default of ASP+6 percent [was] appropriate ***at this time***" for a variety of reasons, and required "no further adjustment" because it "represent[ed] the combined ***acquisition*** and pharmacy overhead ***payment*** for drugs and biologicals for CY 2013." 77 Fed. Reg. at 68,383 (emphasis added). Contrary to Plaintiffs' assertions, then, the 2013 OPPS Rule expressly recognized that "adjustments" under § 1395*l*(t)(14)(A)(iii)(II) may be necessary to account for drug "acquisition" costs. That is precisely what the 2018 OPPS Rule did: it reduced the OPPS payment rate for 340B drugs to, among other things, "more closely align with the acquisition costs" for 340B drugs, in light of recent data indicating that payment rates and drug acquisition costs were substantially misaligned. 82 Fed. Reg. at 52,501.

"with the acquisition costs" for 340B drugs, and to "lower" 340B drug costs "for Medicare beneficiaries." 82 Fed. Reg. at 52,496, 52,501.

Plaintiffs contend that the Secretary acted improperly because "subclause (II)…mandates payment based on *average sales price*, not acquisition cost." Pls.' Mem. at 16. But Plaintiffs are mistaken in two respects. First, subclause (II)'s plain 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 ("one 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." 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 that providers are reaping outsized profits from the program, and that beneficiaries are paying unduly high insurance 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' drug costs in exercising his adjustment authority under § 1395*l*(t)(14)(A)(iii)(II).[10]

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

Plaintiffs' final theory is that the Secretary exceeded his authority under § 1395*l*(t)(14)(A)(iii)(II) because the "340B Provisions of the [2018] OPPS Rule undermine the 340B Program as it applies to hospitals." Pls.' Mem. at 17. As an initial matter, Plaintiffs are not permitted "to couch this type of reasonableness challenge in terms of the agency's exceeding its statutorily-defined authority." *Fla. Health Scis. Ctr.*, 830 F.3d at 523. But, in any event, Plaintiffs mischaracterize the 2018 OPPS Rule and its purported impact on the 340B Program. Most notably, they incorrectly claim that the Rule's reduced payment rate for 340B drugs will "close the gap" between hospital acquisition costs and Medicare payment rates, and thus eliminate the profit that Congress purportedly intended hospitals to retain under the 340B Program. Pls.' Mem. at 17. That is false. The Rule is designed not to *eliminate* providers' profit margin on 340B drugs, but 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)

[10] Plaintiffs also claim that "GAO agrees with this limited view of CMS's authority." Pls.' Mem. at 16-17, 19. But GAO's interpretation of the Secretary's statutory authority is not binding on this Court. And GAO's statements, in any event, provide 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).

that this was "an amount that ***allows hospitals to retain a profit*** on [340B] drugs." 82 Fed. Reg. at 52,497 (emphasis added); *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 minimum of 22.5 percent that MedPAC found through its analysis."). Thus, the core premise underlying Plaintiffs' assertion that the 340B drug payment reduction "undermines" the 340B Program is flawed.

Plaintiffs also fail to identify anything in the text or legislative history of either the Medicare statute or the 340B statute reflecting a "clear [congressional] purpose" to "separate … hospitals' costs of purchasing 340B prescription drugs" from the "Medicare payment[]" rate for those drugs. *See* Pls.' Mem. at 18. It bears emphasizing that the 340B Program and Medicare are distinct programs, administered by separate agencies and governed by different statutory schemes. Thus, absent clear evidence to the contrary, Congress's intent with respect to the 340B Program is immaterial to Medicare Part B and the OPPS. *See PBGC v. LTV Corp.*, 496 U.S. 633, 645-46 (1990) (agency implementing one statute need not "give effect to the policies and goals of other statutes"). And while is true that the *general* intent behind the 340B Program was to "stretch scarce Federal resources as far as possible," Pls.' Mem. at 18—an intent that the 2018 OPPS Rule actually fulfills by allocating federal funds more efficiently—Plaintiffs point to nothing demonstrating a *specific* congressional objective that OPPS payment rates be set in a manner to ensure that providers reap outsized profits on 340B drugs. Nor is such a requirement necessary to meet the core goals of the 340B Program, which are achieved not through Medicare reimbursement, but through the significantly discounted ceiling prices that 340B providers obtain from drug manufacturers. Indeed, even if the Secretary were hypothetically to set the OPPS

payment rate to *match* the acquisition costs for 340B drugs and thus eliminated 340B providers' profit margin (which, as noted above, the 2018 OPPS Rule explicitly does *not* do), providers would still be able to obtain 340B drugs at significantly discounted ceiling prices, consistent with the 340B Program's purpose.

In any event, Plaintiffs cite no authority supporting their claim that the Secretary could exceed his authority under one statute (the Medicare statute, § 1395*l*(t)(14)(A)(iii)(II)) by purportedly "undermining" the purposes of a different statute (the 340B statute, 42 U.S.C. § 256b). Plaintiffs rely on *Howard v. Pritzker*, 775 F.3d 430 (D.C. Cir. 2015), Pls.' Mem. at 17-18, but that case lends them no support. There, the Circuit held that the general six-year statute of limitations for suits against the United States set forth in 28 U.S.C. § 2401(a) does not apply to discrimination claims under Title VII of the Civil Rights Act brought by federal employees. *Id.* at 432. In so holding, the court reasoned that there was an "irreconcilable conflict" between the two statutes. *Id.* at 437-38. The court explained that "[s]tatutes are to be considered irreconcilably conflicting where 'there is a positive repugnancy between them' or 'they cannot mutually coexist.'" *Id.* at 397. The court found such a conflict because Title VII imposes "an exhaustion requirement without setting a time limit for administrative resolution of an employee's discrimination complaint," and provides that "an employee 'may file a civil action'" within time limits specifically tied to the administrative process, whereas § 2401(a) imposes a blanket six-year statute of limitations that would apply "regardless of the status of the administrative proceedings." *Id.* at 432. Thus, "[c]ontrary to the fixed six-year limit of § 2401(a)," Title VII does "not establish a time limit after which judicial relief would cease to be available due to the passage of time while employees pursued administrative remedies." *Id.* at 439.

There is no such "irreconcilable conflict" between the Secretary's exercise of his adjustment authority under § 1395*l*(t)(14)(A)(iii)(II) and the 340B Program. Unlike *Howard*, this is not a case where the application of one statute (§ 2401(a)) would result in a shorter limitations period that would otherwise apply under a different statute (Title VII). In other words, there is no direct conflict between the two statutes here. Rather, Plaintiffs make only an amorphous claim that the Secretary's exercise of his adjustment authority under § 1395*l*(t)(14)(A)(iii)(II) undermines the "purpose" of the 340B Program. But, as noted, the Secretary's payment adjustment does nothing to alter providers' ability to acquire drugs at significantly discounted prices under the 340B Program, nor does it threaten the continued existence of the 340B Program. This is therefore not a situation where "there is a positive repugnancy between" the Medicare statute and the 340B statute, or where the two statutes "cannot mutually coexist." *Howard* provides no support for Plaintiffs' position.[11]

* * *

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

[11] 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 19. But this has no bearing on the scope of the Secretary's adjustment authority under § 1395*l*(t)(14)(A)(iii)(II). As noted, Congress's actions with respect to the 340B Program are immaterial to Medicare Part B and the OPPS, because they are separate programs governed by different statutory schemes and administered by different agencies. *See LTV Corp.*, 496 U.S. at 645-46.

(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). And Plaintiffs certainly fail to satisfy the even more deferential standard for *ultra vires* review, since they have identified no "patent" or "obvious" violation of agency authority. Plaintiffs' APA claim 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.* Here, each factor weighs strongly against granting a preliminary injunction.[12]

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 claim because (1) it is statutorily precluded by § 1395*l*(t)(12); (2) it challenges agency action that is "committed to agency discretion by law" and thus

[12] The D.C. Circuit has historically used a "sliding scale" approach to evaluate the preliminary injunction factors, under which a "strong showing on one factor could make up for a weaker showing on another." *Sherley*, 644 F.3d at 392. But the Circuit has questioned the continued validity of this approach in light of the Supreme Court's decision in *Winter*, which suggests "that a likelihood of success is an independent, free-standing requirement for a preliminary injunction." *Id.* at 393. This remains an "open question" in this Circuit. *Aamer v. Obama*, 742 F.3d 1023, 1043 (D.C. Cir. 2014). The question need not be resolved here, however, because none of the preliminary injunction factors weigh in Plaintiffs' favor.

unreviewable under the APA; (3) Plaintiffs failed to exhaust administrative remedies under the Medicare statute; and (4) the claim fails 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. Plaintiffs Have Failed To Demonstrate Irreparable Harm

The D.C. Circuit "has set a high standard for irreparable injury." *Chaplaincy of Full Gospel Churches v. England*, 454 F.3d 290, 297 (D.C. Cir. 2006). To satisfy this standard, "the injury must be beyond remediation." *Id.* "Mere injuries, however substantial, in terms of money, time and energy necessarily expended in the absence of a stay are not enough. The possibility that adequate compensatory or other corrective relief will be available at a later date, in the ordinary course of litigation weighs heavily against a claim of irreparable harm." *Id.* In addition, "the injury 'must be both certain and great; it must be actual and not theoretical.'" *Id.* (quoting *Wisconsin Gas Co. v. FERC*, 758 F.2d 669, 674 (D.C. Cir. 1985) (per curiam)). The movant "must show '[t]he injury complained of is of such *imminence* that there is a clear and present need for equitable relief to prevent irreparable harm.'" *Id.* Here, Plaintiffs fall well short of the Circuit's "high standard for irreparable injury."

First, Plaintiffs' claimed injury is not "irreparable," because it is purely economic. *See* Pls.' Mem. at 20-21 (alleging only financial losses as a result of the 2018 OPPS Rule). It is well established in this Circuit that "economic loss does not, in and of itself, constitute irreparable harm." *Wisconsin Gas*, 758 F.2d at 674; *see Davis v. PBGC*, 571 F.3d 1288, 1295 (D.C. Cir. 2009)

(the "general rule [is] that economic harm does not constitute irreparable injury."). "Recoverable monetary loss may constitute irreparable harm only where the loss threatens the very existence of the movant's business." *Wisconsin Gas*, 758 F.2d at 674. Plaintiffs' alleged economic loss here would be recoverable if the Court were to enter a final judgment in their favor (assuming that the Court would have jurisdiction to do so). Indeed, if Plaintiffs hypothetically were to prevail and obtain an order directing Defendants to reinstate the ASP+6% OPPS payment rate for 340B drugs, they could seek payment for their Medicare claims under the higher ASP+6% rate in a variety of ways, depending on the processing status of the claim. *See, e.g.*, 42 C.F.R. § 405.942(a); 42 C.F.R. § 405.980(a)(1). Plaintiffs do not argue otherwise.[13]

Nor do Plaintiffs make any claim that the 340B drug payment reduction "threatens the very existence" of their business. Plaintiffs have therefore failed to show any economic loss sufficient to constitute irreparable injury under the law of this Circuit. *See Wisconsin Gas*, 758 F.2d at 675 ("[N]either party has shown that the alleged loss is unrecoverable, and neither petitioner has alleged that in the interim they will be forced out of business by the loss. . . . This is the type of 'mere economic loss' which will not support a finding of irreparable injury."); *ConverDyn v. Moniz*, 68 F. Supp. 3d 34, 47 (D.D.C. 2014) (no irreparable injury where plaintiff's "evidence does not establish that its alleged losses 'threaten[] the very existence of [its] business,' the only circumstance in which this Circuit has endorsed a finding of irreparable harm based on monetary loss"); *Mylan Labs., Inc. v. Leavitt*, 484 F. Supp. 2d 109, 123 (D.D.C. 2007) (no irreparable injury where "movants [did] not argue that [alleged financial] losses would threaten the continued

[13] Because any alleged economic loss here is recoverable, Plaintiffs' reliance on *Texas Children's Hospital v. Burwell*, 76 F. Supp. 3d 224, 243 (D.D.C. 2014), *see* Pls.' Mem. at 21, is misplaced. There, the court found irreparable injury where the economic losses at issue were, among other things, "unrecoverable." *Tex. Children's Hosp.*, 76 F. Supp. 3d at 242-43.

existence of their business"); *Isong v. Apex Petroleum Corp.*, 273 F. Supp. 2d 1, 2 (D.D.C. 2002) (same); *Clipper Cruise Line, Inc. v. United States*, 855 F. Supp. 1, 4 (D.D.C. 1994) (same).[14]

Second, Plaintiffs have failed to offer sufficient proof that their claimed injury is "certain" and "great." *See Nat'l Ass'n of Mortg. Brokers v. Bd. of Governors of Fed. Reserve Sys.*, 773 F. Supp. 2d 151, 181 (D.D.C. 2011) (plaintiff must "adequately describe and quantify the level of harm" it faces). Regarding the alleged impact of the 2018 OPPS Rule, the Hospital Plaintiffs provide affidavits stating that they "would be forced to evaluate—and likely curtail, if not cut altogether—some programs as soon as the 340B Provisions of the OPPS Rule and the new payment rate take effect." Filer Aff. ¶ 18, Pls.' Ex. I [ECF No. 2-12]; Whitbread Aff. ¶ 20, Pls.' Ex. J [ECF No. 2-13]; Barber Aff. ¶ 19, Pls.' Ex. K [ECF No. 2-14]. But being "forced to evaluate" something is not an irreparable injury, nor is the "likely" curtailing of certain programs. *See Wisconsin Gas*, 758 F.2d at 674 ("Bare allegations of what is ***likely*** to occur are of no value since the court must decide whether the harm will ***in fact*** occur.") (emphasis added). Similarly, Plaintiff Eastern Maine Healthcare Systems' affidavit states in conclusory terms that the 2018 OPPS Rule will have a "significant impact" on its "overall service capabilities, affecting its budgeted operations, bond covenants, and other systems and arrangements that allow it to offer essential health care to Maine's communities." Filer Aff. ¶ 19, Pls.' Ex. I [ECF No. 2-12]. But merely stating that a rule will have a "significant impact" falls far short of Plaintiffs' burden to "adequately describe and quantify" the alleged harm it faces. *See Nat'l Ass'n of Mortg. Brokers*, 773 F. Supp. 2d at 181.

[14] Even if the economic loss were *not* recoverable, that would "'not, in and of itself, compel a finding of irreparable harm'"; such "harm must also be great, certain and imminent." *Cardinal Health, Inc. v. Holder*, 846 F. Supp. 2d 203, 211-12 (D.D.C. 2012) (holding that $1 billion of alleged "unrecoverable economic loss," which reflected less than 1% of plaintiff's total sales, was not "of the magnitude necessary to constitute irreparable harm").

Because Plaintiffs fail to offer specific details explaining how the 2018 OPPS Rule will allegedly harm them, they have not shown irreparable injury.

Third, Plaintiffs have also failed to demonstrate that the 2018 OPPS Rule poses any "imminent" threat of harm creating a "clear and present need" for injunctive relief. Although the 2018 OPPS Rule becomes effective January 1, 2018, providers have 12 months after the date of service to timely file a claim for payment for 340B drugs. *See* 42 U.S.C. § 1395n(a); 42 C.F.R. § 424.44. Thus, 340B providers have up to a year after the 2018 OPPS Rule takes effect before they must make a claim seeking reimbursement under the reduced 340B drug payment rate. None of the Hospital Plaintiffs' affidavits indicate when they intend to submit claims for Medicare reimbursement for 340B drugs, nor have they described any pressing need to immediately submit such claims after the 2018 OPPS Rule goes into effect on January 1, 2018. Plaintiffs have therefore failed to show any "imminent" threat of harm.

Fourth, even if Plaintiffs do face imminent harm, they have failed to show that a preliminary injunction would remedy that harm. As noted, their affidavits allege that they will be harmed by budgeting uncertainty in face of the adjusted payment rates in the 2018 OPPS rule. But a preliminary injunction would do nothing to remedy that uncertainty; only a final judgment, after appeal, could accomplish that.

Because Plaintiffs have failed to show any irreparable injury that a preliminary injunction would remedy, their motion for a preliminary injunction must be denied. *See Chaplaincy*, 454 F.3d at 297 ("A movant's failure to show any irreparable harm is … grounds for refusing to issue a preliminary injunction, even if the other three factors entering the calculus merit such relief.").

C. 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). It is precisely for these reasons 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 preliminary injunction—in the Secretary's administration of the OPPS.

Despite the well-documented effects their requested relief may have, Plaintiffs attempt to downplay its significance by claiming that a preliminary injunction will cause no "harm" and would merely "preserve the *status quo*." Pls.' Mem. at 22. This is not so. Temporarily suspending the 340B provisions of the 2018 OPPS Rule would have significant repercussions throughout the OPPS system. It may require the Secretary to recalculate the $1.6 billion "budget neutrality" increase he made to the payment rates for non-drug items and services in the 2018 OPPS Rule. Such recalculation would result in lower rates for non-drug items and services to all hospitals paid under the OPPS, including 340B hospitals. And because the injunction would only be temporary, it would create uncertainty in the market concerning the correct OPPS payment rate for not only 340B drugs, but also non-drug items and services, frustrating providers' ability to budget and plan appropriately for the fiscal year. The balance of equities and public interest thus tip heavily in Defendants' favor.

In sum, each of the preliminary injunction factors weighs strongly against granting injunctive relief. Plaintiffs' motion for a preliminary injunction should therefore be denied.[15]

CONCLUSION

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

[15] Count 2 of the Complaint seeks interim injunctive relief under 5 U.S.C. § 705. *See* Compl. ¶¶ 50-51. Such claims are evaluated under the standard "four-part preliminary injunction test." *Sierra Club v. Jackson*, 833 F. Supp. 2d 11, 30 (D.D.C. 2012). As explained above, Plaintiffs have failed to satisfy that test. So their claim under 5 U.S.C. § 705 likewise fails and should be dismissed.

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Counsel for Defendants

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

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

[PROPOSED] ORDER

The Court having considered Defendants' Motion to Dismiss, Plaintiffs' Motion for Preliminary Injunction, and the parties' submissions relating thereto, it is hereby

ORDERED that Defendants' Motion is GRANTED. It is further

ORDERED that Plaintiffs' Motion is DENIED. It is further

ORDERED that the Complaint is DISMISSED.

SO ORDERED.

_____
The Honorable Rudolph Contreras
United States District Judge

DATED: